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The Duty to Warn: The Conflict between Patient Privacy and Harm Prevention

Introduction: I decided to focus my final paper on the physician's "duty to warn" because I think this is going to become a common problem in the near future. Physicians need a clear set of guidelines regarding when to break physician-patient confidentiality, and that simply does not exist at present. Leaving physicians to use their best judgment places them in a difficult position, both legally and ethically.

Methods: Most of the research for this paper consists of reviews and court briefs, all of which are listed in the references section.

Results:

Physician-patient confidentiality is a long-established feature of modern medicine. Patients have the expectation that their personal health information (PHI) will not be disclosed to a third party without their permission. This ensures that patients feel they are able to discuss sensitive matters with their physician, and that they will not face discrimination based on their health status. However, the recent rise in genetic testing poses a unique challenge to confidentiality. The results of a genetic test certainly qualify as PHI, and therefore fall under the purview of patient privacy regulations. However, genetic tests reveal more than just the genotype of the patient. They can also reveal the likely genotypes of the patient's parents, siblings, children, and other relatives. One genetic test can reveal an increased disease risk in a number of people, most of whom never requested the test and are unaware of its existence. The question, then, is what should a physician do if the results of a genetic test indicate that a patient's relatives are at an increased risk of a treatable or preventable inherited condition? Do

they have a duty to warn the relatives of their increased disease risk, or is this a violation of patient privacy?

The "duty to warn" pits two of the most vital components of medicine against each other: physician-patient confidentiality and the concept of beneficence, which requires physicians to prevent harm. There has been no clear legal answer to this conflict, and there is no universal set of guidelines governing the duty to warn. In this paper I will argue that because the failure to warn can result in preventable deaths, there are situations in which the physician is ethically compelled to break confidentiality and warn relatives of their increased disease risk. However, the duty to warn only applies when knowledge of the results of a genetic test are of benefit to the relative; that is, if the relative has a high disease risk and the disease is preventable or treatable with early detection.

A Legal Nightmare

The duty to warn is regulated by a combination of statutes, legal precedents, and professional guidelines spanning the past several decades.

Federal Regulations

The only federal regulation governing the duty to warn is the Standards for Privacy of Individually Identifiable Health Information (also known as the Privacy Rule), which is part of the Health Insurance Portability Insurance Portability and Accountability Act of 1996 (HIPAA) (Offit 2004). The Privacy Rule prohibits the disclosure of any PHI to a third party without the consent of the patient (U.S. Dept. of HHS 2003). This includes information indicating that a genetic test was either requested or performed, as well as the results of the test. However, there are a limited number of exceptions to the Privacy Rule. A healthcare professional may disclose PHI to public health authorities in the case of an infectious disease outbreak, to law enforcement

in the case of abuse, neglect, or domestic violence, or to the court system for judicial or administrative proceedings (U.S. Code of Federal Regulations 2013). There is one additional exception, which allows disclosures "to prevent or lessen a serious and imminent threat to the health or safety of a person or the public" (U.S. Code of Federal Regulations 2013). Presumably, this is the only exception under which the duty to warn could fall. However, it is debatable whether or not adult-onset inheritable diseases constitute "imminent threats" to one's health, especially when the penetrance of a particular allele is fairly low. Early-onset diseases, such as PKU, would likely fall under this exception, since dietary restrictions are required at birth to prevent mental retardation and delayed development.

Court Precedents

The first instance of the duty to warn surfaced in the California Supreme Court case *Tarasoff v. Regents of the University of California* (1976). In this case, a patient told his psychologist that he had planned on killing a woman who had spurned his advances. While the psychologist notified law enforcement (who briefly detained the patient), he did not notify the woman in danger. After the patient carried out his plan to kill the woman, the woman's family sued the psychologist, on the grounds that their daughter would have avoided the patient, had she known his intent. The court ruled that healthcare professionals have a duty to warn a third party if a patient poses a serious and imminent threat to the health or safety of the third party (*Tarasoff v. Regents of the University of California)*. This was later codified into law as the aforementioned "serious threat to health or safety" exception to the Privacy Rule. Although this case was decided before the advent of modern genetic testing, it was later used as precedent to justify the duty to warn in the context of genetic testing.

