MEDICAL ERROR AND VULNERABLE COMMUNITIES

PHOEBE JEAN-PIERRE^{*†}

ABSTRACT

More than two decades have passed since the influential report from the Institute of Medicine, To Err Is Human. Despite the report's spotlight on medical error, the issue persists and is presently the third leading cause of death in the United States. Aside from the physical, emotional, and mental harm to patients and their families, medical error destroys the trust between doctors and their patients. For vulnerable communities, such as minorities, women, and the transgender community, a history of mistreatment and exposure to bias within the healthcare system further impairs this trust. Addressing medical error presents a unique opportunity to make healthcare safer for all patients and offers an opportunity to repair trust, address bias, and examine how vulnerable communities are treated within the healthcare system.

This Article asserts that the current response to medical error is grossly insufficient, harmful, and further contributes to patient harm and a loss of trust, particularly within historically marginalized communities. The introduction of federal legislation to encourage clearer apology laws and the expanded use of communication and resolution programs offer a new avenue to reduce the occurrence of error. Introducing federal legislation to encourage apology laws creates consistency on the issue of error; it also protects physicians and encourages them to apologize and take responsibility. Communication and resolution programs call for disclosure of the error, open communication, and transparency into how to address and prevent future harm to patients. Enacting federal apology laws and introducing communication and resolution programs will not only help to reduce the occurrence of error but will also help to reduce the widespread social harm and lack of trust that has long persisted between vulnerable communities and the healthcare system. To err is human, and thus it is impossible to eliminate all harm. But it is possible to create a safer system overall, reduce the occurrence of error, and use a transparent approach to address the history of bias and discrimination against vulnerable communities while rebuilding their trust in the healthcare system.

^{*} Visiting Assistant Professor, University of Iowa College of Law, JD/PhD from Northwestern University and the Northwestern Pritzker School of Law. Many thanks to Adrien Wing, Ann Estin, Jason Rantanen, and Anya Prince for the helpful comments and conversations that made the Article better. A special thank you to Bruce Lambert and Candice Player for helping me formulate and develop my ideas.

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INTRODUCTION

This Article evaluates why—over two decades after the groundbreaking report by the Institute of Medicine ("IOM"), *To Err Is Human*¹—medical error and harm to patients and their families persist. Further, this Article explores the disproportionate harm and suffering within historically marginalized communities due to exposure to error, bias, and discriminatory treatment within the medical system.

Preventable errors are one of the leading causes of death in the United States.² Fear of liability, the use of "deny and defend" in response to errors, a fragmented healthcare system, implicit bias and the prevalence of sexism and racism, and a history of mistreatment within vulnerable communities are all reasons why patients remain affected by preventable harm.³ Although it is impossible to prevent all harm, there are systematic changes that can make patients safer and minimize similar future harm. This includes recognizing when an error occurs, apologizing and taking responsibility, addressing implicit bias, rebuilding trust in marginalized communities, and keeping patients and their families informed as to the harm they suffered and what happened.⁴ In 2016, the British Medical Journal ("BMJ") published a study indicating that medical error was the third leading cause of death in the United States, just behind cancer and heart disease, and asserted that a higher number of people died from medical error than previously believed.⁵ The BMJ study estimated more than 250,000 deaths result from these errors each year.⁶ Shocking as this number may seem, a more recent study suggests that deaths due to medical error may even be as high as 440,000 per year.⁷ These studies reflect the magnitude with which medical error affects society and rival numbers introduced by the IOM in To Err Is Human.⁸

¹ See COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 109-31 (Linda T. Kohn, Janet M. Corrigan & Molla S. Donaldson eds., 2000) [hereinafter TO ERR IS HUMAN].

² See Martin A. Makary & Michael Daniel, *Medical Error—a Leading (but Hidden) Cause of Death*, 353 BRIT. MED. J. 236, 236-37 (2016) (estimating that medical error is the third leading cause of death in the United States based on statistical calculations suggesting a mean rate of 251,454 deaths from medical error per year between 1999 and 2013).

³ See infra Section II.B (describing responses to medical error in the United States).

⁴ See discussion *infra* Part IV (proposing federal legislation and communication and resolution programs as systematic changes).

⁵ See Makary & Daniel, *supra* note 2, at 236-37 (arguing that the Center for Disease Control underestimates the rate of deaths by medical error in the United States because U.S. death certificates do not record medical error).

⁶ See *id.* (calculating a rate of 251,454 deaths per year from medical error between 1999 and 2013).

⁷ See John T. James, *A New, Evidence-Based Estimate of Patient Harms Associated with Hospital Care*, 9 J. PATIENT SAFETY 122, 127 (2013) (estimating that up to 440,000 preventable adverse events contribute to patient deaths each year in hospitals).

⁸ See To ERR IS HUMAN, supra note 1, at 26 (estimating that between 44,000 and 98,000 Americans die in hospitals each year due to medical errors).

