A New Way of Healing: Regulating Healthcare AI

Rose Angelique Dizon[★]

★ '19 LL.M., Kyushu University; '14 J.D., Ateneo de Manila University School of Law. The Author is currently an Associate Corporate Counsel in Renesas Electronics Corporation headquartered in Tokyo, Japan. She served as the In-House Counsel of PayMaya Philippines and as an Associate at SyCip Salazar Hernandez & Gatmaitan.

Cite as 64 ATENEO L.J. 1127 (2020).

I. INTRODUCTION

A. Background of the Study

Ella is a 30-year old housewife who lives in a small fishing village located in Palawan, Philippines. Her hometown has a barangay health center, which is manned by a community health worker and a doctor, who only comes two to three times a week. The center only provides primary healthcare services to the community. For complex cases, the village folks have to go to the nearest provincial hospital, which is three hours away from their village in order to get diagnosed and treated. One day, Ella felt a sharp pain in her stomach. She hurriedly went to the barangay health center in order to have herself checked. At that time, only the community health worker was available, and thus, Ella was advised to travel to the provincial hospital to see a doctor.

Manu, on the other hand, is a 40-year-old lawyer, who is working for one of the top law firms in the Philippines. He eats nutritious food and exercises at least three times a week. He even joins a couple of marathons a year and religiously goes to his doctor annually for a routine physical check-up. He believes that he has a healthy lifestyle — or so he thought. One morning, while he was jogging around his village, he suddenly became dizzy and felt his legs go numb. Not long after, he collapsed on the pavement.

After being rushed to the city hospital, the emergency doctor ordered a blood test to be performed on Manu. When the results came out, it showed that Manu was only suffering from a mild case of anemia and was sent home with a couple of prescription medicines. A month after, Manu experienced a seizure. This time his wife brought him to a large private hospital. After a series of tests, the results did not look promising. Manu's x-ray revealed a number of dot-like features, scattered over his right lung. The general practitioner referred Manu to an oncologist for an expert opinion. After two weeks of waiting for his schedule, Manu went to the oncologist and showed him his x-ray.

Off-hand, the oncologist said that the features found on Manu's x-ray do not completely give a picture of his condition. The doctor then asked Manu to get a biopsy test and a positron emission tomography (PET) scan to

confirm. After a week, the results came in and Manu showed them to his oncologist. This time, the specialist confirmed that Manu had Stage III-A adenocarcinoma, his cancer had already spread to his lymph nodes.[1]

The stories of Ella and Manu are common narratives of patients in the Philippines. Ella's condition could have been immediately addressed if a doctor was immediately available. Manu's cancer could have been earlier detected if the first healthcare provider was properly equipped with the tools to detect his cancer. In hindsight, the two are even considered fortunate because they were immediately attended to by healthcare providers, others are not that lucky.

Technology is generating huge waves in healthcare delivery.[2] In Dubai, a telemedicine doctor called RoboDoc can examine a patient through the use of a smartphone.[3] Diagnosis is done remotely through the use of video-conferencing between doctors and patients.[4] This kind of technology is especially promising for an archipelagic nation like the Philippines, where hospitals are not only scarce but also distantly located from far flung communities.[5] Through telemedicine, a patient's life as well as his time and money can be saved.[6]

1. Cancercare, Lung Cancer 101, *available at* https://www.lungcancer.org/find_information/publications/163-lung_cancer_101/268-types_and_staging (last accessed Feb. 29, 2020).

2. *See generally* Iman Ghosh, 5 Ways Technology is Transforming the Healthcare Industry, *available at* https://www.visualcapitalist.com/5-ways-technology-healthcare-industry (last accessed Feb. 29, 2020).

3. Jad Doudar, Healing From a Distance: A Robot Today Can Keep a Doctor Away, *available at* https://www.stalawfirm.com/en/blogs/view/healing-from-a-distance.html?fbclid=IwAR3QvKSEunvIJ6k9c64LU8wj6u1cZuLYg69uDpdRmdfHGWGmXVsoCiombLk (last accessed Feb. 29, 2020).

4. *Id.*

5. *See* Hans Jesper Del Mundo, Shortage of hospitals and health workers in the Philippines (An Essay Published Online by the Medical Research Information Center Global), *available at* https://www.mricg.info/single-post/2018/02/14/Shortage-of-hospitals-and-health-workers-in-the-Philippines (last accessed Feb. 29, 2020).

6. Evan Sweeney, Telemedicine saves patients time and money, study shows, *available at* https://www.fiercehealthcare.com/mobile/telemedicine-saves-patients-time-and-money-study-shows (last accessed Feb. 29, 2020).

Another promising innovation is the clinical decision support system used by physicians and other healthcare professionals in diagnosing and treating patients.[7]

KroniKare, an end-to-end AI-driven integrated system, is able to assess and manage chronic wounds works via smartphone.[8] It uses thermal imaging and Machine Learning (ML) to measure wound size, classify wound type, and predict any possible complications or infection.[9] Data from the smartphone is cascaded to the KroniKare dashboard of the attending wound nurse to remotely check the patient.[10] Likewise, the smartphone is linked to a server, which uses an AI-engine to analyze the data and provide higher-level of insights on tracking, predicting and case matching.[11] Kronikare can give its diagnosis within 30 seconds, which is way faster than a wound nurse.[12]

IDx-DR, the first United States Food and Drug Authority (U.S. FDA) certified autonomous AI system, can spot signs of diabetic retinopathy through retinal image.[13] A trained operator uses a camera to capture the patient's eye images.[14] The images are then sent to IDx-DR enabled computer and analyzed.[15] Within a minute, and if the images are of sufficient quality, the software provides an output: if positive, a physician will refer the patient to an eye care specialist; if negative, patient can be rescreened at a later date.[16]

---

7. Christian Castaneda, et al., *Clinical decision support systems for improving diagnostic accuracy and achieving precision medicine*, 5 J. CLIN. BIOINFORMA. 1, 5.

8. KroniKare, AI-Based System for Assessment and Management of Chronic Wounds, *available at* http://kronikare.com (last accessed Feb. 29, 2020) & StartUp Health, Video, *Accenture HealthTech Innovation Challenge 2018: KroniKare Pitch*, Feb. 15, 2018, YOUTUBE, *available at* https://www.youtube.com/watch?v=a9JfG8pwJX0 (last accessed Feb. 29, 2020).

9. *Id*.

10. *Id*.

11. *Id*.

12. *Id*.

13. IDx, How It Works, *available at* https://www.eyediagnosis.co/idx-dr-eu-1 (last accessed Feb. 29, 2020).

14. *Id*.

15. *Id*.

16. *Id*.

Google's DeepMind Health Streams is a mobile application (app) developed to automatically review test results for acute kidney injury.[17] If a medical issue is discovered, the AI system transmits an urgent secure smartphone alert to the relevant doctor to help.[18] The alert comes with the information about prior conditions of the patient so that the doctor can make an immediate diagnosis.[19]

Aside from being used as an aid for clinicians, AI is also at the forefront in battling the novel corona virus or COVID19. AI is being used to predict which available drugs in the market or existing compounds can be used to treat the virus.[20] It is also being used to understand the behavioral patterns of the pandemic in order to manage and contain its effects.[21]

The foregoing are just some examples of how artificial intelligence is being used in the healthcare industry. As these healthcare AI become more sophisticated, their potential to predict, diagnose, treat, or prevent medical conditions will become more powerful. In fact, today, Google's neural networks can already detect skin cancer as effectively as a seasoned dermatologist.[22]

Imagine what they could achieve five or ten years from now. Ella could have used a barangay health center smartphone to get herself checked. This not only saves her time and money, it also provides an accurate diagnosis of her medical condition. Manu, through AI systems, could have had his lung cancer diagnosed and treated earlier. Healthcare AI has the potential to provide a quicker, more accurate and, probably, more affordable healthcare

17. DeepMind Technologies Limited, Frequently Asked Questions, *available at* https://deepmind.com/applied/deepmind-health/deepmind-health-faqs/#image-17200 (last accessed Feb. 29, 2020).

18. Royal Free London NHS Foundation Trust, Video, *DeepMind Health Streams application*, Nov. 19, 2016, YOUTUBE, *available at* https://www.youtube.com/watch?v=ik9ps7L-p2E (last accessed Feb. 29, 2020).

19. *Id.*

20. Jun Wu, How Artificial Intelligence Can Help Fight Coronavirus, *available at* https://www.forbes.com/sites/cognitiveworld/2020/03/19/how-artificial-intelligence-can-help-fight-coronavirus/#1d5369f14d3a (last accessed Feb. 29, 2020).

21. *Id.*

22. A. Michael Froomkin, et al., *When AIs Outperform Doctors: Confronting the Challenges of a Tort-Induced Over-Reliance on Machine Learning*, 61 ARIZ. L. REV. 33, 39 (2019) (citing Andre Esteva, et al., *Dermatologist-Level Classification of Skin Cancer with Deep Neural Networks*, 542 NATURE 115, 118 (2017)).

service.[23] Nevertheless, no matter how powerful these innovations become, they are not infallible.[24] Just like any product or physician, they can malfunction or provide a wrong diagnosis or treatment.[25] When that time comes, will our traditional product liability or medical negligence rules still be relevant?

B. Statement of the Problem

The field of medicine is experiencing unprecedented gains due to the merging of two contemporary developments in big data[26] and Machine Learning. Big data in healthcare is a result of the accumulation of vast amounts of health information coming from electronic health records, clinical trials, data from insurance claims, pharmacy records, medical literature, and even information collected by smartphones or digital wearables.[27] Machine Learning techniques, on the other hand, are employed in order to unravel patterns in big data.[28] The convergence of the two results in algorithms, which can be used to predict as well as to classify information that can be useful in medical diagnosis and treatments.[29] The problem, however, is that Machine Learning techniques cannot explain why or how

23. *See* Karen Weintraub, How AI is Transforming Healthcare, *available at* https://www.webmd.com/special-reports/artificial-intelligence/20200102/how-ai-is-transforming-health-care (last accessed Feb. 29, 2020).

24. *Id.*

25. *See* Robert David Hart, When artificial intelligence botches your medical diagnosis, who's to blame?, *available at* https://qz.com/989137/when-a-robot-ai-doctor-misdiagnoses-you-whos-to-blame (last accessed Feb. 29, 2020).

26. Big data is defined as —

> large, diverse sets of information that grow at ever-increasing rates. It encompasses the volume of information, the velocity or speed at which it is created and collected, and the variety or scope of the data points being covered. Big data often comes from multiple sources and arrives in multiple formats.

Troy Segal, Big Data, *available at* https://www.investopedia.com/terms/b/big-data.asp (last accessed Feb. 29, 2020).

27. *See* Wullianallur Raghupathi & Viju Raghupathi, *Big data analytics in healthcare: promise and potential*, 2 HEALTH INFO. SCI. & SYS. 1, 1 (2014).

28. Manoj Debnath, Understanding Big Data Analytics, *available at* https://www.developer.com/db/understanding-big-data-analytics.html (last accessed Feb. 29, 2020).

29. William Nicholson Price II, *Artificial Intelligence in Health Care: Applications and Legal Implications*, SCITECH LAW., Fall 2017, at 10.

they arrived at their conclusion. Thus, it is fitting to call them "black-box medicine[.]"[30]

Safety and efficacy are the essential considerations in producing and operating health products and in providing health services. As much as possible the risk of harm must be minimized, if not totally prevented. Licensing requirements for medical device and healthcare providers were enacted precisely to promote public safety and public health. In case the risk is not averted and actually causes harm to an individual, the injured party has the right to claim from the person who failed to prevent the risk and caused the harm.

In this undertaking, the challenge is to determine whether the technological shift in the delivery of healthcare calls for a change in regulation. This Note will examine current liability regimes in the Philippines and will determine if these are still sufficient to address the harm caused by healthcare AI. In so doing, the Note intends to resolve the issue on whether a new liability regime should be developed and introduced in light of these innovations. Finally, in case these existing liability regimes are insufficient, the study will recommend a practical solution on how healthcare AI should be regulated in the Philippines.

C. Thesis Statement

Existing liability regimes such as medical negligence and product liability are insufficient to address the harm caused by a healthcare AI. Attribution of negligence on the doctor or defect on the product will be difficult, if not impossible, to prove. Hence, an equitable solution is to apply a sliding scale approach in establishing medical negligence and a common enterprise liability framework in addressing the gaps of product liability law in light of the unique characteristics of healthcare AI (i.e., inherently opaque, self-learning, and autonomous).

D. Objectives of the Study

The primary objective of this Note is to determine a liability framework by which an injured party can obtain redress from the harm caused by a healthcare AI without stifling the production and use of these innovations. In order to make such determination, this Note will examine existing liability regimes in the Philippines such as medical negligence and product liability and analyze whether these regimes are sufficient or whether a new regime should be developed in light of the characteristics of healthcare AI.

---

30. *Id.*

E. Scope and Limitation.

The main topic of this Note concerns civil liability regimes and healthcare AI. The Author will limit the scope to two liability regimes available under Philippine law, as well as medical negligence and product liability. Although a number of healthcare AI will be discussed throughout the Note, analysis on the applicability of existing liability regimes will focus on healthcare AI which are inherently opaque, self-learning, and autonomous.

This Note will briefly discuss how the field of artificial intelligence has come about and how it is being used in the healthcare sector.

The Note will provide a general overview of the Philippine healthcare system as well as the country's geopolitical and socio-economic conditions, which greatly affects the delivery of healthcare in the country. It will also introduce Philippine regulations on the practice of medicine as well as medical devices.

Since most of the medical devices used in the Philippines today are imported from foreign countries such as the United States of America (U.S.), the European Union (EU), and Japan, this Note will also look at these countries' medical device regulations as well as their AI initiatives. It will also provide a limited discussion on several issues surrounding healthcare AI such as bias, security, data privacy, and its black-box nature. Intellectual property issues on the use of data and algorithms in healthcare AI will not be discussed.

Finally, this Note will examine and analyze three liability framework proposals addressing the harm caused by artificial intelligence and determine their applicability to resolve the problems posed by this undertaking.

F. Organization

This Note is divided into six main Chapters.

Chapter I serves as an introduction to the subject matter and the problem.

Chapter II traces the history of AI. It also provides a working definition of artificial intelligent systems and healthcare AI that will be employed in this study. It will also introduce the concept of Machine Learning as well as provide a non-exhaustive list of AI devices used in the delivery of healthcare today.

Chapter III talks about the Philippines and its healthcare system. It gives the reader an idea not just about the health issues in the country but also the

geographical, economical, and political issues, which affect the delivery of healthcare.

Chapter IV will look at the medical device regulations as well as AI initiatives of the U.S., the EU, and Japan. The brief survey will give an idea on the status of AI regulation which can help in developing a relevant framework for healthcare AI.

Chapter V integrates the findings and analyzes the authorities read to answer the main problems of this Note. The Author will examine existing legal regimes in the Philippines and how they are relevant or not in regulating healthcare AI given its inherent characteristics. The Author will discuss and provide a critical analysis of several proposals to regulate healthcare AI. Finally, the Author will provide a conclusion of findings and a recommendation.

G. Methodology

In writing this Note, the Author examined Philippine constitutional provisions, relevant statutes, and court decisions concerning medical devices, the practice of medicine, product liability, tort, and quasi-delict. The Author also looked at the laws and regulations on medical devices of U.S., EU, and Japan. A brief survey of these countries' AI initiatives was also done. The Author also examined books and journal articles discussing medical device, product liability, medical malpractice, and artificial intelligence. Finally, the Author consulted medical professionals to verify medical terms and techniques.

II. UNBOXING ARTIFICIAL INTELLIGENCE

A. Definition of Artificial Intelligence

Artificial Intelligence has no universal definition.[31] One accepted characterization of AI is that it is a "branch of computer science dedicated to the creation of systems that perform tasks that usually require human intelligence,."[32] Incidentally, Stuart Russel and Peter Norvig came up with four approaches that illustrate how an AI performs:

---

31. ALLESSANDRO ANNONI, ET AL., ARTIFICIAL INTELLIGENCE: A EUROPEAN PERSPECTIVE 19 (Max Craglia ed., 2018).

32. Filippo Pesapane, et al., *Artificial Intelligence as a medical device in radiology: ethical and regulatory issues in Europe and the United States*, 9 INSIGHTS INTO IMAGING 745, 745-46 (2018) (citing Gabriel Chartrand, et al., *Deep Learning: A Primer for Radiologists*, 37 RADIOGRAPHICS 2113, 2114 (2017)).

(1) AI acts humanly (e.g., natural language processing, knowledge representation, automated reasoning, machine learning);[33]

(2) AI thinks humanly (e.g., cognitive architectures and neural networks);[34]

(3) AI thinks rationally (e.g., logic solvers, inference and optimization);[35] and

(4) AI acts rationally (e.g., intelligent software agents and embodied robots).[36]

The success of the AI systems under the first and second approaches is measured according to their "fidelity to *human* performance."[37] On the other hand, the success of the AI systems under the third and fourth approaches is measured "against an *ideal* performance measure called rationality."[38] An AI is said to be rational if it does "the 'right thing,' given what it knows."[39] Despite the apparent differences, the approaches appear to be less delineated and converge in modern AI systems. One good example is Apple's Siri. Siri has natural language processing[40] capabilities, which allows it to understand and analyze the voice command of its user and is also considered as an intelligent software agent because it can arrive at a decision based on its user's input, its environment as well as its experiences.[41]

---

33. STUART RUSSEL & PETER NORVIG, ARTIFICIAL INTELLIGENCE A MODERN APPROACH 2-3 (3d ed. 2016).

34. *Id.* at 3.

35. *Id.* at 4.

36. *Id.* at 4-5.

37. *Id.* at 1.

38 *Id.*

39. RUSSEL & NORVIG, *supra* note 33, at 1.

40. Badreesh Shetty, Natural Language Processing (NLP) for Machine Learning, *available at* https://towardsdatascience.com/natural-language-processing-nlp-for-machine-learning-d44498845d5b (last accessed Feb. 29, 2020). Natural language processing is "a field in machine learning with the ability of a computer to understand, analyze, manipulate, and potentially generate human language." *Id.*

41. Margaret Rouse, Intelligent Agent, *available at* https://searchenterpriseai.techtarget.com/definition/agent-intelligent-agent (last accessed Feb. 29, 2020). An intelligent agent is "a program that can make decisions or perform a service based on its environment, user input[,] and experiences." *Id.*

For this Note, the Author will adopt the definition of artificial intelligence devised by the High-Level Expert Group on Artificial Intelligence formed by the European Commission —

> [AI] systems are software (and possibly also hardware) systems designed by humans that, given a complex goal, act in the physical or digital dimension by perceiving their environment through data acquisition, interpreting the collected structured or unstructured data, reasoning on the knowledge, or processing the information, derived from this data and deciding the best action(s) to take to achieve the given goal. AI systems can either use symbolic rules or learn a numeric model, and they can also adapt their [behavior] by [analyzing] how the environment is affected by their previous actions.[42]

From this definition, the three main capabilities of an AI system can be deduced to be: perception, [43] reasoning and decision making, [44] and actuation.[45] From these capabilities, AI systems can be classified into three kinds: (1) those which possess narrow artificial intelligence; (2) those which possess artificial general intelligence; and (3) those which are self-conscious.[46] Narrow AI is also known as weak AI and it refers to a "system that addresses specific application areas."[47] Examples of narrow AI are recommendation systems, self-driving cars, and image recognition software. Artificial General Intelligence or Strong AI "exhibits apparently intelligent behavior at least as advanced as a person across the range of cognitive, emotional, and social behaviors."[48] Finally, self-conscious AI are systems which "evolves into a

42. Independent High-Level Expert Group on Artificial Intelligence set up by the European Commission, *A Definition of AI: Main Capabilities and Scientific Disciplines*, at 6 (2019), *available at* https://www.aepd.es/sites/default/files/2019-09/ai-definition.pdf (last accessed Feb. 29, 2020) [hereinafter AI HLEG, *A Definition of AI*].

43. *Id.* at 2.

44. *Id.* at 2–3.

45. *Id.* at 3.

46. The Medical Futurist, Top Smart Algorithms in Healthcare, *available at* https://medicalfuturist.com/top-ai-algorithms-healthcare (last accessed Feb. 29, 2020).

47. A Bill to Require the Secretary of Commerce to Establish the Federal Advisory Committee on Development and Implementation of Artificial Intelligence, and for Other Purposes, H.R. 4635, § 3 (3), 115th Cong., 1st Reg. Sess. (2017) (U.S.).

48. *Id.* § 3 (2).

stand-alone consciousness[ ]" and are yet to be developed by scientists today.[49]

B. Brief History of Artificial Intelligence

"Can machines think?"[50] Alan Turing posed this question in his 1950 seminal work Computing Machinery and Intelligence.[51] In answering this question, Turing came up with the "imitation game[,]" a behavioral exercise aimed to test whether machines were capable of thinking.[52] His proposition was simple: a machine can pass the test if a human interrogator, after asking written questions, will not be able to tell whether the written answers came from a human or a computer.[53]

A year after the publication of Turing's paper, Stochastic Neural Analog Reinforcement Calculator (SNARC), the first machine learning neural network was built by Marvin Minsky and Dean Edmonds.[54] The machine was inspired by the earlier model of artificial neurons developed by Warren McCulloch and Walter Pits and it used 300 vacuum tubes to simulate a network of 40 neurons.[55] SNARC worked like a rat labyrinth wherein "[a] 'rat' would be created at some point in the network and would then set out to learn a path to some specified end point."[56] Initially, the rat would randomly work its way throughout the maze.[57] Subsequently, "correct choices would be reinforced by making it easier for the machine" to choose the correct choice in order to increase the probability of choosing the correct option.[58]

The summer of 1956 is singled out as the most important event in artificial intelligence history. John McCarthy, together with Minsky and

49. The Medical Futurist, *supra* note 46.

50. Alan Turing, *Computing Machinery and Intelligence*, 49 MIND 433, 433 (1950).

51. *Id.*

52. *Id.*

53. *Id.* at 433-34

54. RUSSEL & NORVIG, *supra* note 33, at 16.

55. *Id.*

56. Jeremy Bernstein, Marvin Minsky's View of the Future, *available at* https://www.newyorker.com/magazine/1981/12/14/a-i (last accessed Feb. 29, 2020).