The first case to address the duty to warn in the context of genetic testing was the Florida Supreme Court case *Pate v. Threlkel* (1995). In this case, a woman was treated for medullary thyroid carcinoma, a genetically inherited disease. Three years later, her adult daughter was also diagnosed with the disease. The daughter sued her mother's physician, on the grounds that if she had been told about the genetic nature of her mother's disease, she would have requested her own screening, as early detection of medullary thyroid carcinoma greatly improves the disease outcome. The court ruled that a healthcare professional does have the duty to warn a patient's children of a genetically-inherited condition, as long as this knowledge is of benefit to the children. However, the duty to warn is satisfied as long as the healthcare professional advises the patient to warn their children of their increased disease risk (*Pate v. Threlkel*). As such, healthcare professionals were not required to break confidentiality in order to discharge their duty to warn.

Shortly after the decision in *Pate v. Threlkel*, a New Jersey appellate court again weighed in on the duty to warn. In *Safer v. Estate of Pack* (1996), a patient was treated for polyposis and colon cancer in 1961. Thirty years later, the patient's daughter, now age 36, was also diagnosed with polyposis and colon cancer. The daughter sued the estate of her father's physician, on the grounds that polyposis was known to be inheritable at the time of her father's diagnosis, and that early detection and treatment of polyposis could prevent it from developing into colon cancer. The court ruled in favor of the daughter, stating that the duty to warn extended to the patient's immediate family, and that the duty to warn could not always be satisfied by advising the patient of the inheritability of their disease (*Safer v. Estate of Pack*). This ruling is in direct conflict with *Pate v. Threlkel*, and since the cases were decided at the state level in two different states, one

case does not take precedence over the other. The case law, therefore, is unclear as to the circumstances under which the duty to warn applies in the context of genetic testing.

Professional Guidelines

In response to the murky legal stance on the duty to warn, professional medical organizations have published their own set of guidelines. The American Medical Association (AMA) periodically publishes their *Code of Medical Ethics*, which is a comprehensive set of guidelines governing all aspects of the practice of medicine, from social policy issues to the ethics of fees and charges. The most recent version of the *Code of Medical Ethics* mandates that healthcare providers warn patients before genetic testing that they will be expected to inform their relatives of increased disease risk (Schleiter 2009). This guideline echoes the decision in *Pate v. Threlkel*, in which the duty to warn can be discharged through the patient.

In contrast, the American Society of Human Genetics (ASHG) and the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research maintain that the physician's duty to warn may require the physician to break confidentiality and directly inform a patient's relatives of their increased disease risk. Both organizations described four requirements that must be met in order for the physician to break confidentiality: attempts to convince the patient to inform their relatives have failed, the at-risk relatives are identifiable, harm to a relative is serious and highly likely to occur, and early detection of the disease will improve the disease outcome (Schleiter 2009). These guidelines are more in line with the decision in *Safer v. Estate of Pack*, which requires the physician to take a more active role in preventing harm to third parties, at the expense of the patient's right to confidentiality.

Many of the regulations governing the duty to warn are in direct conflict, depriving physicians of a clear set of guidelines for when to break physician-patient confidentiality. Because health care professionals are liable both for breaking confidentiality and for failing to warn relatives of an increased risk of disease (Offit 2004), the choice is between the lesser of two evils.

Does the Duty to Warn Exist?

The concept of beneficence is a core value in medical ethics. In the context of medicine, beneficence is "an obligation on the part of the physician to help others further their important and legitimate interests and abstain from injuring them in any way, that is, psychologically, morally, or physically" (Munyaradzi 2012). If, for example, a physician receives the results of a genetic test, and the results indicate that the patient is at an increased risk for a preventable disease, then beneficence would require them to inform the patient of their risk. Withholding this information would be impermissible on both moral and legal grounds, and the physician would be liable for malpractice. However, do these same obligations apply to third parties? Does beneficence require that a physician extend their services to non-patients?

The definition of beneficence does not distinguish between patients and non-patients; it simply states that physicians must "help others." Clearly this does not imply that physicians must help everyone in the world, as this would be an impossible task. Rather, physicians are expected to help others "to the best of their ability" (Munyaradzi 2012). If a physician knows that a patient's relatives are at an increased risk for disease, then it is well within their ability to contact these relatives, and inform them of their risk. Therefore, the principle of beneficence justifies a physician's duty to warn third parties of health risks. This does not, however, imply that the physician must directly contact these relatives. Under this rationale, the duty to warn is

satisfied as long as the relatives are informed of their risk, either by the physician, the patient, or a third party. However, discharging the duty to warn through the patient or a third party carries its own risks, and may do more harm than good.

