How Technology is Shifting Agency from Doctors to Patients: The Cost and Impact of Medical Technologies to Traditional Liability and Malpractice

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I. INTRODUCTION

Modern medicine has long been the domain of physicians and been restricted to medical facilities. This is changing as technological advances have begun to alter conventional doctor-patient relationships and modern medicine. Recent innovations allow patients to remove hospitals from the process of diagnosis, and in increasingly common situations, even remove doctors. This Note examines how the application of new and old technologies in medicine affects the relationship of patients to the medical field, and the impact on liability. In Part II, this Note discusses the background of technological changes in the doctor-patient relationship by examining telemedicine and home diagnostic tools (HDTs). Specifically, it discusses how medical tools have evolved and the different types of technology that reflect these changes. Part III analyzes how these changes alter current standards of liability. Our understandings of liability law must adapt as technology redefines the actors and objects at the center of conventional liability suits. Finally, this Note will make recommendations to corporations regarding oversight and corporate responsibility in the manufacturing and distribution of new home medical technologies.

II. BACKGROUND

To appreciate emerging liability issues with advancing medical technologies, one must first understand how those technologies are changing. There are two specific technologies this Note will address: telemedicine and Home Diagnostic Tools (HDTs). By examining these technologies, we can recognize why they are changing both products liability and the medical field.

A. Telemedicine

Telemedicine is the use of technology to enable the "practice[] [of] medicine at a distance."[1] The Food and Drug Administration (FDA) provides a more technical definition. They describe "'telemedicine' as the delivery and provision of health care and consultative services to individual patients and the transmission of information related to care, over distance, using telecommunication technologies, and incorporating [] direct clinical, preventive, diagnostic, and therapeutic services and treatment . . . ."[2] Telemedicine was initially used in difficult circumstances, such as offering care in deep-sea mining ships or military endeavors.[3] Telemedicine has expanded to the public sphere due through innovation and increased access to technology.[4] Telemedicine provides information to patients in an environment they control. Currently, 71% of medical practitioners are using telemedicine, primarily for diagnosis and patient monitoring. It is especially common in smaller medical practices.[5] Telemedicine has the potential to save $6 billion in annual healthcare costs for employers.[6]

The advantages of telemedicine are numerous, ranging from increased access of care to administrative ease. Telemedicine offers patients in remote areas increased access to health care and reduced cost of care.[7] It also offers better "utilization of specialist expertise, system coordination . . . and availability of patient records."[8] Because technology allows doctors to practice in remote areas, telemedicine creates a geographic displacement of health care while allowing professionals to "practice medicine in the normal manner."[9] This is because technology bridges the distance and allows doctors to collect and offer information without being physically present. Although some argue this increases the risk

1. Judith D.F. Daar & Spencer Koerner, *Telemedicine: Legal and Practical Implications*, 19 WHITTIER L. REV. 3, 4 (1997).

2. Peter S. Reichertz & Naomi Joy Levan Halpern, *FDA Regulation of Telemedicine Devices*, 52 FOOD DRUG L.J. 517, 517 (1997).

3. *See* Kathleen M. Vyborny, *Legal and Political Issues Facing Telemedicine*, 5 ANNALS HEALTH L. 61, 62 (1996) (discussing the increased use of telemedicine).

4. *See id.*

5. Thomas Beaton, *71% of Healthcare Providers Use Telehealth, Telemedicine Tools*, MHEALTH INTELLIGENCE (Apr. 28, 2017), https://mhealthintelligence.com/news/71-of-healthcare-providers-use-telehealth-telemedicine-tools.

6. *Current Telemedicine Technology Could Mean Big Savings*, WILLIS TOWERS WATSON (Aug. 11, 2014), https://www.towerswatson.com/en-US/Press/2014/08/current-telemedicine-technology-could-mean-big-savings.

7. *See id.* (discussing potential healthcare savings using telemedicine).

8. *See* Diane Hoffmann & Virginia Rowthorn, *Legal Impediments to the Diffusion of Telemedicine*, 14 J. HEALTH CARE L. & POL'Y 1, 2 (2011) (examining the benefits of telemedicine).

9. Vyborny, *supra* note 3, at 72 (emphasis omitted).

of mistakes and erodes the bond of trust between doctor and patient, there is little proof to substantiate these concerns.[10] Note, the term "medical professional" commonly includes vocations like midwives and physical therapists as well as licensed doctors.[11] That stated, this Note will primarily evaluate telemedicine practiced by licensed physicians. However, the same issues likely arise across all medical professionals, regardless of state categorization. Telemedicine faces three primary issues. The first is individual state licensing for permission to practice medicine in certain jurisdictions. The second is concerns of privacy when confidential information is moved to a new medium, thereby risking unauthorized access. The final issue concerns malpractice and what kind of liability is most appropriate in telemedicine.

1. Licensure

Medical licenses permit doctors to practice medicine in their licensing state. When doctors practice telemedicine they provide advice in the state they are licensed; but the advice is transmitted to a state in which they are not permitted to practice medicine.[12] Licensure is the first barrier to the growth of telemedicine. Medical licenses are the purview of states, with each state having its own criteria and requirements of practice.[13] This complicates matters when a doctor in State A provides medical services to a patient in State B without a license in State B via technological conduit.[14] Some states have hindered telemedicine by implementing laws that sanction interstate medical practice or define telemedical services as consultations.[15] Other states simply forbid the practice of medicine by out-of-state telepractitioners.[16] It can be difficult to determine where an injury has occurred when trying to file a malpractice claim in such cases.[17] Some argue that a suit must be filed in the state where the injury occurred, but it is also possible that the injury occurred in the state where the consultant is.[18] This is further complicated depending on what state licenses the doctor carries at the time of injury.[19]

2. Privacy

In an information age, privacy is fiercely defended. Telemedicine offers a flow of confidential information between parties, but many have criticized the lack of security of the transmission of information.[20] Telemedicine information is regulated as confidential

10. *See* Susan E. Volkert, *Telemedicine: Rx for the Future of Health Care*, 6 MICH. TELECOMM. TECH. L. REV. 147, 182 (2000) ("There is . . . no empirical evidence of malpractice claims increasing as a result of telemedical practice."); *but see* Joseph P. McMenamin, *Telemedicine and the Law*, 21 INT'L LEGAL PRAC. 126, 127 (1996) ("[T]he adversarial atmosphere engendered by litigation or the threat thereof, may be intensified by the distance, literal and figurative, inherent in telemedicine.").
11. *See* Vyborny, *supra* note 3, at 80–81 (evaluating state licensure policy).
12. Daar & Koerner, *supra* note 1, at 16.
13. *See* Volkert, *supra* note 10, at 166 (discussing licensure issues in telemedicine).
14. McMenamin, *supra* note 10, at 126.
15. Volkert, *supra* note 10, at 166–68.
16. *Id.* at 168.
17. *Id.*
18. McMenamin, *supra* note 10, at 127.
19. Volkert, *supra* note 10, at 168 n.80.
20. *See id.* at 214–15 n.292 (discussing the need for confidentiality standards in telemedicine).

information by the Health Insurance Portability and Accountability Act (HIPAA)[21] but the risk of un-authorized access is intrinsic to telemedicine and cannot be legislated away. Ethical considerations and legal safeguards specifically protect medical information.[22] Any time information is conveyed to multiple parties it is vulnerable in some way.[23] This is not just the nature of telemedicine, but the nature of any industry that relies on technology. However, taking appropriate precautionary measures and exercising care mitigates this risk.[24] With the appropriate measures, the danger of data breach in telemedicine can be minimized.[25]

3. Malpractice

There is not a great deal of material regarding telemedicine malpractice suits, but the implications are no less important. The doctor-patient relationship is established when "the professional services of a physician are accepted by another person for the purposes of medical or surgical treatment."[26] Accordingly, there is a duty of care in telemedicine, which is not weakened by distance.[27] A medical malpractice case requires a plaintiff to establish negligence by proving: "(1) a duty by a physician to act according to certain standards; (2) a breach of this standard of care; (3) an injury; and (4) causation between the breach of care and the patient's injury."[28] Despite the level of removal from patients, the standard of care should be the same for telemedical doctors as it is for traditional doctors.[29] The issue of what state to hold someone liable in arises again in telemedicine malpractice suits. For instance, in which state should a practitioner purchase medical insurance? And in which state a practitioner is required to appear in a malpractice suit?

