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# FAST BREAK

Digital Health after *Dobbs*



# Presenters



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# Agenda

- The *Dobbs* Decision
- What Digital Health Products Are Impacted?
- FDA Oversight?
- State AG Enforcement Authority
- Responding to AG Subpoenas
- OCR Guidance on HIPAA
- Case Studies

# The *Dobbs* Decision

- *Dobbs* is a June 2022 Supreme Court decision that held that the US Constitution does not confer a federal right to abortion, overturning long-standing Supreme Court jurisprudence
  - *Dobbs* does not outlaw abortion nationally, but instead gives power to individual states to regulate abortion
  - Prior to the decision, several states passed laws prohibiting or restricting access to abortion and related reproductive health care services
    - In the wake of a leaked version of the *Dobbs* decision, several additional state legislatures passed restrictions on abortion that would be triggered on the basis of a change in Supreme Court jurisprudence
  - At this point, 15 states prohibit abortion or restrict access to abortion after the 1<sup>st</sup> trimester

# Digital Health Products Potentially Impacted

- Fitness trackers/wearables
- Period tracking and other general wellness apps
- Fertility monitoring devices/apps
- Digital health and general consumer apps with geo-location functionality
- EMR/EHRs
- Telehealth/virtual health apps
- Appointment scheduling apps
- Remote monitoring systems
- Health insurance coverage/billing systems

# Impact of FDA Oversight

- Many digital health devices/apps subject to direct FDA oversight
  - Premarket review
  - Cybersecurity requirements
  - Postmarket compliance (QSR, MDR, etc.)
  - Special controls
- No explicit prohibition on data sharing for law enforcement purposes
- No explicit preemption

# State Attorney General Authorities

- State Attorney's General (AGs) are the chief legal officers in each of the 50 states
  - Enjoy nearly unfettered discretion in deciding what civil or criminal matters to investigate (or ignore)
  - While they do not have independent legislative authority to add, repeal or modify existing laws, their level of discretion enables them to set state enforcement priorities
- In the context of the *Dobbs* decision in removing federal control over state reproductive rights laws or prohibitions, this greatly heightens the importance of the AG's decision making

# AG Discretion Upheld

- AG authority has been subject to challenge in multiple state supreme courts
  - In virtually every instance, the courts have found that AGs hold virtually sole discretion about what and how their offices investigate possible civil and criminal violations of state (and sometimes federal) law
  - In a Hawaii Supreme Court decision related to an AG investigatory subpoena which the target felt was retaliatory, the state Supreme Court rules that the determination of whether an investigation was in the public interest “rests squarely with the Attorney General.”
  - Likewise, a recent Mississippi Supreme Court decision found that “any decision to investigate a case and present said case to a grand jury as well as a decision to decline prosecution as unwarranted is within the sole and sound discretion of the Attorney General or her designee”



# Responding to a Subpoena

- In general, *even before a governmental authority requests information*, companies should consider the following issues:
  - Having an established primary point of contact
  - Crafting a policy on interactions with AGs, including a protocol that establishes who responds, when and how, as well as a documentation retention policy
- After receiving a subpoena, companies should fully the scope of the request from the government (e.g., mandatory or voluntary, statutes and regulations at issue, types of documents, communications and records sought)
  - Determine whether there is a basis to challenge the subpoena as being overbroad or unreasonable (e.g., motion to quash)

# OCR Responds to *Dobbs*

- On June 29, 2022, the HHS Office for Civil Rights (OCR) issued guidance discussing the role that HIPAA plays in safeguarding the protected health information of women
  - “Permissions for disclosing PHI without an individual’s authorization for purposes not related to health care ... are narrowly tailored to protect the individual’s privacy and support their access to health services.”
  - In discussing HIPAA exceptions for disclosures (1) required by law, (2) for law enforcement purposes and (3) to avert a serious threat to health or safety, OCR emphasizes that HIPAA *permits but does not require* these disclosures.
- Example: A woman goes to a hospital experiencing a miscarriage. Even if the hospital worker suspects that the woman took medication to end her pregnancy in violation of state law, *if the state law does not expressly require such reporting*, the hospital worker *may not report* the patient to law enforcement.