The Dangers of *Pate v. Threlkel*

The precedent set by *Pate v. Threlkel*, and the current stance of the AMA, is that physicians may satisfy their duty to warn by advising patients to warn their relatives of any increased disease risk that could benefit from early detection and treatment. Essentially, the physician is transferring the duty to warn to the patient, leaving the patient in a difficult position. If the patient shares their test results, then this could negatively impact the relationships between the patient and their spouse, parents, siblings, and children (Greely 1998). If the disease is fatal, then the patient might want to withhold this information from their family, so as not to cause concern. On the other hand, if the patient decides to withhold the information, then they could be risking the health of their relatives. This could be a traumatic decision for a patient, and may not always lead to the best outcome. This decision is best left to an unbiased third party, such as the physician.

Furthermore, the patient should never be tasked with conveying medical information to a third party. Patients are not trained to explain inherited disease risk or equipped to field medical questions from their relatives. Research has shown that most people are unable to correctly evaluate inherited disease risk based on the results of a genetic test. One study estimated that only 23.8% of users of direct-to-consumer genetic tests (such as those provided by 23andMe) were able to correctly estimate their disease risk after viewing their test results (McGrath and Bastola 2014). It is easy to conflate increased disease risk with absolute disease risk (for example, a 50% increased disease risk could translate into a 1% increase in absolute disease

risk). Errors in disease risk estimation could increase the stress of family members and lead to unnecessary preventative measures. Therefore, it is important that a healthcare professional explain how the results of a relative's genetic test relate to one's own risk of inheriting a disease.

It is important to note that all of the aforementioned regulations and guidelines rely on the patient as the primary means of satisfying the duty to warn. Although the ASHG guidelines permit the physician to break confidentiality, this is only as a last resort, after all efforts to convince the patient to warn their family have failed. This requirement carries the same disadvantages as *Pate v. Threlkel*, and should be removed from the guidelines.

The Right Not to Know

Let us assume that Jane Smith is a middle-aged woman concerned about developing breast cancer. There is a history of breast cancer in her extended family, but neither of her parents (age sixty) have been diagnosed with breast cancer. Nevertheless, Jane decides to get tested for mutations in *BRCA1* and *BRCA2*. There is a high degree of association between deleterious mutations in these genes and the incidence of breast cancer, with mutations in *BRCA1* leading to breast cancer in 65% of women by age 70, and mutations in *BRCA2* leading to breast cancer in 45% of women by age 70 (Antoniou *et al* 2003). Jane sees her physician, who orders the test, after informing her about his duty to warn. The results come back, and, unfortunately, Jane has inherited a mutation *BRCA2*. Because Jane detected this mutation early, she is able to reduce her risk of developing breast cancer by 72% with a salpingo-oophorectomy (removal of the fallopian tubes and ovaries) (Kauff 2008). Overall, Jane is glad that she got tested.

However, Jane has a sister, Mary. Jane has not talked to Mary in 15 years, and she does not plan on telling her of the results of her genetic test. Because breast cancer poses a serious

health risk, preventative treatment exists to reduce the risk of developing breast cancer, and Mary is at a significantly higher risk of developing breast cancer, the physician has a duty to warn Mary of her risk. Thus far, our discussion has focused primarily on the patient's right to confidentiality versus the physician's duty to prevent harm to third parties. However, another factor must be considered. It is generally recognized that patients have the right not to know their genetic status (Andorno 2004). What if Mary does not wish to know whether or not she is at a higher risk for breast cancer? This is not an unreasonable scenario. Research has shown that the results of a genetic test can have a negative impact on a person's happiness, regardless of the actual result (Greely 1998). Are Mary's rights being violated by being informed of her sister's test results? If so, does the duty to warn still take precedence?

If one accepts the right not to know one's genetic status, then warning Mary is a clear violation of her right not to know. Warning Mary, then, is a violation of two people's rights: Jane's right to confidentiality, and Mary's right not to know. Is warning Mary still the most ethical choice? If one weighs the advantages and disadvantages of warning Mary, then the answer becomes evident. Warning Mary could cause her mental distress, and alter her outlook on life. She would have to make the difficult decision about whether or not to have a salpingo-oophorectomy, and at what age. If Mary chooses not to have a salpingo-oophorectomy, then she would have to live with the fear of developing breast cancer for the rest of her life. However, if the physician does not warn Mary, and she has the mutation, then Mary will not be able to pursue preventative treatment, and will have a 45% chance of developing breast cancer. The number of people who would not want to know about their increased disease risk is likely very low relative to the number of people who would benefit from the knowledge. If the choice is between saving

a life in most cases and causing mental duress in a handful of cases, then the choice is clear. The duty to warn takes precedence over the right not to know.

