

# PREVIVORS

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## ABSTRACT

*Individuals who are not yet sick, but who have a genetic predisposition to disease, often identify as “previvors”: a combination of the terms “predisposition” and “survivor.” The previvor experience challenges many of the traditional expectations related to the provision of medical care and individual decision making. This article is the first to define the term “previvor” for the legal literature and the first to examine the role of law in previvor decision making. In essence, this project uses previvorship as a case study to demonstrate how the practice of medicine and medical decision making is evolving to render current law and policy increasingly inapplicable to modern medical practice. It concludes that the legal doctrine of informed consent is inappropriate to ensure adequate medical decision making, as exemplified by the previvor experience. The doctrine’s overemphasis on risk-based disclosures and its failure to address medical uncertainty is representative of the hazards of relying on the biomedical model of disease. Rather, we should begin to envision a legal doctrine that supports a robust shared decision-making approach to truly address individual preferences and values, the increasing complexity of risk/benefit assessment, and inherent (and sometimes irreducible) uncertainty.*

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## INTRODUCTION

In 2000, on a message board on the website of Facing Our Risk of Cancer Empowered (FORCE), a regular contributor posted the following message: “I need a label!” In response, FORCE, an advocacy group dedicated to supporting individuals and families affected by hereditary breast and ovarian cancer, coined the term “previvor.”<sup>2</sup> Seven years later, the term made *Time* magazine’s top ten buzzwords list.<sup>3</sup> And in 2013, the actress Angelina Jolie used her fame to bring attention to her decision to undergo a prophylactic double mastectomy, after she received results from a “blood test” that informed her that she was “highly susceptible to breast and ovarian cancer,” so that she could “then take action.”<sup>4</sup> Research suggests that this announcement

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2. Sue Friedman, *What A Difference A Decade Makes*, FORCE BLOG (Sept. 30, 2010), <https://www.facingourrisk.org/understanding-brca-and-hboc/information/previvors-survivors/cancer-previvors/#:~:text=The%20cancer%20previvor%20term%20evolved,identify%20those%20living%20with%20risk> [https://perma.cc/SZ2Y-CG2C].

3. Gilbert Cruz, *Top 10 Buzzwords*, TIME (Dec. 9, 2007), [http://content.time.com/time/specials/2007/article/0,28804,1686204\\_1686303\\_1690345,00.html](http://content.time.com/time/specials/2007/article/0,28804,1686204_1686303_1690345,00.html) [https://perma.cc/49NM-MVVK] (“A person who does not have cancer, but has precancerous cells or a genetic mutation known to increase the risk of developing it: a pre-survivor”).

4. Angelina Jolie, *My Medical Choice*, N.Y. TIMES (May 14, 2013), <https://www.nytimes.com/2013/05/14/opinion/my-medical-choice.html> [https://perma.cc/SA5A-P3HB].

motivated women to get tested for BRCA mutations,<sup>5</sup> a concept branded the “Angelina effect.”<sup>6</sup>

Today, genetic testing for disease predisposition is almost ubiquitous, particularly for certain cancers. For example, there is a high incidence of mutations in the BRCA genes for individuals of Ashkenazic Jewish descent, which may predispose those with the mutation to a significantly higher risk of breast, ovarian, and other cancers than in the general population. Support networks, research endeavors, and other organizations have proliferated in response to the increasing number of individuals being tested for BRCA mutations.<sup>7</sup> Genetic testing extends beyond BRCA to other hereditary cancer syndromes, including Lynch Syndrome, Cowden Syndrome, Li-Fraumeni Syndrome, CDH1 mutations, and multiple endocrine neoplasia type 2,<sup>8</sup> as well as hereditary diseases besides cancer, such as Alzheimer’s Disease<sup>9</sup> and Huntington’s Disease.

This article introduces the concept of the previvor to the legal literature, in order to evaluate the applicability of existing law to modern medical decision making. In doing so, it evaluates the current popular understanding of the term. Currently, many who test positive for genetic variants in the BRCA gene but who have not been diagnosed with breast or ovarian cancer identify as previvors. However, the application of the term “previvor” is needlessly exclusive, thereby exacerbating existing disparities.

In essence, this project uses previvorship as a case study to demonstrate how the practice of medicine and medical decision making is evolving, making current law and policy increasingly less applicable to modern medical practice. It concludes that the legal doctrine of informed consent is inappropriate to handling medical decision making, as exemplified by the previvor experience. The legal doctrine of informed consent’s overemphasis on risk-based disclosures, at the

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5. Kami A. Kosenko, Andrew R. Binder, & Ryan Hurley, *Celebrity Influence and Identification: A Test of the Angelina Effect*, 21(3) J. HEALTH COMM. 318 (2016).

6. This term was coined by Time Magazine in a cover story after Jolie’s announcement. Jeffrey Kluger & Alice Park, *The Angelina Effect*, TIME, May 27, 2013. Researchers found that “A celebrity like Angelina Jolie announcing her decision to have a surgical procedure to prevent future cancer may have, to a larger extent, influenced these women facing a degree of uncertainty about future breast cancer risk to proceed more aggressively towards prophylactic surgery.” Alexander Liede, Mona Cai, Tamara Fidler Crouter, Daniela Niepel, Fiona Callaghan, & D. Gareth Evans, *Risk-Reducing Mastectomy Rates in the U.S.: A Closer Examination of the Angelina Effect*, 171 BREAST CANCER RESEARCH & TREATMENT 435, 441 (2018).

7. See, e.g., FORCE, [www.facingourrisk.org](http://www.facingourrisk.org); SHARSHERET, <https://sharsheret.org/brcagenetics/> [<https://perma.cc/M3SB-45N8>].

8. And the list continues to grow.

9. For example, an individual may receive genetic testing results indicating that he or she has an increased risk of developing late-onset Alzheimer’s Disease, due to the presence of an APOE mutation. *APOE gene*, MEDLINE PLUS GENETICS, <https://ghr.nlm.nih.gov/gene/APOE> (Mar. 29, 2021).

expense of a more holistic approach to medical decision making, is representative of the hazards of overreliance on the biomedical model of disease. Rather, we should begin to envision a legal doctrine that supports a robust shared decision-making approach to truly address individual preferences and values, the increasing complexity of risk/benefit assessment, and inherent (and sometimes irreducible) uncertainty.

Thus, this article proceeds as follows: Section I examines the role of the previvor within the greater context of the provision of medical care and individual decision making. It offers a working definition of the term “previvor” for the legal literature,<sup>10</sup> one that—unlike the one commonly offered in the popular media—does not categorically exclude individuals with a predisposition to illnesses other than hereditary breast and ovarian cancers. Rather, it proposes a definition that aligns with conceptions of medical and legal justice and includes all individuals with a hereditary mutation, a family history of a specific disease, or some other predisposing factor, that is clinically actionable. The article then addresses previvor identity and how previvor decision making compares to the traditional model of patient decision making, particularly as it relates to risk and uncertainty. It determines that the previvor experience may exacerbate uncertainty in significant ways. Section I concludes with an analysis of the previvor’s relationship with health care providers, addressing important distinctions from the traditional doctor-patient relationship.

Based on this understanding of the role of the previvor, Section II concludes that the existing legal doctrine of informed consent is mismatched with modern medical circumstances.<sup>11</sup> The current model for

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10. While there is some consensus as to the definition of “previvor,” scholars, policy makers, physicians, and patient advocates have presented various conceptions of the term. Despite the number of individuals who currently identify as a “previvor,” a Westlaw search for the term “previvor” returns only two secondary sources. Brittany Ann Heitz, *Introduction: Medical and Legal Advances in Fertility Preservation*, 61 DEPAUL L. REV. 757 (2012); Kelli Swan & Jaellah S. Thalberg, *Cracking the DNA Code: Genetic Testing Case Examples of Interest to Elder Law and Special Needs Planning Attorneys*, 11 NAELA J. 103 (2015) (most recent search on Sept. 4, 2020). Many scholars have considered—and in some cases, argued for a reconceptualization of— informed consent to genetic testing. However, these arguments are often focused on the role of informed consent to the actual testing process, rather than the subsequent post-testing medical decision making. *See, e.g.*, Elizabeth B. Cooper, *Testing for Genetic Traits: the Need for a New Legal Doctrine of Informed Consent*, 58 MARYLAND L. REV. 346 (1999).

11. This Article is not intended to address informed consent in the decision to pursue genetic testing, but rather it focuses on the decisions made *after* testing has occurred. There is a significant amount of literature devoted to informed consent for genetic testing. *See, e.g.*, Gail Geller, Barbara A. Bernhardt, Kathy Helzlsouer, Neil A. Holtzman, Michael Stefanek, & Patti M. Wilcox, *Informed Consent and BRCA1 Testing*, 11 NATURE GENETICS 364 (1995); Gail Geller, Jeffrey R. Botkin, Michael J. Green, Nancy Press, Barbara B. Biesecker, Benjamin Wilfond, Generosa Grana, Mary B. Daly, Katherine Schneider, & Mary Jo Ellis Kahn, *Genetic Testing for Susceptibility to Adult-Onset Cancer: The Process and Content of Informed Consent*, 277(18) J. AM. MED. ASSOC. 1467 (1997); Onora O’Neill, *Informed Consent and Genetic Information*, 32(4) STUDIES IN HISTORY AND PHILOSOPHY OF SCIENCE PART C:

informed consent is already ill-suited to encouraging disclosure of, or coping with, uncertainty. Previvorship challenges some of the most basic assumptions about the legal doctrine of informed consent. Because of the unique levels of uncertainty and special considerations of risk inherent to the previvor experience, the contours of the legal doctrine of informed consent may be inadequate to ensure individual self-determination in medical decision making.

Finally, relying on the example of previvorship, Section III suggests a shift to a more robust shared decision-making approach. It concludes with lessons learned from the previvor experience for medical decision making and application of the biomedical model of illness generally.

## I. THE PREVIVOR

The previvor experience challenges many of the expectations of the traditional patient role. This section will first offer a working definition of the term “previvor” for the legal literature that is compatible with conceptions of medical and legal justice. In Part I.B, it will examine the previvor identity: what it means to be a previvor, and why it matters. The Article will then address how previvor decision making compares to the traditional model of patient decision making, particularly as it relates to risk and uncertainty. Part I.D addresses the previvor’s relationship with physicians, both situating it within and distinguishing it from the traditional doctor-patient relationship.

### A. Defining “Previvor”

In the popular and medical literature, the term “previvor” is almost exclusively limited to individuals with a mutation in the BRCA genes.<sup>12</sup> Mutations in the BRCA1 or BRCA2 genes confer an elevated risk of breast, ovarian, and other cancers.<sup>13</sup> However, there are many

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STUDIES IN HISTORY AND PHILOSOPHY OF BIOLOGICAL AND BIOMEDICAL SCIENCES 689 (2001); Cooper, *supra* note 11; Sharon C. Zehe, *Genetic Testing: Legal and Ethical Issues and Duties for Providers*, 7 J. HEALTH & LIFE SCIENCES L. 92 (2014); Kayte Spector-Bagdady, Anya E.R. Prince, Joon-Ho Yu, & Paul S. Appelbaum, *Analysis of State Laws on Informed Consent for Clinical Genetic Testing in the Era of Genomic Sequencing*, 178(1) AM. J. MED. GENETICS 81 (2018); Jacquelyn Ann K. Kegley, *Genetic Decision-Making: A Template for Problems with Informed Consent*, 21 MED. & L. 459 (2002).

12. Lisa Campo-Engelstein, *BRCA Previvors: Medical and Social Factors that Differentiate Them From Previvors with Other Hereditary Cancers*, 6 BIOÉTHIQUEONLINE (2017) (“Despite the broad definition of previvor, discussions of previvors generally refer to women who have tested positive for one of the BRCA mutations. Yet, there are other hereditary cancers for which prophylactic treatment is available.”).

13. Women with a BRCA1 genetic mutation have a cumulative breast cancer risk of 72% and a cumulative ovarian cancer risk of 44% by 80 years old. Women with a BRCA2 mutation have a cumulative breast cancer risk of 69% and a cumulative ovarian cancer risk of 17% by age 80. Marleah Dean & Carla L. Fisher, *Uncertainty and Previvors’ Cancer Risk Management: Understanding the Decision-Making Process*, 47 J. APPLIED COMM. RESEARCH 460, 461 (2019) (citing Karoline B. Kuchenbaecker, John L. Hopper, Daniel R. Barnes, Kelly-

additional mutations in other genes that also confer increased breast cancer risk, and testing for these mutations is becoming increasingly available.<sup>14</sup> FORCE, the organization that coined the term “previvor,” defined previvors as “individuals who are survivors of a predisposition to cancer but who haven’t had the disease.”<sup>15</sup> FORCE did not limit its definition to those with the specific hereditary genetic mutations that increased a person’s chance of developing breast or ovarian cancer, but extended it to those with a family history of cancer or some other predisposing factor.<sup>16</sup>

Adoption of the term “previvor” has become commonplace, at least for those with a genetic predisposition to hereditary breast or ovarian cancer. Most current definitions of “previvor” hew closely to the original definition proposed by FORCE and do not limit the definition to only those individuals who have taken some preventative action based on knowledge of a genetic variant.<sup>17</sup> However, others have offered definitions that do not necessarily align with FORCE’s original characterization.<sup>18</sup> Some limit the definition of previvor to someone with a specific genetic mutation that increases one’s likelihood of developing a disease. For example, an article discussing how individuals deal with uncertainty in testing for BRCA mutations limits its definition of “pre-

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Anne Phillips, Thea M. Mooij, Marie-José Roos-Blom, Sarah Jervis, Flora E. van Leeuwen, Roger L. Milme, Nadine Andrieu, David E. Goldgar, Mary Beth Terry, Matti A. Rookus, Douglas F. Easton, & Antonis C. Antoniou, *Risks of Breast, Ovarian, and Contralateral Breast Cancer for BRCA1 and BRCA2 Mutation Carriers*, 317 J. AM. MED. ASSOC. 2402 (2017)).

14. Tasleem J. Padamsee, Celia E. Wills, Lisa D. Lee, & Electra D. Paskett, *Decision Making for Breast Cancer Prevention Among Women at Elevated Risk*, 19 BREAST CANCER RESEARCH (2017) (these genes include ATM, CDH1, CHEK2, NBN, NF1, PALB2, PTEN, STK11, and TP53).

15. *What is a Previvor?*, HBOC SOCIETY, <https://www.hbocsociety.org/you-are-a-previvor.html> [<https://perma.cc/WU2F-RTZR>].

16. *Id.* (“[t]he term specifically applies to the portion of our community that has its own unique needs and concerns separate from the general population, but is different from those already diagnosed with cancer.”).

17. For example, in a review of various approaches to managing genetic predisposition to ovarian cancer, Jesus Paula Carvalho and colleagues defined previvors as “individuals who have a much greater predisposition to cancer than individuals in the general population but who have not yet developed the disease. This group comprises individuals with deleterious mutations, family histories of cancer, and other high-risk factors for cancer.” Jesus Paula Carvalho, Edmund Chada Baracat, & Filomena Marina Carvalho, *Ovarian Cancer Previvors: How to Manage these Patients?*, 74 CLINICS 1343 (2019).

18. And, in fact, in September 2020, FORCE updated its mission, to “include[] individuals and families who face hereditary breast, ovarian, pancreatic, prostate, colorectal and endometrial cancers that are caused by an inherited mutation in a BRCA, ATM, PALB2, CHEK2, PTEN or other gene, as well as those associated with Lynch syndrome.” FORCE BLOG, *Meet the New FORCE: Many Mutations. Many Cancers. One Community*, (Sept. 25, 2020), <https://www.facingourrisk.org/blog/meet-the-new-force-many-mutations-many-cancers-one-community> [<https://perma.cc/2WH7-9TN7>]. Siddharta Mukherjee describes the term “previvor” more broadly as well, as “a strange new term invented to describe a person who is a survivor of an illness that she is predisposed to, but has yet to have.” *Cancer, Our Genes, and the Anxiety of Risk-Based Medicine*, 37(5) HEALTH AFFAIRS 817 (2018).

vivor” to those “who carry the deleterious mutation.”<sup>19</sup> Researchers who have developed decision aids for women with breast cancer gene (BRCA) mutations define previvors as “unaffected carriers of a [genetic] mutation.”<sup>20</sup>

The current limitation of the term “previvor” to individuals with BRCA mutations is problematic for law and policy as it applies to medical decision making and access to medical and scientific resources. Recent developments highlight the term’s exclusive nature in the law. For example, in 2010, Representative Debbie Wasserman-Schultz introduced a simple resolution in Congress to designate the last Wednesday of September as National Previvor Day.<sup>21</sup> The day is intended to honor the “750,000 people in the United States [who] carry a gene mutation that causes a predisposition to breast and ovarian cancer” and “rais[e] awareness of hereditary cancer and knowledge of a genetic predisposition can directly lead to preventive strategies that can reduce the chance of dying from cancer.”<sup>22</sup> This special treatment of BRCA previvors confers a special status on an already privileged slice of all those living with known deleterious mutations.

Limiting the application of the label “previvor” in the law to only those who know they are BRCA positive, who are by and large white and of Ashkenazi Jewish descent, does a disservice to all other individuals with a genetic predisposition to disease. The vast amount of research and knowledge as it pertains to BRCA mutations may be traced to the BRCA community’s inherent trust and participation in research to further understanding of the BRCA genes.<sup>23</sup> Combined with “preference by researchers to analyze data from well-characterized, well-powered, predominantly European ancestry cohorts,”<sup>24</sup>

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19. Veronica Sloatsky, *Dealing with Uncertainty in Genetic Testing*, 44(7) PSYCHIATRIC ANN. 329, 332 (2014).

20. Terri Jabaley Leonarczyk & Barbara E. Mawn, *Cancer Risk Management Decision Making for BRCA+ Women*, 37(1) WESTERN J. NURSING RESEARCH 66 (2015).

21. Expressing Support for Designation of the Last Week of September as National Hereditary Breast and Ovarian Cancer and the Last Wednesday of September as National Previvor Day, H.R. Res. 1522, 111th Cong. (2010).

22. *Id.*

23. Sherry I. Brandt-Rauf, Victoria H. Raveis, Nathan F. Drummond, Jill A. Conte, & Sheila M. Rothman, *Ashkenazi Jews and Breast Cancer: The Consequences of Linking Ethnic Identity to Genetic Disease*, 96(11) AM. J. PUBLIC HEALTH 1979, 1981 (2006) (“[i]n breast cancer research, as in Tay-Sachs screening programs, ethnic concordance and trust between researchers and the population facilitated recruitment.”).

