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Reporting Incidental Findings: Legal Risks

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Agenda

- Malpractice Liability
  - Duty
  - Potential Impact of FDA Action
- Uncertainty Regarding Incidental Findings
  - Does the term even have a defined meaning?
  - Questions Regarding Medical Impact
  - Unnecessary Care
  - Creating a Duty
- Conflict With State Licensure Laws
- Recommendations

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Malpractice Liability

- Four elements underscore a malpractice claim.
  - Duty, Breach, Causation, and Damage
  - Each must be satisfied before malpractice is found.
- Duty is state-law dependent, but is highly unlikely to exist where the relationship is research-oriented and limited to a radiological read, particularly an independent read.
  - All the more true where the reviewer and the participant are geographically segregated and never communicate
- However, FDA policy on incidental findings could fundamentally alter the analysis, creating a duty where there is none.
  - Incidental findings are inherently difficult to define, and state courts are likely to create a patchwork of duties that do not correspond with each other.

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Duty

- Although a few courts have suggested an expansion of the concept of a duty to research settings, no court has extended a duty to incidental findings.
  - "A special relationship giving rise to duties, the breach of which might constitute negligence, **might** also arise because, generally, the investigators are in a better position to anticipate, discover, and understand the **potential risks** to the health of their subjects." - *Grimes v. Kennedy Krieger Institute, Inc.* (emphasis added)
  - A bit more about that case

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Potential Impact of FDA Action

- Duties can be created where they do not previously exist by nature of a newly-created regulatory or statutory standard.
  - Gives rise to a claim of "negligence per se"
  - Breach, in these cases, is merely a function of the failure of the regulatory or statutory condition.
  - No absence of "due care" or failure to act "reasonably under the circumstances" must be separately shown.
- If the FDA were to create a regulatory obligation to provide incidental findings in a research context, a substantial risk will follow that courts will find a duty on that basis and find liability under negligence per se theories.

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Uncertainty Regarding Incidental Findings

- A review of incidental findings across multiple types of imaging research studies found that 40% of scans revealed incidental findings.
  - Range of 4% (nuclear scans) to 61% (CT abdomen/pelvis) of scans
  - All IFs were recorded in the patient's medical record and conveyed to the PCP if immediate attention was required.
- Only 6.2% of scans with an IF resulted in subsequent clinical attention.
  - Only 1.1% of scans with an IF resulted in clear medical benefit.
  - 4.6% of scans with an IF resulted in unclear medical/benefit burden.
  - 0.5% of scans with an IF resulted in clear medical burden.

Orme, Nicholas M., et al. "Incidental findings in imaging research: evaluating incidence, benefit, and burden." *Archives of internal medicine* 170.17 (2010): 1525-1532.

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Unnecessary Care

- Increasing recognition that unnecessary screenings and care can be detrimental to patients.
  - Radiation exposure, iatrogenic risks, surgical complications, unnecessary stress and mental anguish.
- Some studies have indicated that unnecessary care "may be directly responsible for as many as 30,000 patient deaths per year."

Swensen, Stephen J., et al. "Controlling healthcare costs by removing waste: what American doctors can do now." *BMJ quality & safety* (2011).

- Reporting incidental findings to patients will certainly increase patient stress.
  - In my view, the relatively low rate of incidental findings with clear medical benefits very likely outweighs the burden.

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Questions Regarding Medical Impact

- Duty should only exist when the benefits of imposing the duty exceed and justify the costs.
- Is there clarity as to what incidental findings are?
- Is there clarity as to when they should be reported?
- Will the report of all incidental findings result in clinical interventions at a meaningful level?
- Where they do result in clinical interventions, will those interventions result predominantly in medical benefit or medical burden?

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Creating a Duty

- Back to first principles: negligence is commonly understood as imposing a duty to act where the "costs" of acting are less than the "consequences" of not acting.
- Not at all clear that this is the case here.
- Why create a duty where the case for it is not yet established?

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Conflict With State Licensure Laws

- Most states expressly prohibit physicians not licensed in that state from practicing within that state.
  - Although some states do have consultation exceptions that allow out-of-state doctors to opine, they typically require the out-of-state doctor to be "in actual consultation" with an in-state doctor.
  - Some states permit consultations under "telehealth" statutes, which require patient consent, and could, therefore, complicate the already over-burdened research consent process.
    - "(b) **Prior** to the delivery of health care via telehealth, the health care provider initiating the use of telehealth shall inform the patient about the use of telehealth and obtain verbal or written consent from the patient for the use of telehealth …" California Bus. & Prof. Code § 2290 (emphasis added)

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Conflict With State Licensure Laws

- Some state consultation requirements can be extremely restrictive and open consulting physicians to additional liability.
  - Establishes that a person, who through the use of any medium performs an act that is part of patient care initiated in Texas, that would affect the diagnosis or treatment of the patient, is engaged in the practice of medicine in the state of Texas and is treated as practicing in Texas. Exception for a medical specialist who provides only episodic consultation services **on request to a person licensed in Texas who practices the same medical specialty**. *Tex. Occupations Code Ann §151.056 (*emphasis added*)*

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Conflict With State Licensure Laws

- Across many states, consultation exceptions are limited by the frequency of consultations
  - "Regular basis" (OK), "episodic consultation" (TX), "consulting capacity … for a period of not more than three months… on a one-time only basis" (WV), "irregular basis" (NC), "regular or frequent" "teleradiology services" (NH)
- What types of consultations will trigger these exceptions?
- Does a "regular basis" apply to the same patient or a practice of regularly reviewing scans from multiple patients?
- Because of the number of scans reviewed in clinical trials, physicians may quickly approach the thresholds of consultations exceptions when providing feedback to in-state physicians via incidental findings.

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Recommendations

- For the reasons discussed, a standard that incidental findings must be reported should not, in our view, be created.
- Based primarily on the following:
  - No existing legal duty
  - Malpractice considerations
  - Cost-benefit analysis does not clearly establish the case for creating a duty
  - State licensure issues

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