The system for addressing and dealing with medical error needs to change. Currently, nationwide efforts to address medical error are fragmented at best, and medical error remains a major public safety concern. The initial publication of *To Err Is Human* prompted a flurry of activity.⁹ Just after the report's release, then-President Bill Clinton "directed the Quality Interagency Coordination Task Force . . . to develop a plan of action to reduce the incidence of medical errors."¹⁰ The following year, the United States Joint Commission on Accreditation of Healthcare Organizations "mandated an open disclosure of any critical event during care to either the patient or their family" as "an essential accreditation standard for a medical institution."¹¹ In the years following, several states passed statutes focused on addressing and reducing medical error, including apology laws.¹² Yet even with all these new programs, policies, standards, and laws, medical error continues to needlessly harm patients, and vulnerable communities suffer disproportionately.¹³

Medical error poses a unique threat to minorities, women, and the transgender community, given their exposure to implicit bias¹⁴ and the long history of

¹¹ Jawahar Kalra, *Medical Error Disclosure: A Point of View*, 1 PATHOLOGY & LAB'Y MED. OPEN J. e1, e1 (2016).

¹² See infra Section IV.A (describing relevant state apology laws).

¹³ See infra Section I.B (addressing the disproportionate impact of medical errors on vulnerable communities); see also John F. Dovidio, Louis A. Penner, Terrance L. Albrecht, Wynne E. Norton, Samuel L. Gaertner & J. Nicole Shelton, *Disparities and Distrust: The Implications of Psychological Processes for Understanding Racial Disparities in Health and Health Care*, 67 Soc. Sci. & MED. 478, 478 (2008) ("Despite large differences in focus and methodology, [two decades of] studies yield a common conclusion: people who self-identify as White are healthier than members of all other racial/ethnic groups[,] with the exception of people who self-identify as Asian or Pacific Islander" (citation omitted)).

¹⁴ See, e.g., Karthik Balakrishnan & Ellis M. Arjmand, *The Impact of Cognitive and Implicit Bias on Patient Safety and Quality*, 52 OTOLARYNGOLOGIC CLINICS N. AM. 35, 42 (2019) ("Examples of [implicit] biases in health care abound. A recent systematic review identified 42 studies assessing implicit bias in health care providers, mostly focusing on race. The investigators concluded that clinicians had a similar degree of implicit bias as the general population. Meanwhile, experimental studies have demonstrated repeatedly that these biases measurably affect clinical assessments and treatment decision making.... In turn, these biases appear to affect how patients perceive clinical encounters, driving patient satisfaction and confidence in their care." (footnotes omitted)); Chloë FitzGerald & Samia Hurst, *Implicit Bias in Healthcare Professionals: A Systematic Review*, BMC MED. ETHICS, Mar. 1, 2017, at 1, 14 ("A variety of studies, conducted in various countries, using different methods, and testing different patient characteristics, found evidence of implicit bias and indicators of

⁹ See Kelly J. Devers, Hoangmai H. Pham & Gigi Liu, *What Is Driving Hospitals' Patient-Safety Efforts?*, 23 HEALTH AFFS. 103, 103 (2004) (describing *To Err Is Human* as prompting a "watershed period" where "medical error became a national problem" for medical professionals to address).

¹⁰ Kevin A. Schulman & John J. Kim, Commentary, *Medical Errors: How the US Government Is Addressing the Problem*, 1 CURRENT CONTROLLED TRIALS CARDIOVASCULAR MED. 35, 36 (2000).

mistreatment in our medical system.¹⁵ Further, medical error, alongside these historic inequalities, contributes to these communities' mistrust of the healthcare system.¹⁶ Members of these communities enter the healthcare space with a sense of mistrust and an expectation that their concerns will not be adequately addressed or taken seriously—or they avoid health care outright.¹⁷

Addressing medical error cannot fully repair the history of mistreatment, bias, and discrimination experienced by vulnerable communities within the healthcare system, but adopting communication and resolution programs ("CRP") is a step forward. CRPs are built on open communication and transparency; further, they provide the opportunity to reduce error, to reexamine both bias and the poor treatment of marginalized communities within the medical system, and to begin to repair trust.¹⁸

This Article argues that the current patchwork of disparate state apology laws and current policies are insufficient to address the persistence of medical error and the disproportionate harm to vulnerable communities. Instead, this Article calls for a two-pronged approach: the introduction of federal legislation to encourage apology laws and the adoption of CRPs more broadly within the healthcare system. Adopting this approach would provide more effective tools to curb rates of medical error and to address long-standing and unique harm to historically marginalized populations.

quality of care."); see also, e.g., Dovidio et al., supra note 13, at 484 ("[I]mplicit biases are manifested in subtle, often unintentional forms of discrimination that produce less favorable outcomes for Blacks than for Whites, contribute to error and miscommunication, and create racial distrust."); David M. Peña-Guzmán & Joel Michael Reynolds, *The Harm of Ableism: Medical Error and Epistemic Injustice*, 29 KENNEDY INST. ETHICS J. 205, 227 (2019) ("[M]edicalization of trans identities fuels transphobia and contributes to the ongoing marginalization of trans subjects." (citation omitted)); Cheryl B. Travis, Dawn M. Howerton & Dawn M. Szymanski, Risk, Uncertainty, and Gender Stereotypes in Healthcare Decisions, 35 WOMEN & THERAPY 207, 214 (2012) ("Disparities in healthcare for women are far ranging and long standing. We argue that these disparities are shaped by sexism that goes unchallenged because it appears to be benign.").