These are some of the primary issues that prevent telemedicine from becoming fully realized as a medical tool. Disjointed policies across multiple states limit the national reach of telemedicine. Telemedicine has moved from an exclusively diagnostic tool to a clinical tool as well.[30] It has expanded into several smaller fields like telesurgery and teletrauma care, but all of them are limited by the above issues. Telemedicine is beginning to evolve

21. *Id.* at 217–18.

22. 42 U.S.C. §§ 1320d–1320d8 (2012) (requiring healthcare providers who transmit medical data electronically to take reasonable precaution and safeguards against interception). *See also*, Volkert, *supra* note 10, at 217–19 (detailing how HIPAA enforces its policy requirements).

23. *See* Mike Orcutt, *Your Doctor's Office Is Vulnerable to Hackers, but Congress Could Change That*, MIT TECH. REV. (June 12, 2017), https://www.technologyreview.com/s/608052/your-doctors-office-is-vulnerable-to-hackers-but-congress-could-change-that/ (discussing how hospitals have historically weak digital security and are thus an attractive target for hackers and digital attacks).

24. *See id.* (discussing measures which could be taken to mitigate the risk of digital attacks).

25. *See id*.

26. Christopher Caryl, *Malpractice and Other Legal Issues Preventing the Development of Telemedicine*, 12 J.L. & HEALTH 173, 194 (1997).

27. *Id.*

28. Heather L. Daly, *Telemedicine: The Invisible Legal Barriers to the Health Care of the Future*, 9 ANNALS HEALTH L. 73, 100 (2000).

29. *See* Hoffmann & Rowthorn, *supra* note 8, at 34–35 (mentioning that states determine the standards of malpractice. While there is debate as to what that standard is, most states will hold that the standards for malpractice should not be different in telemedicine than conventional medicine as it is possible to establish all of the same elements in a telemedicine malpractice suit).

30. C. Cazac & G. Radu, *Telesurgery — An Efficient Interdisciplinary Approach Used to Improve the Health Care System*, 7 J. MED. & LIFE 137 (2014) (evaluating the merit of telesurgery).

in other ways; innovations in medical technology are beginning to re-shape the definition of tele-healthcare, which are discussed below.

B. Home Diagnostic Tools

Technology has started advancing in a way that renders some of the traditional uses of telemedicine obsolete. Conventional telemedicine reflects a change in access to patients by eliminating the need for proximity, but technology is slowly eliminating the reliance on medical professionals for diagnoses as well.[31] New technology gives patients previously inconceivable access and control over their medical care. These innovations are pushing conventional telemedicine into something less recognizable. The advent of Home Diagnostic Tools (HDTs) is one example of this phenomenon. These tools offer patients the ability to diagnose themselves with a multitude of medical conditions by making a simple purchase, without any input from a doctor.[32] At-home HIV testing kits represent one specific example. In 1997, the FDA considered home specimen collection kits used for HIV testing to be a form of telemedicine.[33] Users collected samples in their own homes, then submitted them to a central laboratory for testing.[34] The results were only available via phone, thus meeting the conventional understanding of telemedicine.[35] Less than 1% of HIV testing was conducted with home collection kits at the time and kits were not always readily available.[36] Now, HIV self-testing kits can be bought from Walmart for $40, and provides results in 20 minutes.[37] The significant change here is that the user does not need to contact anyone to obtain those results.[38] These HIV kits, and many similar kits, are all available over the counter and require no interaction with any medical professional to purchase or use.[39] Consumers can diagnose themselves without any analysis of their medical record or any medical authority to counsel them on issues of treatment, care, or preventative measures for future complications.[40]

There are many other examples of HDTs outpacing the need for telemedicine. The home pregnancy test, patented in 1969, was one of the first, and most common of these technologies.[41] Additionally, the FDA has approved home testing for colon cancer, hepatitis C, cholesterol, and many other conditions.[42] These tests are only a few of the

31. Lars Noah, *Treat Yourself: Is Self-Medication the Prescription for What Ails American Health Care?*, 19 HARV. J.L. & TECH. 359, 367 (2006).

32. Nguyen, *infra* note 43.

33. Reichertz & Halpern, *supra* note 2 and related text.

34. Ishani Ganguli et al., *Home testing for HIV Infection in Resource-Limited Settings*, 6 CURRENT HIV/AIDS REPORTS 217, 219 (2009).

35. Reichertz & Halpern, *supra* note 2 and related text.

36. Christopher B. Hurt & Kimberly A. Powers, *Self-Testing for HIV and Its Impact on Public Health*, 41 SEXUALLY TRANSMITTED DISEASES 10, 10 (2014).

37. Ganguli et al., *supra* note 34, at 218.

38. *What is OraQuick?*, ORAQUICK, http://www.oraquick.com/what-is-oraquick/oraquick-in-home-hiv-test (last visited Sept. 1, 2017).

39. *Id.*

40. *With Home Testing, Consumers Take Charge of Their Health*, LAB TESTS ONLINE, https://labtestsonline.org/articles/home-testing (last updated Jan. 3, 2019).

41. Cari Romm, *Before There Were Home Pregnancy Tests*, ATLANTIC (Jun. 17, 2015), https://www.theatlantic.com/health/archive/2015/06/history-home-pregnancy-test/396077/.

42. Sue Byrne, *Do-It-Yourself Health Screening Tests That Are Worth the Money*, CONSUMER REP. (Aug.

increasingly common goods for sale that allow patients to self-diagnose conditions and monitor their health privately.[43] These are examples of modern technologies that are shifting agency from doctors to patients, allowing patients unprecedented discretion and control over their health.

These technologies are growing very quickly. Markets for telemedical devices and self-health monitoring technologies are expected to grow by several billion dollars by 2021.[44] With this growth comes regulation. The FDA considers activity trackers to be "general wellness products" instead of medical devices because they do not provide a medical function, but an informational one.[45] This is a fine line for the FDA to walk, as activity trackers provide data for exclusively informational purposes, but so do technologies like blood glucose monitors and heart pressure cuffs, both of which are considered medical devices. The FDA's standard for medical device is:

> [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 Pharmacopeia, 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.[46]

There are three different types of medical device under this definition.[47] The FDA categorizes devices based on how much regulation they think is appropriate.[48] Class I devices are considered low risk, such as tongue depressors or cotton swabs, requiring only the most basic and general controls. Controls include inspection, registration, manufacturing standards, and notification of risk to consumers.[49] The controls of a Class I device apply to all other classes.[50] Class II includes more interactive devices, such as

11, 2015), https://www.consumerreports.org/cro/news/2015/08/do-it-yourself-health-screening-tests/index.htm.

