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This issue is dedicated to the scientists, researchers, and clinical trial participants who made the COVID-19 vaccines possible so that we can return to a society better than the one we left.

Acknowledgements:
We would like to thank our advisor, Lindsay F. Wiley for her support. We are also grateful to the American University Washington College of Law for providing a legal education that empowers us to champion what matters.

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LETTERS FROM THE EDITORS

Dear Reader:

On behalf of the Editorial Board and Staff, we proudly present Volume 15, Issue 2 of the *Health Law & Policy Brief* (HLPB). As we began working on the Note and Article below, we realized that, above all else, the American healthcare system is complicated. Within this issue, we see the complexities of laws that regulate health insurance and the nuances of the doctor-patient relationship when there is a present risk to third parties. These complexities have allowed our healthcare system to resist change, but as the discussions below will show, change is inevitable.

Our first piece explores a recent U.S. Supreme Court case regarding state and federal healthcare regulation and the problems that arise from a potential overlap. The Arkansas legislature had taken upon itself to reign in the cost of pharmaceutical drugs, which the Court found was not preempted by the infamous Employee Retirement Income Security Act of 1974 (ERISA). Author Stuart I. Silverman discusses how this decision signals potential state-level change throughout the country as states begin relying on this holding to find a way to control the price of pharmaceuticals.

In the second piece, we see a glimpse into the uniquely personal aspects of health care regarding the identification of two hereditary gene mutations that indicate a higher risk of developing breast cancer. Complications arise when the patient is unable or unwilling to disclose the existence of the gene to blood relatives who may be at risk. In other areas of law, there is sometimes a mandatory disclosure of the risk to the third party, which in this instance would fall on the physician. However, health privacy laws have made the existence of a duty to disclose unclear. Author Elizabeth Hummel argues that, considering the available preemptive treatments, patient autonomy must come first, and doctors must disclose if patients refuse.

We would like to thank the authors for their hard work and cooperation in writing, researching, and editing their work. We would also like to thank HLPB's article editors and staff members who worked diligently on this issue. Their efforts are greatly appreciated, and we are proud of their work.

To all our readers, we hope you enjoy this issue, that the never-ending complexities of this area of law inspire your own scholarship, and that you anticipate and are prepared for the inevitable metamorphosis our healthcare system will experience during our lifetime.

Sincerely,
Cale & Elizabeth

Cale H. Coppage
Editor-in-Chief

Elizabeth Raterman
Executive Editor

* * *

U.S. Supreme Court Rules that Arkansas Statute Regulating PBMs Is Not Preempted Under the Employee Retirement Income Security Act of 1974

Stuart I. Silverman[*]

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[*] Stuart I. Silverman is a member of the District of Columbia Bar. During his professional life, he has practiced healthcare law.

I. Introduction

In this era of healthcare reform, state governments have enacted legislation to regulate pharmacy benefit managers (PBMs).[1] PBMs act as the middlemen for the payment to pharmacies for prescription drugs acquired by those pharmacies on behalf of beneficiaries in prescription drug plans and enter into separate contracts with prescription drug plans and pharmacies to effectuate the provision of these drugs. The drug plans pay PBMs, and the PBMs, in turn, reimburse pharmacies for the acquisition of drugs. PBMs maintain maximum allowable cost (MAC) lists that specify the reimbursement rate for each drug.

On December 10, 2020, the U.S. Supreme Court in *Rutledge v. Pharmaceutical Care Management Ass'n*[2] ruled that the Employee Retirement Income Security Act of 1974 (ERISA) did not preempt Arkansas Act 900 to regulate reimbursement rates paid by PBMs to pharmacies for the provision of drugs to beneficiaries of prescription drug plans.

A. Arkansas Act 900

In 2015, the Arkansas legislature passed Act 900, which mandates minimum reimbursement rates that PBMs must pay to Arkansas pharmacies for the provision of drugs by pharmacies to beneficiaries of prescription drug plans.[3] The legislature enacted Act 900 in response to practices by PBMs whereby these middlemen did not reimburse pharmacies the amount at least equal to their wholesale acquisition drug costs, leading to financial losses by pharmacies, and in some cases, closure of rural and independent pharmacies.[4]

Act 900 accomplishes several things. Specifically, the Act requires that PBMs update their MAC lists that set the minimum reimbursement rates for pharmacies that sell drugs to beneficiaries of prescription drug plans. In effect, the rates that PBMs pay to pharmacies must be equal to or higher than a pharmacy's wholesale acquisition cost for a drug. The enactment requires that the updates to the MAC lists be effectuated "on a timely basis" as enumerated under the statute, including when there is an increase in wholesale drug prices.[5] The statute also allows a pharmacy to file an administrative appeal to challenge a PBM's listed rate if it falls below a

[1] For information on pharmacy benefit managers (PBMs), *see Pharmacy Benefit Managers and Their Role in Drug Spending*, COMMONWEALTH FUND (Apr. 22, 2019), https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending.
[2] No. 18-540, slip op. at 9–10 (Dec. 10, 2020) (delivering the opinion of the Court, Justice Sotomayor was joined by other members including Justice Thomas who filed a separate concurring opinion; Justice Barrett did not take part in the decision of the case).
[3] *See* 2015 Ark. Acts 3622 (amending ARK. CODE ANN. § 17-92-507 (West 2019)).
[4] *Rutledge*, slip op. at 2.
[5] ARK. CODE ANN. § 17-92-507(c)(2) (West 2019).

pharmacy's wholesale acquisition cost.[6] Such appeals are made internally with the PBM.[7] If it is determined that a pharmacy was not able to acquire a drug at a lower price than the one listed by the PBM, then the PBM must increase the reimbursement rate for the drug to cover the pharmacy's acquisition cost.[8] The Act also provides that PBMs must allow a pharmacy to "reverse and rebill" a claim from the pharmacy when the pharmacy was not able to procure the drug at a price equal to or less than the MAC listed rate.[9] Lastly, a pharmacy may elect to choose not to sell a drug to a drug plan beneficiary if the PBM will reimburse the pharmacy at less than its acquisition cost.[10] There is no provision for judicial review of a PBM's appeal determination.

II. Legal Challenge to Arkansas Act 900

Pharmaceutical Care Management Association (PCMA) filed a lawsuit in the U.S. District Court for the Eastern District of Arkansas alleging, among other things, that ERISA preempts Act 900.[11] The district court ruled that the Arkansas law was preempted by ERISA, and the Eighth Circuit affirmed.[12]

The Supreme Court's ruling in *Rutledge* determined that ERISA did not preempt Arkansas Act 900 and thus was a valid exercise of state authority in regulating PBMs.[13] In reaching its decision, the Court construed the provision under ERISA, as relevant to the case, that explicitly preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan."[14] The Court went on to explain that a state law "relates to" an employee benefit plan if it has a "connection with" or "reference to" such an ERISA plan.[15] The Court concluded that Act 900 did not meet either of those two tests, and thus ERISA does not preempt the state law.[16]

The Supreme Court in *Rutledge* set the frame of reference to determine whether a state law has an impermissible "connection with" an ERISA plan. The Court's established jurisprudence on this inquiry is to first recognize Congress's intended central purpose for ERISA. To ensure the overarching goal of securing benefits provided through ERISA plans, Congress required

[6] *Id.* § 17-92-507(c)(4)(A)(i)(b).
[7] *See id.*
[8] *See id.* § 17-92-507(c)(4)(C)(i)(b).
[9] *See id.* § 17-92-507(c)(4)(C)(iii).
[10] *See id.* § 17-92-507(e).
[11] *See* Pharm. Care Mgmt. Ass'n v. Rutledge, 240 F. Supp. 3d 951 (E.D. Ark. 2017), *aff'd*, 891 F.3d 1109 (8th Cir. 2018). *See generally* 29 U.S.C. § 1001, *et seq.*
[12] *Rutledge*, 240 F. Supp. 3d at 958.
[13] *Rutledge*, slip op. at 9–10 (Dec. 10, 2020).
[14] *Id.* at 4 (citing 29 U.S.C. § 1144(a)).
[15] *Id.* (quoting Egelhoff v. Egelhoff, 532 U.S. 141, 147 (2001)) (internal quotation marks omitted).
[16] *Id.* at 10.

"oversight systems and other standard procedures" under ERISA.[17] By doing so, Congress intended that employee benefit plans would be "subject to a uniform body of benefits law."[18] The intent was to avoid "administrative and financial burden" that may arise from "conflicting directives" imposed by states and the burden of "tailoring substantive benefits to the particularities of multiple jurisdictions."[19] The Court in *Rutledge* made clear that, fundamentally, if a state law "governs a central matter of plan administration or interferes with nationally uniform plan administration,"[20] then the state law is preempted.