Conclusion: Diagnostic genetic testing has added a new level of complexity to the practice of medicine. Genetic tests are not just representative of the patient; they are representative of the patient's "genetic family," which includes the patient's parents, siblings, and children. Personal health information is no longer personal, but familial. The rise of diagnostic genetic testing presents a serious challenge to patient privacy, and the full ramifications of this shift have yet to be seen. Because the duty to warn traps physicians in a legal and ethical quagmire, governmental and professional organizations need to come together to develop a clear and comprehensive set of guidelines detailing the circumstances under which physicians are expected to break confidentiality and satisfy the duty to warn. It is not enough to encourage patients to inform their relatives of increased disease risk, as patients are not qualified to interpret the results of a genetic test or dispense medical advice to their relatives. Furthermore, patients should never be placed in a situation in which they have to choose between their own privacy and the health and well-being of their family. It is the responsibility of the physician to inform relatives of increased disease risk, as long as the disease is serious and likely to occur, and early detection of the disease will improve the disease outcome. While this is certainly an affront to patient privacy, it is a small price to pay to save the lives of others.

References

Andorno, R. The right not to know: an autonomy based approach. *J Med Ethics* **30(5)**: 435-439 (2004) <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1733927/>.

Antoniou, A. *et al*. Average risks of breast and ovarian cancer associated with BRCA1 and BRCA2 mutations detected in case series unselected for family history: a combined analysis of 22 studies. *Am J Hum Genet* **72(5)**: 1117-1130 (2003) < http://www.sciencedirect.com/science/article/pii/S0002929707606405>.

Greely, H.T. Legal, ethical, and social issues in human genome research. *Annu Rev Anthropol* **27**: 473-502 (1998) <http://www.ncbi.nlm.nih.gov/pubmed/15977340>.

Kauff, N.D. *et al*. Risk-reducing salpingo-oophorectomy for the prevention of BRCA1- and BRCA2-associated breast and gynecologic cancer: A multicenter, prospective study. *J Clin Oncol* **26(8)**: 1331-1337 (2008) <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3306809/>.

McGrath, S. and Bastola, D. DTC genetic testing and consumer comprehension. *Proceedings of the 5th ACM Conference on Bioinformatics, Computational Biology, and Health Informatics*: 582-583 (2014) <http://dl.acm.org/citation.cfm?id=2660559>.

Munyaradzi, M. Critical reflections on the principle of beneficence in biomedicine. *Pan Afr Med J* **11**: 29 (2012) <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3325067/>.

Offit, K *et al*. The "duty to warn" a patient's family members about hereditary disease risks. *JAMA* **292(12)**: 1469-1473 (2004) <http://jama.jamanetwork.com/article.aspx?articleid=199466>.

Pate v. Threlkel. 661 Florida Supreme Court. 1995 <http://lib.law.washington.edu/ref/pate.pdf>.

Safer v. Estate of Pack. 677 Superior Court of New Jersey, Appellate Division. 1996 <https://

scholar.google.com/scholar_case?q=Safer+v.+Estate+of+Pack&hl=en&as_sdt=2006&as_vis=1&case=8527382299363818391&scilh=0>.

Schleiter, K.E. A Physician's Duty to Warn Third Parties of Hereditary Risk. *Virtual Mentor* **11(9)**: 697-700 (2009) <http://journalofethics.ama-assn.org/2009/09/hlaw1-0909.html>.

Tarasoff v. Regents of the University of California. 551 California Supreme Court. 1976 <http://www.publichealthlaw.net/Reader/docs/Tarasoff.pdf>.

United States. Dept. of Health and Human Services. *Standards for Privacy of Individually Identifiable Health Information*. Washington: GPO, 2003 <http://www.hhs.gov/ocr/privacy/hipaa/news/2002/combinedregtext02.pdf>.

United States. Code of Federal Regulations. Title 45 § 164.508. Washington: GPO, 2013 <https://www.law.cornell.edu/cfr/text/45/164.512>.