¹⁵ See discussion *infra* Part III; *see also, e.g.*, NAT'L P'SHIP WOMEN & FAMS., PAST AS PRESENT: AMERICA'S SORDID HISTORY OF MEDICAL REPRODUCTIVE ABUSE AND EXPERIMENTATION 2-3 (2020) (listing incidents of racism and sexism in reproductive care and experimentation); Darcell P. Scharff, Katherine J. Mathews, Pamela Jackson, Jonathan Hoffsuemmer, Emeobong Martin & Dorothy Edwards, *More than Tuskegee: Understanding Mistrust About Research Participation*, 21 J. HEALTH CARE FOR POOR & UNDERSERVED 879, 880 (2010) (describing history of "medical and research abuse of African Americans").

¹⁶ See Peña-Guzmán & Reynolds, *supra* note 14, at 213 ("[M]edical error can change people's experience of the health care system for the worse and corrode their trust in this system").

¹⁷ See infra Part III (discussing social trust in the medical system); Peña-Guzmán & Reynolds, *supra* note 14, at 213 ("[P]oor [patient-provider communication] erodes [patient] trust by making patients feel unheard and under-valued, as if the very experts on whom they depend do not see them as persons to be cared for but as names on a list to be crossed off...." (citation omitted)).

¹⁸ See infra Section IV.B (describing communication and resolution programs).

Part I examines the harms caused by medical error and what leads to the occurrence of error. This Part also reviews how medical error affects vulnerable communities, including racial and ethnic minorities, women, and the transgender population.

Part II reviews the historical response to medical error—"deny and defend" and the destructive nature of refusing to acknowledge the occurrence of an error. This Part also acknowledges the persistence of medical error, discrimination and bias within our healthcare system, and other current obstacles to effectively reducing the occurrence of error.

Part III explores social trust and medicine. Specifically, it details the past harm and poor treatment of marginalized communities throughout the history of the medical field. In highlighting this discriminatory history, this Part considers how medical errors presently affect these communities.

Part IV discusses state apology laws and calls for the need to introduce federal legislation to better support and encourage apology laws. This Part also argues for the importance of integrating CRPs into our approach to addressing medical error. The use of CRPs presents a unique opportunity to both address medical error and to start to repair the lack of trust in the healthcare system among vulnerable communities.

This Article concludes with recommendations to introduce federal legislation for promoting apology laws, integrating CRPs to successfully reduce the widespread occurrence of error, and beginning to repair harm within vulnerable communities.

I. THE PERSISTENCE OF MEDICAL ERROR

The Hippocratic Oath instructs medical providers to do no harm.¹⁹ That concept has long been a guiding principle within the practice of medicine and the delivery of health care around the world.²⁰ Unfortunately, harm occurs every day in healthcare.²¹ Aside from the harm, there is now a growing public awareness about medical errors and adverse patient outcomes.²² This in turn

²² See Medical Errors Concern Most of Public, Study Says, RELIAS MEDIA: HEALTHCARE

¹⁹ See LUDWIG EDELSTEIN, THE HIPPOCRATIC OATH: TEXT, TRANSLATION AND INTERPRETATION 3 (Henry E. Sigerist ed., 2d prtg. 1954) ("I will apply dietetic measures for the benefit of the sick according to my ability and judgment; I will keep them from harm and injustice.").

²⁰ See Julius Rocca, Inventing an Ethical Tradition: A Brief History of the Hippocratic Oath, 11 LEGAL ETHICS 23, 24 (2008) ("[The Hippocratic Oath's] fortunes and reputation have waxed and waned over the 25 centuries since its composition. Nevertheless, to the public at large, the Hippocratic Oath still remains the cornerstone of medical ethics.").