57. *Id.*

58. *Id.*

other computer scientists, organized the Dartmouth Conference.[59] In their proposal, they introduced the purpose of the conference, to wit —

> [They] propose[d] that a [two-]month, 10 man study of artificial intelligence be carried out during the summer of 1956 at Dartmouth College in Hanover, New Hampshire. 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. An attempt will be made to find how to make machines use language, form abstractions and concepts, solve kinds of problems now reserved for humans, and improve themselves. [They] think that a significant advance can be made in one or more of these problems if a carefully selected group of scientists work on it together for a summer.[60]

This very document was the first time the term "artificial intelligence" was used. The Dartmouth Conference was attended by Claude Shannon, Arthur Samuel, and Nathan Rochester of IBM; Trenchard More of Princeton University; Ray Solomonoff and Oliver Selfridge of Massachusetts Institute of Technology (MIT); and Allen Newell and Herbert Simon of Carnegie Tech University.[61] This event was significant because it gathered the leading names in AI for the first time.[62]

The 1960s and 1970s were promising decades for AI. Newell and Simon introduced the General Problem Solver (GPS), a computer program designed to mimic human problem-solving protocols.[63] Joseph Weizunbaum developed ELIZA, a computer program capable of processing natural language. [64] Computer-aided diagnosis was also developed during this period.[65] In the early 1970s, studies on actual problem-solving behaviors of

59. Karl Tate, History of A.I.: Artificial Intelligence (Infographic), *available at* https://www.livescience.com/47544-history-of-a-i-artificial-intelligence-infographic.html (last accessed Feb. 29, 2020).

60. John McCarthy, et al., A Proposal for the Dartmouth Summer Research Project on Artificial Intelligence at 2, *available at* http://jmc.stanford.edu/articles/dartmouth/dartmouth.pdf (last accessed Feb. 29, 2020).

61. RUSSEL & NORVIG, *supra* note 33, at 17-18.

62. *Id.* at 18.

63. *Id.*

64. Rockwell Anyoha, The History of Artificial Intelligence, *available at* http://sitn.hms.harvard.edu/flash/2017/history-artificial-intelligence (last accessed Feb. 29, 2020).

65. Peter Szolovits, et al., *Artificial Intelligence in Medical Diagnosis*, 108 ANNALS OF INTERNAL MED. 80, 80 (1988).

experienced clinicians resulted in the development of expert systems.[66] These expert systems were classified into two: the rule-based system and the matching strategies. Rule-based systems like MYCIN[67] contain "large number[s] of independent, situation-specific rules and [ ] computers [ ] simulate expert reasoning by stringing these rules together in chains of deduction."[68] In contrast, matching strategies like INTERNIST-I[69] "construct and evaluate hypotheses by matching a patient's characteristics with stored profiles of the findings in a given disease."[70] Due to these developments, various government agencies like the U.S.'s Defense Advanced Research Projects (DARPA) invested resources on AI research.[71] This initial success inspired AI researchers and scientist to brag about and predict their future achievements.[72] These predictions created very high expectations from funders.[73] Eventually, these expectations were not met for various reasons.[74] Since expectations were not met and criticisms started to pile up, the funding from government agencies was cut off, resulting in the slowdown of the field or a period which would later be known as the AI winter.[75]

In the 1980s, the Japanese Government played a pivotal role in resuscitating the field of AI. The Japanese Ministry of International Trade and Industry provided a US$850 million investment in a 10-year project

66. *See generally* William B. Schwartz, et al., *Artificial Intelligence In Medicine Where Do We Stand?*, 27 JURIMETRICS 362, 363 (1987).

67. MYCIN is a "system specialized in the diagnosis of blood diseases and prescription drugs[.]" Council of Europe, History of Artificial Intelligence, *available at* https://www.coe.int/en/web/artificial-intelligence/history-of-ai (last accessed Feb. 29, 2020).

68. Schwartz, et al., *supra* note 66, at 363 (citing RULE-BASED EXPERT SYSTEMS: THE MYCIN EXPERIMENTS OF THE STANFORD HEURISTIC PROGRAMMING PROJECT (W.J. Clancey & E.H. Shortliffe eds., 1984)).

69. INTERNIST-I "is an expert system designed ... to diagnose multiple diseases in internal medicine by modelling the [behavior] of clinicians." D.A. Wolfram, An appraisal of INTERNIST-I, 7 ARTIFICIAL INTELLIGENCE IN MED. 93, 93 (1995).

70. Schwartz, et al., *supra* note 66, at 364.

71. Anyoha, *supra* note 64.

72. RUSSEL & NORVIG, *supra* note 33, at 20-21

73. Anyoha, *supra* note 64.

74. RUSSEL & NORVIG, *supra* note 33, at 21-22.

75. Tate, *supra* note 59.

called the Fifth Generation Computer Project.[76] The intent of the Japanese Government was "to create new technology and take the lead in the computer industry."[77] This initiative tugged the United Kingdom and the U.S. Governments to follow.[78] Once again, the field of AI gained traction. During this era, new AI techniques were introduced but what is really significant is that AI started to be used commercially.[79] R1, considered as the first successful commercial expert system, was used by the Digital Equipment Corporation to configure order for new computer systems.[80] As a result, this expert system became a cost saving device for the company.[81] Towards the end of the decade, more than half of the Fortune 500 companies were "involved in either developing or maintaining [ ] expert systems."[82]

In the 1990s and 2000s, AI continued to grow and was utilized in both military and commercial endeavors. In the 1991 Gulf War, the U.S. military used the Dynamic Analysis and Replanning Tool or DART "to do automated logistics planning and scheduling for transportation."[83] DARPA later noted that DART paid back its 30-year investment in AI.[84] In 1997, IBM's Deep Blue defeated world chess grandmaster Gary Kasparov.[85] After the match game, "Kasparov said that 'he felt a new kind of intelligence' across the board from him."[86] This victory also resulted in the increase of IBM stock prices.[87] In 2002, iRobot launched Roomba, an autonomous robotic vacuum cleaner for household use, and deployed iRobot PackBot, a tactical mobile robot used by U.S. troops in Iraq and Afghanistan to handle

76. *See generally* University of Washington, The History of Artificial Intelligence at 22-24, *available at* https://courses.cs.washington.edu/courses/csep590/06au/projects/history-ai.pdf (last accessed Feb. 29, 2020).

77. *Id.* at 22.

78. *See, e.g.*, RUSSEL & NORVIG, *supra* note 33, at 24.

79. *Id.*

80. *Id.*

81. *Id.*

82. *See, e.g.*, University of Washington, *supra* note 76, at 12.

83. RUSSEL & NORVIG, *supra* note 33, at 29.

84. *Id.*

85. *Id.*

86. *Id.*

87. *Id.*

hazardous materials and clear explosives.[88] In 2007, IBM continued to embark on its AI development and announced that it was building a computer system that can compete in a game of Jeopardy.[89] In 2011, IBM Research publicly introduced IBM Watson, an open-domain question-answering system. IBM Watson bested Jeopardy champions in a two-game match.[90] Today, IBM Watson evolved into IBM Watson Health, a clinical decision support system for physicians.[91]

Since the turn of the century, AI has rapidly evolved and is continually growing because of the availability of big data coming from online platforms, like social media and e-commerce, and traditional platforms, like corporate and government data. These information serve as a vital ingredient to improve machine learning techniques and algorithms, which run on powerful computer systems.[92] From curating our social media feeds to diagnosing life threatening diseases such as stroke and cancer, AI has undeniably changed and will continue to transform the way we live and interact with our environment.

C. Machine Learning

Machine Learning (ML) has changed the face of computing. Gone are the days when computer programmers collaborate with human domain experts "to learn the rules and criteria to make decisions, and translate those rules and criteria into software code."[93] The software code then processes data

88. iRobot, Our History, *available at* https://www.irobot.com/about-irobot/company-information/history (last accessed Feb. 29, 2020).

89. Ana Paula Appel, et al., *Cognitive Computing: Where Big Data is Driving Us*, *in* HANDBOOK OF BIG DATA TECHNOLOGIES 836 (Albert Y. Zomaya & Sherif Sakr eds., 2017).

90. John Markoff, *Computer Wins on 'Jeopardy!': Trivial, It's Not*, N.Y. TIMES, Feb. 16, 2011, *available at* https://www.nytimes.com/2011/02/17/science/17jeopardy-watson.html (last accessed Feb. 29, 2020).

91. *See* IBM Watson Health, Clinical Decision Support, *available at* https://www.ibm.com/watson-health/solutions/clinical-decision-support (last accessed Feb. 29, 2020).

92. U.S. Office of Science and Technology Policy, Preparing for the Future of Artificial Intelligence (A Report by the National Science and Technology Council's Subcommittee on Machine Learning and Artificial Intelligence) at 6, *available at* https://obamawhitehouse.archives.gov/sites/default/files/whitehouse_files/microsites/ostp/NSTC/preparing_for_the_future_of_ai.pdf (last accessed Feb. 29, 2020).

93. *Id.* at 8.

inputs to get an answer as output. Rather than being explicitly programmed, ML systems today are trained to learn.[94] ML, as an artificial intelligence technique, is proven advantageous especially in cases wherein it is "difficult to write down explicit rules to solve a problem."[95]

But what exactly is Machine Learning? Arthur Samuel[96] intuitively described it as a "[f]ield of study that gives computers the ability to learn without being explicitly programmed."[97] Tom Mitchell,[98] on the other hand, described ML as "a computer program [that] 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."[99] Basically, an ML system learns from the data set that it is given or taught. Today ML is trained to do various tasks and one of which is to classify spam emails. To illustrate, classifying spam emails will be task T while watching an email user label emails as spam or not spam will be experience E.[100] Performance measure P will be the fraction of emails correctly classified.[101] Thus, an ML system learns and improves in classifying spam emails by watching a user label his emails as spam or not spam.[102] As a result, performance measure P will improve through the process.[103]

94. *See generally* AI HLEG, *A Definition of AI*, *supra* note 42, at 3-5.

95. U.S. Office of Science and Technology Policy, *supra* note 92, at 8.

96. Arthur Samuel is one of the attendees of the Dartmouth Conference in the Summer of 1956. CRINA GROSAN & AJITH ABRAHAM, INTELLIGENT SYSTEMS: A MODERM APPROACH 6 (2011).

97. Carnegie Mellon University Qatar, Machine Learning, *available at* http://www.contrib.andrew.cmu.edu/~mndarwis/ML.html (last accessed Feb. 29, 2020).

98. Tom Mitchell is a US AI researcher and was the former chair of the Machine Learning Department of Carnegie Mellon University. Tom M. Mitchell, Carnegie Mellon University Risk and Regulatory Services Innovation Center, *available at* https://www.cmu.edu/risk-reg-center/people/tom-mitchell.html (last accessed Feb 29, 2020).

99. Andrew Ng, Video, *What is Machine Learning?*, COURSERA, *available at* https://www.coursera.org/lecture/machine-learning/what-is-machine-learning-Ujm7v? (last accessed Feb. 29, 2020).

100. *Id.*

101. *Id.*

102. *Id.*

103. *Id.*

Neural network and deep learning are subsets of Machine Learning that are equally important.

A neural network[104] is inspired by the human brain and just like the neurons in the brain, it is composed of small processing units, which have weighted connections.[105] "In [a] neural network, the associations between the outcome and the input variables are depicted through multiple hidden layer combinations of pre-specified functionals. The goal is to estimate the weights through input and outcome data so that the average error between the outcome and their predictions is minimized."[106] Neural networks are used to analyze large sets of data in order to extract patterns and have been proven to be effective in diagnosing strokes, cancer, and neurological disorders such as Parkinson's disease.[107]

Deep learning comprises of deep neural networks with multiple "hidden layer [ ] algorithms [which can] handle complex data with various structures."[108] It learns by itself by using its multiple hidden layers to filter information.[109] Due to its capacity to process complex and large volume of data, deep learning is used to diagnose skin cancer and diabetic retinopathy through image analysis.[110]

There are a number of ways to train a ML system, but the most common methods used are supervised learning and unsupervised learning.

In supervised learning, a human supervisor provides a training set to the ML system. The training set has specific data and pre-set patterns, which gives a background on what is the intended outcome or solution. Through its pattern recognition skills coupled with consistent training, the ML system

104. Bernard Marr describes an artificial neural network as having three layers: an input layer, a hidden layer, and an output layer. The input layer receives the data while the hidden layer processes the data. Meanwhile, the output layer decides what to do based on the received and processed data. Bernard Marr, Deep Learning vs Neural Networks: What's the Difference?, *available at* https://bernardmarr.com/default.asp?contentID=1789 (last accessed Feb. 29, 2020).

105. *See generally* AI HLEG, *A Definition of AI*, *supra* note 42, at 4.

106. Fei Jiang, et al., *Artificial Intelligence in healthcare past, present and future*, 2 STROKE & VASCULAR NEUROLOGY 230, 235-36 (2017).

107. *Id.* at 237.

108. *Id.*

109. Marr, *supra* note 104.

110. Jiang, et al., *supra* note 106, at 238.

is able to recognize new data. Ideally, through this process, the ML system will eventually come up with analogous or "even better solutions than those that would have been provided by its human supervisor."[111] In healthcare, "supervised learning is suitable for predictive modelling via building some relationships between the patient traits (as input) and the outcome of interest (as output)."[112]

In unsupervised learning, an ML system basically extracts correlations between data.[113] Hence, the task of the algorithms is to search for "structure in the training data, like finding which examples are similar to each other, and group them into clusters."[114] In healthcare, this kind of learning technique is typically used for feature extraction.[115]

Through the years, artificial intelligence used in diagnostics and treatments have come a long way since earlier expert systems MYCIN and INTERNIST-I. As of this writing, various software, as well as hardware, employing various ML techniques have been assisting healthcare providers, as well as consumers, in providing faster and more accurate diagnosis.

D. AI Systems Used in the Delivery of Healthcare

To have a broader picture on how AI systems are used in the delivery of healthcare, this section will discuss several examples grouped according to the typology presented by Nicolas Terry in his article *Of Regulating Healthcare AI and Robots*.[116] The typology is non-exhaustive; nevertheless, it provides a good representation of AI systems that are already existing and are being developed as of this writing.

111. Tjasa Zapusek, *Artificial Intelligence in Medicine and Confidentiality of Data*, 11 ASIA PACIFIC J. HEALTH L. & ETHICS 105, 118 (2017).

112. Jiang, et al., *supra* note 106, at 233.

113. Zapusek, *supra* note 111, at 118.

114. Jean Francois Puget, What is Machine Learning?, *available at* https://web.archive.org/web/20190604140740/https://www.ibm.com/developerworks/community/blogs/jfp/entry/What_Is_Machine_Learning?lang=en (last accessed Feb. 29, 2020).

115. Jiang, et al., *supra* note 106, at 233.

116. Nicolas Terry, *Of Regulating Healthcare AI and Robots*, 21 YALE J.L. & TECH. 3, 3 (2019).

1. Administrative

Routine office administration can be drudging. To address this, AI systems ranging from computer software to robotic systems are being used and developed. Recently, a number of offices in the U.S. are using "robotic process automation" in order to improve workflows. Based on their experience, automation of accounting, billing, customer service and payments not only saved hours of human work, it also made work more efficient.[117] This back office type of automation will be introduced in hospitals and clinics to take care of tasks such as booking doctor appointments and billing patients.[118] In fact, Ali Health, the health care arm of Alibaba, and the health department of Yuhang, a district in China, have already started using facial recognition technology to make registration and billing of patients faster and more efficient.[119]

2. Mobile Medical Apps and Wearables

Cortez in his article, *The Mobile Health Revolution?*, presents a separate typology of mobile medical apps and wearables, as follows:

> (1) Connectors expand the capabilities of a [U.S] FDA-regulated device by connecting it to a mobile device like a smartphone or a tablet.[120] An example of this is Mobile MIM, which is an application that allows a doctor to view computed tomography scans (CT scan), magnetic resonance images (MRI), PET scans and other diagnostic tests on mobile devices.[121]
>
> (2) Replicators use a mobile device to function as "a medical device by replicating the functionality of an [U.S] FDA-regulated device."[122] An example of this is the iStetoschope Expert, which

117. Steve Lohr, *'The Beginning of a Wave': A.I. Tiptoes Into the Workplace*, N.Y. TIMES, Aug. 5, 2018, *available at* https://www.nytimes.com/2018/08/05/technology/workplace-ai.html? (last accessed Feb. 29, 2020).

118. Terry, *supra* note 116, at 11.

119. Liang Chenyu, Zhejiang Hospital Scans Faces to Register Patients, *available at* https://www.sixthtone.com/news/1003064/zhejiang-hospital-scans-faces-to-register-patients (last accessed Feb. 29, 2020).

120. Nathan Cortez, *The Mobile Health Revolution?*, 47 U.C. DAVIS L. REV. 1173, 1182 (2014).

121. *Id.* at 1183.

122. *Id.* at 1184.

uses a mobile phone's built-in microphone to replicate the sound emanating from the heart, lungs[,] and bowel.[123]

(3) Automators and customizers are apps or devices that assist healthcare providers in arriving at a clinical decision through the use of algorithms, formula, questionnaires, medical calculators, or other software parameters.[124] An example of this is the WebMD Symptom Checker, which provides valuable data and support to those who search for health information.[125]

(4) Informers and educators are "medical reference texts and educational apps that primarily aim to inform and educate."[126] Some examples are Physicians' Desk Reference, Merck Manuel, and Gray's Anatomy in app format.

(5) Administrators are not medical devices per se but are used to automate office work. Nevertheless, these apps may be developed into automators and customizers by generating pre-appointment questionnaires to assist healthcare providers in administering primary care.[127]

(6) Loggers and trackers are used to log, record and make choices on the general health and wellness of an individual.[128] Generally, these devices are not subject to medical device regulation for "as long as they do not try to diagnose, treat, mitigate, or prevent specific, identifiable diseases or conditions."[129] Asthma MD app is an example of a logger. It "allows users to easily and quickly log their asthma activity, their medications, causes of their asthma in a form of a diary."[130] "Users may optionally opt-in and allow the application to securely send encrypted and anonymous data in connection with

123. iStetoscope Expert, Publisher Description, *available at* https://istethoscope-expert-ios.soft112.com (last accessed Feb. 29, 2020).

124. Cortez, *supra* note 120, at 1186.

125. *See* WebMD, WebMD Symptom Checker, *available at* https://symptoms.webmd.com/default.htm#/info (last accessed Feb. 29, 2020).

126. Cortez, *supra* note 120, at 1188.

127. *Id.* at 1189.

128. *Id.*

129. *Id.* at 1190.

130. AsthmaMD, About, *available at* https://www.asthmamd.org/about (last accessed Feb. 29, 2020).

> asthma attacks, triggers, time, date and location to a database managed by Google."[131] This data is used to find correlation between asthma and various relevant data.[132] The Apple Watch is a heart tracker that is equipped with an ECG to monitor one's heart.[133] In fact, it has saved a user's life when it indicated that his heart rate suddenly became abnormal. After the watch's diagnosis, the patient was rushed to the hospital and was later diagnosed to have a supraventricular tachycardia, a condition which is characterized by an abnormal heart rate that originates above the ventricles of the heart.[134]

Medical apps and wearables redefine the traditional concept of a medical device. As Terry noted "[a]s [apps and wearables'] sensors and analytical software become more sophisticated, they will increasingly supplant professional early warning or diagnostic tasks, particularly as they integrate more fully with networked environmental sensors."[135]

3. Chatbots

Normally, chatbots are there to address customer complaints. Today, digital health companies use AI chatbots to diagnose health conditions, prescribe over the counter medicines, and refer a specialist to a patient. To start the process, users of these chatbots type in their health information. In response, the bot will ask a number of questions based on the information that was given. At the end of the session, the bot can inform the user about his condition and suggest the next steps.[136] These chatbots are "AI-based diagnostic triage systems that use language parsing coupled with searches of large database to correlate symptoms and conditions. Subsequently, they

131. *Id.*

132. *Id.*

133. Vaidyanathan Subramaniam, Apple Watch's heart rate monitor saves a man's life, *available at* https://www.notebookcheck.net/Apple-Watch-s-heart-rate-monitor-saves-a-man-s-life.415928.0.html (last accessed Feb. 29, 2020).

134. *Id.*

135. Terry, *supra* note 116, at 12.

136. Laura Lovett, AI triage chatbots trekking toward a standard of care despite criticism, *available at* https://www.mobihealthnews.com/content/ai-triage-chatbots-trekking-toward-standard-care-despite-criticism (last accessed Feb. 29, 2020).

make rule-based recommendations for an over-the-counter remedy or make a physical referral."[137]

4. Medical Delivery Robots

Noah and Tug are medical delivery robots.[138] Equipped with similar technologies found in autonomous vehicle, they navigate through the unpredictable hospital terrain to fetch medicines or carry documents.[139] They were created to assist healthcare professionals to be more efficient and to focus more on important tasks rather than do menial jobs.[140]

Lightstrike is also a robot which is used to disinfect hospitals from healthcare associated infections.[141] This germ zapper uses ultraviolet rays to kill pathogens and disinfect a patient's room.[142]

5. Caregiving

The caregiving industry, from pediatric to geriatric care, is taken over by AI.[143] Snoo, a high-tech crib, autonomously rocks a new-born to sleep.[144] Care-o-bot and BUDDY, on the other hand, are companion robots developed to take care of the elderly and keep them entertained.[145]

According to the Ministry of Economy, Trade and Industry of Japan, the AI caregiving industry will grow to nearly $4 billion annually by 2035. This

137. Terry, *supra* note 116, at 12.

138. YellRobot, Robots in Hospitals are Making Deliveries and Performing Surgery, *available at* https://yellrobot.com/robots-in-hospitals (last accessed Feb. 29, 2020).

139. *Id.*

140. *Id.*

141. Xenex Disinfection Systems, LightStrike Germ-Zapping Robots, *available at* https://www.xenex.com/our-solution/lightstrike (last accessed Feb. 29, 2020).

142. *Id.*

143. Terry, *supra* note 116, at 13.

144. Samantha Murphy Kelly, A robotic crib rocked my baby to sleep for months, *available at* https://money.cnn.com/2017/08/10/technology/gadgets/snoo-review/index.html (last accessed Feb. 29, 2020).