24. Chanita H. Halbert & Barbara W. Harrison, *Genetic Counseling Among Minority Populations in the Era of Precision Medicine*, AM. J. MED. GENETICS 68, 71 (2018); Bentley, *infra* note 24, at Table 1. Health disparities due to a failure to include diverse populations, and in particular African Americans, in genetic research are increasingly being recognized. In August 2016, a study published in the *New England Journal of Medicine* provided concrete support for sequencing the genomes of diverse populations. The researchers concluded that patients of African or unspecified ancestry received misdiagnoses of hypertrophic cardiomyopathy – a disease in which the heart muscle becomes abnormally thick, making it

certain groups and communities have enjoyed greater resources to invest in the research enterprise and access to medical and scientific discoveries.<sup>25</sup> In contrast, research misconduct and discriminatory practices have been—and remain—widespread throughout the history of medicine and medical research, resulting in deep mistrust of the health care system resulting in disparate and unjust treatment.<sup>26</sup> Systemic bias in clinical research and medical treatment is illustrated by the striking fact that although white women have the highest incidence of breast cancer, Black women are more likely to die of breast cancer than women of other races and ethnicities, and are twice as likely than white women to be diagnosed with triple-negative breast cancer, a particularly aggressive subtype. In addition, Black women have an average age of onset of breast cancer in the late 40s, while white women have a later average age of onset.<sup>27</sup>

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difficult for the heart to pump blood, which can lead to sudden death – due to incorrectly classified variants. The researchers also found that had the original research identifying the genetic variants included “even small numbers of black Americans,” these misclassifications may have been prevented. Arjun K. Manrai, Birgit H. Funke, Heidi L. Rehm, Morten S. Oleson, Bradley A. Maron, Peter Szolovits, David M. Margulies, Joseph Loscalzo, & Isaac S. Kohane, *Genetic Misdiagnoses and the Potential for Health Disparities*, 375(7) *NEW ENGL. J. MED.* 655 (2016). “Such misdiagnoses can be life-changing to those who receive them – because the disease often has no symptoms, those who are diagnosed as having hypertrophic cardiomyopathy live with the constant specter of sudden, unexpected death. A positive test result may also lead individuals to seek intense medical follow-up, make major lifestyle changes, or even undergo surgical interventions, such as the implantation of monitoring devices in their chests.” Denise Grady, *Genetic Tests for a Heart Disorder Mistakenly Find Blacks at Risk*, *N.Y. TIMES* (Aug. 17, 2016).

25. Amy R. Bentley, Shawneequa Callier & Charles N. Rotimi, *Diversity and Inclusion in Genomic Research: Why the Uneven Progress?*, 8(4) *J. COMMUNITY GENETICS* 255, 261 (2017). It has been argued that focusing resources on the Ashkenazi Jewish population may divert attention from research on BRCA (and other) mutations in other groups, giving rise to concerns that “[s]uch inattention risks creating health disparities because physicians become less likely to recommend, and individuals less likely to request, genetic tests or preventive treatment based on their group membership.” Sherry I. Brandt-Rauf, Victoria H. Raveis, Nathan F. Drummond, Jill A. Conte & Sheila M. Rothman, *Ashkenazi Jews and Breast Cancer: The Consequences of Linking Ethnic Identity to Genetic Disease*, 96(11) *AM. J. PUBLIC HEALTH* 1979, 1984 (2006); See also Ed Yong, *Clinical Genetics has a Big Problem That’s Affecting People’s Lives*, *THE ATLANTIC* (2016) (acknowledging that “many older studies focused on people of European ancestry. A particular variant might be rare in those populations, but very common in other ethnic groups. It couldn’t be responsible for rare diseases, but you’d never know if you only sequenced white people.”).

26. William B. Feldman, Spencer Phillips Hey & Aaron S. Kesselheim, *A Systematic Review of the Food and Drug Administration’s ‘Exception from Informed Consent’ Pathway*, 37(10) *HEALTH AFF.* 1605, 1611 (2018) (Black people make up only five percent of clinical trial participants); Keolu Fox, *The Illusion of Inclusion – the “All of Us” Research Program and Indigenous Peoples’ DNA*, 383 *N. ENGL. J. MED.* 411 (2020) (Eighty-eight percent of people included in large-scale studies of human genetic variation are of European ancestry, as are the majority of participants in clinical trials).

27. Bruce G. Haffty, Doo-ho Choi, Sharad Goyal, Andrea L.M. Silber, K. Ranieri, Ellen T. Matloff, Min-hyuk Lee, Michael J. Nissenblatt, Deborah Lynn Toppmeyer, & Meena S. Moran, *Breast Cancer in Young Women (YBC): Prevalence of BRCA1/2 Mutations and Risk of Secondary Malignancies Across Diverse Racial Groups*, 20(10) *ANNALS OF ONCOLOGY* 1653 (2009).



While in some ways the health and psychosocial implications of carrying a BRCA mutation may be unique,<sup>28</sup> it would be inappropriate to think they are exceptional. There exist many other hereditary cancers and many other hereditary diseases. And as technology advances, genetic testing will increase the number of previvors in the years to come.<sup>29</sup>

Learning that one has a genetic predisposition to disease adds additional layers of uncertainty to medical decision making. In fact, all those who test positive for a deleterious genetic variant that increases one's risk of developing a disease share a fundamental element: uncertainty.<sup>30</sup> Particularly when there is no standard prophylactic treatment, individuals may be left "floundering to make the 'right' decision and/or the one that most aligns with their values."<sup>31</sup> Importantly, "[t]he term *previvor* is a relatively new one and appropriately describes an entire new population of patients with specific psychosocial and healthcare needs."<sup>32</sup> And just as the term "survivor" is not used exclusively to refer to one specific disease or illness, the term *previvor* should not be used exclusively for those with a genetic predisposition to breast or ovarian cancer due to BRCA mutations.

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28. BRCA mutations may carry with them special meaning due to the press attendant to the actress Angelina Jolie Pitt's public revelation of her BRCA status and her prophylactic double mastectomy in 2013. D. Gareth Evans, Julie Wisely, Tara Clancy, Fiona Lalloo, Mary Wilson, Richard Johnson, Jonathon Duncan, Lester Barr, Ashu Gandhi, & Anthony Howell, *Longer Term Effects of the Angelina Jolie Effect: Increased Risk-Reducing Mastectomy Rates in BRCA Carriers and Other High-Risk Women*, 17 BREAST CANCER RESEARCH 442 (2015). Jolie's announcement brought incredible attention to these specific mutations and increased public understanding of hereditary breast and ovarian cancers, perhaps to the detriment of public knowledge of other hereditary cancers. In contrast to BRCA mutations, for which there is a rather established standard of care, the New York Times reported the story of a woman who tested positive for a genetic variation that increases individuals' probably of developing stomach cancer.); Denise Grady & Andrew Pollack, *Finding Risks, Not Answers*, in *Gene Tests*, N.Y. TIMES (Sept. 22, 2014), <https://www.nytimes.com/2014/09/23/health/finding-risks-not-answers-in-gene-tests.html> [<https://perma.cc/FHG3-BK3N>] (There is no standard of care for prophylactic treatment for such individuals: "In people with a family history of the disease, that mutation is considered so risky that patients who are not even sick are often advised to have their stomachs removed. But no one knows what the finding might mean in someone like Jennifer, whose family has not had the disease.").

29. As Siddhartha Mukherjee, an oncologist and author, explains, "[t]he combinations of gene mutations responsible for such genetically complex diseases are now being identified by powerful computational technologies." Mukherjee, *supra* note 18, at 818.

30. See Marleah Dean, Courtney Scherr, Meredith Clements, Rachel Korou, Jennifer Martinez, & Amy Ross, "When Information is Not Enough": A Model for Understanding BRCA-positive Previvors' Information Needs Regarding Hereditary Breast and Ovarian Cancer Risk, 100(9) PATIENT EDUC. & COUNSELING 1738 (2017).

31. Campo-Engelstein, *supra* note 12.

32. Suzanne M. Mahon, Impact of the Genetic Screening Revolution: Understanding and Meeting the Needs of Previvors with a Known Family Mutation in BRCA1/BRCA2, 14(4) EVIDENCE-BASED NURSING 126, 127 (2011); See also Dean & Fisher, *supra* note 13, at 3 (citing Louise S. Donnelly, Maggie Watson, Clare Moynihan, Elizabeth Bancroft, Gareth R. Evans, Rosalind Eeles, Stuart Lavery, & Elizabeth Ormondroyd, Reproductive Decision-Making in Young Female Carriers of a BRCA Mutation, 28(4) HUMAN REPRODUCTION 1006 (2013)).

Therefore, limiting the definition only to BRCA mutation carriers, or even all cancer-conferring mutation carriers, neglects those with genetic predispositions to other diseases who have the same psychosocial and healthcare needs. According to one study, 11.6 percent of healthy adults will test positive for a clinically actionable, likely pathogenic variant.<sup>33</sup> This suggests that granting special attention and protections to only those with BRCA mutations will exclude a large segment of the population who face similar concerns during the course of medical decision making. Further, those with BRCA mutations often have disproportionate access to medical and scientific advancements and resources to self-advocate, which will further exacerbate health care disparities. Thus, if a broader definition of “previvor” is not adopted, the term may remain inappropriately limited. Extending the definition of “previvorship” in society – and in the law – is one small step toward ensuring fairer and more just treatment of those who learn they have genetic predispositions to disease.<sup>34</sup>

Based on these concerns, the definition of “previvor” for the law should be inclusive of all individuals with a hereditary mutation, a family history of a specific disease, or some other predisposing factor, for which preventative action or prophylactic interventions can be undertaken.<sup>35</sup> In other words, the definition of previvor must be inclusive

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33. Jennifer L. Anderson, Teresa M. Kruisselbrink, Emily C. Lisi, Therese M. Hughes, Joan M. Steyermark, Erin M. Winkler, Corrine M. Berg, Robert A. Vierkant, Ruchi Gupta, Ahmad H. Ali, Stephanie S. Faubion, Stacy L. Aoudia, Tammy M. McAllister, Gianrico Farugia, A. Keith Stewart, & Konstantinos N. Lazaridis, *Clinically Actionable Findings Derived from Predictive Genomic Testing Offered in a Medical Practice Setting*, MAYO CLINIC PROCEEDINGS 1 (2020); Importantly, there is no universal definition of “actionable” in clinical research/medicine. See Patrick Monette, “Actionability” and the Ethics of Communicating Results to Study Participants, BILL OF HEALTH BLOG (Feb. 3, 2021), <https://blog.petrieflom.law.harvard.edu/2021/02/03/actionability-research-findings-ethics/> [<https://perma.cc/3EPE-8NKZ>]; See also Celine Moret, Alex Mauron, Siv Fokstuen, Periklis Makrythanasis, & Samia A. Hurst, *Defining Categories of Actionability for Secondary Findings in Next-Generation Sequencing*, 43 J. MED. ETHICS 346, 349 (2017) (“[f]indings are not actionable in themselves; they are actionable for an individual—or a set of individuals—in specific situations”).

34. As noted, this definition is intentionally broad. As the drafters of the Genetic Information Nondiscrimination Act of 2008 (GINA) recognize, there is little reason to distinguish between a known genetic predisposition and a family history of disease. Amy L. McGuire & Mary Anderlik Majumder, *Two Cheers for GINA?*, 1 GENOME MED. 6 (2009) (Commentators have recognized that the expansive nature of this definition could be interpreted to eventually include the entire population, as everyone has some predisposition to, or is at a higher risk of developing, some form of illness. Such slippery slope arguments are no reason not to endeavor to craft a more just approach to medical decision making, and the proposed definition is certainly open to improvement and modification over time. And there is validity to the argument that we are all, in some sense, previvors. Perhaps this could be one instance of the law leading the way in shaping ethical action.)

35. While it is currently the term used to refer to this population, maintaining the term “previvor” for the broader population of individuals who have a genetic predisposition to, or family history of, disease is not an absolute necessity. To be clear, this article’s primary objection is to the provision of a label with an empowering connotation only to individuals with a BRCA mutation. However, there may be a better-suited term to refer to all those with

of all individuals with a known clinically actionable risk to a life-threatening, severe, or chronic illness or condition.<sup>36</sup>

Defining previvorship for the legal scholarship will ensure that law and policy is inclusive of all medical decisions related to those facing seemingly impossible decisions about their future health and well-being. While, today, most self-identified previvors have BRCA mutations,<sup>37</sup> there is a foreseeable future where genetic tests reveal predispositions to all sorts of diseases and disorders and where individuals have access to various procedures and treatments that may reduce the risk of developing those diseases.<sup>38</sup>

### B. Previvor Identity

The previvor experience challenges many of the basic assumptions underlying traditional understandings of medical decision making. In many ways, previvorship is a category that defies the traditional boundaries of medicine, and the previvor identity is distinct from the long-accepted conceptions of what it means to be a patient.

Previvors encounter unique choices. Individuals who test positive for genetic mutations that confer a higher risk of disease than the

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mutations known to increase the likelihood of illness. One could conceive of another umbrella term that is appropriately inclusive and that recognizes the needs of the broader population. Further, this article does not endorse eliminating the communities that confer important psychosocial benefits such as support and individual empowerment. However, for legal and policy-related purposes, we need a broader, more inclusive definition for similarly situated individuals to avoid prioritizing certain (future) disease states over others for resources and attention.

36. As of 2016, the American College of Medical Genetics and Genomics (ACMG) recommended that mutations in 59 genes for 24 conditions are actionable and should therefore be reported as secondary findings after whole-genome sequencing. Sarah S. Kalia, Kathy Adelman, Sherri J. Bale, Wendy K. Chung, Christine Eng, James P. Evans, Gail E. Herman, Sophia B. Hufnagel, Teri E. Klein, Bruce R. Korf, Kent D. McKelvey, Kelly E. Ormond, C. Sue Richards, Christopher N. Vlangos, Michael Watson, Christa L. Martin, & David T. Miller, *Recommendations for Reporting of Secondary Findings in Clinical Exome and Genome Sequencing, 2016 Update (ACMG SF v2.0): A Policy Statement of the American College of Medical Genetics and Genomics*, 19 *GENETICS IN MED.* 249 (2017). Likewise, the National Heart, Lung, and Blood Institute (NHLBI) Exome Sequencing Project has reported an additional 60 actionable genes to those identified by the ACMG. Tonia C. Carter & Max M. He, *Challenges of Identifying Clinically Actionable Genetic Variants for Precision Medicine*, 2016 *J. HEALTHCARE ENGINEERING* 2, 5 (2016).

37. The lack of clarity around who is or may be categorized as a previvor is complicated by the fact that most previvors self-identify, thereby shaping the composition of the population.

38. Any group designation must be, by definition, inclusive as well as exclusive. While it may be argued that everyone in the population has some sort of predisposition to illness (be it genetic, environmental, or something else), there are some important elements of medical decision making that are relevant, if not unique, to those with genetic predispositions to disease. Thus, the definition proposed in this article for the term “previvor” must be limited in order to serve its intended purpose. Regardless, based on the analysis contained in Parts II and III, it should be recognized that previvorship exposes many of the inadequacies of current medical decision-making law, so that future rules address modern medicine and medical decision making for all.

general population may have medical and lifestyle options that can reduce that risk. For example, bilateral prophylactic mastectomy is considered to be the single most effective prevention method for BRCA positive individuals, reducing breast cancer risk by about 90 percent<sup>39</sup> and breast cancer-specific mortality by more than 80 percent.<sup>40</sup> Other prophylactic options include the use of selective estrogen receptor modulators such as tamoxifen and raloxifene as chemoprevention agents.<sup>41</sup> Individuals may also seek to minimize breast cancer risk through increased surveillance (including frequent mammograms and/or MRIs)<sup>42</sup> or “watchful waiting.”<sup>43</sup> BRCA positive individuals may seek to reduce their risk of developing ovarian cancer by bilateral prophylactic salpingo-oophorectomy (the surgical removal of the fallopian tubes and

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39. Therese B. Bevers, Deborah K. Armstrong, Banu Arun, Robert W. Carlson, Kenneth H. Cowan, Mary B. Daly, Irvin Fleming, Judy E. Garber, Mary Gemignani, William J. Gradishar, Helen Krontiras, Swati Kulkarni, Christine Laronga, Loretta Loftus, Deborah J. Macdonald, Martin C. Mahoney, Sofia D. Merajvr, Ingrid Meszoely, Lisa Newman, Elizabeth Pritchard, Victoria Seewaldt, Rena V. Sellin, Charles L. Shapiro, & John H. Ward, *Breast Cancer Risk Reduction*, 8 NAT'L COMPREHENSIVE CANCER NETWORK 1112, 1124-25 (2010); Lynn C. Hartmann, Daniel J. Schaid, John E. Woods, Thomas P. Crotty, Jeffrey L. Myers, P.G. Arnold, Paul M. Petty, Thomas A. Sellers, Joanne L. Johnson, Shannon K. McDonnell, Marlene H. Frost, Clive S. Grant, Virginia V. Michels, & Robert B. Jenkins, *Efficacy of Bilateral Prophylactic Mastectomy in Women with a Family History of Breast Cancer*, 340 NEW ENGL. J. MED. 77, 82 (1999); Ismail Jatoi, John R. Benson, Siong-Seng Liau, Yijun Chen, Robin M. Cisco, Jeffrey A. Norton, Jeffrey F. Moley, Katherine W. Kalifeh, & Michael A. Choti, *The Role of Surgery in Cancer Prevention*, 47 CURRENT PROBLEMS IN SURGERY 750, 791-92 (2010); Liz Lostumbo, Nora E. Carbine, & Judi Wallace, *Prophylactic Mastectomy for the Prevention of Breast Cancer (review)*, 11 COCHRANE COLLAB. 1, 12 (2010); Katherine L. Nathanson & Susan M. Domchek, *Therapeutic Approaches for Women Predisposed to Breast Cancer*, 62 ANNUAL REV. MED. 295 (2011); Elisabetta Razzaboni, Giovanni Tazzioli, Alessia Andreotti, Elisabetta de Matteis, Laura Cortesi, & Massimo Federico, *Prophylactic Surgery to Reduce the Risk of Developing Breast Cancer: Issues and Clinical Implications*, 8 CURRENT WOMEN'S HEALTH REV. 94, 100-01 (2012); Timothy R. Rebbeck, Tara Friebel, Henry T. Lynch, Susan L. Neuhausen, Laura van 't Veer, Judy E. Garber, Gareth R. Evans, Steven A. Narod, Claudine Isaacs, Ellen Matloff, Mary B. Daly, Olufunmilayo I. Olopade, & Barbara L. Weber, *Bilateral Prophylactic Mastectomy Reduces Breast Cancer Risk in BRCA1 and BRCA2 Mutation Carriers: the PROSE Study Group*, 24 J. CLIN. ONCOL. 1055, 1058 (2004); Elizabeth M. Swisher & Kristine E. Calhoun, *Management of Women with Inherited BRCA1 and BRCA2 Mutations*, THE ROLE OF GENETICS IN BREAST AND REPRODUCTIVE CANCERS 21-45 (2010); Shaheen Zakaria & Amy C. Degnim, *Prophylactic Mastectomy*, 87 SURGICAL CLIN. N. AM. 317 (2007).