²¹ See Debra L. Beck, *When Mistakes Happen...*, ASH CLINICAL NEWS (Dec. 1, 2018), https://www.ashclinicalnews.org/spotlight/when-mistakes-happen/ [https://perma.cc/PBY8-DH6X] ("Using a conservative estimate, the toll of medical mistakes is about 250,000 lives every year, or about 685 people every day." (citing Makary & Daniel, *supra* note 2, at 236-37)).

places additional pressure on the healthcare system to address and reduce the alarming rates of medical error.²³

A. Medical Error and Harm

Broadly speaking, the term "medical error" refers to a preventable adverse event (i.e., harm resulting from health care) that was caused by an error.²⁴ Medical error covers a wide scope of issues as to what went wrong, and the type of harm that patients and their families may have endured.²⁵ Examples of medical error include, but are not limited to, "unjustified exploratory and diagnostic procedures; foreseeable but unanticipated adverse effects of medical interventions or drugs; undesirable or incorrect surgical decisions and their outcomes; [and] treatment unsupported by evidence of its effectiveness, efficiency, and efficacy."²⁶ Other types of errors that may occur include process-based errors such as failures to communicate.²⁷ The scope of the term "medical error" is broad: when mistakes are made during the course of care for a patient, they are generally still considered medical error may also encompass many other adverse events, regardless of whether the occurrence of the adverse event was clearly preventable.²⁹

RISK MGMT. (Sept. 1, 2004), https://www.reliasmedia.com/articles/7220-medical-errorsconcern-most-of-public-study-says ("Three in five Americans (63%) are 'extremely concerned' (39%) or 'very concerned' (24%) about hospital-based medication errors, such as receiving the wrong medication or the wrong dose, and 55% are concerned about hospitalbased surgical errors that might include incorrect amputations or mistaken patient identities — 39% are 'extremely concerned,' and 16% are 'very concerned.'").

²³ See Devers et al., supra note 9, at 103 (discussing "watershed period" for patient safety following IOM's *To Err Is Human* report).

²⁴ See Ethan D. Grober & John M.A. Bohnen, *Defining Medical Error*, 48 CAN. J. SURGERY 39, 42 (2005) (proposing a definition of medical error as "an act of omission or commission in planning or execution that contributes or could contribute to an unintended result").

²⁵ See *id.* at 40-42 (listing outcome dependent and process dependent definitions related to medical errors).

²⁶ MILOS JENICEK, MEDICAL ERROR AND HARM: UNDERSTANDING, PREVENTION, AND CONTROL, at xvi (2011).

²⁷ Steven E. Raper, *No Role for Apology: Remedial Work and the Problem of Medical Injury*, 11 YALE J. HEALTH POL'Y L. & ETHICS 267, 270 (2011) (listing failures to communicate as types of medical errors).

²⁸ See JENICEK, supra note 26, at 2 ("The notion of medical error is separate from medical harm. Medical error does not always lead to harm.").

²⁹ See Angelo P. Giardino & Melissa A. Murrah, *Disclosing an Adverse Event or Medical Error, in* COMMUNICATING WITH PEDIATRIC PATIENTS AND THEIR FAMILIES: THE TEXAS CHILDREN'S HOSPITAL GUIDE FOR PHYSICIANS, NURSES AND OTHER HEALTHCARE PROFESSIONALS 195, 196 (2015) (defining adverse events as any negative event occurring during the patient's care, but noting that some are not readily preventable); *cf.* Grober & Bohnen, *supra* note 24, at 40 ("Although adverse events typically result from medical

Another subset of medical errors is diagnostic errors. This includes errors related to delayed, wrong, or missed diagnoses. Diagnostic errors occur frequently and are often overlooked as a cause of patient injury.³⁰ Diagnostic errors "result in a staggering toll of harm and patient deaths[,]"³¹ with nearly one in twenty patients—or 12 million adults in the United States—experiencing a diagnostic error each year.³² It is unsurprising, then, that diagnostic errors are the leading cause of medical malpractice litigation and account for nearly "twice as many alleged and settled cases as medication errors."³³

An important aspect of patient safety focuses on the reduction of medical errors. To ensure public safety and instill trust in patients, it is important to work to minimize errors and create a safer environment. When an error occurs, this provides "evidence that something has gone wrong in patient and community healthcare."³⁴ Given this evidence, steps need to be taken to prevent and address the occurrence of error.³⁵ Unfortunately, our current healthcare system fails to sufficiently address medical error.³⁶ This in turn raises two questions: (1) Why do errors persist, and (2) How can we effectively address them?

In the conversation about medical error, it is important to understand that many errors that occur cause no harm.³⁷ From the errors that *do* lead to harm, we must consider the different ways that harm can result. The harm from the resulting error extends beyond physical harm, and it may affect patients and their families in a variety of ways and have nonmedical consequences.³⁸ This includes

³³ See Schiff et al., supra note 30, at 1881.

intervention, not all adverse patient outcomes are the result of error. Reflecting this fact, many investigators suggest that only *preventable adverse events* be attributed to medical error.").

³⁰ Gordon D. Schiff, Omar Hasan, Seijeoung Kim, Richard Abrams, Karen Cosby, Bruce L. Lambert, Arthur S. Elstein, Scott Hasler, Martin L. Kabongo, Nela Krosnjar, Richard Odwazny, Mary F. Wisniewski & Robert A. McNutt, *Diagnostic Error in Medicine: Analysis of 583 Physician-Reported Errors*, 169 ARCHIVES INTERNAL MED. 1881, 1881 (2009); *see id.* at 1882 ("We defined diagnostic error as any mistake or failure in the diagnostic process leading to a misdiagnosis, a missed diagnosis, or a delayed diagnosis.").