43. Tuan C. Nguyen, *Home Medical Tests: Which Can You Trust?*, BERKELEY WELLNESS (May 4, 2016), http://www.berkeleywellness.com/self-care/over-counter-products/article/home-medical-tests-which-can-you-trust (listing devices that the FDA trusts as well as an assortment of unreliable HDTs that have not met FDA standards for accuracy or safety).

44. *See* Byrne, *supra* note 42; BCC RESEARCH STAFF, GLOBAL MARKETS FOR TELEMEDICINE TECHNOLOGIES (2018) https://www.bccresearch.com/market-research/healthcare/global-markets-for-telemedicine-technologies-hlc014j.html (discussing future telemedicine markets).

45. Elizabeth A. Brown, *The Fitbit Fault Line: Two Proposals to Protect Health and Fitness Data at Work*, 16 YALE J. HEALTH POL'Y L. & ETHICS 1, 32 (2016).

46. 21 U.S.C. § 321(h) (2012).

47. Volkert, *supra* note 10, at 207.

48. *Id.*

49. *Id.*

50. Ann K. Schooley, *Allowing FDA Regulation of Communications Software Used in Telemedicine: A*

hearing aids. They require more regulation because they need greater standards of safety and quality control to prevent harm and ensure effectiveness.[51] These devices are often evaluated on a device-by-device basis.[52] The final level is Class III, where devices require pre-market approval, and manufacturers must demonstrate safety and effectiveness to the FDA.[53] This long and costly process offers a degree of protection to consumers, though the process of seeking approval is so long that devices risk obsolescence in the time it takes to gain approval.[54] Even if something has alternative, non-medical uses, the FDA may still classify it as a device.[55] Under the Food and Drug Cosmetic Act (FDCA), intent is a primary determination, and thus, if it has an intended use as a medical device, it may be considered a device for FDCA purposes.[56] There are many types of HDTs[57] but it is helpful to break them down into categories. For the purpose of this paper they will be referred to as: instruments, tests, and mobile medical apps (MMAs). FDA classification determines both the level of regulation of these HDTs and, indirectly, the access consumers have to them.

1. Instruments

Instruments are the most widely known HDT because they are familiar items frequently used to deliver first aid.[58] Often times these objects are standard medical devices, not adapted in any special way for regular consumers. Because of this, they are usually either easy to use or explained in great detail. Examples of instruments that people use in their own homes are thermometers, blood glucose meters, and blood pressure monitors.[59] Devices used at home incorrectly may result in adverse events due to lack of calibration, maintenance, or simply ignorance.[60] Adverse events include reliance on faulty information and lack of awareness concerning one's actual medical condition.[61]

If the FDA considered activity trackers to be medical devices, instead of general wellness products, they would also be considered instruments.[62] HDT instruments are

Potentially Fatal Misdiagnosis?, 50 FED. COMM. L.J. 731, 741–42 (1998).

51. Volkert, *supra* note 10, at 207.

52. Schooley, *supra* note 50, at 742.

53. *Id.* at 743.

54. *Id.*

55. Sara Chodosh, *'FDA Approved' Medical Devices Don't Actually Have to Do What They Promise*, POPULAR SCI. (June 5, 2017), https://www.popsci.com/fda-approved-medical-devices#page-5. For a device to qualify for Class I medical device certification, producers simply need to claim a medical use A bracelet that claims to change a person's energy flow qualifies even if its primary purpose is cosmetic. Intent is a determinative factor in classification, as a cotton swab may be used in medical settings or have alternate non-medical uses.

56. *See* Vyborny, *supra* note 3, at 91–92 (noting that the sole basis for a device need not be medical to fall under the scope of the FDCA).

57. Molly Follette Story, *Medical Devices in Home Health Care*, *in* THE ROLE OF HUMAN FACTORS IN HOME HEALTH CARE: WORKSHOP SUMMARY 145, 150 tbl.8-1 (2010).

58. *Id.* at 146.

59. *Id.* at 150 tbl. 8-1.

60. *See Home Use Devices*, FDA, https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/HomeUseDevices/default.htm (last updated Aug. 31, 2018) (explaining what the FDA considers a medical home use device and why the FDA regulates these devices).

61. Story, *supra* note 57, at 153–55.

62. Volkert, *supra* note 10, at 205–08.

characterized by their ability to provide information about the day-to-day metrics of the body as those metrics fluctuate. Based on the FDA definition, it is clear that these HDT instruments qualify as medical devices, and are subject to FDA control and classification.[63]

2. Tests

Unlike instruments, tests offer more binary answers to consumers. There are at-home tests for drug use, infections, and other illness. The popular website 23andMe, a more conventional telemedicine test which still requires technological communications with an official laboratory, offers genetic analyses after customers mail in a saliva swab. The FDA has granted 23andMe permission to test for genomic risks for Parkinson's disease, Late-onset Alzheimer's, several blood clotting disorders, and more.[64] 23andMe boasts the ability to detect over 200 other conditions but has not gained FDA approval for those tests.[65] The primary concern with HDT tests is accuracy, as even FDA approved tests can have false positives.[66] Instruments typically measure information by tracking physical conditions that are being assessed at the time of use, and the accuracy of this information depends on proper calibration.[67] Tests may rely on chemical reactions or some other intervening step between the device and the patient.[68] Instruments are typically used more than once, allowing users the chance to discover any problems with the device. A test is used once, provides an answer, and is discarded.[69] There is less chance that a false result will be revealed because there is no way to double check it without another test.[70] This risk does not mean that the test should not be trusted; the FDA-approved home colon cancer test catches roughly 79% of colon cancer cases.[71] While this number sounds low, traditional doctors often use the exact same test in the early phases of diagnosis before they turn to colonoscopies.[72] This shows that even traditional medicine does not offer 100% accuracy. A greater risk of HDT tests is that false negatives can cause unfounded reassurance that

63. 21 U.S.C. § 321(h)(2016).

64. *See the List of Reports Included in Each Service*, 23ANDME, https://www.23andme.com/dna-reports-list/ (last visited Jan. 17, 2019).

65. *See* Mathew Herper, *23andMe Rides Again: FDA Clears Genetic Tests to Predict Disease Risk*, FORBES (Apr. 6, 2017, 3:18 PM), https://www.forbes.com/sites/matthewherper/2017/04/06/23andme-rides-again-fda-clears-genetic-tests-to-predict-disease-risk/#559614e04fdc (discussing FDA restrictions on what 23andMe is permitted to offer to the public and the reasons for FDA oversight regarding genetic tests offered directly to consumers).

66. *See* Amy Norton, *At-Home Stool Test for Colon Cancer*, WEBMD (Feb. 3, 2014), http://www.webmd.com/colorectal-cancer/news/20140203/at-home-stool-test-for-colon-cancer-called-accurate-but-not-foolproof#1 (mentioning that the FDA allows tests a certain allowable margin of error).

67. Edward Simpson, *Guide to FDA Requirements and Importance of Medical Device Calibration*, MEDICAL DESIGN BRIEFS (July 1, 2018), https://www.medicaldesignbriefs.com/component/content/article/mdb/tech-briefs/29754.

68. *Drugs of Abuse Home Use Test*, FDA, https://www.fda.gov/MedicalDevices/ucm125722.htm (last updated Sept. 27, 2018).