145. Len Calderone, Companion Robots for Seniors, *available at* https://www.roboticstomorrow.com/article/2018/12/companion-robots-for-seniors/12933 (last accessed Feb. 29, 2020).

growth is attributed to its high demand in a country where a quarter of the population is already graying.[146]

6. Education and Research

AI has also changed the way medicine is being taught. Hal, a pediatric patient simulator, is one of many medical training equipment that uses AI technology to react to stimuli.[147] This technology used to train medical students perform medical procedures to a robotic patient before being exposed to actual ones.[148]

Electronic health records not only promote efficiency in the delivery of healthcare, they are also being used to train and improve the performance of AI.[149]

7. Clinical Data Analytics

Clinical data analytics is generating helpful insights from healthcare big data in order to improve care, lower costs, and save lives. This information is collected from various sources, from computerized physician order entry and medical journals to social media posts and news feeds.[150]

8. Imaging, Pathology, and Radiology

Undeniably, AI systems have better pattern recognition skills compared to their human counterparts. They can analyze minute details on image scans and detect diseases such as skin cancer, colon cancer, stroke, and pneumonia.[151] To date, a number medical devices, which have been approved by the U.S. FDA, perform image reading functions to detect fractures and diabetes among others.[152]

146. *Id.*

147. Bob Yirka, Pediatric Robot Patient Offers New Level of Realism for Doctors in Training, *available at* https://medicalxpress.com/news/2018-09-pediatric-robot-patient-realism-doctors.html (last accessed Feb. 29, 2020).

148. *Id.*

149. Terry, *supra* note 116, at 13.

150. *See, e.g.*, Raghupathi & Raghupathi, *supra* note 27.

151. *See, e.g.*, Terry, *supra* note 116, at 14.

152. *Id.* at 15.

9. Predictive Diagnosis

Clinical decision support systems are "computer-based healthcare applications used to integrate clinical and patient information to provide support for decision-making in patient care as well as to generate case-specific advice."[153] Examples of these systems are IBM's Watson and Google's DeepMind.

10. Procedural AI

At the onset, Terry noted that "[p]rocedural aspects of medicine, particularly surgery will likely remain in the human domain longer than other branches of medicine."[154] But the use of AI will still be material in improving the delivery of medical procedures.

At present, there are available surgical robots dependent on human surgeons who perform minimally invasive microsurgery.[155] But AI surgeons can take over sooner rather than later. In fact, Sedasys, a machine which automates the delivery of anesthesia during a surgical operation was already developed.[156] However, regulatory issues arose when the American Society of Anesthesiologist vehemently objected to the approval of Sedasys. The Society emphasized that it is dangerous to replace human expertise with a machine. Nevertheless, the regulatory body approved the machine after the manufacturer agreed to limit the use to certain medical procedures.[157] Another promising invention in the field of procedural AI is the magnetic robot strip developed by German researchers at the Max Planck Institute for Intelligent Systems.[158] The robot is about a seventh of an inch long and is

153. *Id.*

154. Terry, *supra* note 116, at 16.

155. *Id.* at 7.

156. XenonHealth, Sedasys Machines: Are They the Future of Anesthesia, *available at* https://xenonhealth.com/sedasys-machines-future-anesthesia (last accessed Feb. 29, 2020).

157. Tom Simonite, Automated Anesthesiologist Suffers a Painful Defeat, *available at* https://www.technologyreview.com/s/601141/automated-anesthesiologist-suffers-a-painful-defeat (last accessed Feb. 29, 2020).

158. James Gorman, *This Tiny Robot Walks, Crawls, Jumps and Swims. But It Is Not Alive.*, N.Y. TIMES, Jan. 24, 2018, *available at* https://www.nytimes.com/2018/01/24/science/tiny-robot-medical.html (last accessed Feb. 29, 2020).

intended to be used to deliver drugs specifically to a certain problem area inside the body.[159]

E. Defining Healthcare AI

As previously noted in this Chapter, AI systems are built in order to achieve a goal. In the healthcare sector, this goal is to improve the delivery of healthcare. In this regard, the Author submits this working definition of a healthcare AI —

Healthcare AI are artificial intelligence systems designed or intended to diagnose, prevent, monitor, treat, or alleviate any disease or health condition.

The word healthcare is defined as "[t]aking the necessary medical and preventative procedures to improve wellbeing."[160] Meanwhile, the term "artificial intelligence systems" was previously defined in a previous discussion in this Chapter. The Author added the phrase "designed or intended to" in order to differentiate a healthcare AI from search engines and other smart technologies (e.g., Amazon's Alexa or Google Assistant) which can also provide information on diseases or health condition based on a string of words or query submitted by the user.

III. THE PHILIPPINE HEALTHCARE SYSTEM

A. The Philippines

1. Location and Climate

The Philippines is an archipelagic state in Southeast Asia consisting of 7,614 islands, forming together three major island groups: Luzon, Visayas, and Mindanao.[161] It is "bounded by South China Sea (West), the Philippine Sea (East) and the Celebes Sea (southwest), and shares maritime borders with Taiwan (North), Vietnam (West), Palau (East), and Malaysia and Indonesia

159. *Id.*

160. The Law Dictionary, What is Health Care?, *available at* https://webcache.googleusercontent.com/search?q=cache:vqyz3SF9-jAJ:https://thelawdictionary.org/health-care/+&cd=1&hl=en&ct=clnk&gl=ph (last accessed Feb. 29, 2020).

161. National Government Portal, About the Philippines, *available at* https://www.gov.ph/about-the-philippines (last accessed Feb. 29, 2020).

(South)."[162] The capital city of the country is Manila, which is situated in the National Capital Region. Due to its location, the Philippines has a tropical and maritime climate with relatively high temperature (i.e., average of 26.6 degrees centigrade), high humidity (i.e., average 71-85%), and abundant rainfall (i.e., 965 to 4,064 millimeters annually).[163] Likewise, it is very much exposed to natural phenomena like earthquakes, volcanic eruptions, droughts, and typhoons[164] making it the third most disaster prone country the world (index value 26.70), next to Vanuatu and Tonga.[165]

2. Population and Economy

As of 2018, the Philippines recorded a population of almost 106 million, which makes it the 13th most populated country in the world and continually grows with an annual population growth rate of 1.55%.[166] One-eight of its population or approximately 13.482 million individuals reside in Manila, the country's capital.[167]

Currently, the Philippines is considered as a newly industrialized country with an economy transitioning from agriculture-based to service and manufacturing based. Considered as one of the fastest growing economy in Asia, the country registered a Gross Domestic Product growth of 6.5% in the first quarter of 2018.[168] The poverty incidence[169] among Filipino individuals

162. World Population Review, Philippines Government, *available at* http://worldpopulationreview.com/governments/philippines (last accessed Feb. 29, 2020).

163. Philippine Atmospheric, Geophysical and Astronomical Services Administration, Climate of the Philippines, *available at* http://bagong.pagasa.dost.gov.ph/information/climate-philippines (last accessed Feb. 29, 2020).

164. Philippine Institute for Development Studies, Dealing With Disasters and Climate Change, *available at* https://www.pids.gov.ph/infocus/56 (last accessed Feb. 29, 2020).

165. BÜNDNIS ENTWICKLUNG HILFT & RUHR UNIVERSITY BOCHUM: INSTITUTE FOR INTERNATIONAL LAW OF PEACE AND ARMED CONFLICT (IFHV), WORLDRISKREPORT 2018 6 (2018).

166. Central Intelligence Agency, World Factbook Philippines, *available at* https://www.cia.gov/library/publications/the-world-factbook/geos/rp.html (last accessed Feb. 29, 2020).

167. *Id.*

168. Press Release *by* Philippine Statistics Authority, *PH GDP posts 5.6 percent growth in the first quarter of 2019* (May 9, 2019), *available at* https://psa.gov.ph/content/

fell from 27.6 to 21.0 during the first semester of 2018. During the same period, the subsistence incidence among Filipino individuals[170] dropped from 13.0 in 2015 to 8.5%.[171] The poverty reduction was partly due to the implementation of the Conditional Cash Transfer Program, which is a well-targeted social protection program, remittances from Overseas Filipino Workers, and availability of job opportunities outside the agricultural sector.[172] Despite these promising data, more than one-fifth of the country's population or roughly 22 million individuals are still living below the poverty line.[173]

3. Governance

"The Philippines is a democratic and republican State."[174] The powers of the government are equally divided among the three independent branches

---

ph-gdp-posts-56-percent-growth-first-quarter-2019 (last accessed Feb. 29, 2020).

169. This refers to the proportion of the population living below the poverty line to the total population.

170. This refers to the proportion of Filipinos whose income fall below the food threshold.

171. Press Release *by* Philippine Statistics Authority, *Proportion of Poor Filipinos registered 21.0 percent in the First Semester of 2018* (Apr. 10, 2019), *available at* http://www.psa.gov.ph/content/proportion-poor-filipinos-registered-210-percent-first-semester-2018 (last accessed Feb. 29, 2020).

According to the Philippine Statistics Authority,

> a family of five needed no less than [₱]7,337 [approximately US$138], on average, to meet the family's basic food needs for a month [i.e., food threshold]. ... On the other hand, no less than [₱]10,481 [approximately US$198], on average, was needed to meet both basic food and non-food needs of a family of five in a month [i.e., poverty threshold].

Id.

172. Rappler, PH economy growing but poverty still high – World Bank, *available at* https://www.rappler.com/business/203680-economy-poverty-rate-philippines-world-bank-report-2018 (last accessed Feb. 29, 2020).

173. Press Release *by* World Bank, *Philippines' Poverty Rate Declines; More Well-Paying Jobs and Opportunities Needed* (May 30, 2018), *available at* https://www.worldbank.org/en/news/press-release/2018/05/30/philippines-poverty-rate-declines-more-well-paying-jobs-and-opportunities-needed (last accessed Feb. 29, 2020).

174. PHIL. CONST. art. II, § 1.

of government: the executive, the legislative, and the judicial department. Executive power or the power to implement the laws reside in the President and is delegated to the 22 different departments.[175] The Department of Health (DOH), which is headed by the Secretary of Health, is the primary institution which "provides the national policy direction and strategic plans, regulatory services, standards and guidelines for health[.]"[176] Legislative power, on the other hand, is held by the Congress, which is divided between the national representatives, the Senate; and the local and party-list representatives, the House of Representatives.[177] The Congress has the plenary power to impact the health system by enacting laws that regulate the delivery of healthcare.[178] Finally, judicial power is vested in the Supreme Court and all the lower courts.[179] These courts have the "duty to settle actual controversies involving rights, which are legally demandable and enforceable."[180]

The Philippines is also divided into territorial and political subdivisions, which facilitate the efficient delivery of services to the people, including basic social and health services. Local Government Units (LGUs), consisting of the 81 provinces, 1,489 municipalities, 145 cities and 42,044 barangays, as well as 17 regions,[181] enjoy certain level of autonomy and are entitled to an equitable share of the national wealth.[182]

The Philippines also pursues an independent foreign policy[183] and plays an active role in the international community by forging international commitments and free trade agreements with other countries and regional institutions like the ASEAN.[184]

---

175. *See* PHIL. CONST. art. VII, §§ 1 & 17.

176. MANUEL M. DAYRIT, ET AL., THE PHILIPPINES HEALTH SYSTEM REVIEW 23 (2018).

177. PHIL. CONST. art. VI, § 1.

178. DAYRIT, ET AL., *supra* note 176, at 9.

179. PHIL. CONST. art. VIII, § 1.

180. PHIL. CONST. art. VIII, § 1.

181. Department of Health, National Objectives for Health Philippines, 2017-2022 (A Report Published Online by the Health Policy Development and Planning Bureau of the DOH) at 4, *available at* https://www.doh.gov.ph/sites/default/files/publications/NOH-2017-2022-030619-1.pdf (last accessed Feb. 29, 2020).

182. PHIL. CONST. art. X, §§ 2 & 7.

183. PHIL. CONST. art. II, § 7.

184. *See, e.g.*, DAYRIT, ET AL., *supra* note 176, at 60-61.

B. Health Status of the Filipinos

The Constitution of the World Health Organization (WHO) defines health as "a state of complete physical, mental[,] and social well-being and not merely the absence of disease or infirmity."[185] Life expectancy is one of the key indicators to measure how effective health policies are.[186] In the Philippines, Filipinos today seem to live longer. There is an increase in life expectancy from 62.2 years in 1980 to 69.9 years in 2018, with females (73.3 years) outliving their male counterparts (66.1 years).[187] The positive figures are greatly attributed to better standards of living, better administration of treatment for infectious diseases such as tuberculosis and malaria, and improved accessibility to health services in general.[188] Despite this, Filipinos are still hampered with the so-called triple burden of disease.[189] Frenk and Gomez-Dantes illustrate the triple burden of disease as a condition wherein there exists "the backlog of common infections, undernutrition and maternal mortality, the emerging challenges of non-communicable diseases (NCDs), such as cancer, diabetes, heart disease and mental illness, and the problems directly related to globalization, like pandemics and the health consequences of climate change."[190]

In 2016, the leading causes of death in the Philippines are NCDs such as ischemic heart disease, neoplasms or cancer, cerebrovascular diseases or stroke, hypertensive disease, diabetes and other heart diseases, and communicable diseases like pneumonia, respiratory tuberculosis, and chronic lower respiratory infections.[191] The NCDs, which collectively accounted for 82% of the reported deaths in the Philippines, are lifestyle-related and primarily triggered by an unhealthy diet, smoking, and physical inactivity.[192] Also, as previously mentioned, the Philippines is vulnerable to natural disasters like earthquakes, typhoons, and volcanic eruptions, which greatly affect the overall health status of the populace.

185. Constitution of the World Health Organization pmbl., *adopted* July 22, 1946, 14 U.N.T.S. 185.

186. Department of Health, *supra* note 181, at 9.

187. DAYRIT, ET AL., *supra* note 176, at 12.

188. *Id.* at 14.

189. *Id.* at 13.

190. Julio Frenk & Octavio Gomez-Dantes, *The Triple Burden Disease in Developing Nations*, HARV. INT'L REV., Fall 2011, at 36.

191. Department of Health, *supra* note 181, at 11.

192. *Id.* at 50.

It is important to note that although there is a general improvement in the health status of the Filipinos over the past decades, inequalities still persist. This is largely due to the "social, economic[,] and geographical barriers" which translate to variations in access of services, and in turn, "eventually result in inequity in health outcomes."[193] Dayrit observed that the "disadvantaged subset of the [Philippine] population is often located in remote and hard-to-reach areas, rendering it difficult [for them] to avail health care when they need it."[194]

C. The Philippine Healthcare Sector

The Philippine health system comprises of the public and the private sectors.[195] The public sector is mostly funded by government taxes and are delivered via government facilities operated by the national and local governments.[196] The DOH is the primary health agency which outlines the government's health policies and plans, develops technical health standards, and enforces health regulations.[197] Aside from this, the DOH, together with the Philippine Department of National Defense for military hospitals, delivers tertiary care,[198] and oversees government corporate hospitals, specialty and regional hospitals.[199] The LGUs, on the other hand, focus on the delivery of primary and secondary health services in their respective areas. These units enjoy full autonomy to run and finance their local health systems. The provincial government is in charge of delivering primary and secondary health care while the municipal or city government is in charge of primary health care, promotive and preventive health programs and basic ambulatory clinical care.[200]

193. DAYRIT, ET AL., *supra* note 176, at 17.

194. *Id.*

195. *Id.* at 22.

196. *Id.*

197. *Id.* at 31.

198. Tertiary care is "[s]pecialized consultative care, usually on referral from primary or secondary medical care personnel, by specialists working in a center that has personnel and facilities for special investigation and treatment." John Hopkins Medicine, Tertiary Care Definition, *available at* https://www.hopkinsmedicine.org/patient_care/billing-insurance/insurance_footnotes.html (last accessed Feb. 29, 2020).

199. Department of Health, *supra* note 181, at 7.

200. DAYRIT, ET AL., *supra* note 176, at 21.

Conversely, the private sector is largely driven by market forces, "where health services are generally paid through user fees at the point of service, though the Philippine Health Insurance Corporation (PhilHealth) also purchases services from both the public and private sectors."[201] It is composed of thousands of for-profit and non-profit institutions, consisting of "clinics, infirmaries, laboratories, hospitals, drugstores, pharmaceutical and medical supply companies, health insurance companies, academic research institutions[,] and informal service providers."[202] The private health sector serves "only about 30[%] of the population[,] but it is far larger than the public system in terms of financial resources and staff."[203] "The private sector is regulated by the government through a system of standards and guidelines implemented through the licensure procedures of DOH and accreditation procedures of PhilHealth."[204] The private sector is essential in augmenting the inadequacy of the public sector.[205]

D. Philippine Healthcare Regulation

The right to health is enshrined in the Philippine Constitution.[206] To breathe life into this state policy, the Philippine Government has enacted and enforced laws to regulate medical and preventive procedures to improve one's well-being.[207] Regulations in healthcare covers healthcare providers, such as healthcare professionals, healthcare facilities, healthcare financing; and food, drug, cosmetics and medical devices. For this Study, focus will be given on the regulation of the practice of medicine and medical devices in the Philippines.

---

201. *Id.*

202. *Id.*

203. Department of Health, *supra* note 181, at 7.

204. DAYRIT, ET AL., *supra* note 176, at 30.

205. *Id.*

206. PHIL. CONST. art. II, § 15. The Constitutional provision provides that: "[t]he State shall protect and promote the right to health of the people and instill health consciousness among them." PHIL. CONST. art. II, § 15.

207. Healthcare is defined as "taking the necessary medical and preventative procedures to improve well being." The Law Dictionary, What is HEALTH CARE?, *available at* https://webcache.googleusercontent.com/search?q=cache:vqyz3SF9-jAJ:https://thelawdictionary.org/health-care/+&cd=1&hl=en&ct=clnk&gl=ph (last accessed Feb. 29, 2020).

E. Regulation of Practice of Medicine

1. Licensing and Practice

Healthcare is delivered by professionals like physicians, nurses, dentists, medical technologists as well as by informal service providers like traditional healers and birth attendants. Yet, the practice of medicine in the Philippines is generally reserved only to medical doctors.

Republic Act No. 2382 or the Medical Act of 1959 (the Medical Act) is the primary legislation which regulates medical education, qualification for physicians, and the practice of medicine in the Philippines.[208]

As a prerequisite to enter medical school, one has to complete a bachelor's degree and take the National Medical Aptitude Test. In medical school, a medical student must complete a four-year medical course to obtain a degree of Doctor of Medicine (MD).[209] A 12-month internship, which is a technical training course consisting of duties in various departments of a hospital, follows.[210] Before an MD can practice medicine, he has to satisfactorily pass the Philippine Medical Board Examination and receive a valid license[211] from the Philippine Professional Regulatory Commission (PRC).[212]

In the Philippines, a person is engaged in the practice of medicine when he or she:

> (a) ... for compensation, fee, salary or reward in any form, paid to him directly or through another, or even without the same, physical[ly] examine any person, and diagnose, treat, operate[,] or prescribe any remedy for any human disease, injury, deformity, physical, mental[,] or physical condition or any ailment, real or imaginary, regardless of the nature of the remedy or treatment administered, prescribed[,] or recommended; or

208. *See generally* The Medical Act of 1959, Republic Act No. 2382 (1959) (as amended).

209. *Id.* § 6.

210. *Id.* § 9 (6).

211. *Id.* § 8.

212. The Professional Regulatory Commission (PRC) is in charge of the licensing and regulation of various professions and occupations in the Philippines. An Act Modernizing the Professional Regulation Commission, Repealing for the Purpose Presidential Decree Numbered Two Hundred and Twenty-Three, Entitled "Creating the Professional Regulation Commission and Prescribing its Powers and Functions," and for Other Purposes [PRC Modernization Act of 2000], Republic Act No. 8981, § 7 (2000).

> (b) ... by means of signs, cards, advertisements, written or printed matter, or through the radio, television or any other means of communication, either offer or undertake by any means or method to diagnose, treat, operate or prescribe any remedy for any human disease, injury, deformity, physical, mental or physical condition; or
>
> (c) ... falsely use the title M.D. after his [or her] name.[213]

The following individuals can practice medicine in a limited capacity without the necessary license to practice:

> (a) Physicians and surgeons from other countries called in consultation only and exclusively in specific and definite cases, or those attached to international bodies or organization assigned to perform certain definite work in the Philippines provided they shall limit their practice to the specific work assigned to them and provided further they shall secure a previous authorization from the Board of Medical Examiners.
>
> (b) Commissioned medical officers of the United States armed forces stationed in the Philippines while rendering service as such only for the members of the said armed forces and within the limit of their own respective territorial jurisdiction.
>
> (c) Foreign physicians employed as exchange professors in special branches of medicine or surgery whose service may in the discretion of the Board of Medical Education, be necessary.
>
> (d) Medical students who have completed the first four years of medical course, graduates of medicine and registered nurses who may be given limited and special authorization by the Secretary of Health to render medical services during epidemics or national emergencies whenever the services of duly registered physicians are not available. Such authorization shall automatically cease when the epidemic or national emergency is declared terminated by the Secretary of Health.[214]

After obtaining his or her medical license, a physician can pursue specializations through a residency training offered by accredited hospitals and clinics. Professional medical associations like "the Philippine College of Physicians, Philippine College of Surgeons, Philippine Academy of Family Physicians, Philippine Pediatrics Society[,] and Philippine Obstetrical and Gynecological Society among others are involved in the accreditation of training institutions, administration of qualifying examinations and granting of certificates for diplomates and fellows for medical specialist."[215] These

213. Republic Act No. 2382, § 10.

214. *Id.* § 12.

215. DAYRIT, ET AL., *supra* note 176, at 30-31.a

associations are private professional entities recognized by the PRC and are allowed to institute their own board certification system to control the admission of specialists (e.g., cardiologist, surgeons, obstetricians, etc.).[216] After taking their specialization, a physician can still pursue further subspecialty training.

A physician can have his or her license administratively revoked or be reprimanded or suspended from the practice of the medicine if he committed any of the following:

(1) Conviction by a court of competent jurisdiction of any criminal offense involving moral turpitude;

(2) Immoral or dishonorable conduct;

(3) Insanity;

(4) Fraud in the acquisition of the certificate of registration;

(5) Gross negligence, ignorance or incompetence in the practice of his or her profession resulting in an injury to or death of the patient;

(6) Addiction to alcoholic beverages or to any habit forming drug rendering him or her incompetent to practice his or her profession, or to any form of gambling;

(7) False or extravagant or unethical advertisements wherein other things than his name, profession, limitation of practice, clinic hours, office and home address, are mentioned;

(8) Performance of or aiding in any criminal abortion;

(9) Knowingly issuing any false medical certificate;

(10) Issuing any statement or spreading any news or rumor which is derogatory to the character and reputation of another physician without justifiable motive;

(11) Aiding or acting as a dummy of an unqualified or unregistered person to practice medicine; [and]

(12) Violation of any provision of the Code of Ethics as approved by the Philippine Medical Association.[217]

The foregoing grounds are also basis for criminal prosecution and an independent civil action for damages.[218]

216. *Id.* at 31.