40. Ismail Jatoi, John R. Benson, Siong-Seng Liau, Yijun Chen, Robin M. Cisco, Jeffrey A. Norton, Jeffrey F. Moley, Katherine W. Kalifeh, & Michael A. Choti, *The Role of Surgery in Cancer Prevention*, 47 CURRENT PROBLEMS IN SURGERY 750, 788-89 (2010); Liz Lostumbo, Nora E. Carbine, & Judi Wallace, *Prophylactic Mastectomy for the Prevention of Breast Cancer (review)*, 11 COCHRANE COLLAB. (2010).

41. Erika A. Waters, Timothy S. McNeel, Wortia McCaskill Stevens, & Andrew N. Freedman, *Use of Tamoxifen and Raloxifene for Breast Cancer Chemoprevention in 2010*, 134 BREAST CANCER RESEARCH AND TREATMENT 875 (2012).

42. Dean & Fisher, *supra* note 13, at 9.

43. NATIONAL CANCER INSTITUTE, *Dictionary of Cancer Terms*, <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/watchful-waiting> [<https://perma.cc/G8HS-KS3A>] (defining “watchful waiting” as “[c]losely watching a patient’s condition but not giving treatment unless symptoms appear or change”).

ovaries) or by regular screening, including regular ultrasounds and CA 125 tests.<sup>44</sup>

While each of these strategies offer significant risk reduction, they also carry with them significant health implications and side effects, many of which can be life-long. For many individuals, preventative action does not prevent sickness; rather, it trades the risk of developing one disease state for another. Prophylactic action “raises particular anxieties because the risks of both having surgery and not having it are considerable, yet abstract and hypothetical[.]”<sup>45</sup> Moreover, preventative surgeries may raise “taboo issues concerning sexual organs, sexuality and physical attractiveness.”<sup>46</sup> For example, bilateral prophylactic oophorectomy induces early menopause, “as well as increased risk of cardiovascular disease, osteoporosis, and cognitive impairment.”<sup>47</sup>

Significantly, the previvor identity only recently emerged and remains particularly within the BRCA community.<sup>48</sup> Lisa Campo-Engelstein explained: “the absence of a standard of care for breast cancer risk for women with a BRCA mutation, coupled with a broad range of genetic penetrance and lower mortality, makes BRCA different than other hereditary cancers that have clear and established guidelines.”<sup>49</sup>

One of the elements that makes BRCA mutations unique compared to other hereditary cancers is the lack of a clear standard of care to prevent hereditary breast cancer.<sup>50</sup>

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44. The author notes that much of the literature referenced throughout this article discusses previvorship in the context of BRCA mutations; unfortunately, this is not due to a lack of trying. It is the author’s hope that future research will focus on individual decision making in the context of genetic tests for other diseases and disorders, in order to get a more complete consideration of the role of informed consent in previvor decision making.

45. Robert Klitzman & Wendy Chung, *The Process of Deciding about Prophylactic Surgery for Breast and Ovarian Cancer: Patient Questions, Uncertainties, and Communication*, 152A(1) AM. J. MED. GENET. 52 (2010).

46. *Id.*

47. Padamsee et al., *supra* note 14.

48. Campo-Engelstein, *supra* note 12, at 2 (Campo-Engelstein provides a very literal definition of previvor, explaining that it is short for “**survivors** of a **predisposition** to cancer[.]”) (emphasis in original).

49. *Id.*

50. *Id.* at 3 (explaining, “[m]ost hereditary cancers have established prophylactic treatments that are routinely recommended by health care professionals.”).

In the age of precision medicine,<sup>51</sup> individuals may adopt multiple identities when navigating the medical system.<sup>52</sup> In a 2019 study of women's acceptance of the previvor identity as a pre-illness identity, Hannah Getachew-Smith and colleagues identified two types of previvor identity: (1) the *experiential* previvor identity, which views the previvor label as applicable upon receipt of a positive genetic test result, and (2) *physical* previvor identity, which conditions the previvor label on action, or something to be earned through uptake of surgical risk reduction strategies which result in changes in bodily appearance.<sup>53</sup> Both of these previvor identities distinguish the previvor from the traditional patient identity, and therefore confer unique roles and responsibilities as they navigate complex decision making.

The advantages of adopting a label such as "previvor" can empower an individual at a time of great uncertainty in that person's life.<sup>54</sup> Previvors are often seen as proactive in the face of uncertainty. Generally, previvors self-identify.<sup>55</sup> Self-identification may make previvors feel less alone; a previvor is part of community of similarly situated individuals. Self-identification and group/community identity directly shape the composition of the previvor population, excluding those who do not choose to define themselves as previvors. This has "implications for behavioral norms related to information-seeking and medical decision-making as well as knowledge sharing among those in the previvor

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51. "[P]recision medicine is 'an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person.' This approach will allow doctors and researchers to predict more accurately which treatment and prevention strategies for a particular disease will work in which groups of people. It is in contrast to a one-size-fits-all approach, in which disease treatment and prevention strategies are developed for the average person, with less consideration for the differences between individuals." *What is Precision Medicine?*, MEDLINEPLUS, at <https://medlineplus.gov/genetics/understanding/precisionmedicine/definition/> [<https://perma.cc/RX7Q-UAJF>].

52. Identifying as a previvor "replaces the traditional taxonomy of diseases with a multilayer characterization of individuals[.]" Gil Eyal, Maya Sabatello, Kathryn Tabb, Rachel Adams, Matthew Jones, Frank R. Lichtenberg, Alondra Nelson, Kevin Ochsner, John Rowe, Deborah Stiles, Kavita Sivaramakrishnan, Kristen Underhill, & Paul S. Appelbaum, *The Physician-Patient Relationship in the Age of Precision Medicine*, 21 *GENETICS IN MED.* 813, 813 (2019).

53. Hannah Getachew-Smith, Amy A. Ross, Courtney L. Scherr, Marleah Dean, & Meredith L. Clements, *Previving: How Unaffected Women with a BRCA1/2 Mutation Navigate Previvor Identity*, 35(10) *HEALTH COMM.* 1256 (2019).

54. *Id.* at 1261 ("[a]dopting the previvor label empowered women to assume responsibility for their health and take control of their lives.").

55. Robin E. Grubs, Lisa S. Parker, & Rebekah Hamilton, *Subtle Psychosocial Sequelae of Genetic Test Results*, 2 *CURRENT GENETIC MED. REPORTS* 242 (2014); Ronda Wendler, *With Elevated Risks, These Survivors and 'Previvors' Aren't Taking Any Chances*, <https://www.mdanderson.org/publications/annual-report/annual-report-2014/with-elevated-risks-these-survivors-and-previvors-arent-taking-a.html> [<https://perma.cc/K6DF-8W9H>].

community, potentially impacting health outcomes.”<sup>56</sup> Previvorship identification allows individuals to embrace a future identity and “en-vision themselves in alternate situations in order to decide how to confront their risk.”<sup>57</sup>

Significantly, the previvor experience raises important questions for the practice of medicine. For example, what does it mean to treat something that has not yet manifested as a disease? And what does it mean to be treated for risk rather than illness? Traditionally, society categorizes individuals as either healthy or sick.<sup>58</sup> Adopting the previvor label can reveal an important shift in identity: non-symptomatic (perhaps never-symptomatic) individuals become “patients” (or “patients-in-waiting”<sup>59</sup> or “pre-diseased”<sup>60</sup>) by virtue of a lab test, seeking medical treatment or surgical interventions that normally are reserved for the sick. With the advent of precision medicine, Gil Eyal and colleagues argue that precision medicine “replaces the traditional taxonomy of diseases with a multi-layer characterization of individuals[.]”<sup>61</sup> They state, “[t]o be sick is a dichotomous social role[.]” explaining that “[i]nstead of one dichotomous role, there will be a multiplicity of hybrid statuses.”<sup>62</sup> Thus, when an individual learns that he or she has a genetic predisposition to a certain disease state, he or she may

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56. Hannah, *supra* note 53, at 1261. However, some individuals with genetic variants that predispose them to disease may dispute the previvor characterization. They may avoid being labeled a previvor because they believe they are not sick or may be reluctant to confront the possibility of getting sick. For example, a study by Talya Salant and colleagues found that women at a high risk of developing breast cancer may be resistant to taking preventative medication, observing that “[m]any women noted that a medication is taken only when a problem arises, to control it.” Talya Salant, Pamela S. Ganschow, Olufunmilayo I. Olopade, & Diane S. Lauderdale, “Why Take it If You Don’t Have Anything?” *Breast Cancer Risk Perceptions and Prevention Choices at a Public Hospital*, 21 J. GEN. INT. MED. 779, 783 (2006).

57. Hannah, *supra* note 53, at 1257.

58. Eyal et al., *supra* note 52 at 813. The concept of the “sick role” was introduced in 1951 by a sociologist, Talcott Parsons, in *THE SOCIAL SYSTEM* (Glencoe, IL: The Free Press, 1951) (describing illness as sanctioned deviance and explaining that being sick is, in part, a social construction). Parsons also argued that the incessant advancement of science and medicine would increase biomedical uncertainty. *Id.* Notably, some scholars have recognized “the death of the sick role,” heralding a “new epoch” in the history of medicine in the twenty-first century. John C. Burnham, *The Death of the Sick Role*, 25(4) *SOCIAL HISTORY OF MED.* 761 (2012). Burnham describes a new role – the “at-risk role” – that emerged as the prevalence of chronic disease began to increase (in contrast to acute disease). *Id.* at 774.

59. Eyal et al., *supra* note 52 at 813.

60. Gayle A. Sulik, *Managing Biomedical Uncertainty: the Technoscientific Illness Identity*, 30(7) *SOCIOLOGY OF HEALTH & ILLNESS* 1059, 1062 (2009) (“A person may unexpectedly learn (or even seek out the knowledge) that she is predisposed to a particular medical condition, or is a genetic carrier of a disease. Instead of simply acknowledging the biomedical marker as a piece of information, the person begins to think of herself as *pre-diseased*.”).

61. Eyal et al., *supra* note 52 at 813.

62. *Id.*

begin to occupy a hybrid role: “[t]he persons thus characterized will no longer be either healthy or sick, but will occupy liminal spaces between the two poles.”<sup>63</sup>

### C. *Previvor Decision Making and the Roles of Risk and Uncertainty*

Previvor decision making around which – if any – prophylactic interventions or actions to accept, reject, or delay is particularly complex. This section analyzes medical decision making through the literature of risk and uncertainty and applies that literature to the previvor experience.

Although they are often used interchangeably, risk and uncertainty are distinct concepts.<sup>64</sup> At a basic level, risk refers to the probabilities associated with the possible outcomes that are assumed to be known or measurable, while uncertainty refers to probabilities that are assumed to not be known or measurable.<sup>65</sup> However, more work is needed to differentiate the construct of uncertainty from the construct of risk in various conceptual models and theories of health behavior.<sup>66</sup>

63. *Id.* at 814. In *The Death of the Sick Role*, John Burnham discusses the “at-risk role” – a role between the “sick role” and the healthy role, explaining why the sick role may no longer be an accurate and appropriate concept to apply to ill people or to asymptomatic patients. Burnham, *supra* note 58.

64. In 1921, Frank H. Knight attempted to illuminate the distinctions between risk and uncertainty. RISK, UNCERTAINTY, AND PROFIT (1921) (pg. 19-20) (“Uncertainty must be taken in a sense radically distinct from the familiar notion of Risk, from which it has never been properly separated”).

The essential fact is that “risk” means in some cases a quantity susceptible of measurement, while at other times it is something distinctly not of this character; and there are far-reaching and crucial differences in the bearings of the phenomenon depending on which of the two is really present and operating. There are other ambiguities in the term “risk” as well, which will be pointed out; but this is the most important. It will appear that a *measurable* uncertainty, or “risk” proper, as we shall use the term, is so far different from an *unmeasurable* one that it is not in effect an uncertainty at all. We shall accordingly restrict the term “uncertainty” to cases of the non-quantitative type. It is this “true” uncertainty, and not risk, as has been argued, which forms the basis of a valid theory of profit and accounts for the divergence between actual and theoretical competition.

In 1980, Renée C. Fox described the “problem of medical uncertainty (and its concomitants – risk, hazard, error, and limitation...)” Renée C. Fox, *The Evolution of Medical Uncertainty*, 58(1) THE MILBANK MEMORIAL FUND QUARTERLY. HEALTH AND SOCIETY 1, 4 (1980).

65. Amos Tversky & Craig R. Fox, *Weighing Risk and Uncertainty*, 102(2) PSYCHOLOGICAL REV. 269 (1995). See also Joanna K. Sax, *Biotechnology and Consumer Decision-Making* 47 SETON HALL L. REV. 433, 474 (2012) (“[S]cientific uncertainty is part of the scientific process. Unknowns always exist in science, but this is different than having enough information to be able to assign a probability of risk. Consumers may have trouble differentiating between scientific uncertainty and risk.”).

66. Mary C. Politi, Paul K.J. Han, & Nananda F. Col, *Communicating the Uncertainty of Harms and Benefits of Medical Interventions*, 27 MED. DECISION MAKING 681, 691 (2007). In their study of communicating uncertainty, Politi and colleagues recognized that “there is



### 1. *Previvors' Understanding and Management of Risk*

In medical decision making, individuals are presumed to weigh the risks and benefits of a proposed intervention in order to make an informed voluntary decision. Individuals understand and manage risk in a myriad of ways, and the act of assigning value to risk is noted by scholars of medical decision making. Despite “advances in technology and practice..., little is known about how women categorized as ‘high risk’ understand the meaning of their risk and decide about available prevention options.”<sup>67</sup> Thus, despite being at similar risk of disease, previvors may vary significantly in how they process risk and the decisions they make.<sup>68</sup> Individuals with genetic predisposition to disease may “understand risk not as a numerical probability or chronic disease state suitable for prophylaxis but as an immediate physical sign or symptom warranting medical intervention or early detection.”<sup>69</sup> Cultural, religious, socioeconomic, and other perspectives may play an enormous role in risk perception, risk communication, and conception of illness, and therefore the extent to which decisions stem from factors outside the biomedical model of illness must be examined.

Thus, scholars and health care providers have recognized that numerical risk is only one aspect of an individual’s decision making around whether – and when – to undergo preventative interventions. Other “less quantifiable influences”<sup>70</sup> include experiences with a family history of disease,<sup>71</sup> whether the individual has children, the individual’s level of risk aversion,<sup>72</sup> and generalized anxiety and depression. The medical model geared towards “rational” risk decision

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no universally acceptable absolute level of acceptable risk”; rather, “deciding between various treatment options is inherently situation specific,” and therefore “[a]cceptable risk refers to the risk associated with the most acceptable option in a particular decision.” They then queried whether there is an analogous concept of acceptable uncertainty, seeming to conclude that the answer, theoretically is “yes,” but that “[r]esearch is needed to develop these measures of component and composite uncertainty and to validate them.”

67. Salant et al., *supra* note 56.

68. *Id.* The authors noted that “clinical studies have demonstrated persistent heterogeneity in subjective risk perceptions and prevention decisions among women at similar levels of objective breast cancer risk.”

69. *Id.* at 783. The authors continued, “Despite understanding their categorization as ‘high risk,’ many women did not feel high risk and thus were unwilling to take a medication that may itself cause problems. Furthermore, reluctance to state one’s personal risk and concern about the health effects of worrying signify an etiological model different from the causal (i.e., hormonal) logic underlying current prevention strategies. Such tendencies may also directly oppose physicians’ efforts to maintain their patients’ risk awareness.”

70. Lynn C. Hartmann & Noralene M. Lindor, *The Role of Risk-Reducing Surgery in Hereditary Breast and Ovarian Cancer*, 374 NEW ENGL. J. MED. 454, 466 (2016).

71. Krishna Singh, Jenny Lester, Beth Karlan, Catherine Bresee, Tali Geva, & Ora Gordon, *Impact of Family History on Choosing Risk-Reducing Surgery among BRCA Mutation Carriers*. 208(4) AM. J. OBSTET. GYNECOL. 1 (2013).

72. Sandra van Dijk, Mariëlle S. van Roosmalen, Wilma Otten, & Peep F.M. Stalmeier, *Decision Making Regarding Prophylactic Mastectomy: Stability of Preferences and the Impact of Anticipated Feelings of Regret*, J. CLIN. ONCOLOGY (2008).

making “do not begin to capture the variety and iterative nature of [previvor] decision making.”<sup>73</sup>

After an individual has received genetic testing results, “little is known about [previvors’] subsequent risk management decision-making.”<sup>74</sup> Previvors encounter unique circumstances in deciding which prophylactic interventions to undergo, and when, with a lack of clarity around how they can weigh the benefits against the risks in such circumstances. Currently asymptomatic (and perhaps never symptomatic) individuals may balance the known risks of preventative surgeries or pharmaceutical treatment against the unknown probability of getting sick at a later date. They may also consider the unknown probability of getting sick later if they do not take preventative action or choose certain less successful (but potentially less risky) preventative actions. The severity of the risk influences individuals to take preventative action.<sup>75</sup> Further, the risks of complications associated with the proposed prophylactic intervention may be amplified compared to other medical interventions. Peter Angelos, an endocrine surgeon and medical ethicist, asks, “[a]re the complications of cancer previvors more difficult to live with than the complications from treatment of cancer?”<sup>76</sup>

Even where it might be possible to provide specific and personalized risk assessments to an individual to make informed medical decisions, there are barriers to reliance on these measurements. For example, research has demonstrated that some individuals may not believe their personalized risk numbers. In a study of women who were provided with tailored information about their personal breast cancer risk, nearly twenty percent of women did not believe their personalized risk numbers, often rejecting the risk estimate based on the belief that “the numbers did not adequately account for their personal background and circumstances.”<sup>77</sup> Interestingly, a majority of disbelievers believed that the estimated risk assessment was too low, believing that “their numbers should be *more* concerning and threatening.”<sup>78</sup> Thus, even when tailored risk assessments can be determined and

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73. Sharlene Hesse-Biber & Chen An, Genetic Testing and Post-Testing Decision Making among BRCA-Positive Mutation Women: a Psychosocial Approach, 25 J. GENETIC COUNSELING 978, 987 (2016).