# Interpreting HIPAA Post-*Dobbs*

- Nothing in the OCR *Dobbs* guidance alters the HIPAA disclosure rules, but it does suggest that OCR intends to interpret HIPAA in a manner that favors safeguarding access to abortion and reproductive health services.
- If a HIPAA covered entity opposes a requested disclosure of reproductive health information from a law enforcement agency or other third party, OCR seems unlikely to pursue that conduct as a HIPAA violation.
  - This doesn't mean that HIPAA covered entities might not face potential liability under state law causes of action, such as "aiding and abetting" abortion services in states in which those services are illegal.

# OCR Personal Device Guidance

- On June 29, OCR also issued the guidance, “Protecting the Privacy and Security of Your Health Information When Using Your Personal Cell Phone or Tablet.”
  - Unlike the HIPAA privacy guidance, OCR focuses on the activity of individual patients rather than covered entities.
  - Recognizes that health information collected through an individual’s personal devices, such as cell phones or tablets, is generally not subject to HIPAA protections.
  - FTC privacy principles generally apply to “direct-to-consumer” digital health products.
    - Unless they are provided through a HIPAA covered entity.
- Personal devices often collect geolocation data, Internet search history, and private messages – all of which may be considered evidence of violations of state reproductive health laws.
- In 2017, the Mass. AG settled an enforcement action against Copley Advertising, a digital advertising company, for using mobile geofencing technology to target ads to women entering reproductive health facilities.
  - Key was lack of consumer notice and consent.
  - That same sort of geolocation data may now be sought by state law enforcement authorities.

# Case Studies

- A large technology company that maintains geolocation data based on phone location receives a state AG subpoena for all data of any user within 50 feet of an abortion clinic.
  - Overbroad?
  - Reasonable exercise of AG authority?
  - HIPAA or state privacy law concerns?

# Case Studies

- A software and device manufacturer whose product tracks ovulation receives a third-party subpoena for the data of an individual under investigation for having an unlawful abortion
  - Overbroad?
  - Reasonable exercise of AG authority?
  - HIPAA or state privacy law concerns?

# Case Studies

- A company maintains software that enables users to communicate via its platform for both healthcare and non-healthcare purposes. It receives a subpoena seeking information regarding a physician who is believed to have performed an abortion. It receives a second subpoena for all messages of any user that has written a message containing the word “abortion.”
  - Overbroad?
  - Reasonable exercise of AG authority?
  - HIPAA or state privacy law concerns?

# Questions?

- Please enter any questions in the chat at this time.



# Biography



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Michele counsels clients on US Food and Drug Administration (FDA) compliance and enforcement matters related to medical devices, combination products, and digital health technologies, such as software as a medical device (SaMD), telemedicine systems, clinical decision support software, wearable devices, artificial intelligence systems, and mobile medical apps. Michele serves as the leader of the firm's Digital Health initiative and as co-leader for the firm's cross-practice Healthcare Industry team.

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W. Reece Hirsch co-heads the firm's privacy and cybersecurity practice and counsels clients on a wide range of US privacy issues, specializing in healthcare privacy and digital health. Reece counsels clients on development of privacy policies, procedures and compliance programs, security incident planning and response, and online, mobile app, and Internet of Things privacy. In Chambers USA rankings, Reece was recognized by his peers as "a consummate expert in privacy matters" and "probably the leading expert in HIPAA in the country."

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Jacob Harper advises stakeholders across the healthcare industry, including hospitals, health systems, large physician group practices, practice management companies, hospices, chain pharmacies, manufacturers, and private equity clients, on an array of healthcare regulatory, transactional, and litigation matters. His practice focuses on compliance, fraud and abuse, and reimbursement matters, self-disclosures to and negotiations with OIG and CMS, internal investigations, provider mergers and acquisitions, and appeals before the PRRB, OMHA, and the Medicare Appeals Council.

