



九州大学  
KYUSHU UNIVERSITY

# A New Way of Healing

*Rose Angelique Dizon*

Regulating  
Healthcare  
Artificial Intelligence



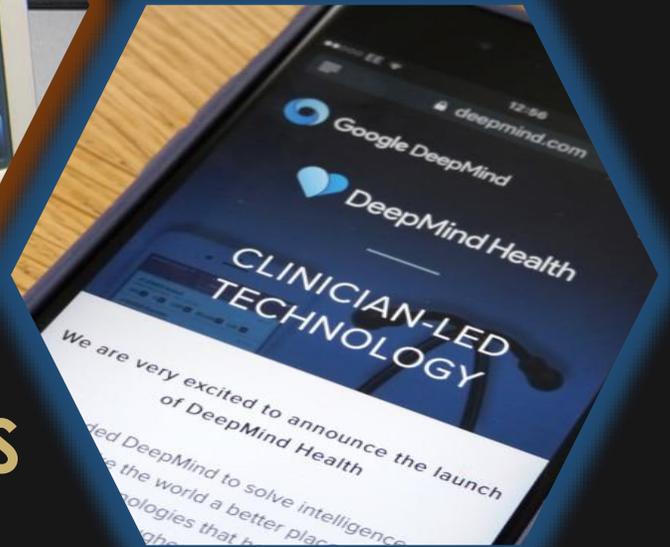
Baymax

**BLACK-BOX**  
Kronikare



IDx-DR  
**AUTONOMOUS**

**SELF-LEARNING**



Google  
DeepMind  
Health Streams

**HEALTHCARE**  
**ARTIFICIAL INTELLIGENCE**

# /Outline

- Problem
- Background of the Study
- Healthcare AI
- Insufficiency of Existing Legal Regimes
- Conclusion
- Recommendations

# /Problem

- Whether the current technological shift in healthcare delivery, from traditional doctors and medical devices to healthcare AI, calls for a change in regulation.
- How should healthcare AI, including algorithms used in these kinds of technology, be regulated?

# /Background of the Study

- The right to health is a constitutionally protected right
- 2 areas of law are affected: practice of medicine and medical device law
- Under this 2 areas, we can further classify into licensing and liability laws
- Licensing and liability laws basically complement each other.

# /Healthcare AI

- Healthcare is taking the necessary medical and preventive procedures to improve well-being.
- Artificial intelligence 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 a 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.
- Artificial Intelligence systems designed or intended to diagnose, prevent, monitor, treat or alleviate any disease or health condition

# /Insufficiency of Existing Legal Regimes (Licensing)

- In the Philippines, healthcare AI falls under the definition of medical devices. Thus, before obtaining a certificate of product registration, a manufacturer is required to submit clinical investigations to know how safe and effective healthcare AI are. A medical device is effective if it produces the intended effect of the manufacturer
- However, the unpredictability of healthcare AI can cause difficulty
- Healthcare AI have cognitive intelligence partly comparable to humans (e.g., IBM Watson). can they be considered as doctors?
- Training and licensing requirements of physicians; incapable of fulfilling the duties of a physician to a patient; "gutfeel"

# /Insufficiency of Existing Legal Regimes (Liability)

- When human involvement in machine decision making is evident, there is no need to examine liability rules
- Negligence, vicarious liability and product liability are not completely irrelevant but are rather insufficient in dealing with injuries caused by healthcare AI because of foreseeability
- The thought process of an AI may be based on patterns that we as humans cannot perceived thus 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
- This makes causation test to determine negligence not applicable

# /Insufficiency of Existing Legal Regimes (Other Issues)

- Training bias
- Data Protection
- Data Security

# // Conclusion

- Healthcare AI are more than just medical devices. They exhibit cognitive intelligence, which is comparable to a licensed physician.
- Current licensing and liability regimes were drafted based on human conduct. Hence, they are insufficient when it comes to dealing with healthcare AI.
- To establish medical negligence and product defect, causation is necessary. With healthcare AI, it is difficult, if not impossible to establish causation due to lack of foreseeability.
- New issues such as training bias, data protection and data security should be taken into consideration.

# /// Recommendations

To address the issue of foreseeability, a two-pronged approach should be employed:

Sliding Scale Approach

Common Enterprise Liability

# /// Recommendations

1. Institutionalize a **special government body**
2. **Licensing** before market release
3. **Design**: a) secure; b) follow data privacy laws and other relevant laws; c) have a manual fall back mechanism, automatic shutdown mechanism and built-in warning system; d) trained on representative data sets; e) if possible, actions must be traceable, explainable and auditable.
4. Ensure **after-sales support and training**
5. Establish **guidelines** for use
6. A **patient** must be **fully aware** of all the probable risks and must give a proper **consent to the treatment**

# //// Epilogue

- The recommendations may serve as guidelines to determine the fault or negligence of manufacturers, healthcare institutions, medical professionals or users and assess the liability of each actor in case an injury occurs.
- Laws and regulations on healthcare AI should be continuously evaluated and updated in light of the continuous development of technology.
- Ultimately, healthcare AI will address the problems that the Philippines is facing in the area of healthcare delivery. Thus, it is imperative to revise existing regulations in order to protect the citizens' right to health and promote the use and development of these technological innovations.