74. Dean & Fisher, *supra* note 13, at 461.

75. Padamsee et al., *supra* note 14, at 7.

76. Peter Angelos, Univ. of Chi., Surgical Informed Consent, at the Dorothy J. MacLean Fellows Conference on Clinical Medical Ethics (Nov. 9, 2019), <https://youtu.be/bJBliRmSNmk?t=818> [<https://perma.cc/UB96-PXL6>].

77. Laura D. Scherer, Peter A. Ubel, Jennifer McClure, Sarah M. Greene, Sharon Hensley Alford, Lisa Holtzman, Nicole Exe, & Angela Fagerlin, *Belief in Numbers: When and Why Women Disbelieve Tailored Breast Cancer Risk Statistics*, 92 PATIENT EDU. & COUNSELING 253, 256-57 (2013).

78. *Id.* at 257.

communicated effectively, it is evident that an individual's decision making does not depend solely on medical risks.<sup>79</sup>

## 2. *Previvorship and the Exacerbation of Uncertainty*

The fundamental uncertainty in health care, and the added uncertainty inherent to previvor decision making, makes already-complex risk assessment even more difficult. Despite the recognition of the role of uncertainty in medical decision making, there has also been a historic absence of acknowledgment of uncertainty in diagnosis, prognosis, and treatment in traditional settings.<sup>80</sup>

Generally, uncertainty is defined as “the inability to determine the meaning of illness-related events[.]”<sup>81</sup> and it “occurs in a situation in which the decision maker is unable to assign definite value to objects or events and/or is unable to predict outcomes accurately.”<sup>82</sup> Merle Mishel, whose Uncertainty in Illness Theory (UIT) is utilized in understanding uncertainty in medical diagnosis and treatment (and whose Reconceptualized Uncertainty in Illness Theory (RUIT) applies to chronic or recurrent illness), identifies four types of uncertainty as they related to illness: “(a) ambiguity concerning the state of the illness, (b) complexity regarding treatment and system of care, (c) lack of information about the diagnosis and seriousness of the illness, and (d) unpredictability of the course of the disease and prognosis.”<sup>83</sup> As Mishel and her coauthors explained in 2018, the desired health outcome of applying both UIT and RUIT is “to regain personal control.”<sup>84</sup> The desired outcome of application of RUIT is “a growth to a new value

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79. Finally, previvor decision making may mean a shifting on the emphasis from risks to benefits. Today, most physicians focus on one particular element above the others—risk—when participating in the informed consent process. See Tyler R. Chesney & Margaret L. Schwarze, *Patient-Centered Surgical Decision Making*, in *PRINCIPLES AND PRACTICE OF GERIATRIC SURGERY* 81, 81-82, 86 (Ronnie Ann Rosenthal, Michael E. Zenilman, & Mark R. Katlik, eds., 2020) (“Surgeons use this information to help patients make decisions about whether to have surgery, but they focus on objective quantification and physiologic risk disclosure without describing outcomes in a way that is relevant to patients and families.”). Risk is difficult, if not impossible, to quantify. However, when recommending surgery, surgeons believe that risk is the patient's primary concern; many preoperative information brochures emphasize risks, and many surgeons believe that focusing on risks will reduce likelihood of malpractice lawsuits if a complication occurs. Angelos, *supra* note 76.

80. M.S. Henry, Uncertainty, Responsibility, and the Evolution of the Physician/Patient Relationship, 32 *J. MED. ETHICS* 321, 321 (2006).

81. Merle H. Mishel, *Reconceptualization of the Uncertainty in Illness Theory*, 22 *IMAGE: J. NURSING SCHOLARSHIP* 256, 256 (1990).

82. Merle H. Mishel, *Uncertainty in Illness*, 20 *IMAGE: J. NURSING SCHOLARSHIP* 225, 225 (1988).

83. *Id.*

84. Margaret F. Clayton, Marleah Dean & Merle Mishel, *Theories of Uncertainty in Illness*, in *MIDDLE RANGE THEORY FOR NURSING* 49, 58 (Mary Jane Smith & Patricia R. Liehr eds., 4th ed. 2018).

system, whereas the outcome of the UIT is a return to the previous level of adaptation or functioning.”<sup>85</sup>

Relying on Mishel’s UIT, at least two groups of scholars have attempted to develop systematic taxonomies of uncertainty in medicine. In doing so, Paul Han and colleagues<sup>86</sup> and Austin Babrow and colleagues<sup>87</sup> recognized that although certain types of uncertainty may be reducible, other types—particularly probability and ambiguity uncertainty—may be irreducible, even when all mandated disclosures have been made.<sup>88</sup>

In addition to offering a taxonomy of the sources of uncertainty, Han and colleagues also provide a categorization of the “second dimension of uncertainty in health care”—the substantive issues associated with uncertainty.<sup>89</sup> They identify three main categories of concerns: (1) scientific concerns are disease-centered, including diagnosis, prognosis, causal explanations, and treatment recommendations; (2) practical concerns are system-centered, and focus on the “structures and processes of care”; and (3) personal concerns are patient-centered, addressing “psychosocial and existential issues including the effects of one’s illness or treatment on one’s goals or outlook on life, one’s personal relationships, the welfare of loved ones, or one’s sense of meaning in life.”<sup>90</sup> Finally, the authors identify a third dimension of uncertainty: its locus. In other words, they note that “uncertainty can exist

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85. *Id.* at 49.

86. Paul K.J. Han, William M.P. Klein & Neeraj K. Arora, *Varieties of Uncertainty in Health Care: A Conceptual Taxonomy*, 31 MED. DECISION MAKING 828, 835-36 (2011). Mary Politi and colleagues also identify five types or sources of uncertainty: 1) risk, or uncertainty about future outcomes; 2) ambiguity, or uncertainty about the strength or validity of evidence about risks; 3) uncertainty about the personal significance of particular risks (e.g., their severity, timing); 4) uncertainty arising from the complexity of risk information (e.g., the multiplicity of risks and benefits or the instability of risks and benefits over time); and 5) uncertainty resulting from ignorance. Politi et al., *supra* note 66, at 682.

87. See Austin S. Babrow, Chris R. Kasch & Leigh A. Ford, *The Many Meanings of Uncertainty in Illness: Toward a Systematic Accounting*, 10 HEALTH COMM’N 1, 17-18 (1998). As Newson and colleagues explain, “Babrow et al’s first and second forms of uncertainty overlap with Han et al’s three sources of uncertainty. In their third, fourth and fifth forms, Babrow et al. seem to more explicitly recognize the experiential or subjective properties of uncertainty.” Ainsley J. Newson, Samantha J. Leonard, Alison Hall & Clara L. Gaff, *Known Unknowns: Building and Ethics of Uncertainty into Genomic Medicine*, 9 BMC MED. GENOMICS, 3 (2016).

88. However, irreducible uncertainty may be manageable. See Newson et al., *supra* note 87, at 5-6. As described by Ainsley Newson and colleagues (according to Han et al.), (1) *probability* uncertainty “occurs where there is indeterminacy of future outcomes[,]” (2) *ambiguity* uncertainty “arises when the information or evidence is imprecise, where there is conflicting opinion or where information is not known[,]” and (3) *complexity* uncertainty “arises when there are features of the available information that make it hard to understand.” Newson et al., *supra* note 87, at 2.

89. Han et al., *supra* note 86, at 833.

90. *Id.*

in the minds of patients, clinicians, both, or neither, manifesting the fundamentally relational character of health care.”<sup>91</sup>

While illuminating for analyzing and improving patient understanding, the particular categories of uncertainty may be less relevant to exploring previvor decision making than is the lesson that, if left unmanaged, uncertainty can contribute to poor decision making.<sup>92</sup> Further, uncertainty cannot and should not be treated as a monolithic concept.<sup>93</sup> Rather, some types of uncertainty are reducible, while others are not. And uncertainty may reside in various players in the medical decision-making process. Importantly, uncertainty may be viewed as being either a danger or an opportunity.<sup>94</sup> These considerations become relevant when considering how previvors learn of, process, and cope with uncertainty and risk.<sup>95</sup>

The introduction of genetic testing to medicine, and more specifically, genetic testing results that reveal a predisposition to certain diseases, only exacerbates already-existing uncertainty in medicine,<sup>96</sup> which will certainly affect individuals’ decision making. Scholars of sociology and medicine have argued that scientific and medical advances intensify biomedical uncertainty “even as they increase the medical system’s reliance on them.”<sup>97</sup> For previvors, outcomes are uncertain both with and without prophylactic interventions. “Genomic uncertainty is a status quo that arises when information that is obtained from genomic testing is imperfect or unknown, leading to uncertainty

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91. *Id.* at 834.

92. Dean & Fisher, *supra* note 13, at 462 (citing Mishel, *supra* note 84; Mary C. Politi & Richard L. Street, *Patient-Centered Communication During Collaborative Decision Making*, THE ROUTLEDGE HANDBOOK OF HEALTH COMMUNICATION 399-413 (Teresa L. Thompson, Roxanne Parrott & Jon F. Nussbaum eds., 2011); Carol A. Wong & Lillian Bramwell, *Uncertainty and Anxiety After Mastectomy for Breast Cancer*, 15 CANCER NURSING 363 (1992)).

93. See Newson et al., *supra* note 87, at 2-3.

94. Mishel, *supra* note 84, at 225.

95. “Because of patients’ complex cognitive, emotional, and behavioral responses to uncertainty, many argue that the focus of risk communication should be on helping patients tolerate and cope with uncertainty rather than simply helping them understand it.” See Politi et al., *supra* note 66, at 690; Austin S. Babrow & Kimberly N. Kline, *From “Reducing” to “Coping with” Uncertainty: Reconceptualizing the Central Challenge in Breast Self-Exams*, 51 SOC. SCI. & MED. 1805, 1812 (2000); Dale E. Brashers, *Communication and Uncertainty Management*, 51 J. COMM’N 477, 477-78 (2001) (describing the Uncertainty Management Theory, or UMT, which was built upon many of the central assumptions of UIT and stressed that communication has the potential to arouse and reduce uncertainty and that through communication, uncertainty can be reduced, maintained, or even increased).

96. Soo Jung Hong, *Uncertainty in the Process of Communicating Cancer-Related Genetic Risk Information with Patients: A Scoping Review*, 25 J. HEALTH COMM’N 251, 251-52 (2020) (identifying six types of uncertainty that serve as a taxonomy for developing, validating, and utilizing future measures of uncertainty in the context of cancer-related genetic risk communication).

97. Sulik, *supra* note 60, at 1062; see TALCOTT PARSONS, THE SOCIAL SYSTEM 302 (Bryan S. Turner ed., Routledge 1991) (1951).

in clinical diagnosis or management.”<sup>98</sup> It “can arise from the probabilistic, ambiguous or complexity uncertainty inherent to the information arising from testing, or from the provider’s or recipient’s views on and uses of it.”<sup>99</sup> Genomic uncertainty may stand apart from other types of medical uncertainty, and thus, “[u]ncertainty will be an inherent aspect of clinical practice in genomics for some time to come.”<sup>100</sup>

The theories of uncertainty may be specifically applied to previvor decision making. Because Mishel’s theories are self-defined “middle range” theories—meaning that they are applicable from initial symptoms to outcomes (including diagnosis, treatment, and chronic illnesses)—they may be extended to uncertainty in the context of living with and coping with predisposition information. Previvors occupy a position of medical limbo compared to the type of patients anticipated by Mishel and colleagues. They are faced with heightened uncertainty when deciding which interventions to undergo, which drugs to take, and which lifestyle changes to make—if any.<sup>101</sup> For previvors, the desired health outcomes may be both those of the UIT and the RUIT; primarily, individuals may seek to avoid sickness, thereby maintaining the level of functioning previously experienced before receiving genetic predisposition information. However, where individuals decide to undergo prophylactic interventions or procedures, they may be forced to live with a “new normal” and – perhaps – a new value system or “view of life.”

Mishel’s RUIT has been applied to the experiences of women who tested positive for a mutation of the BRCA1 or BRCA2 genes.<sup>102</sup> In one study, three different sources of uncertainty were identified: (1) uncertainty toward a potential of developing an illness, (2) uncertainty with regards to which course of action to take in relation to prophylactic interventions, and (3) uncertainty associated with the potentiality of a disease trajectory.<sup>103</sup> In another study applying the RUIT to previvor decision making, the authors recognized that, “[u]ncertainty can

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98. Newson et al., *supra* note 87, at 3.

99. *Id.*

100. *Id.* at 2.

101. Hong, *supra* note 96, at 251 (“While these tests and sequencing technologies offer significant benefits, they also contribute to a context of greater clinical uncertainty among patients.”); Caren J. Frost, Vickie Venne, Dianne Cunningham & Ruth Gerritsen-McKane, *Decision Making with Uncertain Information: Learning from Women in a High Risk Breast Cancer Clinic*, 13 J. GENETIC COUNSELING 221, 231-32 (2004).

102. See generally Julia DiMillo, André Samson, Anne Thériault, Sandra Lowry, Linda Corsini, Shailendra Verma, & Eva Tomiak, *Living with the BRCA Genetic Mutation: An Uncertain Conclusion to an Unending Process*, 18(2) PSYCHOLOGY, HEALTH & MED. 125 (2013). According to DiMillo and colleagues, uncertainty is understood to derive from an inability to form a cognitive schema for an illness. *Id.* at 126.

103. *Id.* at 131. In the context of the third source, the authors ask, “[u]nlike patients fighting cancer, [does] the very nature of the BRCA1 or BRCA2 genetic predisposition creates a kind of uncertainty, which is almost impossible to minimize because there is no way to tackle a potentiality that may still lead to a fatal outcome[?]” *Id.*

become chronic, meaning an individual must constantly manage inconsistency, ambiguity, and unpredictability about health and illness over a long period of time.”<sup>104</sup> Thus, “[p]revivors need to manage uncertainty (and enhance health) in the present moment (particularly given distressful chronic risk/uncertainty) as well as in the long term by reducing disease risk. However, their appraisals will vary and, therefore, inform which risk management option they choose differently.”<sup>105</sup> The decisions previvors make have “significant implications for their physical and psychological well-being.”<sup>106</sup> They concluded,

[P]revivors choosing surgery appraised uncertainty as a danger, and after making their medical decision, experienced health-promoting outcomes associated with reduced uncertainty. In contrast, women appraising uncertainty as an opportunity opted for surveillance. These women encountered a mixture of health-promoting and health-inhibiting outcomes as their uncertainty was not managed in the long term. These previvors eventually viewed uncertainty as a danger and encountered ongoing, cyclical uncertainty and distress as they constantly reassessed their decision and described feeling like they were gambling with their lives. Ultimately, women in this pathway exhibited persistent distress – heightening the practical need for intervention in assisting these women across time rather than just at the time of their risk-reducing decisions.<sup>107</sup>

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104. Dean & Fisher, *supra* note 13 at 463. They stated,

[p]atients’ responses to ... uncertainty impact their health. Several overlapping theoretical features of [uncertainty management theory] and RUIT are pertinent to understanding how uncertainty informs previvors’ cancer risk management: (1) the nature of uncertainty (e.g. sources and antecedents), (2) appraisals or assessments (and emotional responses) of the uncertainty, and (3) strategies or coping approaches to manage uncertainty.

*Id.* In her earlier PhD dissertation, Marleah Dean recognized various sources of medical uncertainty for previvors. Marleah Dean, “It’s Not if I Get Cancer, It’s When I Get Cancer”: Exploring Previvors’ Management of Uncertainty for Hereditary Cancer in Clinical Encounters 108 (Aug. 2014) (Ph.D. Dissertation, Texas A&M University) (ProQuest). The types of medical uncertainty she identified include uncertainty about the future (“the unknown future”), the “ups and downs” or the anxieties that peak at the time of medical consultations, and personal scares of a possible cancer (or disease) diagnosis. *Id.* at 45-48. She then categorized types of familial uncertainty, including previvors’ traumatic family experiences with disease and the impact of decision making for current and future children. These uncertainties manifest themselves through the following factors that contribute to previvors’ medical decision making: “1) risk perception of developing cancer, 2) scares of identifying potential cancer, 3) traumatic family experiences with cancer, and 4) current life status.” *Id.* at 75. Finally, Dean identified four main strategies that previvors employ to manage uncertainty: “1) seeking clinicians as an informational source, 2) seeking clinicians as a partner for decision-making, 3) seeking clinicians as an emotional support, and 4) seeking referrals from clinicians for emotional support.” *Id.* at 58.

105. Dean & Fisher, *supra* note 13 at 464.

106. *Id.* at 461.

107. *Id.* at 475.

### D. *The Previvor-Physician Relationship*

Because decision making is significantly reliant on the doctor-patient relationship, this section will explore that relationship as it applies to physicians and previvors. In so doing, it will lay the groundwork for Part II, which will investigate the applicability of the legal doctrine of informed consent to explore whether existing doctrine fits modern circumstances.

#### 1. *Shifting Expectations and Obligations*

In the context of medical decision making for previvors, the roles of the physician and the “patient” may further shift away from the traditional roles of the physician-patient relationship. Considerations of the degree and incidence of risk of proposed interventions has always played a significant role in shaping the conventional physician-patient relationship. And particularly with the advent of precision medicine, patients will be progressively more burdened by shifting risk.<sup>108</sup> With the evolution of the doctor-patient relationship and the introduction of new and more advanced technologies, patients also increasingly bear the burden of dealing with uncertainty. Advances in modern medical technologies have brought with them new levels of uncertainty in medicine.<sup>109</sup> Consequently, “[p]hysician failure to disclose and the inherent misunderstanding of uncertainty on the part of patients have caused a clear increase in patient responsibility.”<sup>110</sup>

Even when physicians make all appropriate risk disclosures, certain responsibilities may still shift within the previvor-clinician relationship. The circumstances of previvorship are particularly prone to shifting the full responsibility of medical decision making to the individual. Physicians have recognized that discussions with previvors about possible interventions and discussions with patients already diagnosed with a disease may differ, because the exploration of preventative or prophylactic interventions do not fit the traditional mold of the physician-patient interaction.<sup>111</sup>

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108. Eyal et al., *supra* note 52 at 814 (“[t]he sociopsychological burden of uncertainty will be shifted to patients. Paradoxically, the burden of uncertainty inherent in a probabilistic diagnosis will be increased by the expectation that the purportedly ‘precise’ diagnosis will empower patients by giving them the opportunity to make better-informed decisions about future treatment.”).