A. The Preemptive Reach of the Employee Retirement Income Securities Act of 1974

In concluding that Act 900 did not have an impermissible "connection with" ERISA plans, the Court looked to its decision in *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co.*[21] There, the Supreme Court considered surcharges enacted by the New York legislature.[22] One surcharge was against hospital in-patients with coverage from commercial insurers but not Blue Cross/Blue Shield plans.[23] Another surcharge was against certain health maintenance organizations.[24] The inquiry in *Travelers* was whether the billed in-patient surcharges paid by commercial employee health plans and the surcharges billed to members of health maintenance organizations and paid by ERISA plans had an impermissible connection with ERISA plans and thus were preempted.[25]

The Court in *Travelers* declined to conclude that the surcharges fell within ERISA's preemptive reach.[26] It derived this view because the Court deemed the surcharges as having a mere indirect economic effect on rates charged to members of ERISA plans.[27] Such an indirect effect does not restrict ERISA plan administrators to a particular benefits package,[28] or preclude uniform plan administration.[29] Rather, the surcharges simply reflect the cost of benefits in the marketplace of insurance products.[30]

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[17] *Id.* at 4 (quoting Gobeille v. Liberty Mut. Ins. Co., 577 U.S. 312, 320–21 (2016)).
[18] *Id.* (quoting Ingersoll-Rand Co. v. McClendon, 498 U.S. 133, 142 (1990)).
[19] *Id.*
[20] *Id.* at 5 (quoting *Gobeille*, 577 U.S. at 320).
[21] 514 U.S. 645 (1995); *see Rutledge*, slip op. at 5.
[22] *See Travelers Ins.*, 514 U.S. at 649.
[23] *Id.*
[24] *Id.*
[25] *Id.*
[26] *Id.* at 668.
[27] *Id.* at 659.
[28] *Id.*
[29] *Id.* at 660.
[30] *Id.*

The Court in *Rutledge* deemed the scheme under Act 900, designed to provide pharmacies with adequate rates, as a form of cost regulation, analogous to the surcharges in *Travelers*.[31] In so doing, the rates imposed on PBMs under Act 900 were of no concern for the preemptive inquiry, assuming the prescription drug plans were ERISA benefit plans. Even the prospect that PBMs may pass on to employee benefit plans the additional costs arising from higher reimbursement to pharmacies under Act 900 did not militate, in the Court's view, in favor of finding preemption. Although ERISA plans may pay more for prescription-drug benefits than in some other states, the Court cautioned "cost uniformity was almost certainly not an object of pre-emption."[32]

The Arkansas law also escaped preemption since its effect was not so "acute that it will effectively dictate plan choices."[33] Like the analysis in *Travelers*, the rates under Act 900 had only an indirect connection with prescription drug plans, too tenuous to invoke federal preemption. Under this analysis, the scheme to set rates under Act 900 did not govern a central matter of plan administration or interfere with nationally uniform plan administration.

Separately, the Supreme Court in *Rutledge* considered whether Act 900 "refers to" an ERISA plan, which is the second test to determine whether the state law is federally preempted.[34] The Court declined to so find. The Court explained that a law "refers to" ERISA if it "acts immediately and exclusively upon ERISA plans or where the existence of ERISA plans is essential to the law's operation."[35] Act 900, by its own terms, does not act immediately and exclusively upon ERISA plans since the law applies to all PBMs in Arkansas, regardless of whether a particular PBM manages an ERISA plan. More specifically, the law's effect on ERISA plans may be tenuous at best, since whatever increase in rates paid to pharmacies may be dictated by Act 900, those rates may never be passed on to ERISA prescription drug plans. This is too slim an interpretation to preempt the Arkansas law. The Court recognized that PBMs contract with healthcare plans that are not exclusively ERISA plans but rather can be government-funded health plans and commercial private plans in the marketplace.[36]

Additionally, the Court in *Rutledge* wrote that the existence of ERISA plans is not essential to the operation of Act 900.[37] Act 900 explicitly defines a PBM as an entity that manages "pharmacy benefit plans or program," such plans or program defined as providing pharmacy services to residents of, or those employed in, Arkansas.[38] Thus, by its own terms, the existence of ERISA plans is not essential to the operation of Act 900. To reinforce this analysis, the Court

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[31] Rutledge v. Pharm. Care Mgmt. Ass'n, No. 18-540 slip op. at 6 (Dec. 10, 2020).
[32] *Id.*
[33] *Id. (*quoting *Travelers Ins.*, 514 U.S. at 668).
[34] *Id.*
[35] *Id.* (quoting Gobeille v. Liberty Mut. Ins. Co., 577 U.S. 312, 319–20 (2016) (citation and internal quotation marks omitted)).
[36] *Id.* at 6–7.
[37] *Id.* at 7.
[38] *Id.* at 7 (quoting ARK. CODE ANN. §§ 17-92-507(a)(7), (9) (West 2019)).

made reference to its decision in *Travelers*.[39] There, it held that the New York surcharges did not "refer to" only ERISA plans since they could be imposed on other commercial coverage available in the marketplace.

In the litigation, PCMA argued that Act 900 negatively affects plan design since it required a pricing methodology to ensure a certain level of reimbursement to pharmacies. The Court disagreed, holding that Act 900 does not require plans to provide a particular benefit.[40] PCMA contended that Act 900 encroaches on central matters of plan administration, a hallmark of ERISA preemption, by mandating an administrative appeal procedure afforded pharmacies to challenge reimbursement rates, with a provision to recalculate amounts owed to a pharmacy. Here too, the Court rejected this argument as without merit.[41] PCMA also argued that Act 900 interferes with central matters of plan administration since pharmacies can refuse to sell a drug if the PBM pays less than the pharmacy's acquisition cost for the drug. The Court disagreed, writing that PCMA overlooked the statutory scheme under Act 900.[42] Lastly, in the litigation, PCMA insisted that Act 900 creates "operational inefficiencies" which could lead to increased costs and reduced benefits to plan members. The Court viewed this argument as misguided for ERISA preemption analysis.[43]

III. Observations

There are varied implications that arise from the Supreme Court's decision in *Rutledge*. These focus on the marketplace for prescription drugs, the financial viability of pharmacies, and their access to networks offered by PBMs. The decision enhances the negotiating position of independent and rural pharmacies in their efforts vis-a-vis PBMs to enter into viable commercial contracts. The *Rutledge* decision provides greater financial safeguards for pharmacies, thereby promoting greater access to health care to vulnerable members of the population in rural communities.

To be sure, the Court's ruling also encourages other state legislatures to seek ways to control the cost of prescription drugs. This is particularly significant because states have generally been viewed as having the role of pursuing innovative ways in healthcare reform. Most states have regulated PBMs in some form, and *Rutledge* provides further support in these efforts.

[39] *Id.* (citing N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645 (1995)).
[40] *Id.* at 8.
[41] *Id.* at 8–9.
[42] *Id.* at 9.
[43] *Id.* at 9 (citing Mackey v. Lanier Collection Agency & Serv., Inc., 486 U.S. 825, 831 (1988)).

In another sense, it has been suggested that *Rutledge* offers support to states in areas other than health care rate regulation. This includes reforms that enhance health care affordability, as well as other consumer protections.

The Breast Chance of Survival: An Affirmative Duty to Warn Family of a Patient Who Has Tested Positive for BRCA

Elizabeth Hummel[*]

Scientific research has allowed for genetic diseases such as the Breast Cancer Gene mutation (BRCA) to be more easily identified through genetic testing. Identification of an individual's BRCA status allows patients to take control of their diagnosis with a range of preventive measures available, such as enhanced screening, hormone therapy, or preventive surgery. Each preventive measure helps drastically increase the likelihood of survival for a population of women at a much higher risk of developing breast cancer in their lifetime. However, current genetic testing groups and breast cancer organizations suggest testing only in situations where a family history of breast cancer is present or a family member has tested positive for BRCA, and insurance companies rarely cover testing for those with no family history. As such, individuals who have more complex or challenging familial relationships may not gather the same information or may not be encouraged to get tested, which limits their ability to identify, and therefore address, their own risk. In line with the duty of care to third parties established in the case of Tarasoff v. The Regents of the University of California*, a common law duty to warn third parties should be created in the context of BRCA. The duty should require doctors, within the standard of their profession, to take reasonable steps to inform identifiable blood relatives who are at high risk for the BRCA mutation. This will enable them to take steps to alleviate the substantial harm they may face as a result of their lack of knowledge. This duty will allow all individuals to benefit from the power of knowledge and save the lives of women who would otherwise be at risk.*

[*] J.D., expected May 2021, The George Washington University Law School. I would like to thank the *Health Law and Policy Brief* staff for their support and review of this Article.

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I. Introduction

In late 1994, scientists identified three Ashkenazi families that carried an identical alteration of a particular gene.[1] Despite no family relation, doctors determined that all three families were high risk for cancer.[2] Building upon this identification, an additional study found that one percent of the Jewish population had the same gene alteration.[3] The study itself focused on hereditary breast cancer, and the results led to the discovery of the relationship between the identified gene alteration and the likelihood of developing breast cancer.[4] The identified gene mutation became known as BRCA1 and BRCA2, short for "BReast CAncer Gene."[5] Scientists discovered BRCA1 in 1994 and BRCA2 in 1995, which designated a slight difference in the gene altered, though both indicate a higher likelihood of developing cancer.[6]

Identification of the BRCA genes has been an incredible discovery for those who are diagnosed with and those who treat breast cancer. While the strongest predictor of a woman's likelihood of developing breast cancer is family history,[7] knowing whether one has a BRCA mutation can also help predict the likelihood of cancer and enable an individual to take measures that can greatly increase their likelihood of survival.[8] For example, early identification of one's BRCA status can lead to heightened screening that often allows for far earlier identification of an issue—a necessity when the five-year relative survival rate for early detected breast cancer is over ninety-eight percent.[9] In addition to the option of screening, some elect to have preventative surgery based on their BRCA status. This can include a double mastectomy before cancer has the chance to develop, decreasing the risk of developing cancer by approximately ninety percent.[10]

While few can deny the substantial benefits that result from knowing one's BRCA status, the question of who should be told of their risk and how raises ethical questions that are not easily resolved. In particular, debates arise over whether there should be an affirmative duty for a health care provider to warn third parties—individuals outside of the immediate patient. A common debate exists over whether there is a duty of health care providers to warn their patient's blood relatives, who are at high risk of also having the gene mutation.[11] One outlet

