



PMAIL

Project on Precision Medicine,
Artificial Intelligence, and the Law

A Smart Pill to Swallow

Legal and Ethical Issues of Ingestible
Electronic Sensors

SSCL Annual Lecture

Professor Timo Minssen

Edinburgh, 30 May 2019

Sara Gerke & Glenn Cohen

Petrie-Flom Center for
Health Law Policy, Biotechnology, and
Bioethics at Harvard Law School

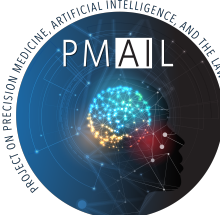
Timo Minssen & Helen Yu

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University of Copenhagen

IESs



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IESs and Future Combinations



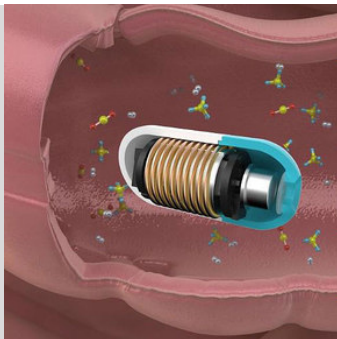
nature
electronics

ARTICLES

<https://doi.org/10.1038/s41928-017-0004-x>

A human pilot trial of ingestible electronic capsules capable of sensing different gases in the gut

Kourosh Kalantar-Zadeh^{1*}, Kyle J. Borean¹, Nam Ha¹, Adam F. Chrimes¹, Kai Xu¹, Danilla Grando², Jian Zhen Ou¹, Naresh Pillai¹, Jos L. Campbell², Robert Brkljača², Kirstin M. Taylor³, Rebecca E. Burgell³, Chu K. Yao³, Stephanie A. Ward⁴, Chris S. McSweeney⁵, Jane G. Muir³ and Peter R. Gibson^{3*}



atmo
BIOSCIENCES™

REPORT

An ingestible bacterial-electronic system to monitor gastrointestinal health

Mark Mimeo^{1,2,*}, Phillip Nadeau^{3,*†}, Alison Hayward^{4,5}, Sean Carim², Sarah Flanagan³, Logan Jerger^{2,6,7}, Joy Collins⁵

+ See all authors and affiliations

Science 25 May 2018:

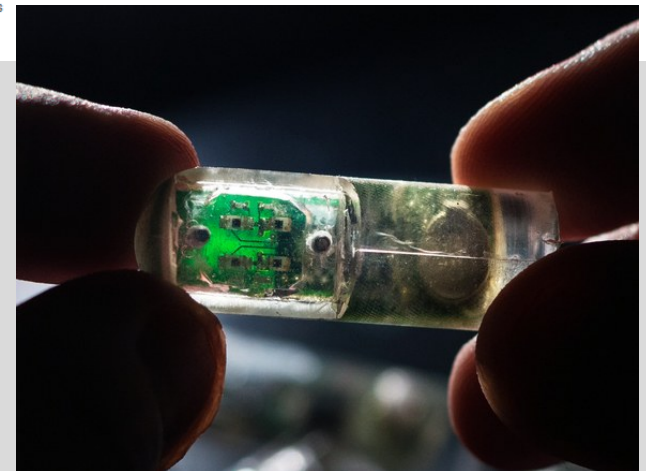


Photo Credit: LILLIE PAQUETTE/MIT

Ethical & Legal Issues



- Patient Issues
- Provider Issues
- Social Issues
- Legal Issues

BIAS, Fairness and socio-economic justice



Regulatory Issues

Wearable sensors including IESs by themselves

- **Medical devices** (US and Europe)
- E.g., Proteus (US: Class II – De Novo; Europe: Class IIa – CE marked)

A drug product is physically embedded with an IES

- **Combination product** (US)
- **Medicinal product** (Europe)
- E.g., Abilify MyCite (US: NDA approval)

New FDA proposal: **Prescription Drug-Use-Related Software**



New EU Regulations- Medical Devices

New: **EU Medical Device Regulation** (2017/745 – MDR)

- Entered into force on 25 May 2017
- With few exceptions, the MDR will **only apply** in each Member State from **26 May 2020**
 - + repeal the **Medical Device Directive** (93/42/EEC - MDD)
 - + the **Directive on active implantable medical devices** (90/385/EEC – AIMD)



New EU Regulations – In vitro diagnostics

New: EU Regulation on in vitro diagnostic medical devices (2017/746 – IVDR)

- Entered into force on 25 May 2017
- With few exceptions, the IVDR will **only apply** in each Member State from **26 May 2022**
+
repeal, inter alia, the **Directive on in vitro diagnostic medical devices** (98/79/EC - IVDD)