109. Henry, *supra* note 80 at 321. Henry opined that “[f]ull disclosure, along with these new found patient responsibilities, will lead to the next level in the evolution of the physician/patient relationship, one of greater patient understanding and satisfaction.” *Id.*

110. *Id.* at 322.

111. Klitzman & Chung, *supra* note 45 at 59 (“Clearly, differences can emerge when surgeons work with newly diagnosed women with cancer (where direct approaches may be well-suited) versus women contemplating prophylactic operations (where non-directive discussions may be more appropriate).”)



Contrary to the expectations of the traditional informed consent process, previvors may not benefit from disclosures initiated by the health care provider, but would be better served by commencing discussions of potential prophylactic interventions on their own terms.<sup>112</sup> For example, in a study of asymptomatic BRCA mutation carriers that looked at women's choices to undergo bilateral prophylactic mastectomy, the most common predictor of post-surgical regret was physician-initiated, rather than patient-initiated, discussion.<sup>113</sup> The authors found that women who prefer prophylactic mastectomy may be very responsive to regret anticipation in cases of a bad outcome, concluding that "[t]his may occur because it is common practice to leave the decision to the patient, thus triggering a sense of personal responsibility for future bad outcomes."<sup>114</sup> This study has implications for how the doctor-patient interaction can best be structured to ensure satisfaction with previvor's decisions, by allowing individuals to initiate discussions about the risks, benefits, and alternatives of possible preventative interventions. But such efforts would run afoul of current expectations.<sup>115</sup>

Even in the context of advising asymptomatic BRCA positive individuals about the possibility of prophylactic bilateral mastectomies, some physicians see their disclosure role as unchanged from normal medical decision making. In a 2000 study, the authors surveyed 572 women who had undergone bilateral prophylactic mastectomy to gauge long-term satisfaction and psychological and social function.<sup>116</sup> They concluded, "[o]ur role as health care professionals is to provide a woman with a family history of breast cancer the best available information and encourage her to take time to consider all the options now available."<sup>117</sup>

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112. Importantly, the informed consent doctrine imposes an affirmative duty on the clinician to make all appropriate disclosures. See *infra* Section III. A for a more detailed discussion about the requirements of the legal doctrine of informed consent.

113. See generally David K. Payne, Carina Biggs, Kathy N. Tran, Patrick I. Borgen, & Mary Jane Massie, *Women's Regrets after Bilateral Prophylactic Mastectomy*, 7(2) ANNALS SURGICAL ONCOLOGY 150 (2000).

114. Sandra van Dijk, Mariëlle S. van Roosmalen, Wilma Otten, & Peep F.M. Stalmeier, *Decision Making Regarding Prophylactic Mastectomy: Stability of Preferences and the Impact of Anticipated Feelings of Regret*, 26 J. CLINICAL ONCOLOGY 2358, 2362 (2008).

115. Omri Ben-Shahar & Carl E. Schneider, *The Failure of Mandated Disclosure*, 159 U. PA. L. REV. 647, 649 (2011).

116. Marlene H. Frost, Daniel J. Schaid, Thomas A. Sellers, Jeffrey M. Slezak, Phillip G. Arnold, John E. Woods, Paul M. Petty, Joanne L. Johnson, Diana L. Sitta, Shannon K. McDonnell, Teresa A. Rummans, Robert B. Jenkins, Jeff A. Sloan, & Lynn A. Hartmann, *Long-term Satisfaction and Psychological and Social Function Following Bilateral Prophylactic Mastectomy*, 284(3) J. AM. MED. ASS'N. 31 (2000).

117. *Id.*

## 2. *Physician Willingness to Provide Prophylactic Interventions*

Physicians may conceptualize risk differently than do previvors.<sup>118</sup> Importantly, “[t]hese distinctions reflect decision-making complexities far deeper than mere incomplete information or irrational decision making.”<sup>119</sup> Based on their unique approaches to conceptualizing risks, some physicians may be reluctant to provide certain prophylactic interventions to previvors, particularly when the intervention is particularly, risky and the physician believes that it is not medically advisable.<sup>120</sup>

Surgeons have claimed that there are important distinctions between operating on a patient with cancer as compared to operating on a patient who has a risk of cancer. As a general rule, medical treatment is intended to address already-existing disease, while preventative interventions are intended to reduce the risk of future illness. All surgery on previvors is, by definition, prophylactic. All treatments or medications provided to previvors are prophylactic. And all lifestyle changes by previvors in response to genetic testing results, including variations to diet and exercise, are prophylactic.

118. Barbara McNeil, Ralph Weichselbaum, & Stephen G. Pauker, *The Fallacy of the Five Year Survival in Lung Cancer*, 29 NEW ENGL. J. MED. 1397, 1397 (1978); Padamsee et al., *supra* note 14 at 5-6.

119. Padamsee et al., *supra* note 14 at 5.

120. This is true for patients as well as previvors. Scholars have expressed concern that patients have access to “a wealth of information that they may not employ wisely ... leading to a dramatic paradigmatic shift in the nature of the physician-patient relationship.” Thomas L. Hafemeister & Richard M. Gulbrandsen, *The Fiduciary Obligation of Physicians to “Just Say No” if an “Informed” Patient Demands Services that are Not Medically Indicated*, 39 SETON HALL L. REV. 335, 336 (2009). Hafemeister and Gulbrandsen continued,

Patients today are far more likely to self-diagnose their ailments and to push for or insist upon certain medications or other medical products or procedures. Notwithstanding their physicians’ concerns about the wisdom of the patients’ views, these patients can place considerable pressure on physicians to order this treatment. This pressure may become particularly salient when patients threaten to go to another doctor if their physicians do not comply with their demands, or when physicians operating under the “crush” of daily practice are unwilling or unable to take the time to engage patients in a discussion as to why the requested medical response is contraindicated.

*Id.* at 336-37. They concluded, as have others,

If, however, the treatment being sought is not medically indicated in the physician’s judgment, the doctor has... an ethical and a legal duty to refuse to comply with the patient’s request. The doctor, not the patient, has the education and training necessary to determine when treatment is medically contraindicated under such a scenario and, thus, the responsibility to refuse to provide access to a treatment simply because it was requested or demanded by a patient.

*Id.* at 364-65. See also Rahul K. Parikh, *Showing the Patient the Door, Permanently*, N.Y. TIMES (June 10, 2008), <https://www.nytimes.com/2008/06/10/health/views/10case.html> [<https://perma.cc/E5H5-7275>]; Mark R. Wicclair & Douglas B. White, *Surgeons, Intensivists, and Discretion to Refuse Requested Treatments*, 44(5) HASTINGS CTR. REPORT 33, 33 (2014). There is no reason that this duty would not extend to the previvor-physician relationship.

Angelos argues that, from the surgeon's perspective, prophylactic surgery may be entirely different than "normal" (treatment-focused) surgery.<sup>121</sup> He believes that in the context of prophylactic surgery, complications are easier to accept in the course of treatment than for prophylactic interventions. Although the risks of the specific intervention (e.g., surgery, therapy, or drug) may or may not change based on whether the individual considering the intervention is an already-ill patient or a previvor, the perceived benefits shift when deciding whether to undergo a prophylactic intervention.

### 3. *Informational and Power Asymmetries*

Further, the previvor experience may alter the traditional informational and power asymmetries inherent in the doctor-patient relationship. Historically, "[p]ower in the doctor-patient relationship is distributed unequally. This structural inequality affects all transactions within the relationship, including decision making by the doctor and the patient, the construction of knowledge, and the doctor's performance of legal obligations to the patient."<sup>122</sup>

Often, during "normal" medical circumstances, a patient will receive a diagnosis based on symptoms, and then the physician will consider and recommend a course of treatment based on diagnosis and prognosis, refer the patient to a specialist if necessary, make the appropriate medical disclosures and obtain the patient's informed consent, and generally lead the patient through the course of treatment. Significantly, the informed consent process has traditionally been the forum for the patient to learn about the risks and benefits of a proposed course of treatment from the physician. The legal doctrine of informed consent is premised on ameliorating the information (and therefore power) asymmetry inherent in the physician-patient relationship. The doctor-patient relationship is often considered to be fiduciary in nature in order to ensure that physicians meet their disclosure and care obligations.<sup>123</sup>

As a general rule, "the provision of health information has historically been the responsibility of healthcare providers; however, more and more patients are seeking information outside of medical interactions."<sup>124</sup> In contrast to the more traditional model of medical decision

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121. Angelos, *supra* note 76.

122. Patricia Peppin, *Power and Disadvantage in Medical Relationships*, 3 TEX. J. WOMEN & L. 221, 222 (1994).

123. Maxwell J. Mehlman, *The Patient-Physician Relationship in an Era of Scarce Resources: Is There a Duty to Treat?*, 25 CONN L. REV. 349, 367 (1993) (noting that most courts and commentators agree that the patient-physician relationship is a fiduciary one); Grant H. Morris, *Dissing Disclosure: Just What the Doctor Ordered*, 44 ARIZ. L. REV. 313, 314 n.7 (2002); David Orentlicher, *Health Care Reform and the Patient-Physician Relationship*, 5 HEALTH MATRIX 141, 147 (1995).

124. Dean et al., *supra* note 30 at 1742.

making, once an individual receives genetic test results revealing a predisposition to disease, he or she begins the process of self-identifying (and perhaps embracing their identity) as a previvor and confronting their risk.<sup>125</sup> Thus, previvors may be the ones who seek interventions directly from specialists (e.g., by seeking a prophylactic double mastectomy due to a BRCA1 mutation, in order to avoid the risk of breast cancer).<sup>126</sup> The previvor assumes some level of responsibility for their health, which means that many previvors “have determined their preferred course of management before consulting a care provider.”<sup>127</sup> In such circumstances, the individual may present to the doctor-patient encounter armed with the information necessary for an informed (or at least voluntary) medical decision.<sup>128</sup> This shifts the information dynamic within the physician-patient relationship, allowing patients to take the lead in charting the course of their own treatment. Moreover, breast cancer support networks like FORCE,<sup>129</sup> Sharsheret,<sup>130</sup> and BrightPink,<sup>131</sup> and informational websites intended for previvors may decrease the medical profession’s “information monopoly.”<sup>132</sup>

Historically, authority has rested with physicians, based on “the voluntary character of the sick role; the organization of medicine as a profession with a code of ethics and the authority to self-regulate; and the asymmetry of knowledge between physician and patient.”<sup>133</sup> But as the traditional power asymmetry between physician and patient dissipates, the fiduciary relationship may be even further eroded.<sup>134</sup> The

125. Getachew-Smith et al., *supra* note 53 at 1262.

126. This concern may be exacerbated by circumstances where individual receives genetic testing results via direct-to-consumer genetic testing company.

127. Hartmann & Lindor, *supra* note 70 at 466 (citing Sandra van Dijk, Mariëlle S. van Roosmalen, Wilma Otten, & Peep F.M. Stalmeier, Decision Making Regarding Prophylactic Mastectomy: Stability of Preferences and the Impact of Anticipated Feelings of Regret, *J. CLINICAL ONCOLOGY* (2008)).

128. However, some research indicates that “the majority of previvors turned to healthcare providers for medical knowledge and the Internet and other fellow previvors for personal/social knowledge. This finding supports previous research about uncertainty management and genetic cancer risk that notes healthcare providers are effective informational sources for previvors and tend to offer biomedical information over biopsychosocial or emotionally related information.” Dean et al., *supra* note 30 at 1742.

129. FORCE, (last visited Sept. 29, 2020).

130. SHARSHERET, <https://sharsheret.org/> [<https://perma.cc/PX2V-UQYK>].

131. BRIGHTPINK, <https://www.brightpink.org/?keyword=bright%20pink&matchtype=e&network=g&device=c> [<https://perma.cc/W5KZ-NMS4>].

132. Klitzman & Chung, *supra* note 45. However, participation in communities such as FORCE may fall short of the needs of young previvors because messages tend to skew towards the most negative stories. Lindsey M. Hoskins, Kevin M. Roy, & Mark H. Greene, *Toward a New Understanding of Risk Perception Among Young Female BRCA1/2 “Previvors”*, 3 *FAMILIES, SYS., & HEALTH* 32 (2012).

133. Eyal et al., *supra* note 52 at 813.

134. Some scholars have argued that various transformations to the practice of medicine will erode this fiduciary relationship. Marc A. Rodwin, *Strains in the Fiduciary Metaphor: Divided Physician Loyalties and Obligations in a Changing Health Care System*, 21 *AM. J. L. & MED.* 241, 242 (1995).

shift in the information dynamic from the traditional physician-patient relationship and the correlated erosion to the fiduciary relationship is symptomatic of the diffusion of care within the practice of medicine. As physicians less frequently serve as the gatekeepers to medical knowledge, the traditional expectations, and thus the goals of the informed consent process, will continue to transform.<sup>135</sup>

## II. THE LEGAL DOCTRINE OF INFORMED CONSENT

Often, medical and scientific discoveries outpace the law. The introduction of previvorship to the medical landscape raises special issues for the physician-patient relationship and the legal doctrine of informed consent. It challenges some of the most basic assumptions about the doctrine. However, the previvor experience is not wholly exceptional; rather, it is exemplary of the diminishing utility of the legal doctrine of informed consent<sup>136</sup> and is illustrative of the need to transition to a robust shared decision-making model.

The legal doctrine of informed consent mandates the disclosure of the risks, benefits, and alternatives of a proposed intervention.<sup>137</sup> Uncertainty renders current law potentially ineffective in addressing the reality of the physician-previvor relationship and the difficult decisions that are often left to previvors to make.

### A. Current Law

#### 1. History of the Legal Doctrine of Informed Consent

In the mid-twentieth century, courts began to recognize claims for failure of informed consent,<sup>138</sup> with the understanding that respect for persons is achieved by respecting individual self-determination and autonomous decision making. The doctrine of medical informed consent evolved from the theory that individuals have the right to make health care decisions that further their own health and wellbeing.<sup>139</sup> Therefore, clinicians, scholars, and policy-makers attempted to replace

135. However, the conception of the previvor as self-directed and empowered is not universal. It has also been recognized that many women with genetic mutations do not want to be burdened with these decisions, but instead want clear and unambiguous advice from their physicians about what treatment options to pursue. Klitzman & Chung, *supra* note 45; cited in Campo-Engelstein, *supra* note 12.

136. See Valerie Gutmann Koch, *Eliminating Liability for Informed Consent to Medical Treatment*, 53 U. RICHMOND L. REV. 1211 (2019).

137. Yael Schenker & Alan Meisel, Informed Consent in Clinical Care: Practical Considerations in the Effort to Achieve Ethical Goals, 305(11) J. AM. MED. ASSOC. 1130 (2011).

138. *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972); *Cobbs v. Grant*, 8 Cal. 3d 229 (1972).

139. The term “informed consent” – and with it, a proposed duty to disclose – first appeared in 1957 in the California case *Salgo v. Leland Stanford Jr. Univ. Bd. Of Trs.*, 317 P.2d 170 (Cal. Ct. App. 1957) (holding that physicians had a duty to disclose all facts that were necessary for the patient to make an intelligent health care decision).

the paternalistic “doctor knows best” approach to medicine<sup>140</sup> with increased self-determination in medical decision making. Courts began to emphasize patient autonomy by mandating that physicians disclose the risks, benefits, and alternatives of a proposed intervention.<sup>141</sup>

Under a cause of action for failure to provide informed consent, failure to disclose the risks of a proposed medical intervention or therapy may allow an individual to recover for harm arising from nondisclosure of information material to the individual’s decision to agree to the intervention.<sup>142</sup> Today, all United States jurisdictions have adopted some form of the doctrine of informed consent either by statutory enactment or judicial decision.<sup>143</sup>

However, states vary as to whether they require a standard of disclosure established by law (the reasonable patient standard) or by professional custom (what a reasonable physician concludes a patient ought to know).<sup>144</sup> The professional, or community, standard of disclosure requires disclosure only of what physicians wish the patient to know. Consent is generally legally adequate as long as the patient had notice of the nature and scope of the proposed medical intervention. In the early 1970s, the reasonable person standard replaced the more paternalistic community standard in two seminal cases, *Canterbury v.*

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140. Ryan Childers, Pamela A. Lipsett, & Timothy Pawlik, *Informed Consent and the Surgeon*, 208 J. AM. C. SURGEONS 627, 627 (2009).

141. See, e.g., *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972); *Cobbs v. Grant*. See also Sheldon F. Kurtz, *The Law of Informed Consent: From “Doctor is Right” to “Patient has Rights,”* 50 SYRACUSE L. REV. 1243 (2000).

142. Valerie Gutmann Koch, *A Private Right of Action for Informed Consent*, 45 SETON HALL L. REV. 173, 180 (2015).

143. *Id.*

144. David M. Studdert, Michelle M. Mello, Marin K. Levy, Russell L. Gruen, Edward J. Dunn, E. John Orav, & Troyen A. Brennan, *Geographic Variation in Informed Consent Law: Two Standards for Disclosure of Treatment Risk*, 4 J. EMPIRICAL LEGAL STUD. 103 (2007). See generally Jaime S. King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32(4) AM. J. L. & MED. 429 (2006); Koch, *Eliminating Liability for Informed Consent to Medical Treatment*, *supra* note 136; Koch, *A Private Right of Action for Informed Consent*, *supra* note 142 at 180; Charles L. Sprung & Bruce J. Winick, *Informed Consent in Theory and Practice: Legal and Medical Perspectives on the Informed Consent Doctrine and a Proposed Reconceptualization*, 17(12) CRIT. CARE MED. 1346 (1989). It has been argued that the professional standard encourages “disengaged monologues” on the part of the physician. Jay Katz, *Informed Consent – A Fairy Tale? – Law’s Vision*, 39 U. PITT. L. REV. 137, 146-47 (1977).