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[1] *Questions About the BRCA1 and BRCA2 Gene Study and Breast Cancer*, NAT'L HUM. GENOME RES. INST. (May 1997), https://www.genome.gov/10000940/brca1brca2-study-faq#targetText=The%20first%2C%20BRCA1%20(for%20BReast,search%20for%20other%20genes%20continues.
[2] *Id.*
[3] *Id.*
[4] *Id.*
[5] *Id.*
[6] *Id.*
[7] *Breast Cancer Genetics: What to Do If You've Tested Positive*, NAT'L BREAST CANCER FOUND., https://www.nationalbreastcancer.org/what-to-do-if-youve-tested-positive.
[8] *Id.*
[9] *Id.*
[10] *Id.*
[11] *See* Michael Fay, *Negligence, Genetics and Families: A Duty to Disclose Actionable Risks*, 16 MED. L. INT'L 115, 117 (2016); Daniel P. Sulmasy, *On Warning Families About Genetic Risk: The Ghost of* Tarasoff, 109 AM. J. MED. 738, 739 (2000).

describes three proposals that have been put forward on how to address this issue: (1) a universal duty to warn, (2) a case-by-case assessment based on genetic risk and probability of harm, and (3) no affirmative duty to warn third parties.[12]

However, these are merely suggested proposals; none of these systems have been universally adopted, and relevant case law is silent on the BRCA gene mutation specifically. There are currently only two modern cases that discuss an affirmative duty to warn third parties of genetic diseases, and the holdings are largely conflicting and fact-specific.[13] Those in the medical field have provided no additional clarity, despite being in a better position to weigh the value of knowledge against the concern of patient confidentiality.[14] Requiring an affirmative duty removes the protection of confidentiality in some circumstances because it would hold health care providers liable for not sharing information of risk, regardless of patient consent.[15] Proponents of an affirmative duty to warn tend to value giving individuals the opportunity to reduce the risk of the disease and its complications or the general benefits of early detection and addressing the concern, over any confidentiality issues.[16] This Article aligns with the proponents, where the value of early detection and early action outweigh concerns of confidentiality.

This Article proposes a common law affirmative duty to warn identifiable blood relatives of patients who have tested positive for the BRCA mutation. This duty would extend only to health care providers, excluding direct-to-consumer (DTC) testing. Part I discusses the history of genetic testing and the current available methods of testing. Part I also discusses the BRCA gene generally, including the meaning of testing positive for the gene mutation, the prognosis, and available preventive measures if positive. Part II discusses the affirmative duty to warn standard as it applies to warning third parties, as developed in the case of *Tarasoff v. The Regents of the University of California*. Part III discusses the application of the *Tarasoff* standard to the affirmative duty to warn identifiable blood relatives of patients who tested positive for the BRCA gene mutation. Part IV discusses the limitations and concerns of applying an affirmative duty to warn in this circumstance. However, Part IV also ultimately proposes applying a modified version of the *Tarasoff* standard to require an affirmative duty to warn identifiable blood relatives of patients testing positive for either BRCA1 or BRCA2 gene mutations.

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[12] Shawneequa Callier & Rachel Simpson, *Genetic Diseases and the Duty to Disclose*, 14 AM. MED. ASS'N J. ETHICS, 640, 642, (2012).
[13] *See, e.g.*, Pate v. Threlkel, 661 So. 2d 278, 279 (Fla. 1995) (finding no affirmative duty for a doctor to warn patients' children of genetic risk if consistent with the prevailing standard of care); Safer v. Estate of Pack, 677 A.2d 1188, 1192 (N.J. Super. Ct. App. Div. 1996) (finding an affirmative duty to warn may extend beyond the patient to the immediate family of the patient).
[14] Callier & Simpson, *supra* note 12, at 640.
[15] John Petrila, *Genetic Risk: The New Frontier for the Duty to Warn*, 19 BEHAV. SCI. & L. 405, 408, 410 n.2 (2001).
[16] Anne-Marie Laberge & Wylie Burke, *Duty to Warn At-Risk Family Members of a Genetic Disease*, 11 AM. MED. ASS'N J. ETHICS, 656, 657, 659 (2009).

II. A Brief Introduction to Genetic Testing & BRCA

Genetic testing has become far more common in the modern area, becoming more available on a larger scale based on the decreased costs and time required.[17] As more patients participate in DTC testing and share those results with their health care providers, it is necessary to have a clear standard on a duty of care to third parties. Understanding the history of genetic testing, as well as the consequences of a positive BRCA test result, provides a framework for why there should be an affirmative duty specifically for BRCA.

The importance of an affirmative duty for BRCA is best understood by the impact caused by testing positive for BRCA. Though many refer to it as having the BRCA gene, a more accurate statement of the abnormality that causes concern is having a BRCA gene mutation.[18] The BRCA gene is one of many tumor suppressing genes, which function to prevent the growth of cancerous cells.[19] When these genes do not function correctly, which is a characteristic of the mutated genes, they are ineffective in repairing cells and the accumulated damage may result in cancer.[20] Though having the gene mutation does not guarantee that one will develop cancer, the chances are greatly increased.[21] While in the general population it is estimated that approximately twelve percent of women will be diagnosed with breast cancer, for women who have a BRCA1 mutation, the risk of developing cancer in a lifetime increases to fifty-five to sixty-five percent, and for women with a BRCA2 mutation, the risk is approximately forty-five percent.[22] This means that women who test positive for either gene mutation have at minimum a thirty percent higher risk than the average population.[23]

Additionally, the gene mutations can also impact the treatment of cancer, as women with either mutation have a higher-than-average chance of recurrence[24] and a higher chance of having "triple negative breast cancer," where certain common hormone receptors are not present in the cancer genes and the cancer is generally more aggressive and more difficult to treat.[25] BRCA presents a unique challenge because of the inability to predict outcomes with certainty. Those with a family member who has tested positive for the gene have only a fifty percent chance of

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[17] Asude Alapman Durmaz et al., *Evolution of Genetic Techniques: Past, Present, and Beyond*, 2015 INT'L BIOMED RESEARCH INT'L 1, 4 (Mar. 2015), https://downloads.hindawi.com/journals/bmri/2015/461524.pdf.
[18] See *supra* note 1.
[19] *Enhancing Breast and Ovarian Cancer Care: The Discovery of BRCA1 and BRCA2*, NAT'L CANCER INST. (Mar. 7, 2014), https://www.cancer.gov/research/progress/discovery/brca.
[20] *Id.*
[21] *BRCA: The Breast Cancer Gene*, NAT'L BREAST CANCER FOUND., https://www.nationalbreastcancer.org/what-is-brca (last visited Feb. 26, 2021).
[22] *Id.*
[23] *Id.*
[24] *Id.*
[25] *Triple Negative Breast Cancer*, NAT'L BREAST CANCER FOUND., https://www.nationalbreastcancer.org/triple-negative-breast-cancer (last visited Feb. 22, 2021).

inheriting the gene, and those who have the gene mutation themselves are merely at higher risk of developing cancer, not guaranteed.[26]

However, many continue to find that knowledge of their BRCA status is worthwhile, and genetic testing for the BRCA gene is growing in popularity. Genetic testing is also available through physicians or genetic counselors, who provide more expansive testing and more explanation on the meaning of results.[27] In addition, many DTC organizations even offer testing that is completed at home.[28] In 2018, reports identified that approximately seven million Americans had taken some type of DTC DNA test.[29] Regardless of the type of testing provided, both experts at the National Society of Genetic Counselors and DTC providers, such as 23andMe, still suggest reviewing results with a genetic counselor to truly understand the consequences.[30] As more individuals find out their status via testing, many elect to share that information with health care providers in order to make medical decisions. With no current standard on how health care providers should or must share that information, providers are unsure how to avoid liability in these cases. Clarity over the required duty of care for those health care providers is essential.

Though genetic testing is increasing in popularity, those who are not aware of their risk factors may not be part of the vast movement to learn about one's genetic information. Many individuals at heightened risk may find out from family members, enabling them to take advantage of the available preventive measures and greatly increase their likelihood of survival. Others, who neither follow the excitement of DTC testing nor have the relationship with their family that would provide for information, are less able to take steps to their reduce risk. Further, those who may want to get tested even without knowing their familial history but are concerned about the risks of DTC may find testing cost-prohibitive in many circumstances.[31] The Affordable Care Act requires coverage of genetic counseling and BRCA testing, however, the cost is only covered if the individual's health care provider determines they meet certain guidelines—guidelines that include a family history of BRCA or breast cancer.[32] As a result, the same women who are unaware of their risk due to family circumstances may not even be able to get tested; without this family history, insurance is not likely to cover the patient's testing or counseling. To create an affirmative duty to warn identifiable blood relatives of patients who test positive for BRCA, while limited in scope, attempts to address the individuals that fall into this information gap.

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[26] *Genetic Testing for Breast Cancer*, NAT'L BREAST CANCER FOUND., https://www.nationalbreastcancer.org/genetic-testing-for-breast-cancer (last visited Feb. 22, 2021).
[27] *What is At-Home Genetic Testing*, NAT'L SOC'Y GENETIC COUNSELORS, http://aboutgeneticcounselors.com/Genetic-Testing/What-is-At-Home-Genetic-Testing (last visited Feb. 27, 2021).
[28] *Choose the Service That's Right for YOU*, 23ANDME, https://www.23andme.com/compare-dna-tests/ (offering BRCA testing via an at-home kit for 199 dollars) (last visited Feb. 27, 2021).
[29] Jamie Ducharme, *Millions of Americans Could be Identified Using Consumer Genetic Databases – Even If They've Never Taken a DNA Test*, TIME (Oct. 13, 2018, 10:38 AM), https://time.com/5423170/dna-test-identify-millions/.
[30] *Id.*; *23andMe Genetic Health Risk Reports: What You Should Know*, 23ANDME, https://www.23andme.com/test-info/ (last visited Feb. 26, 2021).
[31] *What Is the Cost of Genetic Testing, and How Long Does It Take to Get Results?*, U.S. NAT'L LIBRARY MED., https://ghr.nlm.nih.gov/primer/testing/costresults (last visited Feb. 27, 2021).
[32] *Coverage of Breast Cancer Screening and Prevention Services,* KAISER FAMILY FOUND. (Sept. 26, 2019), https://www.kff.org/womens-health-policy/fact-sheet/coverage-of-breast-cancer-screening-and-prevention-services/.