³¹ Mark L. Graber, *The Incidence of Diagnostic Error in Medicine*, 22 BRIT. MED. J. QUALITY & SAFETY ii21, ii25 (2013).

³² Hardeep Singh, Ashley N.D. Meyer & Eric J. Thomas, *The Frequency of Diagnostic Errors in Outpatient Care: Estimations from Three Large Observational Studies Involving US Adult Populations*, 23 BRIT. MED. J. QUALITY & SAFETY 727, 727 (2014) ("Our population-based estimate suggests that diagnostic errors affect at least 1 in 20 US adults.").

³⁴ JENICEK, *supra* note 26, at xvi.

³⁵ *Id.* (describing medical errors as evidence "that something has caused harm that should be prevented and corrected").

³⁶ See infra Part II.

³⁷ See JENICEK, supra note 26, at 2.

³⁸ See, e.g., Peña-Guzmán & Reynolds, *supra* note 14, at 213-14 ("The medical error literature is replete with illustrations of the catastrophic effects that medical errors can have on patients, which range from intense physical and psychological suffering (on account of, say, having the wrong leg amputated) to severe chronic illness or death (on account of, say, being systematically misdiagnosed)" (citation omitted)).

the need for "correction and prevention [of the error], legal pursuits [based on the harm suffered], quests for repair and compensation, finding and implementing improvements, or evaluations of these initiatives and activities."³⁹ Further, there may be "[e]conomic, social, physical, and mental health consequences" for those patients who experience an error.⁴⁰

It is also important to consider the financial and economic costs to both patients and society as a whole, due to medical error. These mistakes result in additional costs for care, including: lost income and household productivity, disability, and the medical care itself—all of which amount to costs between \$17 billion and \$29 billion annually in the United States.⁴¹ Beyond the financial repercussions, errors also impose great nonmonetary costs upon society: a loss of patient trust in the healthcare system and diminished satisfaction among patients and healthcare professionals.⁴² Moreover, healthcare professionals suffer from "a loss of morale and frustration at not being able to provide the best care possible" to patients.⁴³ The cost of medical error extends beyond hospital walls and ultimately comes to rest on society, which is left to pay the costs of "lost worker productivity, reduced school attendance by children, and lower levels of population health status."⁴⁴

B. Medical Error and Patient Safety in Vulnerable Communities

At the core of medical error is a concern for patient safety, which functions as a quality indicator within health care.⁴⁵ Patient safety refers to "the absence of preventable harm to a patient such as [sharing the] results of a wrong diagnosis, [a mistake during] a clinical procedure, side-effects of drugs, or

³⁹ JENICEK, *supra* note 26, at xvi.

⁴⁰ *Id*.

⁴¹ See To ERR IS HUMAN, supra note 1, at 27 (finding that "lost income, lost household production, disability, and health care costs" for preventable medical errors cost between \$17 billion and \$29 billion). More recent studies place the cost of medical errors within a similar range. See Thomas L. Rodziewicz, Benjamin Houseman & John E. Hipskind, Medical Error Reduction and Prevention, in STATPEARLS 15 (2021) (ebook) ("Medical errors cost approximately \$20 billion a year."); Jill Van Den Bos, Karan Rustagi, Travis Gray, Michael Halford, Eva Ziemkiewicz & Jonathan Shreve, The \$17.1 Billion Problem: The Annual Cost of Measurable Medical Errors, 30 HEALTH AFFS. 596, 596 (2011) ("We estimate that the annual cost of measurable medical errors that harm patients was \$17.1 billion in 2008."); see also BETSY LEHMAN CTR. FOR PATIENT SAFETY, THE FINANCIAL AND HUMAN COST OF MEDICAL ERROR . . . AND HOW MASSACHUSETTS CAN LEAD THE WAY ON PATIENT SAFETY 1 (2019) [hereinafter BETSY LEHMAN CTR. REPORT] (finding "62,000 medical errors, which were responsible for over \$617 million in excess health care insurance claims in [2019]" in Massachusetts alone).

⁴² TO ERR IS HUMAN, *supra* note 1, at 2.

⁴³ *Id*.

⁴⁴ *Id.* at 2-3.

⁴⁵ See Carlotta Piccardi, Jens Detollenaere, Pierre Vanden Bussche & Sara Willems, Social Disparities in Patient Safety in Primary Care: A Systematic Review, INT'L J. FOR EQUITY HEALTH, Aug. 7, 2018, at 1, 1 ("Patient safety is a quality indicator for primary care").

system errors during the process of healthcare [administration]."⁴⁶ Thus, avoiding or minimizing preventable harm represents the "minimum prerequisite for high quality care."⁴⁷ While patient safety should be based on individual need and be the same across gender and different racial and ethnic groups, studies consistently show that this is not the case.⁴⁸ In particular, women and Black patients are more likely to experience adverse events during primary care.⁴⁹ Overall, research "suggest[s] that some vulnerable social groups are more likely to experience adverse patient safety events [in primary care]."⁵⁰

Adverse events "resulting from the happenstance of mistakes and errors should not occur systematically across racial, ethnic, or socioeconomic subgroups."⁵¹ Yet scholars have found social disparities in diagnostic procedures⁵²—which refer to errors related to a missed, delayed, or wrong

⁴⁹ See Piccardi et al., *supra* note 45, at 7 ("Our results confirm that, in primary care, women and black patients are more likely to receive inappropriate diagnosis, treatment, or referrals compared to men and Whites respectively." (footnotes omitted)).