*Spence*<sup>145</sup> and *Cobbs v. Grant*.<sup>146</sup> These cases changed the prevailing rules for the duty to disclose, holding that the decision to accept or reject therapy is a personal decision and not a medical decision to be made by a doctor. Thus, under this newer standard, doctors have a duty to disclose all information that is material to a reasoned decision by the patient. Whether the information is “material” is determined by what a “reasonably prudent” person would deem material, including the degree and incidence of the risk of the proposed intervention, the available alternatives to the intervention, and the risks and benefits of no treatment at all.<sup>147</sup>

A legal claim of lack of informed consent requires the same elements required to establish a traditional negligence claim: (1) a duty of care owed by the defendant to use reasonable care to prevent harm to the plaintiff, (2) breach of that duty, (3) harm or injury to the plaintiff, and (4) a causal link between the injury and the breach of duty.<sup>148</sup> Importantly, almost every state applies an objective standard for proving causation, whereby the “patient must show that a reasonably prudent person in the patient’s medical condition would not have chosen the procedure had he been fully informed.”<sup>149</sup> Moreover, in order to recover for failure to provide informed consent, it must be proven that the patient experienced actual (usually physical) injury.<sup>150</sup>

## 2. *Erosion of the Legal Doctrine of Informed Consent*

Concerns about the utility of the legal doctrine of informed consent in ensuring voluntary decision making and individual self-

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145. 464 F.2d 772 (D.C. Cir. 1972). The court of appeals for the DC circuit addressed the case of a 19-year-old patient with chronic back pain who underwent a laminectomy, which had an estimated one percent risk of paralysis. The physician requested phone and then written consent from the patient’s mother, but did not tell the patient of the risk, due to concern that it might discourage him from undergoing surgery. At trial, the physician argued that he ought to be able to withhold information if it might deter the patient from accepting “needed” therapy, frighten the patient, delay convalescence, or impose a negative placebo effect. When paralysis occurred, the patient sued.

146. In *Cobbs v. Grant*, the Supreme Court of California focused on the relative information disparity between the doctor and patient, stating, “the patient, being unlearned in medical sciences, has an abject dependence upon and trust in his physician for the information upon which he relies during the decisional process, thus raising an obligation in the physician that transcends arms-length transactions.” In other words, patients need to know the risks because they bear them. 8 Cal. 3d 229 (1972).

147. Jay Katz, *Informed Consent – Must it Remain a Fairy Tale?*, 10 J. CONTEMP. L. & POL’Y 69, 80 (1993).

148. Jessica W. Berg, Charles W. Lidz, Lisa S. Parker, & Paul S. Appelbaum, *Informed Consent: Legal Theory and Clinical Practice*, UMASS CHAN MEDICAL SCHOOL (Oxford Univ. Press, 2001) at 133-34.

149. Evelyn M. Tenenbaum, *Revitalizing Informed Consent and Protecting Patient Autonomy: An Appeal to Abandon Objective Causation*, 64 OKLA. L. REV. 697, 697 (2012).

150. Alan J. Weisbard, *Informed Consent: The Law’s Uneasy Compromise with Ethical Theory*, 65 NEB. L. REV. 749, 753-54 (1986).

determination have existed since the introduction of the doctrine itself.<sup>151</sup> And in context of modern medical practice, the legal doctrine of informed consent is becoming progressively inadequate in protecting patient self-determination in medical decision making. There is an increasing disconnect between the legal doctrine of informed consent in theory and the application of informed consent in practice, and thus, the doctrine already does little to serve the purposes for which it was intended.<sup>152</sup>

In 1994, Peter Schuck addressed the divergence between theory and practice in what “informed consent” does and should mean, noting that clinicians tend to have a “realist” vision of the informed consent doctrine while policy makers and judges tend to have an “idealist” vision.<sup>153</sup> This distinction may be the underlying cause of the obstacles between effectively translating the principles and theory behind the doctrine of informed consent into actual practice. Schuck surveyed empirical studies and concluded that “most physician-patient discussions appear to be rather perfunctory and reinforce physician control[.]”<sup>154</sup> He observed that physicians avoid interactive, open-ended dialogue and concluded that “informed consent law in action is often ritualistic, formalistic, and hollow.”<sup>155</sup>

One of the most common arguments against liability for informed consent is that the informed consent process in the medical context has been coopted by the legal community in an effort to protect health care providers from liability. Thus, it is argued that rather than promoting patient autonomy, in its current incarnation, it serves only to shield doctors. And rather than strengthening the doctor patient relationship, it contributes to its deterioration.<sup>156</sup> Instead of focusing on informing patients and ensuring patient self-determination – the

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151. To be clear, that does not mean that scholars and policy makers have reached consensus regarding the elimination of the doctrine. Many argue that it should be modified or updated to reflect changing circumstances. See Thomas G. Gutheil, Harold Bursztajn, & Archie Brodsky, *Malpractice Prevention through the Sharing of Uncertainty*, 311 NEW ENGL. J. MED. 49 (1984) (“Informed consent need not be a mere formality with a limited medicolegal function. Rather, it can be a focal point in establishing a therapeutic alliance.”).

152. For a more detailed exploration of the arguments in favor of eliminating the tort of informed consent, see Koch, *Eliminating Liability for Informed Consent to Medical Treatment*, *supra* note 136.

153. Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L. J. 899, 903 (1994).

154. *Id.* at 932-33.

155. *Id.* at 933-34.

156. For more on accusations that the legal doctrine of informed consent is both needlessly adversarial and backward-looking, resulting in the process of obtaining informed consent to treatment becoming a defensive endeavor, see Koch, *Eliminating Liability for Lack of Informed Consent to Medical Treatment*, *supra* note 136. See also Jay Katz, INTRODUCTION TO: THE SILENT WORLD OF DOCTOR AND PATIENT, xvi (1984) (arguing that the obtaining of informed consent to treatment is becoming a defensive endeavor. The 2002 introduction to Katz’s seminal work distinguished between “the legal doctrine [of informed consent], as promulgated by judges, and the idea of informed consent, based on a commitment to individual self-determination.”). Katz at xliii.



principles upon which the *Canterbury* and other decisions were based – the practice of obtaining informed consent to treatment may be centered on protecting health care providers from litigation.<sup>157</sup>

Thus, because the legal doctrine of medical informed consent sets the floor for ethical behavior, physicians may only disclose the minimum that the law requires. The threat of liability may lead physicians to over-focus on minimizing that threat, resulting in them neglecting the process of medical informed consent to facilitate discussion and understanding.

A second, and related, critique is that imposition of legal liability for failure of informed consent results in a substitution of form for process. Historically, the informed consent form was intended as an instrument to enhance patient understanding of the proposed intervention. However, the resulting emphasis on the documentation, rather than the substance, of informed consent demonstrates the inadequacies of and overreliance upon consent forms in medical practice.<sup>158</sup>

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157. See Cathy J. Jones, *Autonomy and Informed Consent in Medical Decisionmaking: Toward a New Self-Fulfilling Prophecy*, 47 WASH. & LEE L. REV. 379, 398 (1990) (“[P]atients are not protected; physicians are burdened with requirements that mean little; the law and society’s principles concerning individual autonomy and decisionmaking are effectuated in name only.”); Charity Scott, *Why Law Pervades Medicine: An Essay on Ethics in Health Care*, 14 NOTRE DAME J. L. ETHICS & PUB. POLY 245, 273–75 (2000); Alexander M. Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PA. L. REV. 340, 367 (1974); William M. Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701, 1705 n.8 (1999); John Lantos, *Informed Consent: The Whole Truth for Patients?*, 72(9) CANCER (1993). Clarence H. Braddock, Kelly A. Edwards, Nicole M. Hasenberg, Tracy L. Laidley, & Wendy Levinson, *Informed Decision Making in Outpatient Practice: Time to Get Back to Basics*, 282(24) J. AM. MED. ASSOC. 2313 (1999) (noting the disconnect between legal doctrine and ethical practice. “For too long, informed consent in clinical practice has been influenced by an interpretation of informed decision making as a legal obligation in which the emphasis is full disclosure, rather than an ethical obligation toward mutual decision making by fostering understanding.”).

158. Lisa Rapaport, *Stronger Malpractice Laws May Not Prevent Surgical Complications*, REUTERS (Jan. 27, 2017), <https://www.reuters.com/article/us-health-surgery-malpractice-laws/stronger-malpractice-laws-may-not-prevent-surgical-complications-idUSKBN15B1NM> [<https://perma.cc/7RSC-UAPW>]; Christina A. Minami, Catherine R. Sheils, Emily Pavey, Jeanette W. Chung, Jonah J. Stulberg, David D. Odell, Anthony D. Yang, David J. Bentrem, & Karl Y. Bilimoria, *Association Between State Medical Malpractice Environment and Postoperative Outcomes in the United States*, 224(3) J. AM. COLLEGE SURGEONS 310 (2017) (“Higher risk malpractice environments were not consistently associated with a lower likelihood of surgical postoperative complications, bringing into question the ability of malpractice lawsuits to promote health care quality.”); Victor Ali, *Consent Forms as Part of the Informed Consent Process: Moving Away From “Medical Miranda,”* 54 HASTINGS L. J. 1575 (2003). See also Yael Y. Schenker, *Interventions to Improve Patient Comprehension in Informed Consent for Medical and Surgical Procedures: a Systematic Review*, 31(1) MED. DECISION MAKING 151 (2011). Despite its critical importance to the provision of safe, high-quality, patient-centered health care, the process of informed consent in clinical practice is frequently inadequate, and prior research has demonstrated that patient comprehension of the key elements of clinical informed consent is often poor. Physicians receive little training in how to conduct informed consent discussions. Misunderstandings about consent requirements and goals, differing legal standards for informed consent disclosure, and the time pressures and competing demands of clinical medicine may also hinder the

These forms often provide legally-mandated information without regard to the usefulness of these forms in enhancing patient understanding of the proposed intervention. Thus, it is argued that the consent form has replaced the process it was intended to support and may even enable providers who seek to coopt patients' autonomous informed decision making with their own treatment preferences.

It is also argued that the legal doctrine of informed consent does not serve the realities of the clinical setting.<sup>159</sup> A study by Clarence Braddock and colleagues looked at over a thousand physician-patient encounters and concluded that the "low level of informed decision making suggests that physicians' typical practice is out of step with ethical ideals."<sup>160</sup> The law of informed consent (and medical malpractice or negligence more generally) is notoriously vague and shifting, and physicians are not provided with specific guidance about how to comply. Moreover, the nature of medical interventions does not allow informed consent at every step.<sup>161</sup> The required elements of an informed consent claim may, in fact, hinder the ability to ensure that patients are able to make informed, voluntary medical decisions.<sup>162</sup>

Scholars and medical professionals argue that the law's onerous requirements necessitate over-disclosure rather than comprehension and trust in the doctor-patient relationship.<sup>163</sup> The central element of

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informed consent process. Many consent forms do not contain the key elements of informed consent or are written in a language too complex for many patients to understand. Patients who do not speak English or have limited literacy are at increased risk for poor comprehension. Sprung & Winick, *supra* note 144 ("[U]nfortunately, the consent form has at times replaced the process it was intended to substantiate.").

159. Daniel E. Hall, *Informed Consent for Clinical Treatment*, 184(5) CANADIAN MED. ASSOC. J. 533, 536 (2012) ("Research suggests that physicians rarely meet even minimal standards of disclosure for the purposes of obtaining informed consent."); Weisbard, *supra* note 150 at 766; Alan Meisel & Mark Kuczewski, *Legal and Ethical Myths About Informed Consent*, 156 ARCHIVE INTERNAL MED. 2521, 2522 (1996).

160. Braddock et al., *supra* note 157, at 2319 (looking at 1057 physician-patient encounters involving 59 primary care physicians and 65 general or orthopedic surgeons. Only 9 percent of the 2553 clinical decisions made during these encounters met the criteria for completely informed decision-making).

161. Sprung & Winick, *supra* note 144.

162. *Id.* (explaining that another reason the legal doctrine of informed consent is inadequate to ensuring self-determination is due to the jurisdictional splits regarding the level of disclosure required by a physician. This may lead to a lack of uniformity in the ability to enforce the legal doctrine of informed consent. Thus, the competing materiality standards – approximately half the states apply the professional standard and half apply the reasonable patient standard – may result in unpredictability in one's ability to recover for a failure of informed consent); King & Moulton, *supra* note 144.

163. Erin Donovan and colleagues recognized,

A general premise of informed consent interventions is that giving patients more information is a key component to improving the consent process. We would argue that effective disclosure and informed consent hinges on providing sufficient

the legal doctrine of informed consent is the mandated disclosures. However, the mandated disclosure requirements do not serve the goal of the theory underlying informed consent, because (1) “doctors do not give patients the information that they would need to make educated decisions[,]” (2) “good ways to communicate information have proved elusive. Forms used to provide information frequently exceed readability standards[,]” (3) “even when doctors lavish information on patients, most patients neither understand nor remember it[,]” and (4) “patients regularly make life-and-death decisions without even the most basic information and with many misconceptions.”<sup>164</sup>

Notably, uncertainty has been an important influence in medical decision making since the early days of the legal doctrine of informed consent.<sup>165</sup> Jay Katz, in his work on informed consent, noted the role of uncertainty in undermining the aspirations of the doctrine. In 1993, he declared, “[t]he longer I reflect about doctor-patient decision-making, the more convinced I am that in this modern age of medical science, which for the first time permits sharing with patients the uncertainties of diagnosis, treatment, and prognosis, the problem of uncertainty poses the most formidable obstacle to disclosure and consent.”<sup>166</sup> Case law imposing tort liability for failure to disclose the risks, benefits, and alternatives of a proposed medical intervention does not acknowledge the concept of uncertainty and the role it plays in patient decision making. The influential decision *Canterbury v. Spence* is illustrative of the legal doctrine’s emphasis on risk but not uncertainty: there, the term “risk” appears 56 times, while the term “uncertainty”

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amounts of high-quality, usable information—in other words, patients need *better*, rather than just *more*, information.

Erin E. Donovan, Brittani Crook, Laura E. Brown, Angie E. Pastorek, Camille A. Hall, Michael S. Mackert, & Keri K. Stephens, *An Experimental Test of Medical Disclosure and Consent Documentation: Assessing Patient Comprehension, Self-Efficacy, and Uncertainty*, 81(2) COMMUNICATION MONOGRAPHS 239 (2014). In fact, the authors propose that “greater quantities of information may be inadvisable” due to the uncertainty associated with extensive risk information that feels overwhelming or seems contradictory. The authors recommend modifications to medical disclosure and consent documentation to avoid exceedingly complex documentation and ensure consistency. While such an approach may reduce uncertainty by not exposing patients to it (and seeking to expose individuals only to “quality” health information), it does not fully respect autonomous decision making in terms of determining what information individuals consider material to a decision (e.g. patients may, in fact, find uncertainty useful to their decision making even if it does not indicate a specific path to take, even if that uncertainty leads to ambiguity). This is not a fault of the research, but rather a limitation of focusing solely on medical disclosure and consent documentation rather than the entire process of medical decision making.

164. Omri Ben-Shahar & Carl E. Schneider, *The Failure of Mandated Disclosure*, 159 U. PA. L. REV. 647, 649 (2011) (defining mandated disclosure as a “regulatory technique” that is expected to “improve decisions people make in their economic and social relationships and particularly to protect the naïve from the sophisticated”).

165. Barbara McNeil, Ralph Weichselbaum, & Stephen G. Pauker, *The Fallacy of the Five Year Survival in Lung Cancer*, 299 NEW ENGL. J. MED. 1397 (1978).

166. Katz, *Informed Consent – Must it Remain a Fairy Tale?*, *supra* note 156, at 81.

does not appear a single time.<sup>167</sup> Failure of the legal doctrine to embrace uncertainty itself neglects considering personal concerns such as psychosocial issues and factors in medical choice.

### *B. Against the Legal Doctrine of Informed Consent for Previvors*

Previvorship exemplifies and amplifies the inadequacy of the legal doctrine of informed consent to address the limitations of effective decision making. While the legal doctrine of informed consent may be ineffective in ensuring previvors' self-determination and voluntary decision making, previvorship itself does not represent a "paradigm shift."<sup>168</sup> Rather, it is a definitive example of the defectiveness of the legal doctrine of informed consent to address decision making in modern medical practice. Previvorship is paradigmatic of how medical and scientific innovations and the evolving doctor-patient relationship are rendering the legal doctrine of informed consent ineffective to addressing the parties' needs.

#### *1. Uncertainty and the Legal Doctrine of Informed Consent*

In particular, and as discussed in Part I.C.2, previvors' decisions to pursue or refuse prophylactic therapies or surgeries are often based, in substantial part, on uncertainty. However, the legal doctrine of informed consent may, in fact, serve as a deterrent to full and complete discussions about uncertainty in medical decision making. Thus, the previvor decision making process is illustrative of the increasing inability of the legal doctrine of informed consent to address patient uncertainty. In other words, the effect that uncertainty in previvor

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167. *Canterbury*, 464 F.2d at 772-96; Nor are the terms used interchangeably. In other words, the court did not conflate the concepts of risk and uncertainty in its decision. Babrow and colleagues explained that legal doctrine of informed consent is inadequate in addressing the limitations of effective action in the wake of uncertainty:

Case law on informed consent has historically defined uncertainty as ignorance of available information. As a result, we have been led to overly simple and ineffective practices. For example, informed consent law is founded on the simplistic notion that meaningful informed consent requires the transfer of information from doctor to patient. Moreover, the law requires that information is judged adequate according to some static benchmark, such as the "professional practice" or the "reasonable person" standard. By contrast, it is more accurate and therefore more likely effective to view medical uncertainties as complex, multiform, communicative constructions.... In sum, a firm understanding of the variety of meanings of uncertainty would in all likelihood yield substantially improved scholarship as well as enhancements in medical policies, in practitioners' and patients' communicative competence, and in patients' illness experiences and outcomes.

Babrow et al., *supra* note 95 at 3-4 (internal citations omitted).