The expansion of genetic testing has caused concerns for genetic counselors and doctors, and the growth in testing shows no sign of slowing down.[33] As the hype around testing continues, many who are unaware of their family history are still at a disadvantage for either getting tested or understanding their results. An affirmative duty to warn identifiable blood relatives of a patient who has tested positive for BRCA is a way to curb the inequities between those that are willing to share their status with their families and those who are not, equalizing the likelihood of survival.

III. The Legacy of *Tarasoff*: An Affirmative Duty to Warn Third Parties

Common law often shifts with changing policy interests and social norms of the time. A new common law affirmative duty to warn third parties has been imposed as a result of these shifting norms more than once, and as new technology changes social values, additional affirmative duties may be created. The circumstances by which courts created affirmative duties reflect very similar circumstances to the issue at hand, lending support to the creation of an affirmative duty to warn individuals at risk of having the BRCA mutation.

Historically, there is no "duty to take affirmative action to prevent harm to another,"[34] and where there is no duty, there is no liability.[35] The liability for negligence is found where there is a true legal duty, going beyond just a "purely moral obligation."[36] Courts have long held that where there is physical harm, an actor must exercise a duty of reasonable care only for conduct that actually created the risk;[37] this conduct is described as an "affirmative act."[38] Applying this requirement limits liability in situations in which the only conduct of the actor is inaction—situations such as failure to rescue or failure to protect from risks created by third parties.[39] However, the judiciary has created affirmative duties for policy reasons, either to categorically deny liability that would otherwise conflict with social norms, or to impose liability in order to encourage socially acceptable behavior.[40]

Affirmative duties have been created in circumstances where the policy goal of avoiding harm is valued more highly than the consequences a new duty would cause. One case that exemplifies this policy balancing is *Tarasoff v. The Regents of the University of California*.[41] In this case, the family of a young woman who had been murdered brought suit against a psychiatrist within the

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[33] *At-Home Genetic Testing Position Statement*, NAT'L SOC'Y OF GENETIC COUNSELORS (June 2019), https://www.nsgc.org/p/bl/et/blogaid=1119 ("[C]onsider the risks, limitations, and psychological implications . . . before purchasing an at home genetic test[. . .]).
[34] Schlomo Twerski, *Affirmative Duty after* Tarasoff, 11 HOFSTRA L. REV. 1012, 1013 (1983).
[35] *See e.g.*, Buch v. Armory Mfg. Co., 69. N.H. 257 809, 810 (N.H., 1898).
[36] *Id.*
[37] RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL AND EMOTIONAL HARM § 6 (AM. LAW. INST. 2010).
[38] *Id.*
[39] *Id.*
[40] RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL AND EMOTIONAL HARM § 7 (AM. LAW INST. 2010) (finding modern cases imposing liability on social hosts for serving alcohol to their guests who may depart in a car).
[41] Tarasoff v. The Regents of the Univ. of Cal., 551 P.2d 334 (Cal. 1976).

University of California group of psychiatrists.[42] The victim, Ms. Tarasoff, had been murdered by Mr. Poddar, a patient of the psychiatrist being sued.[43] Mr. Poddar had shared with his therapist his intent to murder Ms. Tarasoff during one of his therapy sessions, and though he was originally detained for a short period, he took Ms. Tarasoff's life upon his release.[44] While the family originally brought suit for failure to detain and failure to warn, the court found no claim of failure to detain due to government immunity.[45] Instead, the court focused on whether the therapists had an affirmative duty to warn Ms. Tarasoff of the danger she faced upon the release of Mr. Poddar.[46]

The Tarasoff family argued that the therapist had an affirmative duty to warn Ms. Tarasoff since the therapist was not only aware of Mr. Poddar's plan, but also knew that he was no longer detained.[47] Aware of the potential danger Ms. Tarasoff faced, the family argued that the therapist had a duty to apprise her of that danger.[48] However, under the law, there did not exist a duty for a psychiatrist to warn a third party of a threat from a patient.[49] The court had to decide whether a duty should even exist, and if so, whether that duty applied here. In analyzing whether there should be a duty, the court noted that duty is based on the "sum total of those considerations of policy" rather than "sacrosanct in itself."[50] The court considered a number of policy factors and weighed the factors against each other and against the consequences a new duty would cause.[51] The policy factors are foreseeability, degree of certainty that injury occurred, closeness between defendant's conduct and the injury, moral blame, policy of preventing future harm, burden to the defendant, and consequences to the community by imposing the duty.[52] Though the court placed additional focus on the factor of foreseeability, the creation of a duty does not rest on foreseeability alone.[53] Having found a duty to warn, the court limits the circumstances and requirements of the duty.[54] First, the court notes that discharge of the duty will vary by circumstances and that the courts will measure the therapist's conduct against the traditional "reasonable care" standard.[55] Additionally, the duty is only applicable to the "foreseeable victim."[56] However, the holding does not give much clarity into the standard of what "foreseeable" is. Some understanding is provided in the description of Ms. Tarasoff as

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[42] *Id.* at 340.
[43] *Id.*
[44] *Id.*
[45] *Id.*
[46] *Id.*
[47] *Id.*
[48] *Id.*
[49] *Id.*
[50] *Id.* at 342.
[51] *Id.*
[52] *Id.*
[53] *Id.* at 342–43. ("[W]hen the avoidance of foreseeable harm requires a defendant to control the conduct of another person, or to warn of such conduct, the common law has traditionally imposed liability only if the defendant bears some special relationship to the dangerous person or to the potential victim.").
[54] *Id.* at 345 ("[O]nce a therapist does in fact determine, or under applicable professional standards reasonably should have determined, that a patient poses a serious danger of violence to others, he bears a duty to exercise reasonable care to protect the foreseeable victim of that danger.").
[55] *Id.*
[56] *Id.*

"readily identifiable."[57] Though subsequent case law in the state utilized a similar standard, the idea of "identifiable" appears to be a highly fact-specific consideration, reviewed on a case-by-case basis and pursuant to standards of the profession.[58]

The limitations on liability the court imposes are important because they reflect the balancing of policy considerations relied upon in finding a new affirmative duty to a third party. The court acknowledges this balancing of factors, noting the holding purports to promote "greater safety for our society," while still considering "devotion to individual liberty."[59] And while critics still discuss the impact of the new expansion of duty, the imposition of duty in this circumstance was in line with the normal shifts of tort law changing to reflect the public values of the time and coinciding policy considerations.[60] With the increase in access and use of genetic testing, and the understanding of BRCA and its impact, the question of what type of duty is appropriate for health care providers is a public policy concern. A similar balancing of the factors put forward by *Tarasoff* provides justification that the creation of an affirmative duty arises.

A. Applying the Tarasoff *Framework to Genetic Testing; Should There be an Affirmative Duty?*

The policy factors that the court considered in the *Tarasoff* case provide a framework for considering whether to create a new affirmative duty for BRCA. In *Tarasoff*, the court considered both legal and public policy factors, including the foreseeability of harm to a third party, whether there is a special relationship present, public policy needs of preventing future harm, and the possible burden on the defendant. In determining whether there should be an affirmative duty to warn a third party in the case of BRCA, the duty of care created by *Tarasoff* should be applied. The policy considerations weigh in favor of an affirmative duty to warn a third party, in this case where identifiable blood relatives are foreseeable victims, a special relationship exists, and future harm can be avoided.

i. Foreseeability

Foreseeability is a key component of liability in tort law—asking whether the harm that occurred was a foreseeable or predictable outcome. The concept of foreseeability is a focus in *Tarasoff*, and ultimately the court notes it is the most important consideration in the creation of a duty to warn.[61] Foreseeability is often utilized to limit liability in tort law by requiring either a

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[57] *Id.* at 341.
[58] *See*, *e.g.,* Mavroudis v. Superior Court, 102 Cal. App. 3d 594, 600 (1980) (noting victim must be identifiable by a "moments reflection"); Williams ex rel. Estate of Anderson v. Northville Reg'l Psychiatric Hosp., 1997 WL 33347863, at *3 (Mich. App. June 17, 1997).
[59] *See* Tarasoff v. The Regents of the Univ. of Cal., 551 P.2d 334, 362 (Cal. 1976).
[60] *See* Twerski, *supra* note 34, at 1017–18 (1983) ("[Cases] did not dismiss the old rules summarily, rather they thoroughly examined the reasons for the traditional rules and abandoned them only upon a determination that their underlying policies were no longer relevant . . . Yet the court observed that the classifications failed to reflect the factors germane to the imposition of liability in the contemporary setting. . . .").
[61] *See Tarasoff*, 551 P.2d at 342.

foreseeable victim[62] or a foreseeable type of harm.[63] In *Tarasoff*, the court considered whether the harm that was caused was foreseeable—ultimately finding that Ms. Tarasoff's harm was a foreseeable result of Mr. Poddar's actions and that the therapist was aware of the risk.[64] Ms. Tarasoff was not only a foreseeable victim, described in the case opinion as "readily identifiable"[65] but also incurred a foreseeable type of harm, as Mr. Poddar had disclosed his intent to murder her to his therapist.[66]

BRCA varies slightly from this, having no explicit foreseeable victim of violence at the hands of another. However, doctors and genetic counselors understand BRCA is inherited within a family, and the scientific probability of inheritance is well-established, making blood relatives a foreseeable "victim."[67] Additionally, the probability of developing breast cancer if an individual has the BRCA mutation is understood, and though capable of variation in stage and magnitude, the risk of cancer itself is a foreseeable type of harm in the case of BRCA.[68] *Tarasoff* created a duty to warn largely on the idea of foreseeability, understanding that where the impending harm is so apparent, we owe a duty to try and avoid that harm.[69] The incredible likelihood of harm falling upon Ms. Tarasoff and the ability of the therapist to alleviate some of that risk was determined to be enough consideration to develop an entirely new duty.[70] Applying an affirmative duty to third parties at risk of BRCA is a rational extension of the *Tarasoff* duty, as the foreseeability of possible inheritance and increased risk of cancer satisfy the same considerations as avoiding foreseeable harm.