69. *Id.*

70. *Do-it-Yourself Medical Tests Can Be Helpful but Should be Overseen by Your Doctor*, WASH. POST (2012), https://www.washingtonpost.com/national/health-science/do-it-yourself-medical-tests-can-be-helpful-but-should-be-overseen-by-your-doctor/2012/06/25/gJQA8mtP2V_story.html?utm_term=.78142c42fe8b.

71. Norton, *supra* note 66.

72. *Id.*

prevent people from seeking care and false positives can cause unnecessary panic.[73] Most tests do come with disclaimers, but it is unclear how much protection the disclaimers offer if the warning is not sufficiently clear.[74]

3. Mobile Medical Apps

The standard smartphone functions like a computer and can do more than a Swiss army knife. Not only can it function as a flashlight, voice recorder, photo album, and television, it can also prevent heart attacks and detect organic compounds found in cancerous cells.[75] The development of medical apps allows patients to offer doctors more personalized information when it comes time for treatment, and with the help of an array of small attachable accessories, offers patients medical tests they could not have accessed before.[76] The MMA industry is growing rapidly, with millions of apps already in circulation. The industry is projected to have a value of $11.22 billion by 2025.[77]

Not all MMAs qualify as devices, and for an app to qualify, it must "*transform[]* the mobile platform into a 'device.'"[78] Usually the programmer's intent when creating the app is sufficient to demonstrate transformation.[79] Regulation of MMAs is further complicated by the fact that the FDA can control medical devices, and the accessories needed to use the app, but not the smartphone that utilizes the app.[80] MMAs that could be considered "medical" but are not created with the intent to treat or diagnose medical issues are not considered devices by the FDA.[81] The FDA typically tries to limit its control of MMAs to those that have the traditional functionality of currently-regulated devices.[82] For example, a breathalyzer device used by law enforcement to measure blood alcohol is considered a Class I medical device by the FDA.[83] *Alcohoot* is an app with a small phone plug-in that measures blood alcohol levels; the device requires FDA approval.[84]

MMAs can serve as HDT instruments and tests depending on function. HDTs are

73. *See* Anahad O'Connor, *Direct to Consumer Lab Tests, No Doctor Visit Required*, N.Y. TIMES WELL BLOG (June 6, 2016), https://well.blogs.nytimes.com/2016/06/06/direct-to-consumer-lab-tests-no-doctor-visit-required/?_r=0 (discussing the risks to consumers that homes testing devices pose and the importance of medical opinions in using these devices).

74. Pilar N. Ossorio, *Product Liability for Predictive Genetic Tests*, 41 JURIMETRICS 239, 256 (2001).

75. Nathaniel R. Carroll, Comment, *Mobile Medical App Regulation: Preventing a Pandemic of "Mobilechondriacs"*, 7 ST. LOUIS U.J. HEALTH L. & POL'Y 415, 416 (2014).

76. *Id.*

77. *Global Mobile Medical Apps Market: Focus on Category, Type, Application, Countries, Patents, Market Share, and Competitive Landscape - Analysis and Forecast (2017-2025)*, RES. & MKTS. (Feb. 1, 2018), https://www.researchandmarkets.com/reports/4466015/global-mobile-medical-apps-market-focus-on.

78. Carroll, *supra* note 75, at 441.

79. *Id.*

80. Volkert, *supra* note 10, at 209–11.

81. Diane Cooper, *Understanding the Impact of the FDA Guidance for Mobile Medical Applications: Is There an App for That?*, 32 QUINNIPIAC L. REV. 95, 100 (2013).

82. Carroll, *supra* note 75, at 421.

83. *Product Classification*, FDA, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DJZ (last updated Feb. 11, 2019).

84. *Alcohoot Successfully Demonstrates Power of Innovation by State Governments to Combat Drunk Driving*, PR NEWSWIRE (Sept. 15, 2015), https://www.prnewswire.com/news-releases/alcohoot-successfully-demonstrates-power-of-innovation-by-state-governments-to-combat-drunk-driving-300143197.html.

developing so fast that multi-use devices are emerging. *Scandu* is an intersectional HDT that connects a small device to a smart phone with an app. It functions as an instrument and a test by providing information about the body's regular conditions while also alerting users to non-typical conditions such as kidney problems and urinary tract infections.[85]

As diagnosis shifts from hospitals to homes, patients are given cheaper options that offer privacy and convenience.[86] There is, however, a larger margin of error when a lay person is involved with a diagnosis, and accuracy may be compromised for comfort.[87] Medical apps offer patients access to a great deal of medical information, and depending on their intent, can provide information about specific medical diagnoses or general information. Medical apps toe the line of being devices, and many medical professionals are against these devices because they do not think that laypeople understand how to interpret the information they have access to, via simple informative apps, or through more complex devices.[88] Despite the concern of some medical professionals, the accessibility of HDTs could "cause a shift from reaction-based care to preventative-based care[]," as doctors get more access to patient information through self-health trackers and patients learn how much control they have over their health.[89] Some health care professionals think HDTs are the future of medicine,[90] though others want informed and engaged patients, and think HDTs provide false reassurances.[91]

III. ANALYSIS

To best analyze these issues, we must evaluate both conventional telemedicine and HDTs in light of the liability issues they face. Those liability concerns must be juxtaposed with the medical malpractice concerns of more conventional medicine. This requires better understanding the different ways telemedicine can be compromised and the specific risks of HDTs.

85. Rachel Metz, *A Gadget that Makes You the Doctor*, MIT TECH. REV. (Nov. 30, 2012), https://www.technologyreview.com/s/507886/a-gadget-that-makes-you-the-doctor/.

86. Steve Dickman, *Direct-To-Consumer Clinical Lab Testing Won't Kill Us—It Will Make Us Stronger*, FORBES (Jun. 16, 2016), https://www.forbes.com/sites/stevedickman/2016/06/16/direct-to-consumer-clinical-lab-testing-wont-kill-us-it-will-make-us-stronger/#5fceabec284f (examining the most common arguments for and against Direct to Consumer medical devices and citing opinions of medical professionals).

87. Byrne, *supra* note 42.

88. *See* Dickman, *supra* note 86 (examining the opinions of medical professionals in regards to direct-to-consumer medical devices).

89. Carroll, *supra* note 75, at 417.

90. Donna Marie Pocius, *Consumers Increasingly Purchase Medical Laboratory Self-Test Kits for Blood Glucose, Cholesterol, and Colon Cancer Screening, According to Consumer Reports*, DARK DAILY (Jan. 20, 2017), https://www.darkdaily.com/consumers-increasingly-purchase-medical-laboratory-self-test-kits-for-blood-glucose-cholesterol-and-colon-cancer-screening-according-to-consumer-reports-12017.

91. Byrne, *supra* note 42. ("'But self-diagnosis has very important risks. Tests can be wrong. They can give false reassurance or cause excessive alarm.' In fact, Nissen says he doesn't understand why the Food and Drug Administration allows them to be sold. Others see the growth of this trend as inevitable—and largely positive. 'This is the future of medicine . . . .'") (quoting first Steven Nissen, M.D., chair of cardiovascular medicine at Cleveland Clinic Foundation; then quoting Eric Topol, M.D., cardiologist and director of Scripps Translational Science Institute).