168. Thomas Kuhn, *THE STRUCTURE OF SCIENTIFIC REVOLUTIONS* (Otto Neurath et al. eds., 2nd ed. 1962).

decision making may have on individual autonomy may undermine the effectiveness of the legal doctrine of informed consent.<sup>169</sup>

First, the absence of a standard of care for many genetic predisposition states<sup>170</sup> adds an additional level of uncertainty to previvor decision making. Further, physicians<sup>171</sup> are often reluctant or unable to disclose or discuss the uncertainty of prophylactic interventions with previvors. Physicians generally do not discuss uncertainty in their regular informed consent interactions with patients.<sup>172</sup> While “the ideal of informed or shared decision making implies a need for communicating uncertainty to patients[,]” there are many reasons why clinicians are unable or unwilling to fulfill this responsibility.<sup>173</sup> In the context of physician disclosure of uncertainty, physicians may “fear that admission of uncertainty will discredit the medical profession and cause more harm than [*sic*] good.<sup>174</sup> It may also be difficult to identify what types or sources of uncertainty should be disclosed to previvors. Consequently, “more work is needed to define the circumstances in which uncertainty ought to be communicated.”<sup>175</sup>

The legal doctrine of informed consent’s emphasis on mandated disclosures does little to address the existence of irreducible uncertainty underlying the previvor experience. As research has demonstrated, “simply providing information to previvors is not sufficient to assist in coping with their high genetic risk.”<sup>176</sup> Having all available information may not eliminate uncertainty.<sup>177</sup> Previvors may have all currently available medical information but may still never know whether they will develop the disease(s) to which they are genetically predisposed and who struggle with making choices that are right over the course of their lifetimes. The legal doctrine of informed consent was not built to address such high levels of uncertainty as those that are

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169. Thomas L. Beauchamp & James F. Childress, *PRINCIPLES OF BIOMEDICAL ETHICS* (Oxford University Press, 4th ed. 1994).

170. These include BRCA mutations or genetic variation that increases individuals’ probably of developing stomach cancer. *See supra* Part I.A.

171. Interpretations of current law generally require that physicians, and only physicians, obtains informed consent from patients. *See* Valerie Gutmann Koch, *Delegating Informed Consent* 47(6) *THE HASTINGS CTR. REPORT* 5 (2017).

172. Henry et al., *supra* note 80, at 321 (“Though physicians are aware of the prevalence of uncertainty that underlies routine practice patterns they face each day, these components do not emerge during the informed consent process.”).

173. Politi et al., *supra* note 66, at 691.

174. Henry et al., *supra* note 80, at 322 (but the authors also recognized that malpractice claims based on disclosure failures have been increasing rapidly since the 1970s).

175. Politi et al., *supra* note 66, at 691. The authors also raise a larger question: is there any level of acceptable uncertainty?

176. Dean et al., *supra* note 30, at 1742. *See also* Hong, *supra* note 95, at 251 (“uncertainty related to genetic risk information is caused in part by uncertainty’s probabilistic nature, which includes ambiguity and complexity.”).

177. Dean, *supra* note 105; citing Dale E. Brashers, *Communication and Uncertainty Management*, 51 *J. COMMUNICATION* 477 (2001).

intrinsic to previvor decision making. With its focus on mandated information disclosures, it is incapable of assisting individuals in coping with irreducible uncertainty. Thus, existing rules are inappropriate to the types of decisions that previvors face because “[t]he needs of this group are different from those actually diagnosed with cancer” and other illness.<sup>178</sup>

Further, as discussed in Section I.D.1, previvors might benefit from initiating the informed consent discussion, rather than relying on physicians to decide when, and if, to initiate discussions to explore possible preventative interventions.<sup>179</sup> However, this approach diverges from the disclosure obligations of the legal doctrine of informed consent, which generally expects physicians to initiate discussions of the risks, benefits, and alternatives of a proposed intervention, thereby making all mandated disclosures without prompting from the patient.

## 2. *Risk, Previvor Decision Making, and the Legal Doctrine of Informed Consent*

The role of risk may take on increasing complexity in previvor decision making. Due to the multiple categories of risk (e.g., the risk of the undergoing prophylactic intervention, the risk of not taking prophylactic action), the risk/benefit calculation may be adjusted for previvors. For example, the risks of “doing nothing” (or, alternatively, increased surveillance) may increase the probability of developing the disease to which the individual is genetically predisposed, and must therefore be identified and balanced.

In light of the increasing burden on patients as a result of the evolving doctor-patient relationship,<sup>180</sup> the current legal rules for informed consent may be inadequate to ensuring patient comprehension and voluntary decision making.<sup>181</sup> The shift in emphasis from risk to benefit during informed consent disclosures not only upends the normal process of the informed consent discussion, but also complicates

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178. Mahon, *supra* note 32, at 127.

179. David K. Payne, Carina Biggs, Kathy N. Tran, Patrick I. Borgen, & Mary Jane Massie, *Women's Regrets after Bilateral Prophylactic Mastectomy*, 7(2) ANN. SURG. ONCOL. 150 (2000).

180. See Section I.D.

181. Moreover, a legal model of disclosures and discussion like that contained in the informed consent doctrine may not be responsive to one of the key deficits in our current medical system. The legal doctrine of informed consent and the biomedical model that has developed in response to the legal mandates is deficient in addressing the complexity and diversity of the patient population. The contours of the legal construct of the informed consent model is based on research and experience related to narrow strata of the general population. Salant et al., *supra* note 56, at 780 (noting, “to the extent that theoretical models are constructed based on the variation within a patient sample, most existing research in this area has focused on predominantly white, educated, and privately insured populations who actively seek ‘high risk’ counseling.”). A more effective and just approach would be constructed based on the variation across the population.

mandated disclosures. Despite the societal reliance on the biomedical model of illness,<sup>182</sup> in reality, previvor decision making around risk and prophylactic interventions are based on more than medical factors; they often include psychosocial factors.<sup>183</sup> For example, one may seek “peace of mind” due to increased confidence that the individual will not develop the illness as a result of his or her genetic predisposition. But the legal doctrine of informed consent is not well-suited to addressing “non-medical” risks and benefits.<sup>184</sup>

In conclusion, the legal doctrine of informed consent is inadequate to ensuring that previvors – and all patients – are supported in their decision making with regard to medical and prophylactic procedures, pharmaceutical interventions, and active surveillance. Particularly in light of shifting doctor-patient dynamics, the ever increasing role of uncertainty, and the complexity of comprehending and processing medical and psychosocial risks and benefits, the time has come to move to a new model of decision making. The mandated disclosure framework of the legal doctrine of informed consent that is currently required by court cases and state statutes does not serve the intended purpose of respecting individual self-determination. The inadequacy of the doctrine of informed consent to safeguard the very principle it is intended to protect supports arguments in favor of moving away from the doctrine toward a new approach. The legal doctrine of informed consent’s emphasis on autonomy – at the expense of other important bioethical principles<sup>185</sup> – renders the doctrine inappropriate to the context of previvor decision making.<sup>186</sup> Rather, we should begin to envision a legal doctrine that supports a robust shared decision-making approach to truly address individual preferences and values, the increasing complexity of risk/benefit assessment, and inherent (and sometimes irreducible) uncertainty.

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182. See Part III.B.

183. Hesse-Biber & An, *supra* note 73.

184. Nadia N. Sawicki, *Modernizing Informed Consent: Expanding the Boundaries of Materiality*, 2016 U. ILL. L. REV. 821 (2016) (“disclosures in clinical practice are limited to information that is considered material from a purely medical perspective: the patient’s diagnosis and prognosis, the nature of the proposed treatment, the treatment’s risks and benefits, and any reasonable alternative treatments.”) (emphasis added).

185. Beauchamp & Childress, *supra* note 169.

186. As Andrew Seely explained,

Acknowledging uncertainty does not mean abandoning patients to their autonomy; it is the physician’s responsibility to manage the decision-making process in a fashion in keeping with each individual patient’s values and beliefs. By acknowledging uncertainty within patient care, the physician-patient relationship can be elevated to one of greater communication and shared decision-making.

Andrew J.E. Seely, *Embracing the Certainty of Uncertainty: Implications for Health Care and Research*, 56(1) PERSPECTIVES IN BIOLOGY AND MED. 65, 72 (2013).

### III. LOOKING TO THE FUTURE

As discussed in Part II.B, the legal doctrine of informed consent has been proving increasingly deficient in protecting individuals' self-determination for quite some time. Robert Veatch, in 1995, called consent a "transition concept" recognizing its declining utility. He argued that consent is the type of concept that "appears on the scene as an apparently progressive innovation, but after a period of experience turns out to be only useful as a transition to a more thoroughly revisionary conceptual framework."<sup>187</sup>

The shared decision-making model may be more responsive to the previvor decision-making experience. Claims that robust shared decision making between patient and physician will further balance the goals of autonomy and beneficence in medicine are underscored by the previvor experience.

#### A. Shared Decision Making

##### 1. The Shared Decision-Making Model in Medicine

In 1994, Jerome Kassirer, the editor of the *New England Journal of Medicine*, presaged a model of shared decision making in which patient's values, interests, and preference are taken into account.<sup>188</sup> He cautioned that "[m]any decisions need to be individualized, especially when they involve choices between possible outcomes that may be viewed differently by different patients."<sup>189</sup> Kassirer acknowledged the fact that "[a]n individual approach is particularly important because of the vast differences in the values subjects place on clinical outcomes even when a single method is used."<sup>190</sup> He observed that even the most insecure patient preferences are entirely relevant because while "patients' preferences are highly idiosyncratic, they still must be respected."<sup>191</sup> The need to emphasize patient preferences has not

187. Robert M. Veatch, *Abandoning Informed Consent*, 25(2) THE HASTINGS CTR. REPORT (1995).

188. Jerome P. Kassirer, *Incorporating Patients' Preferences into Medical Decisions*, 330(26) NEW ENGL. J. MED. 1895 (1994).

189. *Id.*

190. Kassirer noted this fact, in the context of choosing between two different treatment approaches to the treatment of deep vein thrombosis. In addition to the choice between heparin alone and streptokinase plus heparin in the context of treating deep vein thrombosis, Kassirer references many other clinical decisions in which patients' views of utility are critical in swaying choices between alternative interventions or therapies. *Id.*

191. *Id.* Kassirer recommends that physicians be permitted, or perhaps even required, to elicit patient preferences under at least the following circumstances:

(1) [W]hen there are major differences in the kinds of possible outcomes (for example, death versus disability); (2) when there are major differences between treatments in the likelihood and impact of complications; (3) when choices involve trade-offs between near-term and long-term outcomes; (4) when one of the choices can result in a small chance of a grave outcome;



diminished as medicine has evolved; rather, medical decision making requires even more consideration of individual values and preferences.

Shared decision making is viewed as an alternative to the purely autonomy-focused informed consent model of medical decision making, and “includes the notion of a medical encounter as a ‘meeting of experts’ – the physicians as an expert in medicine and the patient as expert in his or her own life, values and circumstances.”<sup>192</sup> Rather than focusing on what the objective reasonable patient would find material to a voluntary medical decision, shared decision making is subjective and patient specific, relying “on the medical evidence, the provider’s clinical expertise, and the unique attributes of the patient and his or her family[,]” including cultural factors and factors that affect patient-clinician interactions.<sup>193</sup>

Shared decision making emphasizes *how* information is communicated. For all patients, “[h]ealthcare providers need to be aware that their approach in framing the information ultimately influences adjustment to the diagnosis and satisfaction with management decisions.”<sup>194</sup> Research emphasizes that individuals “desire... that healthcare providers need to provide factual information; information needs to be continually provided in a supportive and caring manner that encourages the exchange of questions and information.”<sup>195</sup> Such an approach must focus on managing uncertainty, not just simply reducing gaps in knowledge. Thus, the decision-making process should put less emphasis on *who* initiates the conversations, and focus more on assisting “coping efforts so that decisions are not impaired by anxiety but rather informed by the uncertainty.”<sup>196</sup> In fact, “[s]hared decision making is most appropriately applied under conditions of uncertainty.”<sup>197</sup> Shared decision making “requires helping patients—and health professionals—cope with the consciousness of ignorance that

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(5) when the apparent difference between options is marginal; (6) when a patient is particularly adverse to taking risks; and (7) when a patient attaches unusual importance to certain possible outcomes. *Id.*

192. William Godolphin, *Shared Decision-Making*, 12 HEALTHCARE QUARTERLY 186 (2009) (citing David Tuckett, Mary Boulton, Coral Olson, & Anthony Williams, *Meetings Between Experts: an Approach to Sharing Ideas in Medical Consultations* (Tavistock Publications 1985)).

193. France Légaré & Holly O. Wittman, *Shared Decision Making: Examining Key Elements and Barriers to Adoption into Routine Clinical Practice*, 32(2) HEALTH AFF. (2013).

194. Mahon, *supra* note 32, at 127.

195. *Id.* at 127.

196. Han et al., *supra* note 86 at 836. Han and colleagues therefore conclude that we should look to the ideal of informed decision making, which advocates educating patients about the uncertainties regarding benefits and harms of medical interventions. However, as discussed in this paper, the legal doctrine of informed consent is not well-suited for achieving this theoretical ideal. Rather, a robust shared decision making approach may be a more appropriate approach to achieving this goal.

197. Légaré & Wittman, *supra* note 193.

cannot be remediated.”<sup>198</sup> The manner in which physicians handle uncertainty and how uncertainty is presented will have a high degree of impact on patient understanding and satisfaction.<sup>199</sup> The authors of a 1988 study about the role of uncertainty in affecting patient satisfaction recognized that “sharing uncertainty gives patients a greater role in the decision making process, so that decisions can be made by consensus[.]” and concluded “that this mutual exchange of information leading to shared decision making [should] be the model for patient physician interactions.”<sup>200</sup>

When individuals are faced with difficult decisions between more than one – or even many – potential treatment options for a single condition or diagnosis, shared decision making between the patient and the physician may be more effective than informed consent.<sup>201</sup> The shared decision-making model is better suited than the legal doctrine of informed consent to encouraging active participation and respecting the individual’s “values and preferences” in determining a course of treatment.<sup>202</sup> Shared decision making emphasizes education and communication in an effort to improve patient comprehension and ensure full and complete voluntary choice. It relies on the understanding that “[t]reatment, diagnosis, and patient satisfaction will improve with advanced communication.”<sup>203</sup>

To improve communication, the shared decision-making model emphasizes the incorporation of decision aids (informational documents, websites, videos, etc. designed to help patients make decisions about treatment options) to support patient understanding.<sup>204</sup> Decision aids are developed for “preference sensitive” decisions, in order to “increase

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198. Han et al., *supra* note 86 at 836.

199. Henry et al., *supra* note 80, at 322.

200. Clifford G. Johnson, Jeffrey C. Levenkron, Anthony L. Suchman, & Ralph Manchester, *Does Physician Uncertainty Affect Patient Satisfaction?* 3 J. GEN. INTERNAL MED. 144, 148-149 (1988).

201. When there are multiple options, “medical decisions are dependent to an ever-greater extent on individual patient values and life goals.” Tenenbaum, *supra* note 149, at 753. Tenenbaum explains that the example of complex decision making in the wake of progress in genetics demonstrates “the importance of detailed medical disclosure and shared decision-making to help patients navigate the system and select optimal treatments based on their values, preferences, and concerns.” *Id.* at 757.

202. King & Moulton, *supra* note 144.

203. Henry, *supra* note 80, at 322.

204. See, e.g., Allison W. Kurian, Diego F. Munoz, Peter Rust, Elizabeth A. Schackmann, Michael Smith, Lauren Clarke, Meredith A. Mills, & Sylvia K. Plevritis, *Online Tool to Guide Decisions for BRCA1/2 Mutation Carriers*, 30 J. CLINICAL ONCOLOGY 497 (2012) (developing a decision tool that characterizes the multiple health outcomes associated with cancer risk-reduction options in order to clarify a patient’s priorities and guide choices that preserve them); Elissa M. Ozanne, Rebecca Howe, Zehra Omer, & Laura J. Esserman, *Development of a Personalized Decision Aid for Breast Cancer Risk Reduction and Management*, 14 BMC MED. INFORMATICS AND DECISION MAKING (2014) (developing a decision aid prototype intended to integrate risk assessment and decision support in real time, in order to allow for informed, value-driven, and patient-centered breast cancer prevention decisions).

patient participation in decision making and to enhance rather than replace patient-professional communication.”<sup>205</sup> Preference sensitive care means that decisions about which—if any—interventions to accept should reflect patients’ personal values and preferences, and should be made only after patients have enough information to make an informed choice, in partnership with the physician.<sup>206</sup> Decision aids may provide risk information that would not otherwise be accepted by patients,<sup>207</sup> but addressing the patients’ personal circumstances may lead to greater acceptance. For example, these aids, “when used as adjuncts to counseling, improve decision quality and reduce the overuse of surgical treatments by 25 percent.”<sup>208</sup>

## 2. *Applying the Shared Decision-Making Model to Previvorship*

Importantly, in the medical literature, there has been increasing emphasis on the use of decision aids for individuals with genetic mutations that predispose individuals to certain diseases.<sup>209</sup> In particular, previvors may be overwhelmed by genomic uncertainty.<sup>210</sup> According to Han and colleagues’ taxonomy of uncertainty, previvors are more likely to experience probability and ambiguity uncertainty than

205. Natalie Evans, Suzanne Metselaar, Carla van El, Nina Hallowell, & Guy Widdershoven, *How Should Decision Aids be Used During Counseling to Help Patients who are “Genetically at Risk”?*, 21 AM. MED. ASS’N. J. ETHICS 865, 866-67 (2019) (“Decision aids have 3 principle goals: to improve patient understanding of risks and benefits, to help patients clarify their values, and to help patients make decisions consistent with those values.”).

206. Center for the Evaluative Clinical Sciences, *Preference-Sensitive Care*, A DARTMOUTH ATLAS PROJECT TOPIC BRIEF, [https://www.dartmouthatlas.org/downloads/reports/preference\\_sensitive.pdf](https://www.dartmouthatlas.org/downloads/reports/preference_sensitive.pdf) [<https://perma.cc/H4VU-LJB4>].

207. See, e.g., Scherer et al., *supra* note 77.

208. Annette M. O’Connor, John E. Wennberg, France Légaré, Hilary A. Llewellyn-Thomas, Benjamin W. Moulton, Karen R. Sepucha, Andrea G. Sodano, & Jaime S. King, *Toward the ‘Tipping Point’: Decision Aids and Informed Patient Choice*, 26 HEALTH AFF. 716, 717 (2007). One can predict a similar reduction in overuse of surgical treatments for the previvor population. Just like with patient decision making, previvors may seek interventions that are not medically indicated. A shift to shared decision-making moves away from absolute consumerism, and thus previvor demands for unneeded surgical interventions are less likely to be acceded to.

209. See Terri Jabaley, Meghan L. Underhill-Blazey, & Donna L. Berry, *Development and Testing of a Decision Aid for Unaffected Women with BRCA1 or BRCA2 Mutation*, 35 J. CANCER EDUC. 339 (2020); Dean & Fisher, *supra* note 13 (constructing a translational tool to aid genetic counselors and previvors facing these medical decisions); Kurian, *supra* note 203.