While the original duty created by *Tarasoff* is limited to the mental health context,[71] courts have applied the idea of avoiding foreseeable harm in other healthcare contexts. One such example is with the risk of contagious disease and the imposition of a duty on health care providers to non-patients.[72] Courts have held that health care providers have a duty to a third party who is readily at risk of contracting the contagious disease that the patient has tested positive for.[73] Focused on the potential harm to the general population if the disease is transmitted, there is a similar obligation of avoiding the potential harm to others. Contagious diseases do not guarantee transmittance, but the risk is concern enough—as is the case for BRCA, where inheritance is

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[62] Palsgraf v. Long Is. R.R. Co., 248 N.Y. 339, 347 (N.Y. 1928) (finding no negligence where resulting harm to plaintiff was not a foreseeable result of defendant's action).
[63] Doe v. Manheimer, 563 A.2d 699, 706–07 (Conn. 1989) (finding no negligence where sexual assault was not a foreseeable outcome of the failure to trim overgrown bushes).
[64] *See Tarasoff*, 551 P.2d at 340 (finding negligence where the therapist could determine that his patient presents "serious danger of violence to another").
[65] *Id.* at 339.
[66] *Id.*
[67] *BRCA Mutations: Cancer Risk and Genetic Testing,* NAT'L CANCER INST. (Nov. 19, 2020), https://www.cancer.gov/about-cancer/causes-prevention/genetics/brca-fact-sheet.
[68] *See supra* note 7.
[69] *Tarasoff*, 551 P.2d at 342.
[70] *Id.* at 339.
[71] *Id.* at 340 (holding "[w]hen a *therapist* determines" (emphasis added)).
[72] *See, e.g.*, Skillings v. Allen, 173 N.W. 663, 664 (Minn. 1919) (finding that the physician owed a duty to the parents of minor daughter to warn of the contagious nature of the disease).
[73] *See, e.g., id.*; Shepard v. Redford Community Hospital, 390 N.W.2d 239, 241 (Mich. Ct. App. 1986) (finding that the doctor owed the third-party patient an affirmative duty to warn of the nature of the infection).

merely an increased likelihood of getting cancer and not a guarantee. This risk led to a duty in the case of *Reisner v. Regents of University of California*,[74] where a doctor was held to have a duty to warn the partner of a patient of the contagious nature of HIV.[75] Yet transmission rates of HIV for purposes of sexual acts between male and female vary between four to eight cases per 10,000 exposures,[76] far less likely than the probability of inheriting BRCA from a parent who has tested positive. The one-to-one transmission risk of BRCA via inheritance is no different than a communicable disease transfer via sexual intercourse, an area that has clearly established laws on duty to warn.[77] Further, existing law is not limited to cases where the risk of transmitting the disease is to the general population. While there is no public transmission risk inherent in BRCA as a genetically inherited trait, the harm resulting from a failure to warn is as foreseeable as the harm resulting from a contagious disease.

In a more modern case that addresses genetics, the court in *Safer v. Estate of Pack* found the risk associated with genetically inheritable diseases is not distinct from the risks associated with contagious diseases.[78] The court states, "[i]n terms of foreseeability especially, there is no essential difference between the type of genetic threat at issue here and the menace of infection, contagion, or a threat of physical harm."[79] The *Safer* court held where an individual or group at risk is easily identifiable and substantial future harm may be averted by a timely warning, the health care provider has an affirmative duty to warn.[80] Applying this standard to BRCA, while there is no public risk of transmission due to the non-contagious nature of the BRCA gene, the risk of harm to family members is still foreseeable.

Although not as explicit as the threat of violence in *Tarasoff*, the *Safer* court still found the risk of inheritance of the same cancer was sufficiently foreseeable.[81] Perhaps the risk of inheritability is not any less explicit than the statements of Mr. Poddar in *Tarasoff*; *i*n *Tarasoff*, it is merely the physician's medical judgment on whether the patient presents an actual danger, which requires some level of subjectivity and is not a guarantee. Further, the court in *Safer* found that the duty to warn results in saving lives, a benefit that outweighs the risk of unnecessary warnings.[82] In comparison, BRCA and the genetic disease at issue in *Safer* have objective, scientifically derived probabilities of inheritance—a clear, foreseeable risk.[83] This makes the blood relatives of a patient who has tested positive for the BRCA gene highly foreseeable. Following the same

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[74] 31 Cal. App. 4th 1195 (Cal. Ct. App. 1995).
[75] *Id.* at 1203–04.
[76] *HIV Risk Behaviors,* CTRS. DISEASE CONTROL & PREVENTION, https://www.cdc.gov/hiv/risk/estimates/riskbehaviors.html.
[77] *HIV and STD Criminal Laws,* CTRS. DISEASE CONTROL & PREVENTION, https://www.cdc.gov/hiv/policies/law/states/exposure.html.
[78] 677 A.2d 1188 (N.J. Super. App. Div. 1996).
[79] *Id.*
[80] *Id.* at 1192–93.
[81] *Id.* at 1193.
[82] *Id.* at 1193.
[83] *Breast Cancer Risk Factors: Genetics,* BREASTCANCER.ORG (Sept. 11, 2020, 10:28 AM), https://www.breastcancer.org/risk/factors/genetics.

foreseeability requirements set in *Tarasoff*[84] and *Safer*,[85] BRCA is a foreseeable risk. The expectation is not that breast cancer itself is guaranteed, but that there is a foreseeable risk of cancer development. In *Tarasoff*, the risk of murder, not the expectation that the murder would occur, was sufficient for the court to assert a duty.[86] Similarly, *Safer* found that the risk of developing the disease, as opposed to an affirmative showing of the disease, was enough to create a duty.[87] The substantial risk of inheriting the BRCA gene from a blood relative, and the associated risk of developing life-threatening breast cancer, is highly foreseeable. Applying what the *Tarasoff* court identified as the "most important" factor in creating a duty to warn third parties,[88] an affirmative duty to warn such relatives should exist.

ii. Special Relationship

An additional factor of consideration is whether there is a special relationship between the provider who has a duty and the third party. This factor acts as a limit to liability, similar to the foreseeability requirement. In *Tarasoff*, the court determined it need not decide whether foreseeability alone is enough due to the special relationship between patient and doctor.[89] However, there is little analysis of what makes that relationship special, merely that it satisfies the requirement.[90] The Restatement of Torts provides some additional guidance on what constitutes a special relationship for third-party duties, including parent-child relationships, custodian relationships, and mental-health professional-patient relationships, such as the one in *Tarasoff*.[91] It appears to focus on creating a duty only where one party within the special relationship poses a risk to a third party and the other individual in the special relationship has control over the party posing the risk.[92] For example, in a child-parent special relationship, a child poses a risk, and the parent is responsible and able to control the actions of the child. However, some states have adopted the special relationship rule to include the potential victims of contagious disease.[93] In those states, no additional analysis is required, as the state has already included this particular doctor-patient relationship within the special relationship definition.[94]

Since not all states have explicitly stated that genetic disease satisfies the special relationships standard, the relationship must be satisfied under an existing special relationship definition. Under the *Tarasoff* standard of doctor-patient, a relationship between a health care provider and patient in circumstances of BRCA testing would likely also satisfy the requirement of a special relationship. However, this relationship does not clearly comply if the relationship is limited to

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[84] *See* Tarasoff v. The Regents of the Univ. of Cal., 551 P.2d 334, 342 (Cal. 1976).
[85] *See Safer*, 677 A.2d at 1192.
[86] *See Tarasoff*, 551 P.2d at 346.
[87] *See Safer*, 677 A.2d at 1192.
[88] *Tarasoff*, 551 P.2d at 339.
[89] *Id.* at 343.
[90] *Id.*
[91] RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL AND EMOTIONAL HARM § 41 (AM. LAW INST. 2012).
[92] *Id.* ("[T]he relationships identified in this Section are ones in which the actor has some degree of control over the other person.").
[93] Vizzoni v. B.M.D., 212 A.3d 962 (N.J. Super. Ct. App. Div. 2019).
[94] *Id.*

mental health providers and patients as it is in the Restatement. The Restatement explicitly refers to situations where there is control of one party by another, an issue not facially apparent in the BRCA health care provider and patient relationship. However, upon review, the situation is not that different than the case of *Tarasoff*—the therapist was not expected to control Mr. Poddar but was obligated to warn Ms. Tarasoff.[95] Similarly, the health care provider in the context of BRCA is not expected to control the actions of the patient, but instead provide the patient's blood relatives a warning of their risk.

