**The Patient with Diabetes**

By Sara Gerke & Gali Katznelson

Ms. A. is a 52-year-old patient with type 2 diabetes who lives in the country of Ames. She sees her primary care provider for a check-up. They review her glucose levels and adjust her medications. Rather than referring her for eye care, the primary care doctor uses a new health AI software program called 'AIScreen' to assess her eyes for signs of diabetic retinopathy. The competent FDA-equivalent regulator in Ames has recently permitted marketing of AIScreen.

"Reassess in 12 months," AIScreen suggests. The primary care doctor follows the health AI's recommendation and tells Ms. A. her eyes are doing well.

Two months later, however, Ms. A. begins to experience blurry vision problems and is referred to an ophthalmologist. The ophthalmologist determines that Ms. A. has severe diabetic macular edema, a complication of diabetic retinopathy. She undergoes laser treatment and recovers.

It is unclear why AIScreen did not detect the macular edema. But it is known that AIScreen was trained on a small and homogenous sample.

At the ophthalmology clinic, Ms. A. also consents to be enrolled in a clinical trial for diagnostic ML technology. The ophthalmologist runs several tests using another health AI deploying a deep learning-based architecture by the company "AI4Eye" to determine her diagnosis.

Questions:

1. What considerations should a physician make when deciding whether to rely on a health AI for decision-making?
2. What are the differences, if any, between a medical device that is authorized for marketing by a regulator like the FDA and a product being used in research?
3. What, if anything, should Ms. A.'s physicians have told her about AIScreen that was used in her care?
4. What is the role of bias in this case and how could it be mitigated?
5. Should physicians disclose the use of 'black-box algorithms' in patient care, such as the health AI deployed to detect Ms. A.'s diabetic macular edema?