A. Licensing

While many states forbid telemedicine, failing to utilize medical resources to avoid bureaucratic complications is myopic. While each state has their own guidelines for practicing telemedicine, doctors can use certain methods to avoid an illegal practice. It is recommended that medical professionals "(1) provide telemedicine consultations only within the same state that in which he is licensed; or (2) obtains the necessary state license for every state in which he may practice via telemedicine."[92] By following these recommendations, professionals lessen their legal risk. The guidelines offer some guidance on the licensing issue but they do not address the problem of practicing in states that have forbidden telemedicine.[93] The issue is also complicated because seeking a license for every state in which you may practice telehealth is not feasible; the process of receiving a medical license is far too costly.[94] The final problem is that different state policies on telemedicine may be incompatible with each other.[95] While many states are increasingly participating in intrastate compacts that allow cross licensure, there is still no national policy.[96] Until these problems are addressed, the issue of licensure will prevent telemedicine from developing into a truly useful tool in the United States.

B. Liability Concerns

One of the primary concerns with the use of emerging technologies is the issue of liability. As technology takes medical procedures out of hospitals and into homes, the line between products liability and medical malpractice blurs. Traditionally, to determine products liability as opposed to malpractice, courts examine how much information manufacturers give to medical practitioners about the risks associated with particular drugs

92. Caryl, *supra* note 26, at 185.

93. Vera Gruessner, *How Telehealth Implementation Policies Vary Across the States*, MHEALTHINTELLIGENCE (Aug. 18, 2015), https://mhealthintelligence.com/news/how-telehealth-implementation-policies-vary-across-the-states ("Every state imposes a policy that makes practicing medicine across state lines difficult regardless of whether or not telemedicine is used. Michigan, North Dakota, Pennsylvania, and South Dakota are the only states that do not allow some type of licensure exemption for physician-to-physician out-of-state consultation.") (quoting Latoya Thomas & Gary Capistrant, *State Telemedicine Gaps Analysis*, AM. TELEMEDICINE ASS'N, STATE TELEMEDICINE GAPS ANALYSIS 11 (2017)).

94. The costs of telemedicine are not just limited to the expensive technology used to facilitate telemedicine. The costs of training and licensing processes can cost several hundred dollars. To qualify for a telemedicine license, most states require separate board certifications and an active medical license. *Out-of-State Telemedicine License*, TEX. MED. BOARD, http://www.tmb.state.tx.us/page/telemedicine-license (last visited Feb. 13, 2019); Marki Stewart, *Practicing Telemedicine Across State Borders: New Expedited Licenses Permit Physicians to Expand Practice*, ARIZ. TELEMEDICINE PROGRAM (May 11, 2017), https://telemedicine.arizona.edu/blog/practicing-telemedicine-across-state-borders-new-expedited-licenses-permit-physicians-expand. States participating in the Intrastate Medical Compact need only submit one application to qualify in all participating states. *The IMLC*, INTERSTATE MED. LICENSURE COMPACT, https://imlcc.org (last visited Feb. 18, 2019).

95. Gruessner, *supra* note 93 ("Within the past year, over 25 states have considered proposals, with varied results, to revise health professional standards and licensure requirements when using telemedicine. Some states are creating new laws that impact access to care via telemedicine, while others are amending existing policies with greater implications.") (quoting Latoya Thomas & Gary Capistrant, *State Telemedicine Gaps Analysis*, AM. TELEMEDICINE ASS'N 11 (2017), https://utn.org/resources/downloads/50-state-telemedicine-gaps-analysis-physician-practice-standards-licensure.pdf)).

96. Stewart, *supra* note 94.

or devices.[97] If the manufacturer fails to adequately inform health care providers of associated risks, the manufacturer may be liable for any injury caused by the product under products liability.[98] Alternatively, if the doctor does not heed manufacturer warnings they may face a malpractice suit for injuries caused by the device or medicine.[99] As noted previously, to prove malpractice a plaintiff must establish negligence by proving that a physician has a breached a duty of care and that this breach has resulted in injury.[100] Products liability, on the other hand, is a strict liability issue. There are three types of products defects under product liability theory: design defects (defects inherent to the product itself), marketing defects (a manufacturer's failure to provide adequate instruction or warning of risk), and manufacturing defects (defects introduced to an adequate product in the course of production that create a danger).[101] The following sections will examine these defects and how they intersect with malpractice and technology.

1. Telemedicine

While telemedical malpractice may plausibly be evaluated by the same standards as traditional malpractice,[102] products liability cannot be judged through the same lens. Products liability is complicated with telemedicine. In traditional medicine, when a mistake is made the fault lies squarely with the doctor or hospital. In telemedicine, more actors may be blamed if a patient is harmed. A doctor could be at fault if he missed something or was inaccurate, but so could internet provider, computer technician, technology manufacturer, or even the patient. When telemedicine is not primarily informational, such as when it is used for telesurgery, liability is still on the heads of doctors and medical professionals who have medical education and a deep understanding of the procedures and tests they run.[103] The new technological facilitation of medicine brings new complications. With technology comes a host of new devices and actors that all bring potential liabilities. This is especially true when the patient, a non-professional, handles some of that technology.

Technology is fallible. Natural disasters and human error can damage cell towers, power lines, and fiber optic cables, all carrying information from point A to point B.[104] Telemedicine by definition requires a technological conduit.[105] Hospitals have generators

97. *Product Liability vs. Medical Malpractice*, SPANGENBERG, SHIBLEY & LIBER (Aug. 1, 2016), http://www.spanglaw.com/blog/2016/august/product-liability-vs-medical-malpractice/.

98. *Id.*

99. *Id.*

100. *See* Daly, *supra* note 28, at 100 (describing the standards for medical malpractice).

101. Joshua Shulman & Sean Dubois (Dubois Law Group LLC), *Three Types of Product Defects for Products Liability Lawsuits*, HG.ORG LEGAL RESOURCES, https://www.hg.org/article.asp?id=24105 (last visited Feb. 13, 2019).

102. *See* Hoffmann & Rowthorn, *supra* note 8, at 34 (discussing the same standards being applied to telepractioners and traditional practitioners).

103. *See* Cazac & Radu, *supra* note 30 (discussing the telemedicine network that enables telesurgery and the professionals who utilize the system).

104. *See* Ari Shapiro, *Hurricane Maria Leaves Hospital in Puerto Rico Running on Generator Power*, NPR (Sept. 20, 2017) http://www.npr.org/2017/09/20/552418215/hurricane-maria-leaves-hospital-in-puerto-rico-running-on-generator-power (discussing how hospitals in Puerto Rico are functioning after a major hurricane); Patricia C. Kuszler, *Telemedicine and Integrated Health Care Delivery: Compounding Malpractice Liability*, 25 AM. J.L. & MED. 297, 318 (1999) (describing risks to telemedicine).

105. *See* Daly, *supra* note 28, at 73.

in case of power outages, so when a patient is in the same building, it is safe to assume the risk to communication is low. The question facing telemedicine is, if a patient is injured when a technological failure prevents access to important medical information, who is responsible?