Cybersecurity

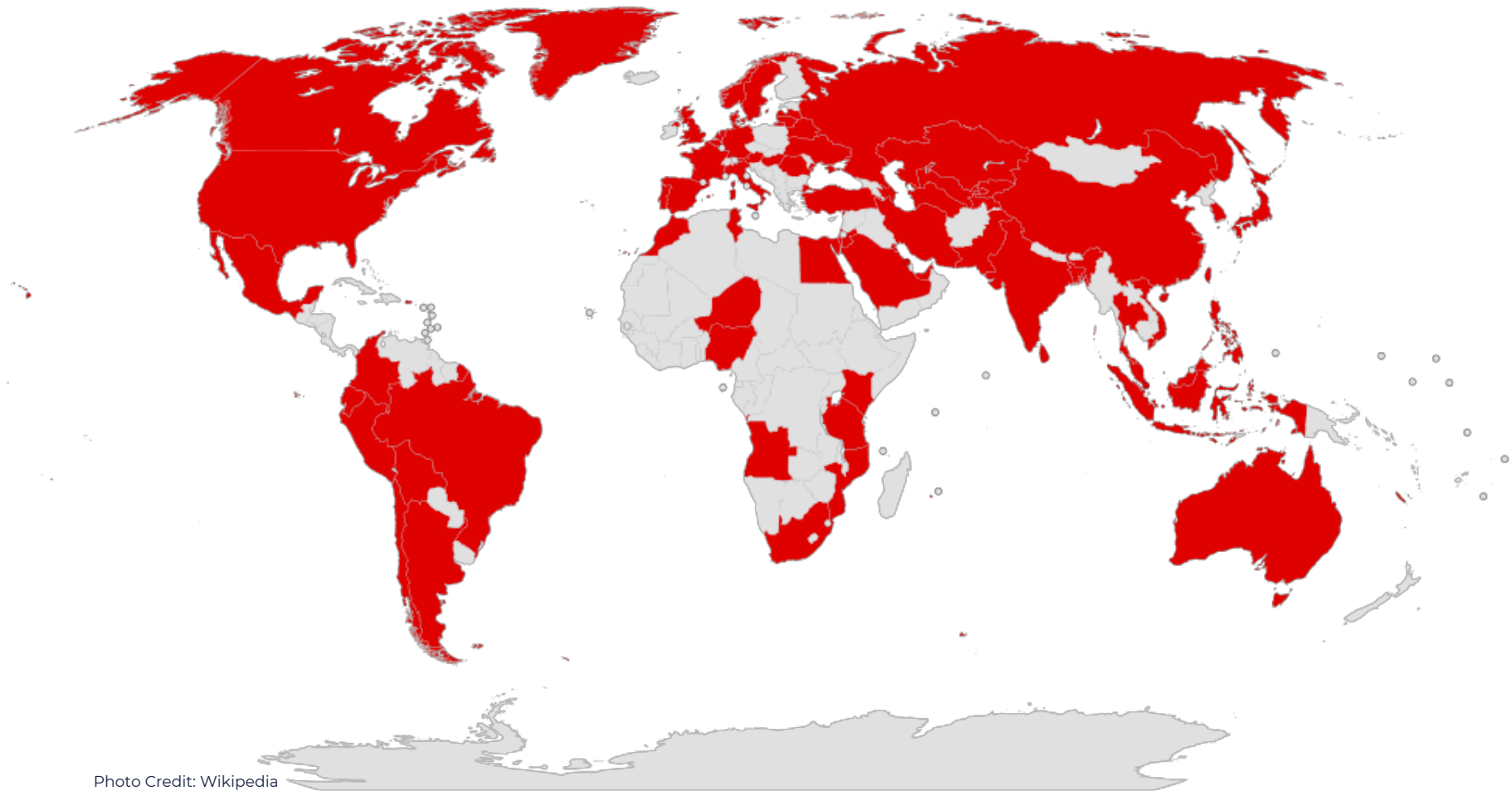


Photo Credit: Wikipedia


Conclusion



IESs are a **promising technology** for improving health outcomes and making health care more effective.



The **ethical issues should be considered at the earliest stages** of the development process of such products - the goal is “**ethics by design.**”



There are **new legal developments** in the US and Europe that are relevant for IESs (e.g., FDA proposal for regulating prescription drug-use-related software).



For IESs products to be broadly accepted by society and markets, it is of vital importance **to enhance public trust.**



Forthcoming paper by **Sara Gerke** (HLS/PFC), **Timo Minssen** (UCPH/CeBIL), **Helen Yu** (UCPH/CeBIL) & **Glenn Cohen** (HLS/PFC):

A Smart Pill to Swallow: Ingestible Electronic Sensors, Cutting Edge Medicine, and Their Legal and Ethical Issues



Thanks! Questions or Suggestions?



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Thanks!



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COPENHAGEN