The relationship of doctor and patient may also fall into a separate special relationship definition, where an affirmative duty is created for the benefit of third persons. In *Tarasoff*, the court looked to the relationship between patient and doctor, as well as any relationship between the doctor and the third party.[96] The court suggested that such a relationship between doctor and patient may "support affirmative duties for the benefit of third persons."[97] The *Tarasoff* court referred to situations where a person is in a position "with regard to another . . . that if he did not use ordinary care and skill is his own conduct . . . he would cause danger of injury[.]"[98] In *Tarasoff*, the duty to warn provided a clear benefit to Ms. Tarasoff, [99] despite the patient not yet causing the harm. The doctor's failure to warn can cause harm—early identification of BRCA allows for far greater preventive measures and increased likelihood of survival.[100] The therapist in *Tarasoff* could not have satisfied that affirmative duty merely by warning Poddar not to do something, but rather needed to warn Ms. Tarasoff herself of the harm she was facing.[101] The clear opportunity to provide warning that would avoid the harm gave the basis for the duty to a third party. *Tarasoff* opened the door to the creation of a duty to a third party where the third party was clearly a beneficiary of that duty.[102]

An affirmative duty where there is a benefitting third party has been accepted in more modern cases as well, such as *Pate v. Threlkel*.[103] In this case, the court determined whether a doctor has an affirmative duty to a child where a patient has tested positive for a genetically transferable disease.[104] Finding that privity is not required where the duty is "obviously for the benefit of a certain identified third party," the court held that the doctor owed the child a duty of care.[105] The legacy of *Tarasoff* is seen in this case, where the court looks to the existence of a special relationship to justify expanding the duty to warn. The court in *Pate* focused not just on being a foreseeable, identifiable victim, but whether the victim is the actual, intended beneficiary of the

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[95] Tarasoff v. The Regents of the Univ. of Cal., 551 P.2d 334, 339 (Cal. 1976).
[96] *Id.*
[97] *Id.*
[98] *Id.* at 342 (quoting Heaven v. Pender, 11 Q.B.D. 503, 509 (1883)).
[99] *Id.* at 344 ("[B]y entering into a doctor-patient relationship the therapist becomes sufficiently involved to assume some responsibility for the safety . . . of any third person whom the doctor knows to be threatened by the patient.").
[100] *See supra* note 1.
[101] Tarasoff v. The Regents of the Univ. of Cal., 551 P.2d 334, 343 (Cal. 1976). ("Such a relationship may support affirmative duties *for the benefit of third persons*.") (emphasis added).
[102] *Id.*
[103] Pate v. Threlkel, 661 So. 2d 278, 279 (Fla. 1995).
[104] *Id.*
[105] *Id.* at 282.

standard of care.[106] The standard is set where the duty is "obviously developed for the benefit of the patient's children as well as the patient."[107]

Pate goes further than the relationships listed in the Restatement but applies the same considerations—custodian relationships have affirmative duties where a party has the opportunity to protect an individual outside of the relationship.[108] In *Pate*, while the doctor did not attempt to control the conduct of the party, the doctor's duty extended to the child who was the clear beneficiary of that warning.[109] This consideration is as prevalent in BRCA situations, where the blood relative of a patient who has tested positive is a clear beneficiary of a duty to warn. While there is no relationship between the doctor and the third party, the existing special relationship between doctor and patient expands to the relative. A blood relative, following the readily identifiable standard set in *Tarasoff*[110] and echoed in *Pate*,[111] is owed a duty of care by the doctor in circumstances where the duty is obviously for their benefit – such as those who are at high risk for the BRCA mutation. The creation of this duty does not rely on the explicitly listed special relationships identified in the Restatement of Torts, but it follows the idea that a duty may exist where there is some relationship between doctor and patient and clear benefit to the third party, regardless of privity or control of conduct.

B. Policy Considerations: Preventing Future Harm & Potential Burdens on Defendants

In addition to foreseeability and special relationships, courts analyze further policy considerations when considering the creation of a new duty.[112] Treated as a sort of balancing test, courts consider whether foreseeability and special relationships, which would otherwise justify a duty, should not create liability because of contrasting policy goals.[113] In *Tarasoff*, the court considers the additional policy goal of preventing future harm and the potential burden of liability on the defendant.[114]

The consideration of preventing future harm is discussed in two areas: first, how the issue at hand compares to the public health concerns of contagious diseases, and second, how a third party can be a clear beneficiary of the duty.[115] The goal of protecting the public is not unknown to the area of law, allowing for state action where there is a risk to public health.[116] Many states already require certain disclosures relating to public health, including doctors in situations of contagious diseases,[117] doctors who fail to communicate to their patient the transmissibility of

[106] *Id.* ("[P]revailing standard of care creates a duty that is obviously for the benefit of certain identified third parties and the physician knows of the existence of those third parties.").
[107] *Id.*
[108] *Supra* note 91.
[109] *Pate*, 661 So. 2d at 282.
[110] Tarasoff v. The Regents of the Univ. of Cal., 551 P.2d 334, 342 (Cal. 1976).
[111] *Pate*, 661 So. 2d at 103.
[112] *Tarasoff*, 551 P.2d at 342.
[113] *Id.*
[114] *Id.*
[115] *Id.* at 346 (asserting that courts "must weigh the public interest in safety from violent assault").
[116] *See, e.g.*, N.Y. Pub. Health Law § 2101 (McKinney 1966).
[117] *Id.*

conditions they have,[118] or in justifying state action otherwise not permissible.[119] As discussed *supra* Part II.A, the risk of breast cancer associated with BRCA and the risk of transmissibility of a contagious disease are not dissimilar. The creation of an affirmative duty in the context of BRCA satisfies similar policy goals of preventing harm to the public and is an area where state action can be appropriate.

Modern cases that consider genetic testing echo the second policy consideration, finding a duty to warn where there is a clear beneficiary to that duty.[120] In *Pate,* the court held that there is an affirmative duty to warn a third party for this exact reason, stating "[w]e conclude that when the prevailing standard of care creates a duty that is obviously for the benefit of certain identified third parties . . . then the physician's duty runs to those third parties."[121] Similarly, in the case of *Safer*, the court focused on the "substantial future harm that may be averted or minimized by a timely and effective warning."[122] The court overturned the lower court's decision, emphasizing that there was not enough focus on the fact that "early monitoring of those at risk can effectively avert some of the more serious consequences," and that such a narrow application can "serve the interests of justice."[123] The idea of a clear beneficiary seems to be limited to cases where the actual harm can in some way be impacted—notably like the situation in BRCA, where a timely warning provides far greater preventative options.

The focus on minimizing harm with warnings may be due in part to the uniqueness of the healthcare field. Where patients rely on a doctor's expertise for health and the doctor's unique position to influence the decision-making of a patient, a warning goes a long way. This idea is reflected in creating unique causes of action specific to the medical context, such as informed consent,[124] and the duty to warn in *Tarasoff*, which limited the holding to those in the mental health field.[125] In an incredibly complex field like genetics, courts appear to consider that it is well within the expectation of and benefit to the public that our health care providers would provide us with the information we need to protect ourselves from harm.[126] Imposing a new affirmative duty to warn is not outside the already existing expectations of doctors in genetics, as it merely applies the public policy consideration of preventing harm in a very specific context.

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[118] *See*, *e.g.*, DiMarco v. Lynch Homes-Chester Cty., Inc., 525 Pa. 558, 564 (Pa. 1990) (holding that a doctor owes a duty to a third party where they are at risk of a communicable disease from the patient).
[119] *See, e.g.*, Douglas Cty. v. Anaya, 694 N.W.2d 601 (Neb. 2005) (holding mandatory newborn screening constitutional despite interference with religious values, where "the state has an interest in the health and welfare of all children born in Nebraska").
[120] *See, e.g.*, *Pate*, 661 So. 2d at 281.
[121] *Id.* at 282.
[122] Safer v. Estate of Pack, 677 A.2d 1188, 1192 (N.J. Super. Ct. App. Div. 1996).
[123] *Id.*
[124] *Code of Medical Ethics Opinion 2.1.1*, AM. MED. ASS'N, https://www.ama-assn.org/delivering-care/ethics/informed-consent.
[125] *See* Tarasoff v. The Regents of the Univ. of Cal., 551 P.2d 334, 334 (Cal. 1976).
[126] Gary E. Marchant & Rachel A. Lindor, *Genomic Malpractice: An Emerging Tide or Gentle Ripple?*, 73 GEO. FOOD & DRUG L. J. 1, 16 (2018) (discussing an uptick in genetic malpractice cases reflects new expectations of health care providers with respect to genetic disease).

As an additional comparison to contagious disease, the goal of a duty to warn is to prevent public harm associated with transmission. A preventive warning, like what exists for contagious diseases, can stop the inheritance of the gene; individuals who test positive for the mutation may choose to not have children or may use assisted reproductive methods to ensure the embryo implanted does not have the gene.[127] Should the mutation be inherited, there still remain countless ways to abate the harm associated. Consistent with creating a legal duty with respect to contagious diseases is the idea that when a health care provider warns others, the contagious disease will not be spread, as individuals are enabled to take actions that can prevent harm to others.[128] This is not unlike the duty proposed by this Article for BRCA; while you cannot prevent the disease itself, it is equally foreseeable that some harm will arise from transmission and there are actionable steps to prevent the resulting breast cancer or mitigate its consequences. In the genetic context, the application is limited to situations where the blood relative can take preventative steps. As the court held in *Safer*, there is a duty only in situations where there is an avertible risk.[129] The affirmative duty to warn proposed by this Article applies only to blood relatives where a patient has already tested positive for BRCA, a mutation that has clear action items that can be taken to avoid the greatest harm from the mutation. BRCA aligns with the public health policy goals as a genetic condition that can abate the harm through countless preventive measures that lead to a higher likelihood of survival.

Weighed against the public harm that is prevented, a second policy consideration is whether the potential burden on doctors is too great. In *Tarasoff,* the court acknowledges that while there are additional burdens on mental health providers as a potential consequence, the court is prioritizing the goal of public safety.[130] This burden is a consideration in the two modern cases focused on genetic disease as well. In *Pate*, the court also held an affirmative duty to warn, but limited the requirements to fulfill that duty.[131] *Pate* suggested that while there is a duty, it is satisfied by warning the patient, rather than an explicit duty to warn family members.[132] The requirement to warn the third party is held to be too "difficult or impractical and would place too heavy a burden upon the physician."[133] In contrast, the court in *Safer* explicitly disagreed, declining to follow the decision that merely warning the patient is enough.[134] Both modern cases agree the policy goal of preventing harm outweighs the concerns; however, they address the potential burden differently by limiting the requirements to fulfill the duty.