217. Republic Act No. 2382, § 24.

Incidentally, since the practice of medicine is circumscribed by legislation, anyone who practices medicine without the necessary license may be criminally prosecuted. In fact, illegal practice of medicine in the Philippines is punishable with "a fine of not less than one thousand pesos nor more than ten thousand pesos with subsidiary imprisonment in case of insolvency, or by imprisonment of not less than one year nor more than five years, or by both such fine and imprisonment[.]"[219] In *People v. Vda. de Golez*,[220] the Supreme Court clarified that a person may be convicted of illegal practice of medicine when he or she is practicing medicine in violation of the Medical Law (i.e., practicing without the necessary license).[221] His or her intention, whether he or she was acting in good faith or without malice, is immaterial.[222] The law is deemed violated even in the absence of any injury resulting from the malpractice.[223]

Regulating the healthcare profession is necessary. Briones, Rodriguez, and Teh, Jr. opine that

> [a]n important justification for the government regulation of entry to the health care professions is the presence of information asymmetry. Information asymmetry occurs when consumers and producers do not have the same information with [regard] to the product or service being exchanged. Under a completely unregulated system, the consumer may be unable to tell the quality of the physician's services because the cost of obtaining the information may be too high. The physician, on the other hand, can obtain rents from maintaining this imbalance or asymmetry in information sets. The market in this case does not provide any incentives for truth-telling to occur. It may be then desirable for the government to impose some form of control over the quality of health care providers by prescribing requirements for entry.[224]

---

218. *See* Ivy Patdu, *Medical Negligence*, 61 ATENEO L.J. 997, 1002 (2017) [hereinafter Patdu, *Medical Negligence*].

219. Republic Act No. 2382, § 28.

220. People v. Vda. de Golez, 108 Phil. 855 (1960).

221. *Id.* at 858.

222. *Id.*

223. *Id.*

224. Augusto S. Rodriguez, et al., The Regulatory Environment in the Health Care Sector (A Discussion Paper Published Online by the Philippine Institute for Development Studies) at 5-6, *available at* https://dirp3.pids.gov.ph/ris/dps/pidsdps9530.pdf (last accessed Feb. 29, 2020)

Furthermore, they believe that the need to license healthcare professional is due to "the welfare loss from the uncertainty faced by consumers of health care services regarding the capabilities or proficiency of producers. By requiring all health care providers to acquire a basic set of skills, this uncertainty in health care quality is suitably diminished."[225]

The Author agrees with the points raised by Briones, Rodriguez and Teh, Jr. Regulation of the practice of medicine is a way to ensure that the right to health of the Filipino people is protected. When an ordinary person goes to a physician, he or she goes there with an expectation that the professional is properly educated and trained to diagnose or treat him or her. The patient impliedly acknowledges that he or she cannot diagnose or treat himself because he or she does not have the same level of medical knowledge or expertise as a licensed doctor. The licensing requirement, more or less, gives him or her an assurance that even without any further investigation, he or she is confident that his or her doctor has passed the minimum criteria set under the law to provide a sound diagnosis or treatment. Nevertheless, regulation of the practice of medicine does not necessarily mean that a licensed physician cannot make any mistakes in diagnosis or treatment. In case the physician exhibits gross negligence, ignorance, or incompetence, he or she can be reprimanded, suspended, or have his licensed revoked under the Medical Act. An injured party also has a separate recourse to recover his or her loss or damage under the legal regime of medical negligence.

2. Medical Negligence

A medical negligence suit is "an action available to [a] victim[ ] to redress a wrong committed by [a] medical professional[ ] who caused bodily harm to, or the death of, a patient."[226] It is interesting to note that Philippine courts have exercised caution in entertaining these kinds of suits, to wit —

> Courts face a unique restraint in adjudicating medical negligence cases because physicians are not guarantors of care and, they never set out to intentionally cause injury to their patients. However, intent is immaterial in negligence cases because where negligence exists and is proven, it automatically gives the injured a right to reparation for the damage caused.[227]

225. *Id.* at 19.

226. Casumpang, et al. v. Cortejo, 752 SCRA 379, 401 (2015) (citing Flores v. Pineda, 571 SCRA 83, 91 (2008)).

227. Cantre v. Spouses Go, 522 SCRA 547, 555-56 (2007).

The Philippines has no specific legislation on medical negligence. The Medical Act does not impose any civil or criminal penalty for acts constituting gross negligence, ignorance, or competence.[228] Nevertheless, a medical professional who committed medical negligence can be held civilly liable for damages[229] under Article 2176 of the Philippine Civil Code — "Whoever by act or omission causes damage to another, there being fault or negligence, is obliged to pay for the damage done. Such fault or negligence, if there is no pre-existing contractual relation between the parties, is called a quasi-delict."[230] Aside from this general provision of law, the Supreme Court contemporaneously used doctrines promulgated by U.S. courts like the captain of the ship doctrine, agency by estoppel, and the doctrine of corporate negligence to attribute liability on a physician as well as on a hospital and to expand the concept of quasi-delict in relation to medical negligence cases.[231]

In order for a medical negligence suit to prosper, the following elements must concur: (1) duty; (2) breach; (3) injury; and (4) proximate causation. The decision of the Supreme Court in *Casumpang et al.* is instructive —

> *Duty refers to the standard of behavior that imposes restrictions on one's conduct. It requires proof of professional relationship between the physician and the patient*. Without the professional relationship, a physician owes no duty to the patient, and cannot therefore incur any liability.
>
> *A physician-patient relationship is created when a patient engages the services of a physician, and the latter accepts or agrees to provide care to the patient*. The establishment of this relationship is consensual, and the acceptance by the physician essential. The mere fact that an individual approach a physician and seeks diagnosis, advice or treatment does not create the duty of care unless the physician agrees.
>
> The consent needed to create the relationship does not always need to be express. In the absence of an express agreement, a physician-patient relationship may be implied from the physician's affirmative action to

228. Patdu, *Medical Negligence*, *supra* note 218, at 999. *See also* Darwin P. Angeles, *Dissecting Philippine Law and Jurisprudence on Medical Malpractice*, 85 PHIL. L.J. 895, 897 (2011).

229. A physician can be held criminally liable under Article 315 of the Revised Penal Code of the Philippines. An Act Revising the Penal Code and Other Penal Laws [REVISED PENAL CODE], Act No. 3815, art. 315 (1930).

230. An Act to Ordain and Institute the Civil Code of the Philippines [CIVIL CODE], Republic Act No. 386, art. 2176 (1950).

231. Ivy Patdu, *Hospital Liability*, 55 ATENEO L.J. 598, 602 (2011) [hereinafter Patdu, *Hospital Liability*].

> diagnose and/or treat a patient, or in his participation in such diagnosis and/or treatment. The usual illustration would be the case of a patient who goes to a hospital or a clinic, and is examined and treated by the doctor. In this case, we can infer, based on the established and customary practice in the medical community that a patient-physician relationship exists.
>
> *Once a physician-patient relationship is established, the legal duty of care follows. The doctor accordingly becomes duty-bound to use at least the same standard of care that a reasonably competent doctor would use to treat a medical condition under similar circumstances.*
>
> *Breach of duty occurs when the doctor fails to comply with, or improperly performs his duties under professional standards.* This determination is both factual and legal, and is specific to each individual case.
>
> *If the patient, as a result of the breach of duty, is injured in body or in health, actionable malpractice is committed, entitling the patient to damages.*
>
> *To successfully claim damages, the patient must lastly prove the causal relation between the negligence and the injury. This connection must be direct, natural, and should be unbroken by any intervening efficient causes. In other words, the negligence must be the proximate cause of the injury.* The injury or damage is proximately caused by the physician's negligence when it appears, based on the evidence and the expert testimony, that the negligence played an integral part in causing the injury or damage, and that the injury or damage was either a direct result, or a reasonably probable consequence of the physician's negligence.[232]

A physician must follow professional standards rather than the ordinary standards of a reasonable man which is required in a normal quasi-delict case. This standard can be shown from "testimony of experts, clinical practice guidelines, the Code of Medical Ethics, the Medical Act[,] or any applicable law."[233] In *res ipsa loquitur* cases, deviation from professional standard need not be proven.[234]

---

232. *Casumpang, et al.*, 752 SCRA at 402-404 (emphases supplied).

233. Patdu, *Hospital Liability*, *supra* note 231, at 617.

234. Cruz v. Agas, Jr., 757 SCRA 549 (2015). The Philippine Supreme Court provided the requisites for the applicability of the doctrine of *res ipsa loquitur*, as follows:

> (1) the occurrence of an injury; (2) the thing which caused the injury was under the control and management of the defendant; (3) the occurrence was such that in the ordinary course of things, would not have happened if those who had control or management used proper care; and (4) the absence of explanation by the defendant.

Id. at 558.

Usually, a doctor cannot be held liable for the acts of another person. However, the captain of the ship doctrine "holds the surgeon in charge of an operation liable for the negligence of his assistants' during the time when those assistants are under the surgeon's control."[235]

Aside from physicians, hospitals may be held liable for negligence. According to Pedro Solis, a hospital can either be liable vicariously or as a corporate entity.[236] The Supreme Court used the doctrine of corporate negligence in the case of *Professional Services Inc., et al. v. Court of Appeals*,[237] wherein a hospital was made liable for its failure to perform its duties as a healthcare institution. Generally, a hospital has the following duties:

> (1) [D]uty to use reasonable care in maintenance of safe and adequate facilities and equipment;
>
> (2) [D]uty to select and retain only competent physicians;
>
> (3) [D]uty to oversee all persons who practice medicine within its walls as to patient care; and
>
> (4) [D]uty to formulate, adopt and enforce adequate rules and policies to ensure quality care for patients.[238]

Furthermore, "a hospital has the duty to make reasonable effort to monitor and oversee the treatment prescribed and administered by physicians practicing in their premises ... it is necessary to show that the [hospital] had actual or constructive knowledge of the defect or procedures which created the harm."[239]

Similar to medical negligence, a negligence action against a hospital is also anchored on Article 2176 of the Civil Code. Obviously, the standard of care for a hospital is in accordance with how a reasonably prudent hospital should act. Understandably, it is different from that of a physician. A hospital cannot engage in the practice medicine because it "cannot be subjected to a government examinations to determine whether it is qualified to diagnose, treat, or employ any form of treatment."[240] Moreover, "if hospitals were

---

235. *Cantre*, 522 SCRA at 556.

236. Patdu, *Hospital Liability*, *supra* note 231, at 620 (citing PEDRO P. SOLIS, MEDICAL JURISPRUDENCE 321-24 (1998)).

237. Professional Services Inc., et al. v. Court of Appeals, 611 SCRA 282 (2010).

238. Patdu, *Hospital Liability*, *supra* note 231, at 655 (citing Thompson v. Nason Hospital, 591 A.2D 703, 707 (1991) (U.S.)).

239. Patdu, *Hospital Liability*, *supra* note 231, at 656.

240. *Id.* at 633.

allowed to practice medicine, then the physician employed by the hospital will merely receive orders from the corporation or its officers who are not licensed to practice medicine."[241]

Vicarious liability of a hospital or the doctrine of *respondeat superior*, on the other hand, is based on Article 2180 of the Philippine Civil Code.[242]

Parenthetically, in a case wherein employer-employee relationship is not established, a hospital can be made liable via the doctrine of apparent authority or agency by estoppel. The doctrine imports that a hospital can be held liable for the negligent acts of an independent contractor when:

> (1) the hospital, or its agent, acted in a manner that would lead a reasonable person to conclude that the individual who was alleged to be negligent was an employee or agent of the hospital;
>
> (2) where the acts of the agent create the appearance of authority, the plaintiff must also prove that the hospital had knowledge of and acquiesced in them; and
>
> (3) the plaintiff acted in reliance upon the conduct of the hospital or its agent, consistent with ordinary care and prudence.[243]

---

241. *Id.*

242. Article 2180 of the Civil Code provides in part —

> The obligation imposed by Article 2176 is demandable not only for one's own acts or omissions, but also for those of persons for whom one is responsible.
>
> ...
>
> The owners and managers of an establishment or enterprise are likewise responsible for damages caused by their employees in the service of the branches in which the latter are employed or on the occasion of their functions.
>
> Employers shall be liable for the damages caused by their employees and household helpers acting within the scope of their assigned tasks, even though the former are not engaged in any business or industry.
>
> ...
>
> The responsibility treated of in this article shall cease when the persons herein mentioned prove that they observed all the diligence of a good father of a family to prevent damage.

CIVIL CODE, art. 2180.

243. Nogales v. Capitol Medical Center, 511 SCRA 204, 222 (2015).

F. Regulation of Medical Device

Republic Act No. 3720 or the Food, Drug, and Cosmetic Act (FDC Act); Republic Act No. 9711 or the Food and Drug Administration Act of 2009 (FDA Act); and Republic Act No. 7394 or the Consumer Act of the Philippines (Consumer Act) are the primary laws which regulate health products such as food, medicines, cosmetics, medical devices and household hazardous substances in the Philippines. The Philippine Food and Drug Administration (FDA) is one of the key institutions responsible for enforcing these regulations. The FDA, through its Center for Device Regulation, Radiation and Health (CRRH), regulates the manufacturing, importing, exporting, distributing, selling, offering for sale, transferring, promoting, advertising, sponsoring of, use, and testing of medical devices. It also "conducts research on the safety, efficacy, and quality of [medical devices] as well as institute standards for the same."[244]

The FDA Act categorizes a device[245] into medical devices, radiation devices and health-related devices and defines a medical device as —

> any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material, or other similar or related article intended by the manufacturer to be used alone, or in combination, for human beings for one or more of the specific purpose(s) of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of, or compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; preventing infection; control of conception; disinfection of medical devices; and providing information for medical or diagnostic purposes by means of in-vitro examination of specimens derived from the human body. This device does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means but which may be assisted in its intended function by such means.[246]

---

244. An Act Strengthening and Rationalizing the Regulatory Capacity of the Bureau of Food and Drugs (BFAD) by Establishing Adequate Testing Laboratories and Field Offices, Upgrading its Equipment, Augmenting its Human Resource Complement, Giving Authority to Retain its Income, Renaming it the Food and Drug Administration (FDA), Amending Certain Sections of Republic Act No. 3720, as Amended, and Appropriating Funds Thereof [Food and Drug Administration (FDA) Act of 2009], Republic Act No. 9711, § 6 (2009).

245. *Id.* § 9.

246. *Id.*

It likewise defines a health-related device as "any device not used in health care but has been determined by the FDA to adversely affect the health of the people."[247]

Before an entity can manufacture, import, export, sell, offer for sale, distribute, transfer, test, promote, sponsor, or advertise a medical device, it has to secure the necessary license to operate (LTO) from the FDA. Subsequently, it needs to file an application for product registration (CPR). Before the medical device is registered, the relevant person must prove that the medical device must be "safe, efficacious[,] and of good quality for use under the conditions prescribed, recommended or suggested in the labelling [of the product.]"[248] Once the requirements are complied, a certificate of product registration will be issued.[249]

The FDA Law prohibits an entity from engaging into the foregoing activities without securing the LTO and the CPR.[250] Likewise, the law prohibits the "manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship of any health product that is adulterated, unregistered and misbranded."[251] In addition, the Consumer Act prohibits the "manufacture for sale, offer for sale, distribute in commerce, or import into the Philippines any product which is not in conformity with an applicable consumer product quality or safety" contained in the law.[252] Any person found to be in violation of these laws may be held administratively and criminally liable and cause their products to be seized or destroyed by the authorities.[253]

In 2014, the members of the Association of South East Asian Nations (ASEAN), in order to harmonize the regulation of medical devices in the region, signed the ASEAN Medical Device Directive (AMDD). The AMDD seeks to address the variation in product registration, quality control and post-market surveillance among the ASEAN member states "by identifying basic requirements for assessing conformity and creating a single

247. *Id.*

248. The Consumer Act of the Philippines [Consumer Act of the Philippines], Republic Act No. 7394, art. 4 (aw) (1992).

249. *Id.* art. 31.

250. Food and Drug Administration Act (FDA) of 2009, § 10.

251. *Id.*

252. Consumer Act of the Philippines, art. 18.

253. *See, e.g.*, Food and Drug Administration (FDA) Act of 2009, §§ 11 & 13 & Consumer Act of the Philippines, art. 19.

classification system based on risk."[254] Last year the DOH issued Administrative Order 2018-0002 (AO 2018-0002) or the Guidelines Governing the Issuance of an Authorization for a Medical Devices, which was based on AMDD.

The AO 2018-0002,[255] in consonance with the AMDD, classified medical devices into four classes according to risk level:[256]

Class	Risk Level
A	Low risk
B	Low-moderate risk
C	Moderate-high risk
D	High risk

To operationalize the above classification, a guidance document will be issued by the FDA, which will contain the list of medical devices per class. "If the product is not included in the list, the applicant shall classify the device based on the intended use and on the classification rules of the AMDD."[257] "All medical devices under class A [are required to] apply for a notification of the medical device product while devices under Classes B, C, and D shall apply for registration of the medical device."[258] Parenthetically, "medical devices [which] are strictly for research, clinical trial, exhibit and/or donated brand new medical devices are exempted from [the requirement of] notification and registration."[259] Nevertheless, the researcher, institution, and/or user of such devices needs to secure a Certificate of Medical Device Listing.[260]

254. PwC Growth Markets Centre, The Future of ASEAN: Time to Act Medical Devices (A Report Published Online by PwC) at 149, *available at* https://www.pwc.com/sg/en/publications/assets/healthcare-future-asean-2018.pdf (last accessed Feb. 29, 2020).

255. Food and Drug Administration, Guidelines Governing the Issuance of an Authorization for a Medical Device Based on the ASEAN Harmonized Technical Requirements, Administrative Order No. 2018-0002 [FDA A.O. No. 2018-0002], (Jan. 6, 2020).

256. *Id.* (V) (1).

257. *Id.* (V) (2).

258. *Id.* (V) (3).

259. *Id.* (V) (7).

260. *Id.*

The FDA was scheduled to implement AO 2018-0002 last 11 April 2019.[261] However, the implementation has been delayed for the reason that the CRRH has to finalize the guidelines for classification and grouping.[262]

Incidentally, FDA has the power to require "all manufacturers, traders, distributors, importers, exporters, wholesalers, retailers, consumers, and non-consumer users of health products to report to the FDA any incident that reasonably indicates that said product has caused or contributed to the death, serious illness or serious injury to a consumer, a patient, or any person."[263]

Likewise, the Consumer Act makes

> any Filipino or foreign manufacturer or importer liable for redress, independently of fault, for damages caused to consumers by defects resulting from design, manufacture, construction, assembly and erection, formulas and handling and making up, presentation or packing of their products, as well as for the insufficient or inadequate information on the use and hazards thereof.[264]

The regulator is given a wide latitude to see if a product is defective and may take into account the presentation of product, the use and hazards reasonably expected of the products, and the time it was put into circulation.[265] Nonetheless, a defective product is not considered defective just because another better quality product has been placed in the market."[266] It is also important to underscore that most of the medical devices are not manufactured locally. Thus, a seller can also be liable to the consumer when it is not possible to identify the manufacturer, builder, producer, or importer of the product supplied.[267] Any person found to be in

261. Bryan Gilburg, Philippines Delays Launch of New Medical Device Regulations, *available at* https://www.asiaactual.com/philippines-delays-medical-device-regulations (last accessed Feb. 29, 2020).

262. *Id.*

263. Food and Drug Administration (FDA) Act of 2009, § 5.

264. Consumer Act of the Philippines, art. 97. The Consumer Act defines a consumer as "a natural person who is a purchaser, les*see,* recipient or prospective purchaser, lessor or recipient of consumer products, services[,] or credit." *Id.* art. 4 (n).

265. *Id.*

266. *Id.*

267. *Id.* art. 98.

violation of the foregoing may be held administratively and criminally liable.[268]

Just like the regulation of the practice of medicine, regulation of health products is a way of protecting and promoting the right to health of every Filipino people. Licensing of manufacturers, sellers as well as importers and registration of products ensures the citizens that persons who deal with medical devices are legitimate and that their products are safe, effective and of good quality. Moreover, it also ensures the public that products on the market are not health hazards and in case that these products cause harm, the laws provides adequate rights and means of redress to an injured party, as well as the public.

Arguably, healthcare AI can fall under the broad definition of a medical device under Philippine laws. However, given the special characteristics of these innovations, there is a need to clarify if the current laws, *ex ante* or ex post legislation, adequately protect the public or an eventual injured party from the hazards that it may bring in the future.

V. REGULATING HEALTHCARE AI

With the immense and exponential growth of AI in the recent years, regulators around the world are still playing catch-up. To date, there is no concerted effort to come up with an international document on artificial intelligence. Rather, the approach appears to be bottom-up, or on a per country or region basis and the country or region which acts first will most likely have the first mover advantage to influence AI legislation as well as AI development around the world. This Chapter will provide a brief survey on the various efforts undertaken by the U.S., EU, and Japan in connection with the regulation of AI general and healthcare AI.

A. Regulation of AI

1. United States

In December 2017, the U.S. Congress introduced its consolidated bill called Fundamentally Understanding The Usability and Realistic Evolution of Artificial Intelligence Act of 2017 (FUTURE of AI Act).[269] The Future of AI Act recognizes that "artificial intelligence evolves [and ...] greatly benefits

268. *Id.* art. 107.

269. A Bill to Require the Secretary of Commerce to Establish the Federal Advisory Committee on Development and Implementation of Artificial Intelligence, and for Other Purposes, S.2217, 115th Cong., 1st Reg. Sess. (2017) (U.S.).

society by powering information economy, fostering better informed decisions[,] and helping unlock questions that, as of the date of the enactment of [the] Act, are unanswerable[.]"[270] Thus, it will be beneficial for the U.S. "to better understand AI and foster its development in a manner that maximizes its benefit to the society."[271] The FUTURE of AI provides definitions for artificial intelligence,[272] artificial general intelligence and artificial narrow intelligence. It also establishes a Federal advisory committee tasked to advise the U.S. Secretary of Commerce on issues relating to the development of AI like accountability and legal rights.[273] To date, neither the U.S. House of Representatives nor the Senate has taken action on the bill except for referring it to the Committee on Commerce, Science, and Transportation.

Another initiative is being led by the U.S. Executive Department. On 11 February 2019, President Donald Trump issued an Executive Order on

---

270. *Id.* § 2 (2).

271. *Id.* § 2 (3).