⁵⁰ *Id.*

⁵¹ *Id.* at 1.

⁵² See, e.g., Katherine E. Fleming-Dutra, Daniel J. Shapiro, Lauri A. Hicks, Jeffrey S. Gerber & Adam L. Hersh, Race, Otitis Media, and Antibiotic Selection, 134 PEDIATRICS 1059, 1065 (2014) (concluding that "Black children ... diagnosed with [Otitis Media] ... were more likely to receive narrow-spectrum antibiotics" and less likely to receive broad-spectrum antibiotics than non-Black children); Rikke Pilegaard Hansen, Frede Olesen, Henrik Toft Sørensen, Ineta Sokolowski & Jens Søndergaard, Socioeconomic Patient Characteristics Predict Delay in Cancer Diagnosis: A Danish Cohort Study, 8 BIOMED CENT. HEALTH SERVS. RSCH. 49, 53-54 (2008) (finding that variables such as being older, retired, wealthy, a nonsmoker, female, and highly educated sometimes predicted less delays in cancer diagnoses than for patients outside those demographic groups); Armin Henning, Marlies Wehrberger, Stephan Madersbacher, Armin Pycha, Thomas Martini, Evi Comploj, Klaus Jeschke, Christian Tripolt & Michael Rauchenwald, Do Differences in Clinical Symptoms and Referral Patterns Contribute to the Gender Gap in Bladder Cancer?, 112 BJU INT'L 68, 68 (2013) (finding that women with bladder cancer are more likely to be treated for urinary tract infections or their symptoms without further investigation or referrals to urologists than men and also tend to be diagnosed in later stages of cancer); C. A. Labarrere, J. R. Woods, J. W. Hardin, G. L. Campana, M. A. Ortiz, B. R. Jaeger, B. Reichart, J. M. Bonnin, A. Currin, S. Cosgrove, D. E. Pitts, P. C. Kirlin, J. A. O'Donnell, D. A. Hormuth & T. C. Wozniak, Early Prediction of Cardiac Allograft Vasculopathy and Heart Transplant Failure, 11 AM. J. TRANSPLANTATION 528, 533 (2011) (noting that recipient's sex and race affected early predictions of cardiac allograft vasculopathy, though race was not a statistically significant

⁴⁶ Id.

⁴⁷ Id.

⁴⁸ See supra note 14 and accompanying text; see also J. Hickner, D. G. Graham, N. C. Elder, E. Brandt, C. B. Emersmann, S. Dovey & R. Phillips, *Testing Process Errors and Their Harms and Consequences Reported from Family Medicine Practices: A Study of the American Academy of Family Physicians National Research Network*, 17 QUALITY & SAFETY HEALTH CARE 194, 200 (2008) ("The odds of a minority patient suffering an adverse consequence from a testing process error was three times that of a white non-Hispanic patient, even after adjusting for the association between implementation errors and race/ethnicity.").

diagnosis.53 Further, research has found that, when compared to White patients, ethnic minorities have a greater chance of experiencing harm and adverse consequences due to errors in the testing process, which includes "ordering the test, implementing the test, performing the test, reporting results to the clinician, clinician responding to the results, notifying the patient of the results and following up."54 One study reviewed the association between the type of testing error and the occurrence of adverse outcomes and found an important association across racial and ethnic groups.55 This research revealed that errors based on test implementation were almost double within minority groups in comparison with non-Hispanic Whites (32% as opposed to 18%).⁵⁶ Overall, the study found minority patients were more likely to experience an adverse event.⁵⁷ The study revealed that minority patients are three times more likely to experience an adverse event due to the testing process than a White patient.58 Further, minority patients in the study were twice as likely to experience harm as White patients.⁵⁹ Unfortunately, testing errors represent another point within our healthcare system where racial and ethnic minorities are disparately harmed.

Significant research indicates disparities in diagnostic errors across social groups.⁶⁰ One study found that although Black patients experience lower levels

⁵³ See Schiff et al., *supra* note 30, at 1882 (defining diagnostic error).

⁵⁴ Hickner et al., *supra* note 48, at 194 ("Minority patients were more likely than white, non-Hispanic patients to suffer adverse consequences or harm [from testing process errors]."). ⁵⁵ *Id.* at 200.