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What's The Updated AdvaMed Code of Ethics Got To Do With It?**

Presented by:

Katie McDermott and Jake Harper

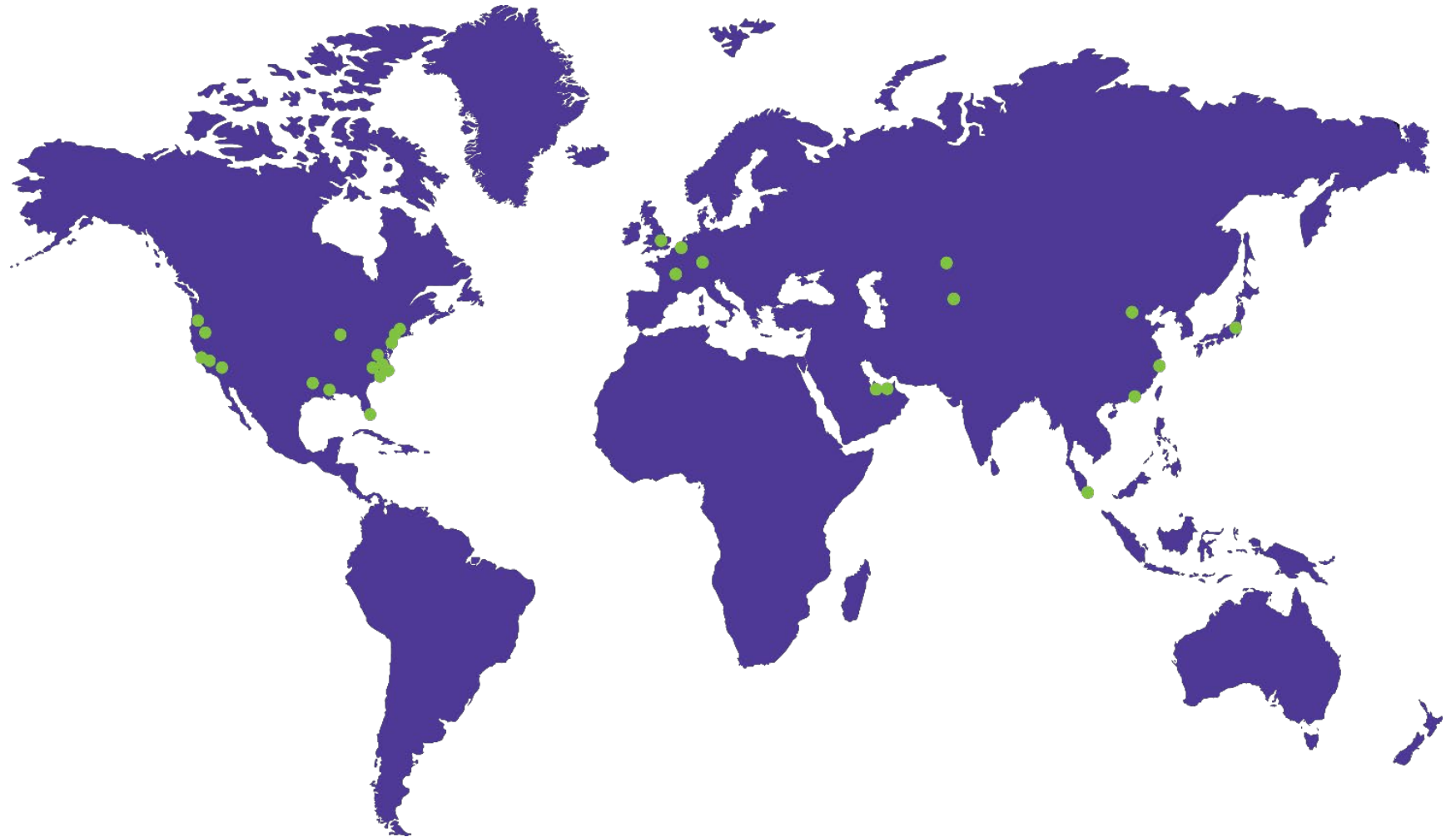
Tuesday, September 6, 2022 3:00 PM (EST)

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