Beyond the external infrastructure that enables telemedicine, the internal technology of telemedicine itself can become a concern. Issues of privacy make software encryption important and security breaches become a possible venue for liability claims. Software as a Service (SaaS) is a software concept whereby users temporarily use software supported on an online platform instead of purchasing it and downloading it onto their own computers.[106] SaaS offers reduced cost to companies and the benefits of cloud storage; however, a great deal of trust is required between companies that utilize SaaS software and SaaS providers.[107] SaaS providers become responsible for security and IT work for users.[108] Hospitals are increasingly using SaaS platforms.[109] SaaS is considered a service, which means medical problems arising from SaaS errors would not be actionable under products liability. Likewise, unless specifically contracted, providers would not be medically liable as they owe no medical duty of care. Products liability is a matter of strict liability while medical malpractice is a matter of negligence.[110] The norm is that strict liability is not suited to malpractice because it would restrict a doctor's ability to provide their services.[111] Doctors are however regularly tested and forced to renew their licensure in order to practice, which acts as a sort of quality control, and they are also held to a higher standard of reasonableness than software providers.[112] Telemedicine-induced damages on the part of SaaS providers are not be ruled by the same accountability and risks, and this creates a weakness in telemedicine accountability. A consumer's only recourse for medical injury as a result of telemedical liability via SaaS is thus limited to claims of negligence or similar actions. These actions lack the strict liability of products liability and the higher standard of care of malpractice, making it a meager remedy compared to other medical injury claims.

Not all telemedicine uses SaaS software. Some healthcare providers use traditional software—software that is installed on private servers and maintained by the purchaser. There is a long-standing debate over the status of software as a good or service, and the

106. Paul Gil, *What is 'SaaS' (Software as a Service)?*, LIFEWIRE, https://www.lifewire.com/what-is-saas-software-2483600 (last updated Dec. 13, 2018).

107. *Id.*

108. *Id.*

109. *The Growing Popularity of SaaS in Healthcare*, BIOIQ (June 30, 2016), https://www.bioiq.com/growing-popularity-saas-healthcare/ ("[SaaS] solutions have become the preferred way to deploy many types of healthcare applications.").

110. Proving Fault in a Product Liability Case, *infra* note 130; Daly, *supra* note 28 (some telemedicine methods qualify as services and thus, are not liable for product defects. This determination depends on the nature of the good. These products require third party services who may assume liability).

111. B. Sonny Bal & Lawrence H. Brenner, *Health Care Provider Liability Related to Defective Products*, HEALIO (Feb. 2011), https://www.healio.com/orthopedics/business-of-orthopedics/news/print/orthopedics-today/%7B8c9b4f01-7a04-44fc-b232-e7c646a8b8f4%7D/health-care-provider-liability-related-to-defective-products.

112. *See State Medical License Requirements*, HEALTHCARE LICENSING SERVS. (Nov. 2011), https://www.healthcarelicensing.com/state-medical-license-requirements (providing information regarding medical license requirements by state).

deciding function is the primary purpose of the software.[113] Software that is generally considered a service faces most of the same pitfalls as SaaS technologies. Software that is a good has separate issues. The FDA claims "devices or software used in aid of telemedical practices are 'devices' within the meaning of the Federal Food, Drug, and Cosmetic Act."[114] Because software that functions as a good is considered a medical device, it is subject to FDA evaluation and approval.[115] Thus, software producers must meet their own regulatory standards, as well as the FDA's standards, which causes many complications. According to guidelines, anytime a device undergoes a substantial change, that change must be evaluated by the FDA and approved.[116] Software is regularly updated, and the FDA has to balance their requirements for regular oversight with routine nature of software updates.[117] Accommodating these strict rules risks the software becoming obsolete by the time it is approved, and failing to provide oversight risks consumer safety. As discussed in Part II, while the FDA can regulate software, they cannot always regulate the technology that the software utilizes.[118] This is another weak point for telemedicine liability. Healthcare providers using telemedicine have a duty to ensure that their technology functions well, but if the patient is using less secure technology on their end, the question arises as to whether the patients assume the risk of future medical problems.[119] An example of this issue comes in the form of a client downloading a program that allows them to communicate with a doctor and receive periodic health updates and then fails to receive a message warning them of a possible risk. It is unclear whether the injury arising from this failure is the client's fault. Assuming the injury is the client's fault seems unreasonable, but it is also unreasonable to hold a healthcare provider liable when they have fulfilled all of their duties; this is another liability issue in telemedicine that needs resolution. Traditionally, a hospital is responsible for both points of contact and the patient would not be able to share in the liability, that is no longer the case and this is a consideration that needs to be addressed.

2. HDTs

The issues of liability and medical malpractice regarding HDTS are equally complex to those of typical telemedicine. Primarily, we turn to liability incurred with product defects. By examining each type of defect, we can evaluate what protections are offered to consumers harmed by HDTs.

Risks to consumers using HDTs with design defects are small. Because the FDA regulates the product, there is an authority figure ensuring some degree of quality control

113. Lawrence B. Levy & Suzanne Y. Bell, *Software Product Liability: Understanding and Minimizing the Risks*, 5 BERKELEY TECH. L.J. 1, 2–6 (1990).

114. Joseph P. McMenamin, *Does Products Liability Litigation Threaten Picture Archiving and Communication Systems and/or Telemedicine?*, 11 J. DIGITAL IMAGING 21, 29 (1998).

115. *Id.*

116. Schooley, *supra* note 50, at 748.

117. *Id.* at 749.

118. *See generally* Carroll, *supra* note 75; *see also* Schooley, *supra* note 50, at 747 ("Regulating systems as a whole would require the FDA to regulate not only the communications software and hardware, but also the equipment used to transmit the data and the manner in which the data is transmitted.").

119. *See* Kuszler, *supra* note 104, at 317 (describing the responsibility of healthcare workers in the event of faulty equipment).

and safety. HDTs that gain FDA approval,[120] but still pose a risk to consumers, face strict liability as any product would. HDTs with design defects are unlikely to be physically dangerous because of the commonly known HDTS, most are not invasive and pose little risk of direct harm if used correctly. The risk is rather that they will provide false information, which patients may rely on to their detriment. HDTs with manufacturer defects pose a slightly elevated risk. Any medical device that does not conform with FDA regulations could have dangerous effects on the human body because the effectiveness of its health monitoring is suspect. Furthermore, a manufacturer defect may be undetected longer than a design defect because not all devices may be affected by the flaw.

The final defect, the marketing defect, is the greatest threat to HDTs, because it may mean that users are unable to effectively use them. Human error may prevent a device from being used properly.[121] If a manufacturer does not provide clear instructions or warnings it is possible for tests to provide misleading results. Medical devices instructions must be especially clear because consumers typically do not have a great deal of experience using them or interpreting the information they provide.[122] All of these defects may result in false results. If patients rely on these false results to make medical decisions there is possible injury, and thus liability. If the FDA finds a device flawed in some way they issue a recall.[123] When issuing a recall, the FDA can try to correct the device, or remove it from the consumer marketplace entirely.[124] The FDA issues recalls by posting on public forums.[125] With traditional medicine, this is an effective method to ensure that faulty devices are not used any longer than necessary. Healthcare providers have a vested interest in knowing if any of their products are a safety risk and staying informed about recalls, as they may be liable for their failure to do so. Consumers are less likely to be aware of every FDA recall. Consequently, even if the FDA takes every step possible to keep consumers educated, there is a chance that it might stay in users' hands.

A further complication is that the FDA classification system is not suited to handling HDTs. For example, the *Breathometer* app, a breathalyzer app similar to *Alcohoot*, was considered a Class I device by the FDA and was approved as such.[126] It was later discovered the app was highly inaccurate and unreliable.[127] Most medical apps do not

120. *See* Part II.B.1 (describing commonly known HDTs).

121. Byrne, *supra* note 42; *With Home Testing, Consumers Take Charge of Their Health*, *supra* note 40 ("Errors can arise with any type of home test because of a number of possible mistakes. These range from using an expired test kit to improper storage to errors in how you perform the test. Mistakes in the testing procedure often involve how you collect the sample, the time of day you collect it, or how precisely you time the test (not waiting long enough or waiting too long before reading the result). Even the impact of medications you may be taking may interfere with the results and may be a source of error to be considered.").