272. *Id.* § 3 (a) (1). The bill defines "artificial intelligence" as —

> (A) Any artificial systems that perform tasks under varying and unpredictable circumstances, without significant human oversight, or that can learn from their experience and improve their performance. Such systems may be developed in computer software, physical hardware, or other contexts not yet contemplated. They may solve tasks requiring human-like perception, cognition, planning, learning, communication, or physical action. In general, the more human-like the system within the context of its tasks, the more it can be said to use artificial intelligence.
>
> (B) Systems that think like humans, such as cognitive architectures and neural networks.
>
> (C) Systems that act like humans, such as systems that can pass the Turing test or other comparable test via natural language processing, knowledge representation, automated reasoning, and learning.
>
> (D) A set of techniques, including machine learning, that seek to approximate some cognitive task.
>
> (E) Systems that act rationally, such as intelligent software agents and embodied robots that achieve goals via perception, planning, reasoning, learning, communicating, decision making, and acting.

Id.

273. *Id.* § 4 (a) (1).

Maintaining American Leadership in Artificial Intelligence (American AI Initiative), which allows the U.S. Federal Government to channel its resources on AI research and development in order to drive the growth of the U.S. economy, enhance its economic and national security, and improve the quality of life of the American people.[274] Briefly, the American AI Initiative also identified the following objectives:

(1) Promoting investment in AI research and development;

(2) Enhancing access to high-quality and fully traceable Federal data models and computing resources;

(3) Reducing barriers to the use of AI technologies;

(4) Ensuring technical standards will minimize vulnerability to attacks from malicious actors;

(5) Training next generation of American AI researchers and users; and

(6) Developing and implementing an action plan to protect the advantage of the U.S. in AI and technology critical to U.S. economic and national security interests against strategic competitors and foreign adversaries.[275]

One of the thriving areas in AI research and development is healthcare. Thus, the U.S. Department of Health and Human Services (HHS) spearheaded several initiatives related to AI.[276] HHS is promoting medical innovation through its Division of Research, Innovation, and Ventures, which uses machine learning in order to find a cure for diseases like sepsis.[277] HHS, together with various private sector organizations, also organized a Health Tech Sprint, to build digital products and apps and improve clinical trials, experimental therapies, and introduce data driven solutions to cure

274. *See generally* Office of the President, Maintaining American Leadership in Artificial Intelligence, Executive Order No. 13859 [E.O. No. 13859], 84 Fed. Reg. 3967, § 1 (Feb. 11, 2019) (U.S.).

275. *Id.* § 2.

276. Paige Minemyer, HHS launches new initiative to address health concerns as national security threats, *available at* https://www.fiercehealthcare.com/regulatory/department-health-and-human-services-drive-security-barda (last accessed Feb. 29, 2020).

277. *Id.*

cancer and tick-borne diseases using the Federal government's data.[278] The U.S. FDA has also taken huge strides in medical device regulation by allowing the marketing of IDx-DR, a medical device powered by AI technology that can detect diabetic retinopathy in April 2018, and an AI based software that can help healthcare providers detect wrist fractures in May 2018.[279]

2. European Union

AI and robots are becoming widely used in Europe and in order to avoid any legislative variances among the EU Member States and the fragmentation of the EU's common market, a uniform regulatory framework must be in place. Accordingly, on 27 January 2017, the European Union Parliament (EU Parliament), in a resolution, made recommendations to the European Union Commission (EU Commission) regarding the issuance of a directive regarding civil law rules on robotics (the Resolution).[280] The Resolution establishes general and ethical principles regarding the development of robotics and AI for civil use. The EU Parliament's proposal is to create a common definition of "smart autonomous robots."[281] It also calls for the creation of a European agency on robotics and AI, with the institutional thrust to lend the necessary technical, ethical and regulatory expertise to support the stakeholders.[282] The salient provisions of the Resolution are the:

(1) introduction of a system of registration for smart robots;[283]

(2) establishment of an obligatory insurance scheme based on the obligation of the producer to take out insurance for the autonomous robots it produces;[284]

278. Davar Ardalan et al., Deep Dive: How a Health Tech Sprint Pioneered an AI Ecosystem, *available at* https://digital.gov/2019/02/27/how-a-health-tech-sprint-inspired-an-ai-ecosystem (last accessed Feb. 29, 2020).

279. White House, Artificial Intelligence for the American People, *available at* https://www.whitehouse.gov/ai/ai-american-industry/ (last accessed Feb. 29, 2020).

280. European Parliament Resolution of 16 February 2017 with Recommendations to the Commission on Civil Law Rules on Robotics, 2018 O.J. (C 252) 239 [hereinafter European Parliament Resolution].

281. *Id.* ¶ 1.

282. *Id.* ¶ 2.

283. *Id.*

(3) creation of a fund to supplement the insurance system;[285]

(4) allowance interoperability, access to code and intellectual property rights;[286]

(5) guarantee of data protection and ownership;[287] and

(6) initiation of amendments to existing relevant international documents or the drafting of new instruments with the objective of introducing specific references to robotics and AI.[288]

With regard to healthcare, the Resolution also specifically underscores the use of AI and robots in diagnosing and treating patients should not harm the doctor-patient relationship but shall only reduce the risk of human error in order to increase the quality of life and life expectancy.[289] It annexed a Charter on Robotics which consists of a Code of Ethical Conduct for Robotic Engineers, Code for Research Ethics Committees, and Licenses for Designers and Users.

Thereafter, on 10 April 2018, the 24 EU Member States including Norway signed a declaration of cooperation on Artificial Intelligence. They agreed to cooperate and ensure the Union's competitiveness in the field of AI as well as deal with the social, economic, ethical, and legal questions related thereto.[290] Later that month, the EU Commission issued a Communication on Artificial Intelligence for Europe (the Communication) on 25 April 2018. The Communication emphasizes three major goals: (1) increase public and private investments in AI; (2) prepare for socio-economic changes in areas like employment; and (3) ensure appropriate ethical and legal framework to strengthen European values.[291] According to the EU

284. *Id.* ¶ 57.

285. *Id.* ¶ 58.

286. European Parliament Resolution, *supra* note 280, ¶ 22.

287. *Id.* ¶ 19.

288. *Id.* ¶ 61.

289. *Id.* ¶ 33.

290. European Commission, EU Member States sign up to cooperate on Artificial Intelligence, *available at* https://ec.europa.eu/digital-single-market/en/news/eu-member-states-sign-cooperate-artificial-intelligence (last accessed Feb. 29, 2020).

291. Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions on Artificial Intelligence for Europe, at 5-16, COM (2018) 237 final (Apr. 25, 2018).

Commission, the Union "must ensure that AI is developed and applied in accordance with a proper framework which not only promotes innovation but also respects EU values, fundamental rights and ethical principles such as accountability and transparency."[292] Thus, the Communication, among other things, introduced the EU Commission's plan to draft an AI ethical guidelines, which can serve as a framework for stakeholders. The EU Commission likewise announced that it will be issuing a guidance document on the interpretation of the existing Product Liability Directive in light of these new technologies by mid-2019.[293] To date, the EU has yet to issue this guidance document. However, the European Commission already formed the High-Level Expert Group on Artificial Intelligence, comprising of experts on the field, which drafted the Ethics Guidelines for Trustworthy AI (the Ethics Guidelines).

The Ethics Guidelines were released last 8 April 2019 and are not meant to substitute any form of current or future policymaking or regulation nor deter the introduction thereof. Rather, the Ethics Guidelines are considered as a "living document" to be reviewed and updated over time to ensure continuous relevance as AI evolve.[294]

Succinctly, the Ethics Guidelines advocate for the development of a Trustworthy AI, which is (1) lawful (compliant with all applicable laws and regulations); (2) ethical (adheres to ethical principles and values); and (3) robust (both from a technical as well as social perspective taking note of the fact that AI systems, even with good intentions, can cause unintentional harm).[295] The Ethics Guidelines are based on four principles rooted from the EU Charter and other international documents: respect for human autonomy, prevention of harm, fairness, and explicability.[296] The Ethics Guidelines emphasize the point that "the allocation of functions between humans and AI systems should follow a human-centric design principles and leave meaningful opportunity for human choice. This means ensuring

292. *Id.* at 2.

293. *Id.* at 16.

294. Independent High-Level Expert Group on Artificial Intelligence set up by the European Commission, *Ethics Guidelines for Trustworthy AI*, at 3 (2019), *available at* https://ai.bsa.org/wp-content/uploads/2019/09/AIHLEG_EthicsGuidelinesforTrustworthyAI-ENpdf.pdf (last accessed Feb. 29, 2020) [hereinafter AI HLEG, *Ethics Guidelines*].

295. *Id.* at 6-7.

296. *Id.* at 12.

human oversight over work processes in AI systems."[297] The document identifies four stakeholders who can ensure the development of a Trustworthy AI:

(1) the developers (those who research, design and/or develop AI systems);[298]

(2) the deployers (public or private organizations that use AI systems within their business processes and to offer products and services to others);[299]

(3) the end-users (those who engage with AI systems directly or indirectly);[300] and

(4) broad society (encompasses all others that are directly or indirectly affected by AI systems).[301]

The core of the Ethics Guidelines are the seven essential requirements of Trustworthy AI:

(1) Human agency and oversight (AI systems should empower human beings, by allowing them to make informed decisions and fostering their fundamental rights. At the same time, proper oversight mechanisms need to be ensured, which can be achieved through human-in-the loop, human-on-the-loop, and human-in-command approaches);[302]

(2) Technical robustness and safety (resilient to attack and secure, fall back plan and general safety, accuracy, reliability, and reproducibility);[303]

(3) Privacy and data governance (privacy, quality, and integrity of data, access to data);[304]

(4) Transparency (traceability, explainability, and communication);[305]

297. *Id.*

298. *Id.* at 14.

299. *Id.*

300. AI HLEG, *Ethics Guidelines*, *supra* note 294, at 14.

301. *Id.*

302. *Id.* at 15-16

303. *Id.* at 15-16

304. *Id.* at 17.

(5) Diversity, non-discrimination and fairness (avoidance of unfair bias, accessibility and universal design, and stakeholder participation);[306]

(6) Societal and environmental well-being (sustainability and environmental friendliness, social impact, society, and democracy); [307] and

(7) Accountability (auditability, minimization and reporting of negative impact, trade-offs, and redress)[308]

In order to ensure that the AI remains trustworthy, these requirements must be evaluated continuously and addressed throughout the system's life cycle.[309] Aside from these requirements, the Ethics Guidelines also contain an assessment list, which can guide stakeholders in developing their own Trustworthy AI.

The Ethics Guidelines emphasizes that AI systems "do not operate in a lawless world" and, in fact, a number of existing EU, national, and international level laws are applicable in the development, deployment and use of AI systems. It further mentions that the EU Medical Device Regulation, as a domain specific rule, apply to AI applications in the healthcare sector.[310]

3. Japan

Japan is beset with a number of social issues like "declining birthrate and aging population, labor shortage, rural depopulation, and increased in fiscal spending."[311] Against this backdrop, Japan is utilizing technologies such as AI, Internet of Things (IoT), robotics and ultra-high-speed broadband communication networks, to turn these challenges into opportunities to

305. *Id.* at 18.

306. AI HLEG, *Ethics Guidelines*, *supra* note 294, at 16-17.

307. *Id* at 19.

308. *Id.* at 19-20.

309. AI HLEG, *Ethics Guidelines*, *supra* note 294, at 14.The stages of the AI system's life cycle are as follows: (1) development, (2) use, (3) analysis, and (4) re-design *Id.* at 20.

310. *Id.* at 6.

311. Japan Council for Social Principles of Human-Centric AI, Social Principles of Human-Centric AI (A Paper Published Online by the Japan Cabinet Office) at 1, *available at* https://www8.cao.go.jp/cstp/english/humancentricai.pdf (last accessed Feb. 29, 2020).

build a more sustainable world.[312] Japan launched its initiative called Society 5.0 in order to create "a human-centered society that balances economic advancement with the resolution of social problems by a system that highly integrates cyberspace and physical space."[313] The major initiatives of this project are mobility, healthcare and caregiving, manufacturing, agriculture, food, disaster prevention and energy.[314] AI will play a big role in analyzing accumulated data from physical space in order to bring "new value to [industries] and to the society in ways which were not previously possible."[315]

In 2016, Japanese Prime Minister Shinzo Abe initiated the establishment of an Artificial Intelligence Technology Strategy Council. In March 2017, the Council released Japan's AI Technology Strategy.[316] The Strategy proposes an Industrialization Roadmap powered by AI and other forms of technologies developed in Japan and how to utilize these technologies in solving social issues experienced not only domestically but also globally. The Industrial Roadmap is divided into three phases: Phase 1 is the utilization and application of data driven AI in various domains; Phase 2 will be the public use of AI and data developed in various domains; and Phase 3 will be the building of an ecosystem through connecting multiple domains.[317] The Council noted that in order for the Industrial Roadmap to work, collective wisdom from the industries, the academe, and the government should all be utilized.[318] The Strategy likewise identified priority areas which include productivity, health, medical care and welfare, mobility, and information security.[319]

The Council for Social Principles of Human Centric AI, which is under the auspices of the Council for Science, Technology and Innovation of

312. *Id.* at 5.

313. Cabinet Office, Society 5.0, *available at* https://www8.cao.go.jp/cstp/english/society5_0/index.html (last accessed Feb. 29, 2020) (Jap.).

314. *Id.*

315. *Id.*

316. Future of Life Institute, AI Policy: Japan, *available at* https://futureoflife.org/ai-policy-japan/?cn-reloaded=1 (last accessed Feb. 29, 2020).

317. *See generally* Japan Strategic Council for AI Technology, Artificial Intelligence Technology Strategy (A Report of the Strategic Council for AI Technology) at 4, *available at* https://www.nedo.go.jp/content/100865202.pdf (last accessed Feb. 29, 2020).

318. *Id.* at 8.

319. *Id.* at 5.

Japan's Cabinet Office, issued a document entitled Social Principles of Human-Centric Artificial Intelligence ("Social Principles"). The Social Principles were prepared with the view of realizing an "AI-Ready Society" and promoting an appropriate and proactive social implementation of AI. The Social Principles can be the basis for a social framework that may be implemented across Japanese society.[320] The Social Principles of a Human-Centric AI are as follows:

(1) The Human-Centric Principle[321]

(2) The Principle of Education/Literacy[322]

(3) The Principle of Privacy Protection[323]

(4) The Principle of Ensuring Security[324]

(5) The Principle of Fair Competition[325]

(6) The Principle of Fairness, Accountability and Transparency[326]

(7) The Principle of Innovation[327]

B. Utilizing Medical Device Regulations For Healthcare AI

1. United States

The U.S. FDA is the chief implementor of the Federal Food, Drug, and Cosmetic Act (U.S. FDA Act), and its corresponding amendments which is the primary legislation on medical device. In the U.S., a certain product is considered as a medical device if it falls under the following definition provided under Section 201 (h) of U.S. FDA Act —

> [an] instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

320. Japan Council for Social Principles of Human Centric AI, *supra* note 311, at 7.

321. *Id.*

322. *Id.* at 7-8.

323. *Id.* at 8-9.

324. *Id.* at 9.

325. *Id.* at 9-10.

326. Japan Council for Social Principles of Human Centric AI, *supra* note 311, 10.

327. *Id.* at 10-11.

(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.[328]

The foregoing definition, however, excludes software listed in Section 520 (o).[329]

---

328. Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 321 (h) (1934) (as amended).

329. *Id.* § 360 j (o). Section 520 (o) of the Federal Food, Drug & Cosmetic Act excludes software, which has the following purpose:

(A) for administrative support of health care facility ... ;

(B) for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, treatment of a disease or condition ... ;

(C) to serve as electronic patient records ... intended to transfer, store, convert formats, or display the equivalent of a paper medical chart ... ;

(D) for transferring, storing, converting formats or displaying clinical laboratory test or other data and results ... ;

(E) unless the function is intended to acquire, process, or analyze a medical image or signal from an in vitro diagnostic device or a pattern or a signal from a signal acquisition system for the purpose of:

(1) displaying, analyzing or printing medical information about a patient or other medical information ... ;

(2) supporting or providing recommendations to a health care professional about prevention, diagnosis or treatment of a disease or condition; and

(3) enabling such health care professional to independently review the basis for such recommendations that the software presents so that it is not the intent of such health care professional to rely primarily on such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

Medical devices can range from a very simple gauze to very complex products such as the da Vinci robotic surgery system. Generally, medical devices are grouped according to 16 classification panels provided in Title 21 of the Code of Federal Regulations (CFR), Parts 862-92 (each part stands for the branch of medicine a device is connected). The CFR is further divided into subsections which briefly describes a specific device, its intended use, its class and some information about its marketing requirements.[330] Aside from the classification panels, medical devices are classified according to classes, which are based on the level of control necessary to assure the safety and effectiveness of the device:

(1) Class I General Controls,

(2) Class II General Controls and Special Controls, and

(3) Class III General Controls and Premarket Approval.

The class will determine, among other things, the premarketing submissions or application procedure to be followed prior to marketing a medical device. Unless exempted, Class I and II, must follow Section 510 (k). Class III devices, on the other hand, require premarket approval application from the U.S. FDA unless such device is considered a pre-amendments device (in circulation before the Medical Device Amendments were passed in 1976 or is substantially equivalent to such a device).[331] Device classification is based on the intended use, indications for use and the risk that the medical device poses to a patient and/or a user. Class I devices are those which have the lowest risk while Class III device are those with the greatest risks.[332] Consequently, regulatory control increases as the class increases.

The use of software as a medical device (SaMD)[333] is continually rising and given its characteristics, regulators, like the U.S. FDA, recognize the

---

Id. § 520 (o).

330. U.S. Food and Drug Administration, Device Classification Panels, *available at* https://www.fda.gov/medical-devices/classify-your-medical-device/device-classification-panels (last accessed Feb. 29, 2020).

331. U.S. Food and Drug Administration, Classify your Medical Device, *available at* https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device (last accessed Feb. 29, 2020).

332. *Id.*

333. U.S. Food and Drug Administration, Software as a Medical Device (SaMD), *available at* https://www.fda.gov/medical-devices/digital-health/software-medical-device-samd (last accessed Feb. 29, 2020). The International Medical

need to create norms that will promote the safe innovations and protect patient safety. The International Medical Device Regulators Forum, an international group of medical device regulators, formed the SaMD Working Group chaired by the U.S. FDA, which came up with several guidelines[334] regulating SaMD.[335]

A number of SaMD use adaptive artificial intelligence and machine learning technologies in order to serve their medical purpose. The U.S. FDA differentiates SaMD which uses adaptive AI as well as machine learning from regular SaMD because the former "have the potential to adapt and optimize device performance in real-time to continuously improve healthcare for patients."[336] Due to its heuristic nature, a different kind of regulatory framework is necessary. On 2 April 2019, the U.S. FDA issued a discussion paper and requested for feedback from the public to solicit comments on their Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD). The proposal sets forth a total product lifecycle-based regulatory approach, which is intended to keep up with the highly iterative, autonomous and adaptive nature of AI and machine learning based SaMD.[337]

Aside from the U.S. FDA, the American Medical Association (AMA) is also keen on developing standards for healthcare AI. In fact, last 14 June 2018, the AMA issued a policy on the use of augmented intelligence in the

---

Device Regulators Forum (IMDRF) defines SaMD as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device." *Id*.

334. These guidelines are: (1) Key definitions for SaMD; (2) Framework for Risk Categorization for SaMD; (3) Quality Management System for SaMD; and (4) clinical evaluation of SaMD.

335. *Id*.

336. U.S. Food and Drug Administration, Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML) Based Software as Medical Device (SaMD) (A Discussion Paper and Request for Feedback) at 3, *available at* https://www.fda.gov/media/122535/download (last accessed Feb. 29, 2020).

337. U.S. Food and Drug Administration, Artificial Intelligence and Machine Learning in Software as a Medical Device at 3, *available at* https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device (last accessed Feb. 29, 2020).

healthcare industry.[338] Rather than using artificial intelligence, the AMA prefers to use augmented AI methods and systems to refer to machine image recognition, natural language processing and machine learning used in healthcare delivery.[339] The AMA champions the view that augmented intelligence should "enhance and scale" human expertise rather than attempt to replicate all aspects of human intelligence.[340]

As of this writing, harm caused by defective products, including medical devices, are regulated through tort. Tort law differs from state to state but in principle it makes a manufacturer, who sells or distributes a defective medical device, liable to a person who was harmed due to the defective product.[341] A defect exists when, at the time of sale or distribution:

(1) the medical device has a manufacturing defect;[342]

(2) the medical device was not reasonably safe due to a defective design;[343] or

(3) the medical device was not reasonably safe due to inadequate instructions or warnings.[344]

A medical device is defectively designed "if the foreseeable risks of harm posed by the medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the medical device for any class of patients."[345] Courts recognized that what may be applicable for one patient may not be beneficial for the other thus a medical

338. Bold Business, AMA Pushes for "Thoughtfully Designed" Artificial Intelligence In Healthcare, *available at* https://www.boldbusiness.com/health/ama-artificial-intelligence-healthcare/ (last accessed Feb. 29, 2020).

339. American Medical Association, Augmented Intelligence in Health Care (A Policy Report Derived from the Augmented Intelligence in Health Care 2018 Annual Meeting) at 2, *available at* https://www.ama-assn.org/system/files/2019-01/augmented-intelligence-policy-report.pdf (last accessed Feb. 29, 2020).

340. *Id.*

341. RESTATEMENT (THIRD) OF THE LAW OF TORTS PRODUCTS LIABILITY § 6 (a) (AM. LAW INST. 1997).

342. *Id.* § 6 (b) (1).

343. *Id.* § 6 (b) (2).

344. *Id.* § 6 (b) (3).

345. *Id.* § 6 (c).

device may only be considered as defective when it has no net benefit to any class of patients.[346]

A medical device, on the other hand, has inadequate instructions or warnings when the

> reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:
>
> (1) prescribing and other health-care providers who are in a position to reduce the risk of harm in accordance with the instructions or warnings; or
>
> (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.[347]

In most cases, the manufacturer has a duty to warn the healthcare provider, not the patient, about the risks involved using a medical device. This is based on the principle of the learned intermediary, to wit —

> only healthcare professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription based therapy. The duty then devolves on the health care provider to supply to the patient such information as is deemed appropriate under the circumstances so that the patient can make an informed choice as to the therapy.[348]

The reason behind this principle is that a healthcare provider makes an individualized decision regarding the suitability of a medical device on a particular patient and decide which risks are relevant to the patient before putting it into use.[349] However, in circumstances wherein a medical device is directly used by the patient without the intervention of a healthcare provider, the manufacturer has the duty to warn the patient.[350]

AI used in the delivery of healthcare are intimately connected with medical devices because they, more often than not, serve the same purpose. However, as the U.S. FDA pointed out, these kinds of technologies differ from the regular medical device. A number of authorities which will be

---

346. *Id.* § 6 cmt. b.