210. In the context of previvors’ decision making, Dean analyzed BRCA previvors’ desires for improving communication between patients and clinicians in her 2014 dissertation. She concluded,

[P]revivors need to actively participate in their own care. Previvors suggest clinicians should encourage and support patient participation. Actively participating means being knowledgeable, understanding one’s body, doing research, asking good questions, and being honest and direct with clinicians about preferences. Because in the end, . . . “You are your own best advocate.”

Dean, *supra* note 177, at 110-11.

traditional patients. These sources of uncertainty may be irreducible,<sup>211</sup> so improving decision making may not just be an issue of improving individual comprehension or processing of risk. Knowledge about the role of uncertainty in previvors' medical decisions can "be used to develop decision tools that help [patients] process their uncertainty, build skills central to uncertainty and risk management, and allow them to compare their risk-reducing (and uncertainty management) choices."<sup>212</sup>

In developing their taxonomy of uncertainty, Han and colleagues created a "decision-making uncertainty management intervention" based on Mishel's theories of uncertainty.<sup>213</sup> They recognized that the decision tool was effective in improving patient knowledge, information seeking and participation in decision making, and lower decisional regret.<sup>214</sup> The uncertainty management intervention did "not differ from previously studied informational interventions such as decision aids, all of which are built on the assumption that the successful management of uncertainty—and the most valid indicator of this outcome—consists of knowledge or care processes related to the provision or acquisition of information alone."<sup>215</sup>

The shared decision-making model may also be more conducive to addressing the long-term—or perhaps life long—consequences of previvors' decisions. Dean and Fisher, after analyzing medical decision making for BRCA previvors, argued for:

[A] life-span theoretical lens highlighting an ongoing experience of uncertainty and risk-related medical decisions can help emphasize critical factors like life course/developmental transitions (e.g. family planning), age and increased risk, generational factors (e.g. offspring's risk), family history/memories, and the evolving nature of science – factors these previvors identified as critical to their decision-making.<sup>216</sup>

The medical, psychological, and familial sequelae of a single surgery (or a decision to refuse prophylactic interventions and opt for "watchful waiting") can be difficult, if not impossible, to predict.<sup>217</sup>

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211. Han et al., *supra* note 86.

212. Dean & Fisher, *supra* note 13, (discussing Padamsee et al., *supra* note 13).

213. Han et al., *supra* note 86.

214. *Id.* However, they found that the intervention did not affect individuals' mood or health-related quality of life. *Id.* Despite this conclusion, many other studies "found linkages between increased patient activation in decision-making and health outcomes." See Jaime S. King, Mark H. Eckman, & Benjamin W. Moulton, *The Potential of Shared Decision Making to Reduce Health Disparities*, 39 J. LAW MED. & ETHICS 30, 31 (2011).

215. Han et al., *supra* note 86.

216. Dean & Fisher, *supra* note 13, at 476.

217. It may be impossible to predict, for example, whether uncertainty will be valued as a danger or an opportunity. Clayton et al., *supra* note 84 (claiming that according to the UIT, individuals appraise uncertainty, defined as "the process of placing a value on the uncertain event or situation[,] resulting in valuing the uncertainty as a danger (the possibility of a harmful outcome) or an opportunity (the possibility of a positive outcome)).

Notably, “uncertainty and risk distress do not necessarily end” after a previvor has made a decision.<sup>218</sup> Any decision tools should address not just medical risks and benefits, but also individuals’ “psychosocial experiences that impact . . . decision-making.”<sup>219</sup> The informed consent model of medical decision making that centers around a single decision point is insufficient; rather, the focus should be shifted to integrate decision making interventions that help individuals cope across their life span.<sup>220</sup>

### 3. *A Legal Doctrine of Shared Decision Making*

Despite the advantages of the shared decision-making model for previvor (and more generally, patient<sup>221</sup>) choice, the law is unfortunately better equipped to regulate the process of informed consent, with its emphasis on unidirectional physician disclosures. In contrast, lawmakers have struggled to craft rules to both ensure adequate patient comprehension and ensure that individuals’ choices are based not just on medical risk and benefit, but on subjective and personal values, circumstances, and preferences. Shared decision making has been recognized as “a vague and imprecise rubric[,]” that may face “conceptual, normative, and practical challenges[,]” but it is argued that “it is ethically dangerous to use [these] problems to undermine its legitimacy.”<sup>222</sup> Rather, in an effort to more actively include patients in medical decision making in order to improve patient care and satisfaction, states have begun to explore laws addressing decision making for patients with preference sensitive conditions.<sup>223</sup> For example, Washington state established increased legal protections to physicians whose patients sign an acknowledgement that patient decision aids were used during medical decision making.<sup>224</sup> The Affordable Care Act provides guidelines for funding, developing, and certifying patient decision aids.<sup>225</sup>

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218. Dean & Fisher, *supra* note 13, at 477.

219. *Id.* at 478.

220. *Id.*

221. King et al., *supra* note 214.

222. James F. Childress & Marcia Day Childress, What Does the Evolution from Informed Consent to Shared Decision Making Teach Us About Authority in Health Care?, 22 AM. MED. ASS’N. J. ETHICS E423 (2020).

223. In 2007, Washington state passed a law in support of shared decision making, encouraging the use of decision aids for preference-based treatment decisions. WASH. REV. CODE ANN. § 7.70.060 (West 2007).

224. *Id.* As of 2009, four other states were considering legislation that would mandate a pilot study of shared decision making. Bridget M. Kuehn, *States Explore Shared Decision Making*, 301 J. AM. MED. ASS’N. 2539 (2009). And at least four more states have considered a legislative approach to test shared decision making in pilot projects since the passage of the Affordable Care Act. Dominick L. Frosch, Benjamin W. Moulton, Richard M. Wexler, Margaret Holmes-Rovner, Robert J. Volk, & Carrie A. Levin, *Shared Decision Making in the United States: Policy and Implementation Activity on Multiple Fronts*, 105 Z. EVID. FORTBILD. QUAL. GESUNDH. 305 (2011).

225. Patient Protection and Affordable Care Act § 3506, 42 U.S.C. § 299b-36 (2010).

However, lawmakers have done little to further codify a legal doctrine of shared medical decision making, beyond the focus on development, certification, and use of decision aids for preference sensitive care.

Special attention must be paid to carefully craft a legal doctrine of shared decision making, in order to avoid inadvertent curtailment of the type of open discussion that the model is intended to encourage.<sup>226</sup> Any approach to a legal doctrine of shared decision making must ensure that existing law is appropriately modified or eliminated in order to remove existing incentives that promote the formalistic disclosure of information from doctors to patients and to avoid conflict with new policies and rules.<sup>227</sup> Legal rules governing shared decision making should reject the singular focus on the clinician's affirmative duty to disclose. Rather, they should increasingly emphasize the patient's awareness and understanding of all material information. Importantly, such a proposal would not eliminate the duty of physicians to ensure that patients receive all information material to a voluntary decision but simply would shift the emphasis away from mandated disclosures to a system of disclosures *and* comprehension. Based on these principles, and consistent with the goals of the Affordable Care Act and Washington state law, reliance on quality certified patient decision aids should constitute evidence that the physician has followed the standard of care.<sup>228</sup> Medical education should emphasize patient engagement, providing the skills for physicians to address patient values and preferences in the context of both medical as well as

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226. We must learn from mistakes made in the context of informed consent to medical treatment. As discussed in Section II.A, the law has coopted the intended goal of ensuring voluntary decision making. See Koch, *supra* note 136.

227. See, e.g., Frank M. McClellan, James E. Wood, & Sherin M. Fahmy, *It Takes a Village: Reforming Law to Promote Health Literacy and Reduce Orthopedic Health Disparities*, 8 J. HEALTH & BIOMEDICAL L. 333, 368, 372 (2013). The authors stated that "the legal doctrine of informed consent" may impede shared decision-making. However, they noted,

There is nothing in existing legal statutes or court decisions that precludes... shared decision-making. However, the concept of the physician-patient relationship as one that should be guided primarily by the importance of deferring to a patient's autonomy has broad implications that may affect the conduct of health care providers and community health workers in a way that discourages active efforts to influence decision-making and behavior.

*Id.* at 368. See also Ann S. O'Malley, Emily R. Carrier, Elizabeth Docteur, Alison C. Shmerling, & Eugene C. Rich, *Policy Options to Encourage Patient-Physician Shared Decision Making*, Nat'l Inst. For Health Care Reform, 5 POLICY ANALYSIS (2011) [https://nihcr.org/wp-content/uploads/2015/03/NIHCR\\_Policy\\_Analysis\\_No.\\_5.pdf](https://nihcr.org/wp-content/uploads/2015/03/NIHCR_Policy_Analysis_No._5.pdf) [<https://perma.cc/A29S-HPFR>] ("Current U.S. legal standards in many ways inhibit shared decision making").

228. For an in-depth analysis of legal mechanisms for ensuring the quality of decision aids, see Nadia N. Sawicki, *Patient Protection and Decision Aid Quality: Regulatory and Tort Law Approaches*, 54 ARIZ. L. REV. 621 (2012). See also McClellan et al., *supra* note 227 at 369 (arguing that laws intended to identify shared decision making as a "preferred strateg[y]" "should provide immunity against tort claims for professionals who provide counseling and advice, so long as they act in good faith and are not engaged in conduct that is willful, wanton, or reckless.").

psychosocial concerns. Finally, physicians must be compensated for the time required to pursue a robust shared decision-making process with their patients.<sup>229</sup>

### *B. Beyond Shared Decision Making and the Biomedical Model of Illness*

While adopting a shared decision-making model may be a significant improvement from the current legal model of disclosures, shared decision making may not be responsive to some of the key deficits in our current medical system. For one, decision aids and other interventions are not a panacea for all informed consent woes; they may not be wholly effective in reducing previvor anxiety or uncertainty in decision making.

Importantly, as discussed throughout this Article, the previvor experience challenges the traditional biomedical model of illness.<sup>230</sup> In addition to substantiating calls for shifting to a robust shared decision-making model in order to respond holistically to the individual's values and preferences, the previvor experience also supports arguments that the biomedical model should be replaced with a new, more expansive and inclusive, model of illness.<sup>231</sup> In the almost 45 years since George

229. Kuehn, *supra* note 224; O'Malley et al., *supra* note 228 at 3 ("The lack of payment for shared decision making contributes to clinician views that there is inadequate time during patient visits for SDM because paid activities take priority."); Glyn Elwyn, Dominick Frosch, Richard Thomson, Natalie Joseph-Williams, Amy Lloyd, Paul Kinnersley, Emma Cording, Dave Tomson, Carole Dodd, Stephen Rollnick, Adrian Edwards, & Michael Barry, *Shared Decision Making: A Model for Clinical Practice*, 27(10) J. GEN. INTERNAL MED. 1361, 1366 (2012) ("We... argue that new systems will be required to appropriately reward truly patient centered practice."). Others have noted various initiatives at the national level that indicate a "context consistent with" shared decision making. Frosch et al., *supra* note 224 at 208 ("These include: the reorganization of primary care into 'patient-centered medical homes', the concept of multispecialty groups as 'accountable care organizations', new incentives for providers to use electronic health records as tools to improve clinical quality, and the PPACA."). Moreover, France Légaré and Holly O. Witteman recommend various policy steps that could speed the adoption of shared decision making, including improving physicians' training and reorganizing medical practice around the principles of patient engagement. Légaré & Witteman, *supra* note 193.

230. According to the biomedical model,

[H]uman beings were viewed as biological organisms (materialism), to be understood by examining their constituent parts (reductionism) using the principles of anatomy, physiology, biochemistry and physics. Disease was seen as a deviation from the biological norms, caused by some identifiable physical or chemical event and intervention involved introduction of a corrective physical or chemical agent. Consequently, health came to be defined as an absence of disease and got associated with activities of doctors to the extent that to most people, medicine became synonymous with health.

Neeta Mehta, *Mind-Body Dualism: A Critique from a Health Perspective*, 9(1) MENS SANA MONOGRAPH 202, 204 (2011).

231. The biopsychosocial model is one in which the biologic basis of disease and the individual's experience with illness are appropriately weighed. James E. Rosenberg & Bernard

Engel proposed the need for a new model for illness to replace the biomedical model,<sup>232</sup> scholars have emphasized the existing model's inadequacies in addressing conditions such as mental illness,<sup>233</sup> chronic disease,<sup>234</sup> HIV,<sup>235</sup> and disability.<sup>236</sup> Critics of the "mechanistic" biomedical model of health describe the view as being "consistent with the ideas of calculability, predictability, and control."<sup>237</sup> However, health care is becoming increasingly uncertain,<sup>238</sup> and the distinctions between "sick" and "well" are becoming increasingly blurred, if not erased.<sup>239</sup>

Previvorship, like other categories before it, challenges the biomedical model of illness, underscoring the problems with focusing solely on medical risk. The emergence of previvorship as a medical status highlights the ambiguity inherent to the conceptualization of disease. Studies have demonstrated that previvors' decision making is often driven by psychosocial factors, "such as feelings of guilt and vulnerability and

Towers, *The Practice of Empathy as a Prerequisite for Informed Consent*, 7 THEORETICAL MED. 181, 181 (1986). Besides the biopsychosocial model of illness, scholars have suggested the social and other model. See Michael Oliver, Bob Sapey, & Pam Thomas, SOCIAL WORK WITH DISABLED PEOPLE (Palgrave Macmillan, 1983); Pierre Minaire, *Disease, Illness and Health: Theoretical Models of the Disablement Process*, 70(3) BULLETIN OF THE WORLD HEALTH ORGANIZATION 373 (1992).

232. George L. Engel, *The Need for a New Medical Model: A Challenge for Biomedicine*, 196 SCIENCE 129 (1977) ("all medicine is in crisis and, further, ...medicine's crisis derives from ... adherence to a model of disease no longer adequate for the scientific tasks and social responsibilities of either medicine or psychiatry").

233. *Id.*

234. Gillian Bendelow, *Chronic Pain Patients and the Biomedical Model of Pain*, 15(5) AM. MED. ASSOC. J. ETHICS 455 (2013); Michele Crossley, *'Sick Role' or 'Empowerment'? The Ambiguities of Life with an HIV Positive Diagnosis*, 20(4) SOCIO. OF HEALTH & ILLNESS 507, 507 (1998) (noting the "increasing predominance of chronic disease changes the temporal structure of the experience of illness"); Derick T. Wade & Peter W. Halligan, *The Biopsychosocial Model of Illness: A Model Whose Time Has Come*, 31(8) CLIN. REHAB. 995 (2017).

235. Crossley, *supra* note 234 at 507 (exploring how the rhetoric of empowerment can co-exist with sick-role dependencies).

236. Julie Smart, *Challenges to the Biomedical Model of Disability*, 12 ADVANCES IN MED. PSYCHOTHERAPY & PSYCHODIAGNOSIS (2006).

237. Soma Hewa & Robert A. Hetherington, *Specialists without Spirit: Limitations of the Mechanistic Biomedical Model*, 16 THEORETICAL MED. 129 (1995).

238. Research indicates that an adoption of the biopsychosocial model of illness is associated with less stress reactions to uncertainty amongst primary care physicians than is a biomedical epistemology. Lance Evans & David R.M. Trotter, *Epistemology and Uncertainty in Primary Care: An Exploratory Study*, 41(5) FAM. MED. 319 (2009).

239. "The boundaries between health and disease, between well and sick, are far from clear and never will be clear, for they are diffused by cultural, social, and psychological considerations. The traditional biomedical view, that biological indices are the ultimate criteria defining disease, leads to the present paradox that some people with positive laboratory findings are told that they are in need of treatment when in fact they are feeling quite well, while others feeling sick are assured that they are well, that is, they have no 'disease.'" Engel, *supra* note 232. See also Crossley, *supra* note 234 at 508 (explaining that the traditional characterization of the sick role "is essentially outdated and fails to capture the nature of illness experienced by many individuals in today's society").



the degree of perceived social support.”<sup>240</sup> As discussed in Section I.B, the biological cannot be separated from the psychological, social, cultural, and personal aspects of the previvor experience.<sup>241</sup> Thus, previvors occupy a “nexus of decision making” routed in psychosocial factors and social network engagements, which “does not, for the most part, mirror... the specific treatment protocols outlined by the medical establishment.”<sup>242</sup>

Significantly, critics of the biomedical model have highlighted the inherent flaws with current approaches to informed consent, arguing that the physician-patient relationship must “be reshaped within a new scientific model of patient care that combines the biomedical analysis of disease with an empathic understanding of the patient’s illness experience.”<sup>243</sup> While shared decision making is more conducive to the biopsychosocial model of illness than informed consent – which focuses primarily on disclosures of biological/physical risks and benefits – it is probably not enough to ameliorate concerns about previvor uncertainty.<sup>244</sup> Thus, in many ways, our legal rules reinforce the biomedical model of illness, by emphasizing the biological over psychological and social factors of medicine. In crafting legal rules for medical decision making, it is necessary to reconsider what it means to be a patient or participant in medicine, in order to find new ways to guide individuals through the “therapeutic odyssey.”<sup>245</sup>

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240. Hesse-Biber & An, *supra* note 73 (the nexus of decision making includes “social factors (such as family and support networks) and psychological factors (such as feelings and internal reactions to the test result).”).

241. Richard D. Lane, Is it Possible to Bridge the Biopsychosocial and Biomedical Models?, 8(3) BIOPSYCHOSOCIAL MED. (2014).

242. Hesse-Biber & An, *supra* note 73 at 978.

243. Rosenberg & Towers, *supra* note 231 at 192 (arguing that “[g]enuine consensus or true ‘informed consent’ will be realized only if this more comprehensive approach to patient care [utilizing the biopsychosocial paradigm] supplants the traditional biomedical model.”).

244. See Eyal et al., *supra* note 52 at 814 (“Instead of anchoring patients in social settings of care, they and their families will be placed in increasingly uncertain situations. Social scientists who have observed the families of patients-in-waiting report high levels of confusion and stress. Families want to know whether their children are healthy or sick. An answer either way could anchor them in familiar institutional scripts. Yet ambiguous results regarding genetic status (e.g., in newborn screening) mean that clinicians are unable to provide straightforward answers, and instead vacillate between warning families to avoid overreaction or complacency. This exemplifies how [precision medicine] can intensify the uncertainty of a previously stable medical encounter when the very goal of treatment—normal functioning—has become a moving target. It raises the possibility that instead of preventing diagnostic odysseys, [precision medicine] will add a new type of “therapeutic odyssey.”).

245. *Id.* at 814.