122. *With Home Testing, Consumers Take Charge of Their Health*, *supra* note 40 (describing the lack of medical knowledge on the part of the consumer).

123. *See What is a Medical Device Recall?*, FDA, https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm (last updated Sept. 26, 2018) (explaining the process of medical device recall and the process of informing the public of the recalls).

124. *Id.*

125. *Id.*

126. Dan Gorenstein, *Medical Apps Get the Once Over from the FDA*, MARKET PLACE (Mar. 28, 2013, 2:44 AM), https://www.marketplace.org/2013/03/28/tech/medical-apps-get-once-over-fda.

127. Jonah Comstock, *FTC: Shark Tank Star Breathometer Must Offer Full Refunds for Inaccurate Smartphone Breathalyzer*, MOBIHEALTHNEWS (Jan. 24, 2017), https://www.mobihealthnews.com/content/ftc-shark-tank-star-breathometer-must-offer-full-refunds-inaccurate-smartphone-breathalyzer.

require approval, but those that do are generally given a perfunctory review and Class I designation, which does not require strenuous testing.[128] Just because a device cannot cause direct harm does not mean that misuse cannot result in significant damages. An inaccurate blood alcohol level can lead to safety risks and legal issues. Alternatively, an app that tells users an inaccurate blood sugar level could have severe health implications. Conventional Class I medical devices do not carry this same risk because they are used by trained professionals who wield them in conjunction with a wealth of medical knowledge, something most consumers lack. Consumers do not recognize the risk of harm because as far as they are concerned the device has been approved by the FDA and may thus rely, to their detriment, on FDA approval.

The issue of malpractice further complicates matters. It is almost impossible to prove medical malpractice with the use of HDTs. The first requirement to prove malpractice is the duty of care by a physician to a patient.[129] This element is not present with HDTs, a consumer does not need to involve a doctor in their purchase of an HDT. Without a physician's involvement in the purchase of the HDT there is no one to bear the duty of care. There are many people involved in the production of the HDT, including people who design and assemble the product, but they cannot be held medically liable for any problems that arise. Physician involvement with HDTs would in many ways defeat their purpose. Without duty, there can be no malpractice. A case for medical malpractice is thus not an option regarding injuries that arise from the use of HDTs.

The problem of HDT liability is that malpractice cannot compensate for mistakes and one cannot prove products liability when the manufacturer has done everything correctly. A plaintiff must demonstrate that the use of the product was (1) unreasonably dangerous, (2) was used in the way it was meant to be used, and (3) was not altered in any significant way.[130] But a consumer can use an HDT that is not unreasonably dangerous and was manufactured correctly and still be injured. If, for example, a consumer purchases a kit testing for drug use and falsely tests positives they may face unexpected repercussions at home or professionally. Many HDTs have a margin of error.[131] Consumers may be unaware of this margin, or it may simply be that they are not using the test correctly. In both cases, there is no true recourse for the consumer. Doctors frequently order more tests than necessary to stave off even the possibility of missing something and facing a malpractice suit. This is such common practice that it has been coined "defensive medicine."[132] When consumers purchase HDTs they assume some risk. They recognize they are not going to a hospital and there is no one fighting a malpractice suit with defensive medicine. With the increasing popularity of HDTs the question remains as to whether it is rational for lawmakers and courts to so rigidly stick to the theory of *caveat emptor*

128. 21 U.S.C. § 321(h) (2018).

129. *See* Daly, *supra* note 28, at 100 (describing the standards for medical malpractice).

130. *Proving Fault in a Product Liability Case*, FINDLAW, http://injury.findlaw.com/product-liability/proving-fault-in-a-product-liability-case.html? (last visited Jan. 16, 2019).

131. *See, e.g.*, Norton, *supra* note 66 (evaluating the accuracy of an at-home test, used by both consumers and medical practitioners, for colon cancer).

132. *See* Michael Blanding, *How Malpractice Reform Affects Medical Device Innovation*, FORBES (Nov. 28, 2016), https://www.forbes.com/sites/hbsworkingknowledge/2016/11/28/how-malpractice-reform-affects-medical-device-innovation/#6deb6955464e- (describing doctors' interests in assuring quality care for patients and why they often over test in order to prevent error).

regarding products that do not present with actionable defects. It is foolish to adhere to this policy regarding HDTs because HDTs are not the typical consumer product; they are medical devices without the supervision of health care professionals. In fact, they are more than products. They are the transformation of what was once a private service (healthcare) into a commodity. Malpractice protects against bad medical service and products liability protects consumers from standard medical devices. But HDTs are medical devices that also appropriate a service. There is currently no adequate protection for consumers in place for such devices. There must be some sort of recourse in place for consumers if the sale of these devices is to continue.

IV. RECOMMENDATION

Many different solutions have been proposed for the issue of licensing regarding telemedicine. Different licensing solutions include a uniform national licensing model, a consultancy system, and special "abbreviated licenses."[133] A uniform licensing model would allow a physician to practice in any state and would eliminate the issues of state boundaries inhibiting the practice of medicine by passing a standard test.[134] One criticism of this system is that it would undermine state control of medical licensure. To handle this possible risk, states should collaborate with each other to find common criteria for practitioners; by providing input to the testing procedure states retain some control over their medical standards. Another possible solution is that licensed doctors could vouch for out of state practitioners of telemedicine. This would create a strong relationship between medical practitioners across the country and create oversight for out of state doctors. If licensed doctors agree to this solution, they would take responsibility for any mistakes made, but in exchange they are granted access to a wealth of new information for patients. Alternatively, an "abbreviated license" would allow practitioners to practice medicine across state lines so long as they only practice telemedicine.[135] This would not however allow practitioners to provide services in informal or emergency situations.[136] Of these solutions, the abbreviated license is the best. It respects state's rights regarding medical licensure unlike the uniform license. An abbreviated license also offers more independence than a consultancy system. Doctors would be able to provide services without having to rely on third-parties. The abbreviated license allows us to treat telemedicine as a new form of medical treatment. By treating telemedicine as something separate from standard medical practice, we begin to establish new frameworks to handle the new problems telemedicine brings.

HIPAA largely addresses privacy issues, protecting confidential medical information.[137] But the involvement of fallible technologies creates vulnerabilities in telehealth. Strict restrictions on access to telemedicine platforms, such as extra passcodes and firewalls, are the most basic solutions. Additional limitations include a restriction on

133. *See* McMenamin, *supra* note 10; Vyborny, *supra* note 3, at 80.

134. *See generally* Vyborny, *supra* note 3, at 78; The Interstate Medical Licensure Compact is an expedited pathway to multi-state licensure that standardizes the telemedicine licensure practice across state lines. Currently, 24 states are participating. *See generally IMLC*, *supra* note 94.

135. Vyborny, *supra* note 3, at 80.

136. *Id.*

137. 42 U.S.C § 1320d–6 (2006).

information collected. By only recording information absolutely necessary for medical records and patient care, the risk of unlawful access to information is limited. The use of telehealth makes it easy to collect information, but for the sake of the patient, it may be best to limit how that aspect of telemedicine is utilized. Some say that the issue of privacy is not a significant issue,[138] but, for the issues that do emerge, the solution to secure privacy in telemedicine is the same as the issue of privacy in most fields, diligence and utilization of current technologies to ensure safe data transmission.

