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## Health Care Provider Liability for Failure to Warn a Patient's Genetically At-Risk Relatives

Mark A. Rothstein, J.D. Herbert F. Boehl Chair of Law and Medicine Director, Institute for Bioethics, Health Policy and Law University of Louisville School of Medicine © 2018

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## 2 Key Cases

### Pate v. Threlkel, 661 So. 2d 278 (Fla. 1995)

1987 -- Marianne New received treatment for an autosomal dominant form of medullary thyroid carcinoma.

1990 – New's adult daughter, Heidi Pate, also was diagnosed with this disorder.

Pate sued her mother's physicians alleging they had a duty to warn New's children, which would have resulted in prompt testing and treatment.

Florida Supreme Court: "[I]n any circumstances in which the physician has a duty to warn of a genetically transferable disease, that duty will be satisfied by warning the patient." Safer v. Estate of Pack, 677 A.2d 1188 (N.J. Super. Ct. App. Div.), cert. denied, 683 A.2d 1163 (N.J. 1996)

1956 – Robert Batkin treated by Dr. George Pack, a surgeon, for colon cancer.

1964 – Batkin died at age 45. His daughter, Donna, was age 10.

1990 – Donna Safer, age 36, diagnosed with metastatic colon cancer.

1992 -- Donna Safer sued the the estate of Dr. Pack (who had died in 1969) alleging that his failure to warn her father of the genetic nature of his cancer prevented her from obtaining prompt treatment.

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1996 – N.J. Super. Ct App. Div.: Physician has a duty to warn those known to be at risk of a genetic disorder, and the duty may not always be satisfied by warning the patient.

2001 – N.J. Legislature effectively overruled *Safer* by enacting a broad genetic privacy law. N.J. Stat. § 10:5-47 (2001). It prohibits disclosure of individually identifiable genetic information without consent. Only exceptions: forensic identification, paternity determinations in accordance with state law, and pursuant to court order.

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American Society of Human Genetics, Social Issues Subcommittee on Familial Disclosure, Professional Disclosure of Familial Genetic Information 62 Am. J. Human Genetics 474 (1998).

Disclosure should be permissible where attempts to encourage disclosure have failed; where the harm is highly likely to occur and is serious and foreseeable; where the at-risk relative(s) is identifiable; and where either the disease is preventable/treatable or medically accepted standards indicate that early monitoring will reduce the genetic risk. NSTITUTE FOR BIOETHICS, HEALTH POLICY AND LAW University of Louisville

## **HIPAA Privacy Rule**

- Operational in 2003.
- Uses and disclosures beyond treatment, payment, and health care operations require an authorization signed by the individual.
- 12 "public purpose" exceptions -- Of seeming relevance is the following: "Uses and disclosures to avert a serious threat to health or safety," which permits disclosure of PHI when the person to be warned is the subject of a serious and imminent threat of physical harm. (*Tarasoff*).

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## **HIPAA Privacy Rule**

 2013 – HHS Office for Civil Rights issues a questionable interpretation:

"Health care providers may share genetic information about an individual with providers treating family members of the individual who are seeking to identify their own genetic risks, provided that the individual has not agreed to a restriction on such disclosure."



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# Assertions of a broad duty to warn are based on . . .

- Over-reading a single, intermediate appellate court decision in New Jersey that has been legislatively overruled.
- 2. Overlooking the effect of the HIPAA Privacy Rule, which prohibits disclosures without authorization of the individual.

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3. Failure to consider the ethical and practical implications.

4. Assume that disclosure of genetic risk is always beneficial.

Should a Physician Defer to a Patient's Decision Not to Disclose Genetic Information to an "At-Risk" Relative?

The patient, a middle-aged widower with an autosomal dominant cancer syndrome, refuses to share the information with his adult daughter.

The patient might know that his daughter is the product of his late wife's infidelity and he does want to share this family secret with anyone, including his oncologist, or have his daughter subjected to needless anxiety and an unnecessary genetic test.

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# Options for and effects of warning a patient's genetically at-risk relatives

	Provider	Patient	Relatives
No warning	+	+	_
Warning given by provider	_	_	+
Warning given by patient	+	+	+

+ Indicates that, on balance, the approach is favorable for the provider, patient, or relatives;

- Indicates that, on balance, the approach is unfavorable for the provider, patient, or relatives.

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### For further reading:

Mark A. Rothstein, *Reconsidering the Duty* to Warn Genetically At-Risk Relatives, 20 GENETICS IN MEDICINE 285 (2018).

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