347. RESTATEMENT (THIRD) OF THE LAW OF TORTS PRODUCTS LIABILITY, *supra* note 341, § 6 (d).

348. *Id.* § 6 cmt. b.

349. *Id.*

350. *Id.* § 6 cmt. e.

discussed in Chapter 5 opined that tort law, as applied today, may not fully address the harm which resulted from the use of healthcare AI.

2. European Union

Last 25 May 2017, the EU Medical Device Regulation (MDR) was adopted and is set to apply on 25 May 2020.[351] The MDR defines medical device as

> any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
>
> (1) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
>
> (2) diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
>
> (3) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
>
> (4) providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,
>
> and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
>
> The following products shall also be deemed to be medical devices:
>
> (1) devices for the control or support of conception[ ]
>
> (2) products specifically intended for the cleaning, disinfection, or [sterilization] of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.[352]

Only devices that are compliant with the MDR can be placed on or put into service on the market.[353] Likewise, devices must meet all the general safety and performance requirements in the MDR, taking into account its

351. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and Repealing Council Directives 90/385/EEC And 93/42/EEC, 2017 O.J. (L 117) 1 [hereinafter EU Medical Device Regulation].

352. *Id.* art. 2 (1).

353. *Id.* art. 5 (1).

intended purpose.[354] EU members states "shall not refuse, prohibit or restrict the entry of a device which complies with the MDR in their territory."[355] The MDR also provides certain obligations for manufacturers, their authorized representatives,[356] importers,[357] and distributors.[358] Devices in the EU are divided into classes I, IIa, IIb, and III which are determined based on classification rules (Annex VIII of the Regulation). This set of rules takes into account the intended purpose as well as the inherent risks of the device.[359]

In case a defective medical device causes damage to a person, the MDR allows the injured party to claim compensation for damage according to the applicable EU and national law. The MDR also directs the manufacturer to have measures in place to provide sufficient financial coverage, taking into the risk class, type of device and the size of enterprise, with respect to its potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law.[360]

In the EU Product Liability Directive,[361] a product refers to all kinds of movables except agricultural products and game.[362] Generally, it imputes liability on a producer or any person who places its name or mark on a product and introduced a defective product in the common market which consequently causes damage to a person.[363] Damage may mean death or personal injury or destruction of property.[364] An importer or supplier which brings in a defective product inside the common market, in certain

354. *Id.* art. 5 (2).

355. *Id.* art. 24.

356. *Id.* art. 11.

357. *See, e.g.*, EU Medical Device Regulation, *supra* note 351, art. 13.

358. *Id.* art. 14.

359. *Id.* art. 51. Annex VIII of the EU Medical Device Regulation provides the Classification Rules for identifying which class a medical device belongs.

360. *Id.* art. 10 (6).

361. Council Directive of 25 July 1985 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products, 1985 O.J. (L 210) 29, [hereinafter EU Product Liability Directive].

362. *Id.* art. 2.

363. *Id.* arts. 1 & 3.

364. *Id.* art. 9.

circumstances, can also be made liable.[365] In order for a case to prosper, the injured person has to prove the damage, the defect, and the causal relationship between the damage and the defect.[366] The EU Product Liability Directive considers a product defective

> when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:
>
> (a) the presentation of the product;
>
> (b) the use to which it could reasonably be expected that the product would be put; at the time when the product was put into circulation.[367]

Furthermore, "a product shall not be considered defective for the sole reason that a better product is subsequently put into circulation."[368] In case the manufacturer proves any of the following circumstances, it shall be exculpated from liability:

> (a) that he did not put the products into circulation; or
>
> (b) that, having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by him or that this defect came into afterwards; or
>
> (c) that the product was neither manufactured by him for sale or any form of distribution for economic purpose nor manufactured or distributed by him in the course of his business; [or]
>
> (d) that the defect is due to compliance of the product with mandatory regulations issued by the public authorities; or
>
> (e) that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered; [or]
>
> (f) in the case of a manufacturer of a component, that the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product.[369]

The producer is still fully liable even if the damage is a result of both a defective product and an act or omission of a third party.[370] However, "the

365. *Id.* art. 3 (3).

366. *Id.* art. 4.

367. EU Product Liability Directive, *supra* note 361, art. 6 (1).

368. *Id.* art. 6 (2).

369. *Id.* art. 7.

370. *Id.* art. 8 (1).

liability of the producer may be reduced or disallowed when, having regard to all circumstances, the damage is caused both by a defective product and by the act or omission of a third party."[371] Furthermore, the producer may not limit or exempt himself from liability, in relation to the person harmed, caused by a defective product.[372]

3. Japan

In Japan, healthcare products are regulated through the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy and Cosmetics. Under this Act, medical devices are

> appliances or instruments, etc. which are intended for use in the diagnosis, treatment or prevention of disease in humans or animals, or intended for use in the diagnosis, treatment or prevention of disease in humans or animals, or intended to affect the structure of functioning of the bodies of humans or animals (excluding regenerative medicine products), and which are specified by Cabinet Order.[373]

The Japan Pharmaceuticals and Medical Devices Agency (PMDA) classifies medical devices as Class I,[374] for extremely low risk products, Class II,[375] for low risk products, Class III,[376] for medium risk products, and Class

371. *Id.* art. 8 (2).

372. *Id.* art. 12.

373. Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, Act. No. 145 of August 10, 1960, art. 2 (4) (Jap.).

374. *Id.* art. (2) (7). Class I devices are considered as general medical devices which have little potential risk to human life and health in the event of a side effect or malfunction occurring." Before marketing a Class I device, marketing notification is necessary. Pharmaceuticals and Medical Devices Agency, Basic concept for Approval and Certification for Medical Device, *available at* https://www.std.pmda.go.jp/scripts/stdDB/pubeng/stdDB_pubeng_regulation.cgi (last accessed Feb. 29, 2020).

375. Act. No. 145 of August 10, 1960, art. (2) (6). Class II devices are considered as a controlled medical devices other than specially-controlled medical devices which "[require] proper management due to their significant potential risk to human life and health in the event of a side effect or malfunction occurring." Before marketing a Class II device, third party certification as well as PMDA Minister's Approval is required. Pharmaceuticals and Medical Devices Agency, *supra* note 374.

IV, for high-risk products. Recently, the PMDA organized the Subcommittee on Artificial Intelligence and its Applications in Medical Field to "examine and report the impact of AI medical care applications ... and clarify the characteristics and potential risks of AI-based technologies, then [ ] propose the basis of clinical use, and to contribute to the future review and consultation services by the PMDA"[377]

A summary of the discussion and the report of the subcommittee was presented in an article written by Kiyoyuki Chinzei. In the article, the Subcommittee concluded that AI-based systems have the following characteristics which differentiate them from the regular medical device:

(1) Plasticity - capable to "self-change" their performance through learning[378]

(2) Unpredictability - system has an unpredictable behavior in responding to unknown outputs (i.e., black box)[379]

(3) Degree of Autonomy - higher degree of autonomy will change the relationship between doctors and patients[380]

In discussing degree of autonomy, they looked into AI-based computer aided diagnosis system (AI CAD) and developed a way to classify AI CAD into five diagnostic levels depending on the level of oversight the doctor has on the final diagnosis.[381] As for AI-based treatment systems, they noted that these technologies produce a direct effect on patients as compared to the AI CAD. Hence, in regulating such systems, "the predictability of outputs and time margin to mitigate erroneous behavior must be considered."[382] Finally, the Subcommittee noted that regulatory bodies, in regulating AI systems,

376. Act. No. 145 of August 10, 1960, art. (2) (5). Class III and IV are also considered specially controlled device which are medical device that "[require] proper management due to their significant potential risk to human life and health in the event of a side effect or malfunction occurring." Before marketing Class C and D devices, PMDA Minister's approval is required. *Id*.

377. Kiyoyuki Chinzei, et al., *Regulatory Science on AI-based Medical Devices and Systems*, 7 ADV. BIOMEDICAL ENG'G 118, 118-19 (2018).

378. *Id*. at 119-20.

379. *Id*. at 120.

380. *Id*. at 120-21.

381. *Id*. at 120.

382. *Id*.

should be mindful of the "overall balance between the risks and benefits of such medical device as a whole, not the piecewise risk of its components."[383]

Generally, product liability in Japan is regulated by the tort regime in Article 709 of the Japanese Civil Code as well as the Product Liability Act ("PLA")[384] In the PLA, products covered are manufactured or processed movable property.[385] It excludes real estate, unprocessed natural products and intangibles such as computer software and information.[386]

C. Challenges

Although the use of AI has far-reaching benefits in improving the delivery of healthcare, pronouncements of state actors like the U.S., the EU, and Japan as well as opinions of several writers on the matter have identified the following essential considerations in the development and use of such technology: bias, security, data privacy, lack of transparency, and liability.

1. Bias

Since AI systems use mathematical process in arriving at their conclusion, they are oftentimes seen as neutral and objective. However, since water cannot rise above its source, so does an AI-derived algorithm relying on the data that it trains with. It is important to underscore that the data sets from which an AI system is trained is created by humans, which are after all imperfect.[387]

Training data for healthcare AI comes from a variety of sources, from patient charts to insurance records, data coming from those who already have access to the health care system. This means that there are less available data

383. Chinzei, et al., *supra* note 377, at 121.

384. Civil Code, Act No. 89 of April 27, 1896, art. 709 (1896) (Jap.) (as amended). Article 709 provides "a person who has intentionally or negligently infringed any right of others, or legally protected interest of others, shall be liable to compensate any damages resulting in consequence." *Id*.

385. Product Liability Act, Act No. 85 of July 1, 1994, art. 2 (1) (1994) (Jap.). Article 2 (1) states that a "'product' as used in this Act shall mean movable which is manufactured or processed." *Id*.

386. Junichi Ikeda, et al., Product Liability and Safety in Japan Overview (A Country Q&A Guide to Product Liability and Safety in Japan), *available at* https://uk.practicallaw.thomsonreuters.com/w-012-7145?transitionType=Default&contextData=(sc.Default)&firstPage=true&bhcp=1 (last accessed Feb. 29, 2020).

387. American Medical Association, *supra* note 339, at 4.

on people who do not have access to the health care system thus putting them on at a disadvantage.[388]

Kirsten Lloyd simply defines bias as undue prejudice, and, in the context of machine learning, it is characterized as "statistics that lead to a skew that inflicts an unjust outcome on the population."[389] Lloyd noted that oversight in data aggregation can lead to bias. An example of this is when the training data sample sets are not representative of the general population or when datasets exclude certain groups or characteristics or overrepresent other groups. It can also arise from error in labelling data. These mistakes may appear to be harmless but these "biases or discrepancies [are] magnified and inflict damage to populations on a large scale."[390] "Bias can be broken down into five major categories[:] dataset bias, association bias, automation bias, interaction bias[,] and confirmation bias."[391]

In 2017, the IBM Watson Health studied how often IBM Watson for Oncology gave the same treatment options as oncologists at different cancer centers around the world. In India, the concordance rate between Watson and doctor for the appropriate treatment for lung cancer is 96.4% of 112 cases, 81% of 126 colon cancer cases and 92.7% for 124 cases of rectal cancer.[392] However, the results were not favorable in South Korea. The concordance rate was only 49% of 185 gastric cancer cases in South Korea. Andrew Nordern, IBM Watson's deputy health officer, attributed the discrepancy from the difference in treatment guidelines for gastric cancer in South Korea and Memorial Sloan Kettering.[393]

388. *Id.*

389. Kirsten Lloyd & Booz Allen Hamilton, Bias Amplification in Artificial Intelligence System (A Research Paper for the 2018 AAAI Fall Symposium on AI in the Public Sector) at ⋆1, *available at* https://arxiv.org/pdf/1809.07842.pdf (last accessed Feb. 29, 2020).

390. *Id.*

391. *Id.* at ⋆2 (citing Joyce Chou, et al., What The Kids' Game "Telephone" Taught Microsoft About Biased AI, *available at* https://www.fastcompany.com/90146078/what-the-kids-game-telephone-taught-microsoft-about-biased-ai (last accessed Feb. 29, 2020)).

392. Lydia Ramsey, Here's how often IBM's Watson agrees with doctors on the best way to treat cancer, *available at* https://finance.yahoo.com/news/often-ibm-watson-agrees-doctors-143843124.html (last accessed Feb. 29, 2020).

393. *Id.*

The Japan AI initiative[394] recognized that existence of bias and that it can be used for malicious intent. In order to develop a Trustworthy AI, the EU Ethics Guidelines require the stakeholders to promote inclusion and diversity throughout the entire AI system's life cycle. In order to avoid unfair bias, the High-Level Expert Group on Artificial Intelligence recommended that development of an oversight process in order to analyze and address the AI's purpose, constraints, requirements, and decisions in a clear and transparent manner. Moreover, they also recommended the hiring of individuals from diverse backgrounds, cultures, and disciplines in order to ensure and encourage diversity of opinions.[395]

In reality, bias may not be eliminated completely because of the availability of data. However, producers of healthcare AI systems must remain vigilant and give attention to the datasets prior to training and deriving insights. They should continually check if the data is representative of the population. For government regulators, they should set comprehensive data standards and policies to govern both government and business organizations in order to help set a normative behavior of fairness in developing and operating AI.

2. Security

In 2016, the EU recorded more that 4,000 ransomware attacks per day and 80% of European companies experienced at least one cyber security incident.[396] In the U.S., last February 2019, health providers reported 31 breaches to U.S. Department of Health and Human Service Office for Civil Rights. More or less 75% of the reports attributed the breaches to hacking, IT incidents, and theft of paper records, films or laptops and unauthorized

394. The Japanese Council for Social Principles of Human-Centric AI underscored that in order to have an AI-Ready Society, "people should have the ability to recognize that biases are included in the algorithms and/or data that will become the information resources of AI and ... that these biases may be used for undesirable purposes." It also further classify biases into statistical bias, bias caused by social conditions and bias arising from malicious intent of AI users. Japan Council for Social Principles of Human-Centric AI, *supra* note 311, at 5.

395. AI HLEG, *Ethics Guidelines*, *supra* note 294, at 18.

396. Press Release *by* the European Commission, *State of the Union 2017 — Cybersecurity: Commission scales up EU's response to cyber-attacks* (Sep. 19, 2017), *available at* http://europa.eu/rapid/press-release_IP-17-3193_en.htm (last accessed Feb. 29, 2020).

access or disclosure.[397] Aside from data, algorithms are also vulnerable to adversarial attacks or "inputs to machine learning models that have been crafted to force the model to make a classification error."[398] According to the Japan Council for Social Principles of Human Centric AI, AI systems automate various social systems and greatly improve safety. However, they cannot always respond appropriately to rare events or deliberate attacks. Thus, posing new risks to security which society must prepare for by conducting risk management measures such as safeguard of cybersecurity.[399] As for the EU, a Trustworthy AI requires technical robustness and safety. This means that "AI systems ... should be protected against vulnerabilities which can allow them to be exploited by adversaries."[400] Furthermore, "AI systems should have safeguards that enable a fallback plan in case of problems."[401]

The EU Cybersecurity Act came into force last 27 June 2019.[402] The regulation defines cybersecurity as any "activities necessary to protect network and information systems, the users of such systems, and other persons affected by cyber threats."[403] While cyber threat is characterized as "any potential circumstance, event, or action that could damage, disrupt, or otherwise adversely impact network and information systems, the users of such systems and other persons."[404] The European Union Agency for Cybersecurity (ENISA) is the primary regional agency tasked to carry out projects related to cybersecurity by providing advice and expertise to the

397. Jessica Kim Cohen, Healthcare breaches reported in February exposed data on 2 million people, *available at* https://www.modernhealthcare.com/cybersecurity/healthcare-breaches-reported-february-exposed-data-2-million-people (last accessed Feb. 29, 2020).

398. Samuel G. Finlayson, et al., Adversarial Attacks Against Medical Deep Learning Systems, at *2, *available at* https://arxiv.org/pdf/1804.05296.pdf (last accessed Feb. 29, 2020).

399. Japan Council for Social Principles of Human Centric AI, *supra* note 311, at 9.

400. AI HLEG, *Ethics Guidelines*, *supra* note 294, at 16.

401. *Id.*

402. Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (Text with EEA relevance) PE/86/2018/REV/1, 2019 O.J. (L 151) 15 [hereinafter EU Cybersecurity Act].

403. *Id.* art. 2 (1).

404. *Id.* art. 2 (10).

EU.[405] The EU Cybersecurity Act also provides "a framework for the establishment of a European cybersecurity certification scheme for the purpose of ensuring an adequate level of cybersecurity for ICT products, ICT services and ICT processes in the Union."[406]

Ensuring that healthcare AI are protected from security attacks go beyond prevention of compromising patient's data, it also means protecting a patient's life. As much as possible, there is a need to minimize, if not eliminate, instances wherein a diagnosis or a treatment is compromised because of hacking or other cybersecurity threats. Manufacturers must ensure that their healthcare AI are equipped with technology which can detect or identify malware vulnerabilities as well as anomalous behavior in networks and act to isolate it (i.e., similar to a notification alert when someone suspiciously log in to one's email account).[407] Likewise, the producer as well as the user must have a fallback plan in order to mitigate further damage when a cybersecurity incident arises. These measures must be considered and in place during the design stage (security-by-design), development and operation.

3. Privacy

Large amount of data is necessary to train healthcare AI. Part of these data sets consists of personal information from individuals. As a result, data protection and privacy is a major concern and has major implications in the development of AI. William Price opines —

> in some respects, privacy and scientific development concerns seem to be directly opposed. Broader sets of available information in a dataset increase the power and the number of relationships that can be identified, but also increase the likelihood that anonymous data can be [re-associated] with an individual. Broader access to datasets increases the likelihood that a greater variety of actors can develop black-box algorithms, but decreases control over information. To the extent that privacy concerns decrease the number of individuals whose information can be included in datasets, these privacy issues also matter for algorithm robustness and ease for development.[408]

---

405. *Id.* pmbl., para. 17.

406. *Id.* art. 1 (b).

407. Healthcare Weekly Staff, 4 Ways AI Can Improve Healthcare Data Security, *available at* https://healthcareweekly.com/four-ways-ai-improves-healthcare-data-security (last accessed Feb. 29, 2020).

408. William Nicholson Price II, *Black-box Medicine*, 28 HARV. J.L. & TECH. 419, 455-56 (2015).

As a general rule, personal information, which includes health information, may only be collected and processed with the individual's permission.[409] Nevertheless, health information can be used without the individual's consent if the information has been anonymized or deidentified. However, deidentification poses problems such as additional work, increase in cost and as more data accumulates to a particular person's record, even if standard identifiers are scrubbed, the possibility of re-identification increases.[410]

Since the right to privacy is considered as a fundamental right, regulators have robustly enacted data protection regulations in the past years. Probably, one of the most commendable privacy law is the EU General Data Protection Regulation (GDPR), which came into force last 25 May 2018. The GDPR sets out the rules relating to the protection of natural persons with regard to the processing of personal data and to the free movement of personal data.[411] Basically, the GDPR requires the consent of a data subject in the collection and processing of his personal information.[412] Interestingly, it gives the data subject "the right not to be subject to a decision based solely on automated processing, including profiling, which produces legal effects concerning him or her or similarly significantly affects him or her."[413] Nicolas Terry opined that the EU's data privacy regulation is mature as compared to that of the U.S.[414] Terry pointed out the weakness of the U.S. data protection legislation. The U.S. Health Information Portability and Accountability Act (HIPPA) only regulates protected health information and covered entities (i.e., health care provider, health insurers, health information clearing houses and business associates of the same). This means that

409. National Privacy Commission, Rules and Regulations Implementing the Data Privacy Act of 2012, Republic Act No. 10173, § 2(c) (2016).

410. *Id.* at 457 (citing Jill Pulley et al., *Principles of Human Subjects Protections Applied in an Opt-Out, De-Identified Biobank*, 3 CLINICAL TRANSLATIONAL SCI. 42, 45 (2010)).

411. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), 2016 O.J. (L 119) 1 [hereinafter GDPR].

412. *Id.* art. 6.

413. *Id.* art. 22 (1).

414. Terry, *supra* note 116, at 84.

anonymized information as well as non-covered entities such as online search engines, who acts as aggregators of Big Data, are not covered by HIPPA.[415]

Meanwhile, Japan is also keen in protecting personal data while recognizing the importance of medical data in improving research and development. Japan's primary data protection regulation is Act No. 57 of 2003 or the Act on the Protection of Personal Information, which was amended in 2015.[416] Just like the GDPR, the Act requires prior consent from the principal before handling his personal information which includes his name, date of birth, other descriptions whereby a person can be identified, as well as, an individual's identification code.[417] Last 28 April 2017, the National Diet enacted a subsequent law, Act No. 28 of 2017 or the Act on Anonymously Processed Medical Information to Medical Research and Development, which authorizes qualified entities to use of anonymously processed medical information for medical research and development.[418]

Privacy being a fundamental right of a human being makes unwarranted disclosure as well as unconsented processing of personal data as an assault to one's autonomy. Although data protection regulations are available, additional caution must be employed especially in the development and operation of healthcare AI. Technical solutions like block-chain technology or sharing of simulated data sets that limit the possibility of re-identification are some of the approaches that stakeholders can adopt in developing and using healthcare AI.[419]

4. Healthcare AI as a Black-Box

Healthcare AI, depending on how it is programmed, can be classified as either transparent or opaque. William Nicholson Price defines black-box medicine as AI systems, which utilize "opaque computational models to

415. *Id.* at 85.

416. Act on the Protection of Personal Information, Act No. 57 of May 30, 2003 (2003) (amended) (Jap.).

417. *Id.* art. 16 (1). The Article provides that "a personal information handling business operator shall not handle personal information without obtaining in advance a principal's consent beyond the necessary scope to achieve a utilization purpose specified." *Id.*

418. Act on Anonymized Medical Data That Are Meant to Contribute to Research and Development in the Medical Field, Act No. 28 of May 12, 2017 (2017) (Jap.)