Solutions for issues with HDTs are slightly more complex because they are a more emerging field. FDA involvement in the production of medical devices ensures that there is already a high standard of care. FDA approval for medical devices requires rigorous pre-testing of devices and analysis of efficacy depending on classification.[139]

Classification of HDTs should be evaluated differently from standard medical devices, the information provided by them is more dangerous than information provided by standard medical devices. Medical devices handled by professionals yield information that is evaluated in light of their superior knowledge and measured for accuracy out of professional duty and risk of liability. A doctor who tests a person's blood sugar may question a result they find unrealistic or unlikely. Due to malpractice concerns they may double check their results. A consumer relies on the result to their detriment because they do not know enough to question it. Results of HDTs are interpreted and acted upon by un-sophisticated consumers who rely on flawed FDA classifications. FDA approval is granted without consideration that HDTs carry different risks than conventional medical devices, due partially to an evolution of supervised patients to unsupervised consumers.

In the past, Congress has been willing to expand existing protections to vulnerable consumers in order to protect them from harm.[140] Regulation is often needed most when there is scientific uncertainty over the efficacy of new products, especially when products are marketed directly to consumers without physician involvement.[141] It is clear that HDTs fall under this umbrella. Increased legislative protection for consumers is one of the most effective solutions to the risk posed by HDTs to consumers. This may involve shifts in current standards of liability or accessibility to HDTs. This needs to be balanced with consumer interests in privacy and autonomy as well as manufacturers rights and interests in selling and developing products. By determining both party's rights and interests, legislators could then determine what interests would be the least harmed by compromise. For example, in the case of home diagnostic tests for devices that test for medical conditions, customer privacy would be held higher than in the case of a medical device that simply recorded hours slept each day. Therefore, the consumer interests would be considered more important than the manufacturer's interest in an issue with the test, but not the sleep measurement device.

Doctors can further protect consumers by reminding them that HDTs are a tool to be used, not a substitute for a medical opinion. Doctors should be sure to ask patients if HDTs have been used, most importantly because results from HDTs are not part of medical

138. Vyborny, *supra* note 3, at 76–77.

139. Volkert, *supra* note 10, at 207–08.

140. Katharine A. Van Tassel, *Slaying the Hydra: The History of Quack Medicine, the Obesity Epidemic and the FDA's Battle to Regulate Dietary Supplements Marketed as Weight Loss Aids*, 6 IND. HEALTH L. REV. 203, 244 (2012).

141. *Id*. at 246.

records and cannot be acted upon until they have been confirmed by hospital tests.[142] This is especially dangerous if a patient attempts to self-treat a condition and does not disclose medications they may be taking to their physician, this can cause drug interactions or mask symptoms. In order to have a complete and accurate medical record, medical practitioners must impress upon patients the importance of full disclosure and responsible treatment, regularly reminding patients that the information provided by these devices is not part of their medical records and that in order to receive the best possible treatment, doctors need as complete and accurate medical records as possible.

Pharmacists are another possible safeguard for consumers. Limiting the over-the-counter status of HDTs would limit liability to retailers and manufacturers. Pharmacists typically counsel consumers about risks and uses of provided medications. Involving pharmacists in the sale of HDTs could create an issue of "learned intermediaries" giving customers a party to hold liable.[143] The utility of HDTs would be defeated by making them prescription devices, but limiting access to them, in a way similar to how certain cough medicines or Plan B contraception is held behind the counter and available upon request, would ensure that providers have a chance to try to educate consumers of risks and utility of HDTs. The FDA vehemently opposes the idea of a third category of drugs beyond prescription and over-the-counter.[144] This limited access would need to be balanced with FDA interests. This solution sacrifices some of the anonymity that makes HDTs so desirable to some people, but that may be a necessary cost for the sake of consumer protection. Contraceptives with semi-restricted access are still frequently used, and, despite the lowered anonymity, there is no reason to think that HDTs will not continue to enjoy the same use and popularity they currently do.

The final actor who can mitigate the risks to consumers is the manufacturer. Manufacturers need to maintain strong relationships with the FDA and stay educated about regulatory schemes and testing processes. By staying informed about FDA policies, manufacturers can guarantee that their products exceed FDA requirements. This helps ensure that the risk of being accused of products defects or other forms of negligence are significantly decreased. It is in manufacturer's best interest to self-regulate their products. Because these products are expensive to produce and get approved, it is more advantageous for companies to incur extra initial costs to ensure safety and prevent costly expenses later, especially as medical device suits can be lengthy and costly to settle.[145] Without a medical figure or entity to blame manufacturers are often consumer's sole option for recourse. Companies should take initial steps to ensure that they do not face legal problems later. They can do this by ensuring that packaging is very clear about risks and use of HDTs. This effort needs to be balanced with ensuring that customers are not intimidated by

142. *With Home Testing, Consumers Take Charge of Their Health*, *supra* note 40.

143. Jennifer L. Smith, *Between a Rock and a Hard Place: The Propriety and Consequence of Pharmacists' Expanding Liability and Duty to Warn*, 2 HOUS. J. HEALTH L. & POL'Y 187, 215 (2002) (The learned intermediary doctrine states "a drug manufacturer owes a duty to warn the physician of a particular drug's danger and the physician, in turn, owes a duty to warn the patient." If there is an educated individual, commonly the pharmacist, who interacts with the product before the consumer receives it that person has an obligation to warn the consumer of any risks and confirm that the consumer fully understands how to use the product).

144. Noah, *supra* note 31, at 376–77 & n.97 (It is implied that the opposition stems from a desire not to complicate the system or change the power dynamic).

145. Van Tassel, *supra* note 140, at 243.

possible risks. By being exceptionally clear with instructions and packaging, manufacturers can head off some potential legal complications. Manufacturers should focus not just on informing consumers about risks associated with the devices, but also on understanding the results. Consumers should fully understand the information they receive from the tests in order to not react inappropriately to the information or seek the wrong sort of medical care later. Additionally, companies should provide customer support access. By providing a 24-hour hotline or internet chat service, companies can enable customers to clarify questions they have about HDTs. By going the extra step to ensure that customers are fully informed, manufacturers significantly reduce the risk of being held liable for warning defects, and reduce the chance that a customer will be able to make a case for products liability.

V. CONCLUSION

Telemedicine offers a host of benefits to patients and doctors, and the use of technology creates a network of learned individuals who have the potential to exponentially further collective medical knowledge. Despite these benefits, it is important to ensure that this system is utilized in a safe and responsible way. HDTs require more attentive oversight and consumer education. Open lines of communication between all involved parties is the best way to prevent future complication in an already complicated situation. Manufacturers should seek to not just meet regulatory standards, but to exceed them. Because the current legal understanding of these issues is so murky, it is important for manufacturers to focus on preventative measures before products are released as the costs of additional safety measures and educational efforts could substantially offset later costs that come from consumer lawsuits. HDTs offer the chance for personalized medical care and an informed population, but in order to achieve this, consumers must not be allowed unfettered access to unregulated products. The FDA regulates medical devices in order to protect consumers and establish a standard of care when it comes to products. Their oversight provides the only currently viable middle ground between products liability and malpractice. Technology is outpacing the law but we must find a way to catch up for the sake of public safety. Current legal frameworks can only be analogized to suit new technologies so much. In order to best handle this medical terra incognita, we will need forward thinking policies and laws specifically tailored to this new world.