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[127] Irina Zhorov, *Genetic Tests Help Parents Avoid Passing on Serious Diseases*, WHYY (Jan. 26, 2017), https://whyy.org/segments/genetic-tests-help-parents-avoid-passing-on-serious-diseases/.
[128] *DiMarco*, 525 Pa. at 562 ("Communicable diseases are so named because they are readily spread from person to person. Physicians are the first line of defense against the spread of communicable diseases because physicians know what measures must be taken to prevent the infection of others.").
[129] Safer v. Estate of Pack, 677 A.2d 1188, 1192 (N.J. Super. Ct. App. Div. 1996).
[130] *Tarasoff*, 551 P.2d at 347 ("In this risk-infested society we can hardly tolerate the further exposure to danger . . . If the exercise of reasonable care . . . requires the therapist to warn the endangered party . . . we see no sufficient societal interest that would protect and justify concealment.").
[131] *Pate*, 661 So. 2d at 282
[132] *Id.*
[133] *Id.*
[134] *Safer*, 677 A.2d at 1192 ("We decline to hold as the Florida Supreme Court did . . . that, in all circumstances, the duty to warn will be satisfied by informing the patient.").

However, the difference in approach may be due to the varying laws on patient confidentiality that existed in each state at the time. The *Pate* case occurred in Florida, where a statute existed that prohibited physicians from disclosing a patients' medical information.[135] Perhaps the more limited duty requirements allowed the court to acknowledge the benefits associated with such a warning, while remaining in accordance with existing law. It is difficult to know whether the court might have held differently without the statute; though notably the court states that "to require the physician to seek out and warn various members of the patient's family would . . . place too heavy a burden upon the physician."[136]

Safer, which occurred in New Jersey and was unburdened by such a statute, had far greater flexibility in creating a duty that required communication beyond just the patient. With that flexibility, the court explicitly chose to state, "we decline to hold as the . . . Court did in *Pate* . . . that, in all circumstances, the duty to warn will be satisfied by informing the patient."[137] Expanding beyond the limited application of *Safer*, *Pate* acknowledges that there may be circumstances where the patient has expressed that nothing be said to family; the very information gap this Article seeks to address.[138] The burden to health care providers is still taken into consideration, and the court refrained from requiring more than "reasonable steps be taken to assure that the information reaches those likely to be affected or is made available for their benefit."[139] The idea of reasonable steps is in some ways aligned with the *Tarasoff* decision itself, holding merely that steps must be taken pursuant to the standards of the profession.[140] This does not inherently eliminate any burden to health care providers but enables states to set their own requirements to satisfy the duty, aligned with the policy considerations, existing laws, and social norms within their area.

Unbridled by state legislation that requires patient confidentiality, the courts appear to prioritize the benefits over the risks that arise when warning a third party. Unable to guess whether Florida would have decided differently had the statute not existed, one can only look to the many comments on prioritizing public safety and avoiding potential harm when the opportunity arises.[141] Best stated in the *Safer* opinion, "[a]lthough an overly broad and general application of the physicians duty to warn might lead to confusion, conflict, or unfairness . . . we are confident that the duty to warn of avertible risk from genetic causes, by definition a matter of familial concern, is sufficiently narrow to serve the interests of justice."[142] The benefits associated with an affirmative duty to warn of the genetic risk outweigh the potential consequences of such a duty.

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[135] *Pate*, 661 So. 2d at 282 (quoting FLA. STAT. § 433.241(2) (1989) ("In most instances the physician is prohibited from disclosing the patient's medical condition to others except with the patient's permission.")).
[136] *Id.*
[137] *Safer*, 677 A.2d at 1192.
[138] *Id.*
[139] *Id.*
[140] Tarasoff v. The Regents of the Univ. of Cal., 551 P.2d 334, 353 (Cal. 1976).
[141] *See, e.g., id.* at 346; *Safer*, 677 A.2d at 1192.
[142] *Id.*

III. An Affirmative Duty to Warn Identifiable Blood Relatives When a Patient Has Tested Positive for BRCA

An affirmative duty to warn identifiable blood relatives where a patient has tested positive for BRCA is consistent with the balancing of policy considerations put forth by *Tarasoff*, *Pate*, and *Safer*. Warning only identifiable blood relatives limits the burden on doctors while promoting the public good of preventing future harm. The countless preventative measures that can be taken for BRCA and the resulting substantially increased likelihood of survival fulfill the foreseeability requirement and the goal of preventing public harm. Lastly, a special relationship exists between patient and health care provider, and despite a lack of privity, the third party would be a clear beneficiary of the duty, as access to the information allows them to decide whether to get tested.

Though an affirmative duty is consistent with policy goals, genetic testing creates unique considerations with respect to doctor-patient confidentiality, familial relations, and discrimination. These issues do not prohibit an affirmative duty, but they do require analysis to be compliant with existing law.

A. Confidentiality

An affirmative duty to warn a third party exists where the patient refuses to share the information, thus requiring a breach of confidentiality. While the ideal scenario is that the patient ultimately informs family members, an ethical question arises when the patient is starkly opposed to doing so. A duty to warn would create liability even in situations where the patient has not given consent, thus requiring the provider to break doctor-patient confidentiality.

The doctor-patient confidentiality doctrine is a staple in the field of medicine but perhaps is a requirement that many in the public take for granted as a guarantee.[143] Today, most view the requirement as essential to maintaining trust and encouraging individuals to be honest and open with their health care providers.[144] However, what many may not understand is that despite the oath and the essential nature of the doctrine, the requirement has never quite been absolute. Historically, family was an exception to the requirement of complete confidentiality,[145] and additional exceptions have been imposed over time, including the limitations imposed in *Tarasoff*.[146] While an affirmative duty may cause a breach of confidentiality in limited circumstances, this is not inconsistent with current exceptions in the field of medicine.

[143] Gerald L. Higgins, *The History of Confidentiality in Medicine: The Physician-Patient Relationship*, 35 CAN. FAM. PHYSICIAN 921 (Apr. 1989).
[144] Lisa Soleymani Lehmann et al., *Disclosure of Familial Genetic Information: Perceptions of the Duty to Inform*, 109 AM. J. MED. 705 (2000).
[145] *See* Higgins *supra* note 143, at 922.
[146] *Tarasoff,* 551 P.2d at 345.

i. Policy Justifications for Breach of Confidentiality

Confidentiality concerns balance a need for trust and open communication with health care providers with a need to prevent harm. In *Tarasoff*, the court focused on the importance of "free and open communication" in psychotherapy, and the defendants argued that if there was a duty to warn third parties, patients would be reluctant to share information, thereby limiting providers' ability to fully and accurately diagnose.[147] The court recognized that the "public [has an] interest in supporting effective treatment of mental illness and in protecting the rights of patients;"[148] however, it ultimately found the public interest in safety outweighs the potential confidentiality concerns.[149] One reason for this is that there already existed a legislative limit on the confidentiality privilege.[150] When the therapist believes the patient to be at risk of harm to himself or another and that sharing this information is necessary to prevent harm, confidentiality may be breached.[151] In addition to the legislative requirement, the court noted that professional ethics provide a comparable exception, stating one cannot breach confidentiality "unless he is required to do so by law or unless it becomes necessary in order to protect the welfare of the individual or of the community."[152]

The breach of confidentiality to fulfill a duty to warn is similarly aligned with existing exceptions to absolute confidentiality. First, there are existing duties to disclose without patient consent, such as with contagious diseases, as discussed in Part III. Second, like in psychotherapy, professional ethics organizations have provided guidelines for when a health care provider may breach confidentiality in situations of genetic risk.[153] The American Society of Human Genetics provides that disclosure that breaches confidentiality may be allowed where (1) attempts to encourage disclosure by the patient has failed, (2) the harm is likely to occur, foreseeable, and serious, and (3) the disease is preventable or treatable, or early monitoring will reduce the genetic risk.[154] Further refinement of this statement has occurred, adding factors such as whether those at risk are identifiable, penetrance levels, age of onset, and others.[155] A duty to warn for BRCA patients would be consistent with each of the previously mentioned considerations. The duty to warn would apply only in circumstances where the patient is unwilling to share the information; the harm in not knowing one's status, which limits preventive measures that can be taken and reduces the likelihood of survival, is foreseeable; and early monitoring will reduce the genetic risk. The duty to warn does not breach confidentiality beyond

[147] *Id.* at 346.
[148] *Id.*
[149] *Id.*
[150] *See* CAL. EVID. CODE § 1024 (West 1967) ("There is no privilege … if the psychotherapist has reasonable cause to believe that the patient is in such mental or emotional condition as to be dangerous to himself or to the person … and that disclosure of the communication is necessary to prevent the threatened danger.").
[151] *Tarasoff,* 551 P.2d. at 347.
[152] *Id.*
[153] *Professional Disclosure of Familial Genetic Information*, AM. J. HUM. GENETICS 62, 474–83 (1998).
[154] *Id*. at 474.
[155] Courtney Storm et al., *Ethical and Legal Implications of Cancer Genetic Testing: Do Physicians Have a Duty to Warn Patients' Relatives About Possible Genetic Risks?*, 4 J. ONCOLOGY PRAC. 229 (2008).

what is already allowed by the standards of the profession; applying the ethical considerations put forth by the American Society of Human Genetics is the professional standard.[156]

ii. Federal Law Considerations

A breach of confidentiality is also potentially limited by the existing federal privacy law of the Health Insurance Portability and Accountability Act (HIPAA).[157] HIPAA prohibits providers from sharing patient information without consent, subject to the exceptions listed in the statute.[158] These exceptions allow for sharing patient information in many instances, such as when required by law to public health authorities in instances of contagious disease or child abuse, among others.[159] Relevant to the proposed duty at hand, however, HIPAA also provides an exception for disclosures to "avert a serious threat to health or safety."[160] Permitted disclosures are allowed where the health care provider believes disclosure is (1) necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public and (2) is to a person or persons reasonably able to prevent or lessen the threat.[161]

It is unclear whether the HIPAA exception that allows for disclosure pursuant to the law would be satisfied by a common law creation of a duty to warn, such as the one proposed here. On its face, it is unlikely based on the preemption rule within the statute, stating that state law is preempted if it is less stringent than HIPAA requires.[162] However, BRCA may fall within the second exception allowed within HIPAA: to avert a threat to health.[163] As discussed, the risks associated with BRCA for an individual with a family history of the genetic mutation are a substantially increased likelihood of developing breast cancer, a risk well above that of the general population.[164] While clearly a serious threat, the question remains on whether the threat is "imminent," as required by the statute. There is no clear definition within the statute itself, and while commentary is provided that reflects a situation very similar to that of *Tarasoff*, it does not further define imminent.[165] Imminency may be defined in the context of the need to address it—here via preventive measures. If so, BRCA would satisfy the exception limitations, as it would be serious, imminent, and avertible.