⁶⁰ See sources cited *supra* note 52; *see also* Balakrishnan & Arjmand, *supra* note 14, at 42 (finding consistency within forty-two studies showing implicit bias's effect on health care);

factor); Alicia Lukachko & Mark Olfson, Race and the Clinical Diagnosis of Depression in New Primary Care Patients, 34 GEN. HOSP. PSYCHIATRY 98, 99 (2012) (finding that Black patients were less likely to be diagnosed with depression during a first doctor's visit than White patients): Nancy N. Masereijan, Carol L. Link, Karen L. Lutfey, Lisa D. Marceau & John B. McKinlay, Disparities in Physicians' Interpretations of Heart Disease Symptoms by Patient Gender: Results of a Video Vignette Factorial Experiment, 18 J. WOMEN'S HEALTH 1661, 1663-65 (2009) (finding that middle-aged female patients were diagnosed with coronary heart disease with less confidence than male patients, and female patients were more likely to be confidently diagnosed with a mental health condition instead); John B. McKinlay, Lisa D. Marceau & Rebecca J. Piccolo, Do Doctors Contribute to the Social Patterning of Disease? The Case of Race/Ethnic Disparities in Diabetes Mellitus, 69 MED. CARE RSCH. & REV. 176, 188-89 (2012) (finding that Type II Diabetes diagnoses were affected by socioeconomic status and race or ethnicity); David E. Newman-Toker, Ernest Moy, Ernest Valente, Rosanna Coffey & Anika L. Hines, Missed Diagnosis of Stroke in the Emergency Department: A Cross-Sectional Analysis of a Large Population-Based Sample, 1 DIAGNOSIS 155, 162 (2014) (finding women, people under the age of forty-five, and Hispanic and non-White patients significantly more likely to be misdiagnosed when showing symptoms of strokes).

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 ⁵⁶ Id.
 ⁵⁷ Id.

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⁵⁸ Id.

⁵⁹ Id.

of depression than White patients, they are more likely to be undiagnosed at the first primary care visit in comparison with White patients.⁶¹ The consequences of such a diagnostic error are serious: a delayed diagnosis of depression may negatively affect the clinical course of depression and put patients at a higher risk for adverse outcomes.⁶²

A study at Johns Hopkins University found that emergency room doctors commonly miss strokes among women, minorities, and patients under age forty-five.⁶³ Unfortunately, each year "doctors overlook or discount the early signs of potentially disabling strokes in tens of thousands of Americans."⁶⁴ Of those overlooked, women, minorities, and younger patients are disproportionately sent home, despite complaints of dizziness or headaches.⁶⁵ Findings from medical records reflect that women, minorities, and individuals under the age of forty-five who exhibited these symptoms were much more likely to be misdiagnosed the week before suffering from a debilitating stroke.⁶⁶ The study also found that women who came to the emergency room with stroke symptoms were 33% more likely to be misdiagnosed, while minorities were 20-30% more likely than White patients to be misdiagnosed.⁶⁷ Based on these findings, study leader Dr. Newman-Toker has stated, "[i]t's clear that ER physicians need to be more discerning and vigilant in ruling out stroke, even in younger people."⁶⁸ Further,

Dovidio et al., *supra* note 13, at 478 (finding consistency in decades of research into the disparate levels of health between social and racial groups).

⁶³ See Newman-Toker et al., *supra* note 52, at 156 ("Younger patients, women, minorities, and those triaged to lower acuity care or seen in non-teaching hospitals may be at higher risk [for misdiagnosis]." (footnotes omitted)).

⁶⁵ See id.; Newman-Toker et al., supra note 52, at 160-61 tbl.4.

⁶⁶ See Johns Hopkins Med., supra note 64; Newman-Toker et al., supra note 52, at 160-61 tbl.4.

⁶⁷ See Newman-Toker et al., supra note 52, at 160-61 tbl.4.

⁶¹ See Lukachko & Olfson, supra note 52, at 99.

⁶² See Ricky Cheung, Siobhan O'Donnell, Nawaf Madi & Elliot M. Goldner, Factors Associated with Delayed Diagnosis of Mood and/or Anxiety Disorders, 37 HEALTH PROMOTION & CHRONIC DISEASE PREVENTION CAN. 137, 137 (2017) ("A delay in treatment of common mental disorders is associated with poorer health outcomes including a worsening of mental health status, the development of other mental disorders, and an increased risk of suicide."); Raúl Huerta-Ramírez, Jordan Bertsch, María Cabello, Miquel Roca, Josep Maria Haro & José Luis Ayuso-Mateos, Diagnosis Delay in First Episodes of Major Depression: A Study of Primary Care Patients in Spain, 150 J. AFFECTIVE DISORDERS 1247, 1247 (2013) ("Diagnosis delay may negatively influence the clinical course of major depression"); Lukachko & Olfson, supra note 52, at 99 ("Failure to detect depression during the initial contact with primary care physicians could result in significant delays in receiving treatment, diminished functioning related to untreated depression and exacerbation of comorbid medical conditions." (footnotes omitted)).