419. American Medical Association, *supra* note 339, at 4.

arrive at decisions related to healthcare."[420] This means that the algorithms used are not transparent and that the correlations that "they capture cannot be explicitly understood and, at times, cannot be explicitly stated."[421] Such feature is an inherent characteristic of the system and not maliciously intended.

Healthcare AI systems are different from transparent AI systems used in personalized medicine because "the information used to develop the relationships and predictions used in treatment recommendations comes from a much larger, broader set of information."[422] This information, together with machine learning techniques, generate voluminous predictions from complex connections between "patient characteristics and expected treatment results without explicitly identifying or understanding those connections."[423] Finally, "the relationships used are generally not susceptible to confirmation through clinical trials. This means that different methods of validation will be needed, but also that the costly and timely consuming process of clinical trials may be avoided."[424] Price points out that black-box medicine can bring remarkable benefits to the practice of medicine as well as the healthcare system.[425] Insights from health data can bring about new diagnosis and treatment procedures and can permit early detection of health conditions.[426]

Incidentally, the Trustworthy AI needs to be transparent. Thus, the EU Independent High-Level Expert Group recommends to have the data sets, the processes which give rise to the AI system's decision as well as the AI system's decisions be documented in accordance with the best possible standards to allow traceability, transparency as well as identification of any erroneous decision in order to prevent future mistakes. Further, the Group recommends that decisions of AI systems should be understood and traced by humans.[427] The Principle of Transparency was also reiterated by the Japan Council for Social Principles of Human Centric AI and recommends the

420. Price II, *supra* note 408, at 421.

421. *Id.*

422. *Id.* at 429.

423. *Id.* at 430.

424. *Id.*

425. *Id.* 434.

426. Price II, *supra* note 408, at 435.

427. AI HLEG, *Ethics Guidelines*, *supra* note 294, at 18.

establishment of a mechanism to ensure trust in AI, and in the data and algorithms that support it.[428]

Since healthcare AI using black-box systems are inherently opaque, it is difficult, if not impossible, to see how they arrived at their conclusion. This makes the risks difficult, if not impossible, to foresee. There is also that issue of worsening performance due to improper training.[429] All of these lead to regulatory challenges. How do we ensure that healthcare AI, which uses black-box systems, are safe and effective? And, if a healthcare AI, which uses black-box systems, arrives at a wrong diagnosis or treatment which causes harm to a user, who is responsible and who will be liable to the injured party? These are the main problems that this study intends to resolve in Chapter 5.

VI. ANALYSIS, CONCLUSION, & RECOMMENDATION

A. Analysis

1. Licensing

The provisions of the Philippine FDA Act as well as the Consumer Act ensure that medical devices are safe, effective and are of good quality. Thus, manufacturers or importers are required to submit reports of clinical investigations conducted in the Philippines and to show that their medical devices are safe, efficacious and of good quality before they can market them to the public.[430] This requirement is also mandatory in other countries.

In the U.S., manufacturers of new medical devices are required to register with the U.S. FDA. In case a device poses greater risks, a manufacturer has to perform pre-market testing before it can be publicly released. Thereafter, once a device is already out in the market, the U.S. FDA may continually assess its risks and utility.[431] Jane Bambauer opines that although the process employed by the U.S. FDA is sensible in assessing safety (by looking at the marginal risks and benefits of each device) the entire process generate considerable cost and delay.[432]

---

428. Japan Council for Social Principles of Human Centric AI, *supra* note 311, at 10.

429. Chinzei, et al., *supra* note 377, at 120.

430. Consumer Act of the Philippines, art. 31.

431. Jane R. Bamabauer, *Dr. Robot*, 51 U.C. DAVIS L. REV. 383, 383 (2017).

432. *Id.* at 386.

According to Bambauer, with the exception of licensing and training, regulation of doctors happens retrospectively or only when or something goes wrong. In the same vein, "AI will pose danger to consumers only if the costs, risks and inaccuracy of its advice are out of line and a bad deal compared to cost, risks and inaccuracy of these human advice givers."[433] Hence, Bambauer proposes to regulate knowledge apps (software emulating doctors or health advisers) in accordance with how the law regulates physicians.[434]

Although the Author sympathizes with the cost and delay issues raised by Bambauer, the Author believes that treating healthcare AI as physicians in the eyes of the law have other legal, ethical and technological implications. As of this writing, healthcare AI still fits within the definition of medical device under the Philippine FDA Act. With that being said, it requires a manufacturer or an importer to submit reports as to the results of clinical investigations to know how safe and effective their products are before releasing to the market. A device is deemed clinically effective if it produces the intended effect of the manufacturer. This is a good indicator of a device performance.[435] However, in case clinical investigations are foregone for the sake of cost and time considerations, there is a risk of sacrificing the performance of a healthcare AI, which opens the public to health and safety hazards. Furthermore, assuming that healthcare AI are only subject to ex post regulations, there is a possibility that fly by night AI developers will saturate the market and in case their products cause harm to the public, they can just pack up and leave or worse, dissolve their company altogether, leaving the victim with an empty redress. A plausible solution is to retain a licensing or a registration system with less stringent requirements to ensure the healthcare AI's safety and efficacy at the point of marketing and to continuously monitor and assess the technology when deployed. This is in consideration of the continuous learning and evolution of healthcare AI. Aside from AI manufacturers, healthcare institutions such as hospitals and clinics must also be monitored to ensure that they are addressing issues such as training bias, security and data protection and privacy. Regulators should require them to have an effective risk management system in case an untoward incident happens.

433. *Id.* at 390.

434. *Id.* at 386.

435. WORLD HEALTH ORGANIZATION, MEDICAL DEVICE REGULATIONS: GLOBAL OVERVIEW AND GUIDING PRINCIPLES 4 (2003).

A healthcare AI, to date, does not have the legal personality on its own to practice medicine. Admittedly, nothing can prevent the legislature from creating an artificial personhood for these technologies, however, a healthcare AI cannot undergo the same training and licensing requirements as physicians, which are sanctioned by law. Moreover, even if a healthcare AI is perfectly trained to have medical intelligence comparable to, or even superior to, a physician, it cannot, at least for now, replace the other faculties of a human doctor. A study made by computer scientists from MIT revealed that artificial intelligence, as yet, cannot replace a human doctor's "gut feel" about a patient's condition. Results of the study showed that the doctor's intuitive behavior is stronger during the first two days of a patient's stay than on subsequent days of confinement and determined how many tests a doctor ordered for a patient. This proves that the sentiment of a doctor about patients still offers a dimension to diagnosis or treatment that artificial intelligence cannot.[436]

Finally, a healthcare AI may not be capable of fulfilling certain duties of a physician to a patient.[437] One of these duties is to provide an informed consent. Before giving an actual medical treatment, a doctor has to examine the patient, undertake preliminary investigations and inquiries, which includes studying a patient's health history, and on the basis thereof form a diagnosis. From there, he will deduce and propose the appropriate treatment.[438] In the same vein, a medical treatment cannot be given without the consent of a patient or a person who has authority over the patient.[439] Once there is a meeting of the minds between the doctor and patient, a doctor-patient relationship is created, and a number of rights and obligations are created out of this relationship. However, given that the algorithms of

436. Jeff Lagasse, AI can't replace doctor's gut instincts, MIT Study Says, *available at* https://www.healthcarefinancenews.com/news/artificial-intelligence-cant-replace-doctors-gut-instincts-mit-study-says (last accessed Feb. 29, 2020).

437. *See generally* World Medical Association, The World Medical Association International Code of Medical Ethics, *available at* https://www.wma.net/wp-content/uploads/2006/09/International-Code-of-Medical-Ethics-2006.pdf (last accessed Feb. 29, 2020) (adopted Oct. 1949). *See also* Philippine, Medical Association, Code of Ethics of the Philippine Medical Association, *available at* https://www.philippinemedicalassociation.org/wp-content/uploads/2019/11/Code-of-Ethics-of-the-Medical-Profession-1.pdf (last accessed Feb. 29, 2020) (adopted Sep. 2019).

438. ROBERT FRANCIS QC & CHRISTOPHER JOHNSTON, MEDICAL TREATMENT: DECISIONS AND THE LAW 5 (2001).

439. *Id.*

certain healthcare AI are opaque and incomprehensible even to the most skilled doctor, it will be difficult, if not impossible, to provide an accurate and understandable explanation of the proposed treatment. The consent given by the patient may not fully constitute an informed one.

2. Liability

a. Tort and Quasi Delict in General

Tort is simply defined as "a civil wrong for which the law provides a remedy."[440] A tortious act can either be intentional or a negligent conduct, which makes a person liable because he invaded a legally protected interest of another party and he has no defense against the claim.[441] In order to establish the first qualification, there must be a substantial causal link between the conduct and the injury. As to the second qualification, defenses against claims exist as a matter of law like contributory negligence, assumption of risks, statute of limitations etc.

"Tort law is ordinarily unwilling to let people injured through no fault of their own bear costs imposed by other."[442] Liability under the tort regime is deeply rooted from the principles of corrective justice, prevention of injuries, and fairness.[443] First, corrective justice obligates a tortfeasor to restore the injured party back to his original condition before the injury occurred. But since the injured party, more often than not, cannot be placed back to his original condition, tort law imposes a duty to a tortfeasor compensate the injured party instead.[444] Second, by imposing a duty to compensate the injured party and making the tortfeasor liable under the law, the legislators expect that the tortfeasor, together with other individuals, will be deterred from committing the same tortious act in the future. Third, "the

440. The Law Dictionary, Torts (Prosser, Wade, and Schwartz's, 12th ed.), *available at* https://thelawdictionary.org/torts-prosser-wade-schwartzs-12-ed/ (last accessed Feb. 29, 2020).

441. RESTATEMENT (SECOND) OF THE LAW OF TORTS § 5 (AM. LAW INST. 1965) (U.S.).

442. *Id.* § 5 cmt. b.

443. Jeffrey K. Gurney, *Imputing Driverhood*, *in* ROBOT ETHICS 2.0 FROM AUTONOMOUS CARS TO ARTIFICIAL INTELLIGENCE 52 (Patrick Lin, et al., eds., 2017).

444. *Id.*

principle of fairness promotes equal treatment and proportionality of damages to the moral culpability of wrongdoing."[445]

Incidentally, the Civil Code has no reference to the word "tort." Instead, it adopts the Roman law concept of "quasi-delict."[446] Nevertheless, the Philippine Courts, on certain occasions, rely on tort doctrines promulgated in common law courts. Cezar Sangco, a Filipino civil law scholar wrote —

> The selection of rules from Anglo-American Law is proper and advisable: (a) because of the element of American culture that has been incorporated into Filipino life during nearly half a century of democratic apprenticeship under American auspices; (b) because in the foreseeable future, the economic relations between the two will continue; and (c) because the American and English courts have developed certain equitable rules that are not recognized in the present Civil Code.[447]

Quasi-delict, however, leaves out intentional acts from its scope and are separately governed by the Revised Penal Code. Similar to tort, an action for quasi-delict has the following elements:

(1) An unlawful act or omission amounting to a fault or negligence, imputable to the defendant;

(2) Damage or injury to the plaintiff;

(3) Such damage or injury being the natural and probable, or direct and immediate consequence of the defendant's wrongful act or omission; and

(4) There being no pre-existing contractual relation between the plaintiff and defendant.[448]

---

445. *Id.* (citing F. PATRICK HUBBARD & ROBERT L. FELIX, THE SOUTH CAROLINA LAW OF TORTS (2d ed. 1997)).

446. ASEAN Law Association, Tort Law in the Philippines at 1, *available at* https://web.archive.org/web/20160705084038/https://www.aseanlawassociation.org/papers/phil_chp7.pdf (last accessed Feb. 29, 2020).

447. CEZAR S. SANGCO, PHILIPPINE LAW ON TORTS AND DAMAGES xxxi-xxxii (1993 ed.).

448. ASEAN Law Association, *supra* note 446, at 1 (citing Prof. Carmelo V. Sison, An Overview of the Law on Torts and Damages (An Unpublished Lecture) (1993) (on file with the Author)).

b. Negligence of Physicians

Medical negligence is an offshoot of tort law. The doctor-patient relationship is essential in all medical negligence suit.

As previously discussed in Chapter III, a doctor is negligent when he fails to comply with or improperly performs his duties in accordance with professional standards, which results in an injury on a patient's body or health.[449] The standard required for a doctor is measured in accordance with the same standard of care that a reasonably competent doctor would provide in treating a patient under similar circumstances.[450] Such standard may be inferred from using expert testimony, clinical practice guidelines, code of ethics and legal statutes regulating the medical profession.[451]

The Supreme Court interestingly opined that a wrong diagnosis does not automatically make a physician negligent. It noted that a physician is not liable for damages resulting from a bona fide error in judgment. Rather, he is liable for medical malpractice when an erroneous diagnosis was a result of his negligent conduct (e.g., neglect of medical history, failure to order appropriate tests, or failure to recognize symptoms).[452]

A physician may also be held liable for the acts of others. In a particular case, the Supreme Court made a lead surgeon liable for the acts of the other physicians by invoking the Captain of the Ship doctrine, to wit —

> the surgeon is likened to a ship captain who must not only be responsible for the safety of the crew but also of the passengers of the vessel. The head surgeon is made responsible for everything that goes wrong within the four corners of the operating room. It enunciates the liability of the surgeon not only for the wrongful acts of those who are under his physical control but also those wherein he has extension of control.[453]

Accordingly, the surgeon has the responsibility to ensure that his subordinates perform their tasks properly, otherwise, he will be held liable.[454]

As earlier mentioned, physicians are negligent when they fail to meet the same standard of care that a reasonably competent doctor would provide in

449. *Casumpang, et al.*, 752 SCRA at 402-04.

450. *Id.*

451. Patdu, *Hospital Liability*, *supra* note 231, at 617.

452. *Casumpang, et al.*, 752 SCRA at 408.

453. Ramos v. Court of Appeals, 321 SCRA 584, 619 (1999).

454. *Id.*

treating a patient under similar circumstances. With the introduction of healthcare AI in medical protocols, such standard of care needs to be reexamined.

William Price devised a risk-based framework, which can serve as a guideline for physicians in using healthcare AI with due care:

> (1) For minimal risk interventions such as increased monitoring or taking widely used low side effect drugs, a physician may not particularly inquire about the recommendations of a black-box algorithm.[455]
>
> (2) For riskier interventions such as taking higher doses of powerful drugs, physicians may require some validation before relying on the black-box algorithm.[456]
>
> (3) For the riskiest and counterintuitive interventions such as prescribing high doses of thalidomide to a pregnant woman, there will be a presumption of harm under a reasonable standard of care and no black box verification is strong enough to overcome that presumption.[457]

According to Price, "doctors can measure the risk associated with a particular intervention and should accordingly measure the level of validation and confidence against the risks entailed."[458] A physician becomes negligent when he fails to properly evaluate black-box algorithms. Thus, making him liable for the injuries caused to the patient.

Incidentally, Max Raskin identifies two types of errors, which a healthcare AI can commit in diagnostics and treatment:

---

455. William Nicholson Price II, Medical Malpractice and Black-box Medicine (A Research Paper Published by the University of Michigan in the Social Science Research Network Electronic Paper Collection) at 9, *available at* https://ssrn.com/abstract=2910417 (last accessed Feb. 29, 2020).

456. *Id.*

457. *Id.* at 10.

458. *Id.* at 15.

	Diagnostics	Treatment
Type I Error	A healthcare AI finds a disease when there is none.[459]	A healthcare AI provides a drug dosage when it should not.[460]
Type II Error	A healthcare AI does not find a disease when there is one.[461]	A healthcare AI did not provide a drug dosage when it should. [462]

Raskin believes that the said errors are typical errors in medical malpractice. The Type I error is called a false positive, wherein a doctor does something he should not have done. The Type II error is a false negative, wherein a doctor does not do something when he or she should have done something.[463] He equates a healthcare AI to a consulting physician, which is not liable to a patient for a missed diagnosis. Instead, the attending physician who conferred with a consulting physician, or in this case a healthcare AI, is liable for the error.[464] The reason being is that the attending physician is expected to weigh the output from the algorithm as well as other relevant factors in arriving at his or her ultimate decision. He or she is thus allowed to exercise his or her own discretion. And if he or she does and a medical error happens, he or she will be liable.[465]

Price's risk-based standard as well as Raskin's consulting physician proposal can be used to determine negligence of a doctor in cases wherein a physician fails to verify the output given by the healthcare AI. Nevertheless, these proposals may not establish negligence in cases wherein the healthcare AI autonomously performs a diagnosis or treatment without any professional intervention. If working autonomously, healthcare AI have "direct effect outputs on patients which makes predictability of output as well as the time

459. Max Raskin, *Designer Babies, Robot Malpractice, and the Cures for Cancer: A Legal Survey of Some Medical Innovations*, 12 NYU J.L. & LIBERTY 151, 181 (2018).

460. *Id.*

461. *Id.*

462. *Id.*

463. *Id.*

464. *Id.* at 184.

465. Raskin, *supra* note 459, at 184.

margin to mitigate erroneous behavior difficult."[466] In light of this, the law on medical negligence should be revisited.

c. Negligence of Hospitals

As discussed in Chapter III, hospitals can also be negligent. Aside from being vicariously liable for their actual and apparent agents, a hospital can be liable in case the following duties are breached:

(1) [D]uty to use reasonable care in maintenance of safe and adequate facilities and equipment

(2) [D]uty to select and retain only competent physicians

(3) [D]uty to oversee all persons who practice medicine within its walls as to patient care

(4) [D]uty to formulate, adopt and enforce adequate rules and policies to ensure quality care for patients.[467]

The foregoing duties of a hospital will evolve with the introduction of healthcare AI in their facility. "Hospitals could be liable for negligently choosing, implementing, and using black-box medical systems."[468] They have the duty to ensure "that algorithms are well-validated and competently developed before implementation."[469] Hospitals shall make sure that their physicians are adequately trained to use healthcare AI and should institute a guideline on the amount of reliance on these technologies. Likewise, they also have an obligation to set a policy on how healthcare AI will be used in their facility. Failure to fulfill these duties will amount to corporate negligence.

d. Negligence of Manufacturers and Other Persons in the Production Chain

Product liability is also a branch of tort law which makes a manufacturer or a seller liable for the harm caused by a defective product.[470] In general, a product is defective when there is:

466. Chinzei, et al., *supra* note 377, at 120.

467. Patdu, *Hospital Liability*, *supra* note 231, at 655 (citing Thompson, 591 A.2D at 707).

468. Price II, *supra* note 455, at 12.

469. *Id.* at 13.

470. RESTATEMENT (THIRD) OF THE LAW OF TORTS PRODUCTS LIABILITY, *supra* note 341, § 1.

(1) a manufacturing defect;

(2) a design defect; or

(3) a warning defect

A manufacturing defect exist "when the product departs from its intended design even though all possible care [was] exercised in the preparation and marketing of the product."[471] Strict liability is imposed on the manufacturer in order to:

(1) encourage the manufacturer to invest more on safety;

(2) discourage the consumption of defective products by causing the purchase price of products reflect the cost of defects (as compared to a simple negligence suit); and

(3) reduce transaction cost of litigation by eliminating manufacturer's fault from plaintiff's case.[472]

A product has a design defect "when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the [manufacturer] and the omission of the alternative design renders the product not reasonably safe."[473] On the other hand, there is a warning defect when "the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the [manufacturer] and the omission of the instructions renders the product not reasonably safe.[474] Both design defect and warning defect are negligence-based signifying that "a reasonably designed product still carries with it elements of risk that must be protected against."[475] "The emphasis is on creating incentives for the manufacturers to achieve optimal level of safety and designing their products."[476]

There are, however, special rules on medical devices. A medical device is defectively designed "if the foreseeable risks of harm posed by the medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and

471. *Id.* § 2.

472. *Id.* § 2, cmt. a.

473. *Id.* § 2 (b).

474. *Id.*

475. *Id.* § 2, cmt. a.

476. RESTATEMENT OF THE LAW (THIRD) OF TORTS PRODUCTS LIABILITY, *supra* note 341, § 2, cmt. a.

therapeutic benefits, would not prescribe the medical device for any class of patients."[477] Courts recognized that what may be applicable for one patient may not be beneficial for the other thus a medical device may only be considered as defective when it has no net benefit to any class of patients.[478]

A medical device, on the other hand, has inadequate instructions or warnings when the reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

> (1) prescribing and other health-care providers who are in a position to reduce the risk of harm in accordance with the instructions or warnings; or
>
> (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.[479]

Product liability regulation serves two essential functions: compensation for the injured party and deterrence to produce defective products. The law allows an injured party to recover damages from the manufacturer or a seller who produced or distributed a defective product while also compelling the manufacturer or seller to manufacture or issue safe and effective products for the benefit of the public.

As earlier discussed, the standard required to prove manufacturing defect is strict liability while the standard required to prove both design and warning defects is reasonableness. In order to be held liable for a manufacturing defect, the injured party only has to prove that his injury was caused by a departure from the manufacturer's intended design. The burden is more difficult in cases involving design and warning defects. It will be difficult to prove that a healthcare AI was unreasonably designed or has failed to provide the adequate warning because it lacks transparency and it continuously learns and evolves as it receives new data sets. The system can evolve in such a way which can be unrecognizable as well as unforeseeable to the manufacturer. Apart from this, it is painstaking for the injured party to "find a responsible party given that there are various persons involved in the production — software developers, hardware engineers, designers and corporations — go into the creation of the AI systems."[480] Finally, an

477. *Id.* § 6 (c).

478. *Id.* § 6, cmt. b.

479. *Id.* § 6 (d).

480. Hannah R. Sullivan & Scott J. Schweikart, *Are Current Tort Liability Doctrines Adequate for Addressing Injury Caused by AI?*, 21 AMA J. ETHICS 160, 163 (2019).

injured patient may not be able to sue a manufacturer directly due to doctrine of learned intermediary.[481] With this, product liability regulation needs to be re-examined.