The disclosure of genetic information may also fall under the treatment exception of HIPAA, which allows for the disclosure of health information for treatment purposes without consent or

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[156] Code of Ethics, AM. SOC'Y HUM. GENETICS (May 2019), https://www.ashg.org/about/code-of-ethics/ (showing the extensive use of the American Society of Human Genetics Ethical Code).
[157] *What Life Was Like Before HIPAA and How It Changed the Healthcare Industry*, PDFFILLER BLOG (2018), https://blog.pdffiller.com/life-like-hipaa-changed-healthcare-industry/.
[158] 45 C.F.R. § 165.512.
[159] *Id.*
[160] 45 C.F.R. § 164.512(j).
[161] *Id.*
[162] 45 C.F.R. § 160.203.
[163] 45 C.F.R. § 164.512(j).
[164] *See supra* note 19.
[165] HIPAA FAQ No. 502, Created 11/25/2008, https://www.hhs.gov/hipaa/for-professionals/faq/520/does-hipaa-permit-a-health-care-provider-to-disclose-information-if-the-patient-is-a-danger/index.html.

authorization.[166] Though this exception likely covers communication within health care providers and other healthcare industry individuals, there is some question of whether communicating to families at risk would equally satisfy the exception.[167] An interpretation of the rule by the Office for Civil Rights of HHS, stated "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," though with a limitation that the patient has not already refused to give consent.[168] Perhaps then, the proposed duty could be satisfied by warning the health care provider of the BRCA positive patient's relatives, rather than a requirement for the provider to communicate directly to the family member themselves.

Patient confidentiality is one of the most substantial concerns at issue for the proposal put forth by this Article. However, the duty proposed contains flexibility for states to set requirements on how to fulfill the duty within the existing legal limitations.

B. Familial Relations

A second unique aspect of BRCA is that the third party at issue will exclusively be blood relatives of the patient. This is in stark contrast to the situation in *Tarasoff*, where an individual was threatening to harm an unrelated young woman who he had developed an interest in.[169] Instead, the idea of creating a duty for genetic disease is due to the inheritable nature of the issue, stated in *Safer* as "by definition a matter of familial concern."[170] The complexities of family dynamics were not directly addressed in either *Safer* or *Pate*, as family dynamics were not within the facts of either case. However, *Safer* briefly addressed the possibility of varying family wishes. The court held that it may be necessary to go beyond just informing the patient when there is a conflict between the duty to warn and the patient's expressed wishes are that nothing is communicated to family.[171]

Today, there is little additional guidance on whether or not the consideration of family dynamics should be a limitation on finding a duty. Medical associations ponder the question, with the American Medical Association Journal of Ethics providing "Virtual Mentor" articles that propose the issue,[172] studies that consider both public perspective and health care providers perspectives on the issue,[173] and other alternatives to attempt to come to one view or standard.

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[166] 45 C.F.R. § 164.506.
[167] *Id.*
[168] Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under the Health Information Technology and Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules; Final Rule, 78 Fed. Reg. 5566-5702, 5668 (proposed Jan. 25, 2013) (to be codified at 45 C.F.R. pt. 160 and 164).
[169] Tarasoff v. The Regents of the Univ. of Cal., 551 P.2d 334, 341 (Cal. 1976).
[170] Safer v. Estate of Pack, 677 A.2d 1188, 1192 (N.J. Super. Ct. App. Div. 1996).
[171] *Id.* at 1192–93.
[172] Anne-Marie Laberge & Wylie Burke, *Duty to Warn At-Risk Family Members of Genetic Disease*, 11 AM. MED. ASS'N J. ETHICS 656–60 (2009).
[173] Lisa Soleymani Lehman et al., *Disclosure of Familial Genetic Information: Perceptions of the Duty to Inform*, 109 AM. J. MED. 705–11, (2000); Sandi Dheensa et al., *Health-Care Professionals' Responsibility to Patients'*

The issue is not merely hypothetical either, with countless stories considered of how family dynamics have interfered with a patient's choice to share their status. Stories such as a woman who shared her BRCA status with her two adult daughters, only to have them not speak to her for two years, a family that forbade telling an unmarried sister her BRCA status for fear she will be "less marriageable," or conversations of "dismal relationship[s]."[174] Yet the issue of BRCA may be one where the likelihood of survival is worth the potential family consequences, with one genetic counselor stating her worst nightmare is where a patient tests positive and doesn't share her status, only to have her sister have cancer later. Her concern was the sister would "find out that there was this information showing she was at risk. And maybe . . . sue me, saying I should have picked up the phone and told her. . . . This is all so new, and there are no clear guidelines."[175]

Family dynamics represent a unique concern; however, it is still aligned with the overarching policy goals that courts have prioritized. Further, without these family complexities, there would be no need for an affirmative duty—as patients would share the necessary information themselves. Though burdens and consequences must be considered, the policy goal of preventing public harm outweighs the existing consequences. The ability to enable individuals to make their own medical choices on the basis of accurate information, preventing future cancer and, in some cases, future premature death, is sufficient to justify an affirmative duty.

C. Discrimination

Discrimination is another concern unique to genetic disease that was not addressed in *Tarasoff*. Here, despite some protection from discrimination under federal laws such as the Genetic Information Nondisclosure Act (GINA), there remain areas that allow discrimination on the basis of one's genetic status.[176] Currently, while banned in the context of employment and health insurance, discrimination remains legal in long-term care insurance, life insurance, and accident insurance.[177] These protections do not begin to cover non-medical discrimination in areas such as housing, schooling, or mortgage lending.[178] This Article does not propose required testing for any family member, merely a warning that the individual may be at risk. However, providing an individual with the knowledge of their risk is largely for the purpose of encouraging testing, and it cannot go unmentioned that there remain risks associated with knowing your own genetic status. Of note, Florida passed a new bill in July of 2020 that prohibits genetic discrimination in

Relatives in Genetic Medicine: A Systematic Review and Synthesis of Empirical Research, GENETICS MED. 18, 290 (2016).

[174] Tamar Lewin, *Boom in Gene Testing Raises Questions on Sharing Results*, THE N.Y. TIMES (July 21, 2000), https://archive.nytimes.com/www.nytimes.com/library/national/science/072100sci-gene-family.html.

[175] *Id*.

[176] *What is Genetic Discrimination?*, NAT'L INST. HEALTH, (Sept. 21, 2020), https://ghr.nlm.nih.gov/primer/testing/discrimination.

[177] *Id*.

[178] Sarah Zhang, *The Loopholes in the Law Prohibiting Genetic Discrimination*, THE ATLANTIC (Mar. 13, 2017), https://www.theatlantic.com/health/archive/2017/03/genetic-discrimination-law-gina/519216/.

life insurance and long-term health insurance.[179] The law would prohibit insurers from canceling, limiting, or denying coverage on the basis of genetics.[180] This removes one major risk associated with knowing one's risk status, and may set an example for other states to follow.

This proposal suggests that state judiciaries should find a common law duty for health care providers, subject to the standards of their profession, to warn identifiable blood relatives of patients who have tested positive for the BRCA gene mutation. The proposal does not require patient's family members to be tested, but merely requires a communication to them of the nature of the BRCA genetic mutation, its inheritability characteristics, and the associated risks of cancer. This Article does not propose exactly how that duty is satisfied, as it is left to the state to regulate in consideration of their own policy and current law. However, it does follow the standard as put forth by *Safer* that communication to the patient alone does not satisfy the duty.[181] Further, while this proposal speaks to "identifiable" family members, it does not contend to explicitly define identifiable; it proposes an initial duty only where a health care provider is the provider for multiple members of the same family. This limitation would eliminate concerns of an overly burdensome requirement on providers, as well as some of the confidentiality concerns. States may further expand this duty as they see fit, however within the current limitations of the laws on confidentiality, it is best left to states to regulate.

Conclusion

The identification of the BRCA gene mutation and the associated risk of developing breast cancer was an incredible development for the scientific community. Knowing one's BRCA status enables individuals to take preventive measures that not only greatly decrease the likelihood of developing cancer at all, but also allows individuals who do develop cancer to have more effective treatment, earlier detection, and a higher survival rate. When family dynamics control the ability of an individual to know their own risk, individuals are limited in taking control of their own health. The requirement of health care providers to affirmatively warn identifiable blood relatives of patients who have tested positive for the BRCA gene would eliminate the obstacles women face in knowing their status and allow for the autonomy deserved in addressing any risks they may face.

[179] John Haughey, *Florida Becomes First State to Enact DNA Privacy Law, Blocking Insurers from Genetic Data*, THE CTR. SQUARE (July 1, 2020), https://www.thecentersquare.com/florida/florida-becomes-first-state-to-enact-dna-privacy-law-blocking-insurers-from-genetic-data/article_19acb7fc-bbe2-11ea-a88d-bf2dbe8939af.html.
[180] *Id.*
[181] Safer v. Estate of Pack, 677 A.2d 1188, 1192 (N.J. Super. Ct. App. Div. 1996).