2. Economics of Liability

According to Robert D. Cooter,

> [l]egal scholars discuss at least three objectives of liability law: compensating victims, deterring injurers, and spreading risk. Economic theories, in contrast, tend to understand liability as a search for efficiency in incentives and risk-bearing.[482]

From an economic stand-point, liability laws, such as those discussed in the previous subsections, are a system of rules to induce "people to behave in socially efficient ways — specifically, in ways [that] minimize the sum of costs associated with injuries and precautions taken to avoid injuries."[483]

Liability laws "provide incentives for precaution."[484] "A negligence rule imposes a legal standard of behavior and imposes liability only on people who fail to comply."[485] Such rule applies to medical negligence, hospital negligence as well as product liability cases involving design and warning defects. On the other hand, strict liability applies to an "injurer [who] is better situated to determine the costs of risk associated with her actions."[486] To illustrate, "a manufacturer of a product is better situated to assess the risk associated with the product, as well as to take preventive measures, if necessary to mitigate such risk."[487] Thus, "if [taking] a precaution costs less than the expected cost of the injury it will prevent, the defendant [manufacture] will take the precaution rather than pay for the injury."[488]

---

481. *Id.* at 162. "The learned intermediary 'prevents plaintiffs from suing medical device manufacturers directly,' as the manufacturer has no duty to the patient directly." *Id.*

482. Robert D. Cooter, *Economic Theories of Legal Liability*, 5 J. ECON. PERSP. 11, 11 (1991).

483. The Bridge, Economic Analysis of Alternative Standards of Liability in Accident Law, *available at* https://cyber.harvard.edu/bridge/LawEconomics/neg-liab.htm (last accessed Feb. 29, 2020).

484. Cooter, *supra* note 482, at 26.

485. *Id.* at 13.

486. Omri Rachum Twaig, *Whose Robot is it Anyway? Liability for Artificial-Intelligence-Based Robots*, 2020 U. ILL. L. REV. 1, 25 (2020).

487. *Id.*

488. The Bridge, *supra* note 483.

Strict liability applies to product liability cases involving manufacturing defects. The economic cost of liability causes the "cost of supplying the good [to be] lower under a negligence rule and higher under a rule of strict liability."[489]

In order to address the economic cost of liability, persons who can be held liable transfer risks by entering into insurance contracts with insurance companies. According to Gerhard Wagner,

> [i]nsurance is a valuable tool to increase the welfare of risk-averse actors by transferring the risk of crushing liability to an insurance company. There, it is pooled with other similar but non-cumulative risks such that the uncertainties cancel each other out. In this sense, the risk disappears in the hands of the insurance company by becoming an actuarial certainty. For the risk-averse actor insurance transforms the threat of an uncertain, large loss into the certainty of a constant stream of relatively small premium payments.[490]

3. Insufficiency of Existing Liability Regimes

Liability is "[t]he state of being bound or obliged in law or justice to do, pay, or make good something."[491] When we talk about liability, it is also important to identify the person responsible. In the case of a healthcare AI, there are four possible actors that can be held responsible: the physician; the hospital or healthcare institution; the manufacturer or other person involved in the production of the healthcare AI; and the healthcare AI *per se*. As discussed in the previous section, existing liability regimes already regulate the conduct of the first three actors. When human participation can be traced, there is no need to reinvent liability regimes. As David Vladek puts it —

> Where the hand of human involvement in machine decision-making is so evident, there is no need to reexamine liability rules. Any human (or corporate entity that has the power to do things that humans do, enter into contracts, hire workers, and so forth) that has a role in the development of the machine and helps map out its decision-making is potentially responsible for wrongful acts — negligent or intentional committed by, or

489. Cooter, *supra* note 482, at 23.

490. Gerhard Wagner, *Tort Law and Liability Insurance*, 31 THE GENEVA PAPERS 277, 278-79 (2006).

491. The Law Dictionary, What is LIABILITY?, *available at* https://webcache.googleusercontent.com/search?q=cache:SniscYtTtscJ:https://thelawdictionary.org/liability/+&cd=4&hl=en&ct=clnk&gl=ph (last accessed Feb. 29, 2020).

> involving the machine. The reason, of course, is that these machines, notwithstanding their sophistication have no attribute of legal personhood. They are agents or instruments of other entities that have legal capacity as individuals, corporations, or other legal "persons" that may be held accountable under the law for their actions.[492]

The rub lies on the fourth actor. Who will be responsible and liable for the acts and omissions of healthcare AI?

The Author submits that negligence, vicarious liability, and product liability are not completely irrelevant but are rather insufficient in dealing with the injuries caused by healthcare AI. As Yavar Bathaee opines, traditional legal doctrines, such as intent for criminal law and causation for tort law, are based on human conduct and may not properly function when dealing with AI employing machine learning algorithms.[493] Bathaee posits that intent and causation

> rely on the ability to find facts as to what is foreseeable, what is causally related, what is planned or expected, and even what a person is thinking or knows. Human can be interviewed or cross-examined they leave behind trails of evidence such as e-mails, letters and memos that help answer questions of intent and causation and we can draw on heuristics to help understand and interpret their conduct. If an AI program is a black box, it will make predictions and decisions as human do, but without being able to communicate its reasons for doing so. The AI's thought process may be based on patterns that we as humans cannot perceive, which means understanding the AI may be akin to understanding another highly intelligent species—one with entirely different senses and powers of perception. This means that little can be inferred about the intent or conduct of the humans that created or deployed the AI, since even they may not be able to foresee what solutions the AI will reach or what decisions it will make.[494]

In a black-box system, "the result of the AI's decision or conduct may not have been [foreseen] by the AI's creator."[495] Thus, the causation test, which is the backbone of tort law, is not applicable because "the causation inquiry will focus on what is foreseeable."[496] Establishing the "proximate

---

492. David C. Vladeck, *Machines Without Principals: Liability Rules and Artificial Intelligence*, 89 WASH. L. REV. 117, 120–21 (2017).

493. Yavar Bathaee, *The Artificial Intelligence Black Box and the Failure of Intent and Causation*, 31 HARV. J.L. & TECH. 889, 892 (2018).

494. *Id.* at 892–93.

495. *Id.* at 924.

496. *Id.* at 922.

cause ensure[s] that only reasonably foreseeable effects give rise to liability."[497] The rationale is to "[encourage] the individual to act reasonably and penalizes those who do not — thus tying the scope of liability to the nature of the conduct at issue."[498] Bathaee also points out that "a person should not be liable for [the] results [which have] nothing to do with what he could have done to limit the risk of harm nor should there be liability for the flukes of chance."[499]

4. Proposals

a. Legal Personhood

Today, healthcare AI continuously become more autonomous and highly intelligent, which allow them to take independent actions without external control or influence and to learn from past experiences. For this reason, the European Parliament expressed that "the more autonomous robots are, the less they can be considered as tools in the hands of other actors (such as the manufacturer, the operator, the owner, the user etc.)."[500] If autonomous systems such as healthcare AI are more than just tools, should they have a separate personality from their users or producers and become solely responsible and liable for the injuries caused by their own acts or omissions?

Robert van den Hoven van Genderen opines that "autonomous systems *per se* cannot be legally responsible unless they have a degree of legal personality and a certain acceptance of a legal position to perform legal actions with legal effect."[501] Legal Personhood is characterized as the ability to have rights and obligations under the law, including "the ability to enter contracts, sue or be sued, and be held liable for one's actions."[502]

497. *Id.* (citing Owens v. Republic of Sudan, 864 F.3d 751, 794 (D.C. Cir. 2017) (U.S.)).

498. Bathaee, *supra* note 493, at 922 (citing Mark F. Grady, *Proximate Cause Decoded*, 50 UCLA. L. REV. 293, 322 (2002)).

499. Bathaee, *supra* note 493, at 923.

500. European Parliament Resolution, *supra* note 280, pmbl & para. AB.

501. Robert van den Hoven van Genderen, *Do We Need New Legal Personhood in the Age of Robots and AI?*, *in* ROBOTICS, AI AND THE FUTURE OF LAW, BUSINESS AND INNOVATION 49 (Marcelo Corrales, et al., eds., 2018).

502. Trevor N. White & Seth D. Baum, *Liability for Present and Future Robots Technology*, *in* ROBOT ETHICS 2.0 FROM AUTONOMOUS CARS TO ARTIFICIAL INTELLIGENCE 70 (Patrick Lin, et al. eds., 2017).

In the Philippines, the fitness to be subject of legal relations or juridical capacity is inherent in every human being.[503] As for corporations and partnerships, this capacity is conferred by law and is deemed separate from that of their shareholders and partners.[504] Thus, conferring juridical capacity on an entity which is not a human being is not a foreign concept in Philippine Law. However, is it necessary in the context of healthcare AI?

Sullivan and Schweikart suggest that personhood should be conferred on artificial intelligence systems in order to elevate them as principals rather than being an agent of an owner or a user.[505] As a principal, an AI will have its own rights and duties. It may also be sued directly for negligence claims. To address its liability, an AI can be required to insure itself in order to pay such claims. Simply put, a healthcare AI will be treated the same as any other physician.[506]

Another similar proposal is to treat IBM Watson, a clinical decision support system, as a medical student. According to Chung and Zink, since the duties[507] of IBM Watson are similar to that of a medical student and both work under the strict supervision of an attending physician[508] then such technology should be classified as a legal person for the purposes of apportioning liability. This will allow IBM Watson's activities to be insured in order to address any future liability.[509] Chung and Zink opine that this functional approach provides a practical fault-based regime which insulates manufacturers from the unpredictable consequences of self-learning machines.[510]

Although conferring a separate legal personality on healthcare AI, whether as a physician or as a medical intern, appears to be an innovative

503. CIVIL CODE, art. 37.

504. *Id.* art. 44.

505. Sullivan & Schweikart, *supra* note 480, at 163-64.

506. *Id.* at 164.

507. Jason Chung & Amanda Zink, *Hey Watson – Can I Sue You for Malpractice – Examining the Liability of Artificial Intelligence in Medicine*, 11 ASIA PAC. J. H.L. & ETHICS 51, 69 (2018). In order to arrive at this conclusion, Chun and Zink listed a number of duties that IBM Watson can do: "collect information from patients, analyze patient records, survey existing texts, and test hypothesis in order to make diagnostic and treatment recommendations." *Id.* at 68.

508. *Id.* at 71.

509. *Id.* at 73.

510. *Id.* at 76.

way of addressing liability, it may not be the best solution available. First of all, society requires safe and effective medical treatment from doctors and safe and effective healthcare AI from manufacturers. Thus, licensing requirements are imposed in order to fulfill this policy. Liability regimes, such as negligence and product liability, complements the purpose of licensing requirements by ensuring that physicians do not negligently cause injuries and manufacturers do not produce defective products which are harmful to the society. By attributing liability solely on the healthcare AI, physicians as well as manufacturers are no longer incentivized to deter from negligent behavior which may affect the safety and efficacy of healthcare delivery in general. As Bathaee posits deterring "behavior that causes harm to others or society and holding individuals liable for the effects that should have foreseen will encourage them to take precautions (or [ ] discourage them from risky behavior[.)]"[511] Secondly, giving legal personhood to a healthcare AI may not be the best solution because no human being is behind its actions. This is contrary to existing juridical persons such as corporations or partnerships whose actions are directly traceable to human beings and their personal decisions. In this regard, Tjasa Zapusek believes that legislative bodies may not be ready to confer a legal personhood on an entity wherein there are no real people with ambitions and visions behind it.[512] Finally, establishing personhood for AI can be a way for egregious manufacturers, healthcare institutions or healthcare providers to escape responsibility by shielding themselves from liability by invoking the healthcare AI's separate legal personality.

b. Sliding Scale Approach

Bathaee proposes a sliding scale approach which modifies the causation test by taking into consideration the level of autonomy as well as transparency of an AI.[513] He notes that

> AI supervised by humans will pose the least problems for intent and causation tests, while autonomous AI will require liability schemes based on negligence, such as those used in agency law for the negligent hiring, training, or supervision of an agent. When AI operates under human supervision, the degree of transparency may shed light on the creator or user of the AI's intent. When the AI is permitted to operate autonomously, the creator or user of the AI should be held liable for his negligence in

511. Bathaee, *supra* note 493, at 923-24 (citing Mark F. Grady, *Proximate Cause Decoded*, 50 UCLA. L. REV. 293, 294 (2002)).

512. Zapusek, *supra* note 111, at 121.

513. Bathaee, *supra* note 493, at 936-68.

> deploying and testing the AI. In the most dangerous settings, strict liability may be appropriate. The overall picture is a sliding scale of intent and foreseeability required for liability.[514]

The sliding scale is illustrated as follows:

	Transparent	Black Box
More Supervision	I. Traditional intent and causation can be applied	II. Use without transparency bears on the intent of the creator or user of the AI and foreseeability of the harm caused by the AI
Less Supervision	III. Relaxed intent and causation; negligent principal standard	IV. Broad scope of liability; creator or user of the AI bears the risks stemming from the AI's lack of transparency

In Quadrant I, when an AI system is supervised and transparent, "the intent of the creator or the user can be assessed through conventional means (i.e., fact-finding mechanisms such as depositions and subpoena) as well as by examining the AI's function and effect."[515] In Quadrant II, "when an AI [system] is supervised but to some degree a black box, intent must be assessed based on whether the creator or the user of the AI was justified in using the AI as he did — with limited insight into the AI's decision making or effect."[516] In Quadrant III, "if the AI is autonomous but supervised, the rule that should apply is the principal-supervision rule from agency law. The question will be whether the creator or user of the AI exercised reasonable care in monitoring, constraining, designing, testing, or deploying the AI."[517] Finally, in Quadrant IV, "when the AI is both autonomous and unsupervised, the sole question will be whether it was reasonable to have deployed such AI at all."[518] If it was not reasonable, "the creator or user of the AI would be liable for the AI's effects, even if he could not foresee them

514. *Id.* at 932–33.

515. *Id.* at 936.

516. *Id.*

517. *Id.*

518. *Id.*

and did not intend them."[519] Instead of foreseeability, the standard becomes one of conceivability.[520]

Now, various scenarios involving a healthcare AI will be examined, applying Bathaee's Sliding Scale Approach.

When a healthcare AI falls under Quadrant I, the doctor supervises the use of the technology. If something goes wrong with the treatment, his or her acts, as well as the algorithms used by the healthcare AI can be examined to determine who is responsible for the injury and who is liable to the injured party. When a healthcare AI falls under Quadrant II, the doctor supervises the use of the technology. However, when something goes wrong, only the acts of the doctor can be examined. Thus, the question becomes whether the acts of the doctor were justified in using the healthcare AI the way he did. If his or her acts are not reasonable, then he or she will be liable to the injured party. When a healthcare AI falls under Quadrant III, the doctor supervises the use of the technology, but the AI performs the task independently. In this case, the doctor is considered as a principal and the healthcare AI as an agent. When the agent commits an error, the principal will be held liable. Thus, it is incumbent upon the doctor to exercise diligence in choosing, training and supervising the healthcare AI. If he or she fails to do so, he or she will be held liable. Finally, when a healthcare AI falls under Quadrant IV, the doctor has no supervision over a black-box system, it is imperative to determine if it was reasonable to utilize the technology. If it was not reasonable, then the doctor will be held liable.

Bathaee's approach is a modification of the principle of proximate cause in establishing negligence by accommodating the unique characteristics of artificial intelligence — transparency and autonomy. This approach upholds corrective justice by making the tortfeasor liable to the injured party, and also promotes safety by ensuring that the tortfeasor, as well as the members of the society, deters from tortious conduct.

c. Common Enterprise Liability

David Vladek proposes a "common enterprise" liability, which makes all persons who work to a common end (i.e., those who design, program, and manufacture an autonomous system and its various parts) [521] jointly responsible for the injury caused by an AI system. It is a form of "strict

519. Bathaee, *supra* note 493, at 936.

520. *Id.* at 938.

521. Vladeck, *supra* note 492, at 149.

liability, completely uncoupled from notions of fault" for cases wherein it would be unreasonable to attribute the injuries on the autonomous system's manner of production or design.[522] Vladek's proposal is to create "an inference of liability" by operation of law to protect the injured party.[523] He presents three strong policy reasons for the common enterprise liability regime:

(1) It provides "redress for persons injured through no fault of their own[;]"[524]

(2) A strict liability regime is justified because the creators, in contrast to the injured party, "are in a position to absorb the cost [ ] through pricing decisions[ ] to spread the burden of loss widely[;]"[525]

(3) Parties will be spared from "enormous transaction costs that would be expended if [they] had to litigate liability issues[.]"[526]

"[A] predictable liability regime" has better potential to promote innovation than a less predictable system, which largely depends on the assignment of fault.[527] Vladek's proposal appears to be a variation of a product liability regime, which takes into consideration the heuristic nature of artificial intelligence systems. Since these technologies have the ability to learn through experience, there is a chance that while it is being used, it is no longer the same AI system as it was when it left the hands of the manufacturer. Thus, it would be difficult to attribute an injury from a manufacturing, design, or warning defect. A common enterprise liability creates a strict liability standard, which eliminates the need to prove fault on the part of the manufacturer or whoever is involved in the production. This allows an injured party to easily claim for compensation while still encouraging the members of the common enterprise to produce safe and effective healthcare AI.

522. *Id.* at 146. In his article, Vladek uses an autonomous vehicle as an example to illustrate how common enterprise liability work. *Id.*

523. *Id.* at 149.

524. *Id.* at 146.

525. *Id.*

526. Vladeck, *supra* note 492, at 147.

527. *Id.*

B. Conclusion

This Note is an exposition of the revolution introduced by artificial intelligence in the field of healthcare. AI is indeed a new way of healing a society, such as the Philippines, as it can greatly benefit from these disruptive technologies. Tele-medicine can address geographical problems. AI-based triage systems can improve deployment of healthcare providers as well as healthcare products efficiently. Clinical decision support systems can assist doctors and other healthcare professionals in giving up-to-date medical advice. Today, a lot of these healthcare systems are used to diagnose and treat heart and vascular diseases, cancer, and diabetes, which are the leading causes of death in the Philippines. With all these great potentials also come greater risks.

Healthcare AI, especially those which uses machine learning systems, are inherently opaque. This means that the manufacturer who made such systems or the doctor who used such systems will have a difficult, if not an impossible, feat to explain how the AI came up with its diagnosis or treatment. Healthcare AI can self-learn and evolve. This means that they may no longer be in the same state as they were when they were deployed in the market. Also, depending on the quality of training it receives, the AI system can improve or degrade. Healthcare AI can also be autonomous, which means that it can act independently without any external controls. Given these characteristics, a healthcare AI cannot fit within the traditional legal framework which governs medical devices as well as healthcare providers and institutions.

These unique characteristics of healthcare AI must be considered in drafting or modifying licensing and liability regulations. Legislators need to ensure safety and effectivity while addressing new issues such as bias, data security, data protection and privacy, and black-box systems. Since current liability regimes such as negligence and product liability laws, were drafted based on human conduct, they are insufficient to address the liability borne out of the injury caused by a healthcare AI.

The proposals of Yavee Bathaee and David Vladeck are instructive.

Bathaee recommends a sliding scale approach which modifies the principle of proximate cause in establishing negligence by accommodating the unique characteristics of artificial intelligence—opaqueness and autonomy. Bathaee's approach sees to it that corrective justice is addressed by making the tortfeasor liable to the injured party while promoting safety by ensuring that the tortfeasor, as well as the members of the society, are deterred from acting negligently.

Vladek's pitch, on the other hand, modifies product liability regime and takes into consideration the heuristic nature of artificial intelligence systems. A common enterprise liability creates a strict liability standard, which eliminates the need to prove fault. This allows an injured party to easily claim for compensation while still encouraging the members of the common enterprise to produce safe and effective healthcare AI.

The Author submits a two-pronged approach in dealing with injuries sustained from healthcare AI. Firstly, the sliding scale approach shall be used in order to determine the negligence of the physician or any other tortfeasor who causes the injury. Secondly, in case the injury was caused by reasons not attributable to the negligence of a physician or a healthcare institution, or in case a healthcare AI is readily available in the market without professional intervention, Vladeck's common enterprise liability framework should be employed in order to make all persons who work to a common end (i.e., those who design, program and manufacture an autonomous system and its various parts) jointly responsible.

In conclusion, the State has the duty to protect every Filipino's right to health.[528] This State policy is the basis for enacting and implementing licensing and liability regulations to ensure that healthcare is delivered safely and effectively and that an injured individual is not left without any meaningful redress. With the disruption brought by these technologies to medical practice as well as traditional medical devices, the State has to revisit its old laws and modify them to accommodate the unique characteristics of healthcare AI. After all, technology and the law should complement each other in making responsible innovations for the benefit of society.

C. Recommendations

Undeniably, healthcare AI is more powerful than a traditional medical device, it exhibits cognitive intelligence, which is comparable to a licensed physician. Due to its *sui generis* characteristics, current regulatory schemes are insufficient to ensure its safety and effectivity. In this regard, the Author recommends the following guidelines addressed to policy makers in order to ensure the safe and effective development and use of these technologies:

(1) A special body within the FDA should be formed in order to ensure that the development and use of healthcare of AI are properly monitored and regulated. This body must be composed of experts not only in the field of medicine but also in the field of AI. This body should establish reportorial requirements for

528. PHIL. CONST. art. II, § 15.

manufacturers as well as healthcare institutions who will produce and manufacture healthcare AI systems to ensure continuous monitoring of training and untoward incidents.

(2) Healthcare AI should be licensed before market release. Rather than classifying them according to pre-determined risks, licensing of a healthcare AI can be similar to how physicians are licensed. Healthcare AI should undergo a certification process in order to test the sufficiency of its training and performance before deployment. Likewise, continued examination should be performed throughout the lifetime of the system taking into consideration its heuristic nature. Aside from these, regulators should also monitor and certify healthcare institutions as well as doctors who use these kinds of technologies.

(3) Ensure that healthcare AI are designed in such a way that:

   a. they are resilient to security attacks;

   b. they are designed to follow data privacy and protection rules;

   c. they have a manual fall back mechanism or automatic shutdown feature, which can be turned on in case automatic function fails;

   d. they should have a built-in warning system which gives out a signal to the user in case there is a suspicious or irregular finding which needs special attention;

   e. they are trained based on representative data sets in order to generate accurate and relevant diagnosis or treatment; and

   f. if possible, their actions should be traceable, explainable and auditable.

(4) Ensure that manufacturers provide ongoing support and after-sales training to healthcare institutions, healthcare professionals as well as user who uses their products. Healthcare institutions, healthcare professionals and users must always be aware of and implement any software updates or patches.

(5) Healthcare institutions such as hospitals and clinics should establish guidelines on how to use healthcare AI in their establishment. If possible, a certified physician shall oversee the use of these technologies. In addition, the consent of the patient

shall be secured before using a healthcare AI in diagnosis or treatment. The patient must be made aware of all the probable risks that are involved in the diagnosis or treatment.

(6) Depending on the circumstances, these guidelines can also assist the court in determining the fault or negligence of manufacturers, healthcare institutions, medical professionals or users and assessing the responsibility and liability of each actor in case an injury occurred.

(7) These guidelines should continuously be updated in light of the continuous development of healthcare AI.