⁶⁴ News Release, Johns Hopkins Med., ER Doctors Commonly Miss More Strokes Among Women, Minorities and Younger Patients (Apr. 3, 2014), https://www.hopkinsmedicine.org/news/media/releases/er_doctors_commonly_miss_more_ strokes_among_women_minorities_and_younger_patients [https://perma.cc/VZ4X-43Z6].

⁶⁸ See Johns Hopkins Med., supra note 64.

additional research has found that women under the age of fifty-five were almost seven times more likely than men in the same age group to be sent home from the hospital in the middle of experiencing certain heart problems.⁶⁹ The results of these studies suggest that race and gender, whether implicitly or explicitly, may play a role in how physicians decide who to treat and who to send home.

Misdiagnosis can have tragic consequences for patients and their families. In the event of a misdiagnosis, the error may lead to no treatment or delayed treatment for a serious condition, leading to injury or death. While misdiagnosis can happen to any patient, the recent spate of studies shows that the race and gender of the patient seems to influence when and whether a patient is diagnosed correctly.⁷⁰ For instance, women have a lower likelihood of receiving a proper and timely diagnosis of cancer and heart disease in comparison to men.⁷¹ This has been particularly pronounced around women experiencing heart attacks. The CDC describes heart attacks as one of the leading causes of death for both men and women, and as the leading cause of death for Black and White women.⁷² Although heart attacks are the leading cause of death of women in the United States, responsible for roughly one in five female deaths,⁷³ doctors still misdiagnose heart attacks in women 50% of the time.⁷⁴ When a heart attack is not properly diagnosed, this can lead to serious health implications for the patient, including mortality.75 Given the current rates of diagnosis, these health implications disproportionately affect women.

⁶⁹ J. Hector Pope, Tom P. Aufderheide, Robin Ruthazer, Robert H. Woolard, James A. Feldman, Joni R. Beshansky, John L. Griffith & Harry P. Selker, *Missed Diagnoses of Acute Cardiac Ischemia in the Emergency Department*, 342 NEW ENG. J. MED. 1163, 1168 tbl.2 (2000) (finding that women under fifty-five are 6.7 times more likely than men under fifty-five to be discharged from the hospital while they are experiencing acute cardiac ischemia).

⁷⁰ See sources cited supra note 52.

⁷¹ See Henning et al., supra note 52, at 68; Maserejian et al., supra note 52, at 1663-65.

⁷² Women and Heart Disease, CDC, https://www.cdc.gov/heartdisease/women.htm [https://perma.cc/ZKV8-34FJ] (last reviewed Jan. 31, 2020) ("Heart disease is the leading cause of death for women in the United States").

⁷³ Id.

⁷⁴ See Rajiv Bahl, Doctors Missed Heart Attack Signs in Women 50% of the Time, HEALTHLINE (Sept. 18, 2018), https://www.healthline.com/health-news/doctors-missed-heart-attack-signs-in-women [https://perma.cc/46BZ-3WLV] (finding that 53% of women admitted to the hospital for a heart attack reported that "their healthcare provider[s] did not think the[ir] symptoms were heart-related" before they were hospitalized).

⁷⁵ See *id.* ("If these symptoms are misinterpreted or ignored, young women have a 'higher risk of mortality' or having complications from a heart attack.").

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II. RESPONDING TO MEDICAL ERROR

Since the 2000 IOM report, there has been a push to reform the way doctors and hospitals deal with medical error.⁷⁶ To err is human.⁷⁷ We cannot expect doctors to be perfect nor do our systems call for perfection. However, the stakes are higher within the medical profession, as human error, systematic breakdowns, and poor communication can result in severe harm to, or even the death of, the patient.⁷⁸ It is impossible to prevent all error, but many errors are avoidable.⁷⁹

A. The Blame Game and Who Is Actually at Fault

It is a common misconception that when an error occurs it is the fault of *someone*.⁸⁰ Human nature often seeks to blame a single person or team,⁸¹ but medical errors are often the result of a combination of individual, systematic, and communication failures.⁸² In this context, it is next to impossible to say that one person or group is at fault. Even if it were possible to find a specific culprit, using blame as a gauge to hold this person responsible would only create a detrimental system focused on shame.⁸³

⁷⁶ See Devers et al., supra note 9, at 103.

⁷⁷ See TO ERR IS HUMAN, *supra* note 1, at ix ("Human beings, in all lines of work, make errors. Errors can be prevented by designing systems that make it hard for people to do the wrong thing and easy for people to do the right thing.").

⁷⁸ See Raper, *supra* note 27, at 270 (calling for the use of "modern principles of systems analysis and human performance to understand why medical errors take place").

⁷⁹ See Nancy J. Crigger, Always Having to Say You're Sorry: An Ethical Response to Making Mistakes in Professional Practice, 11 NURSING ETHICS 568, 568 (2004) (arguing "all health care providers, no matter how expert, conscientious and careful in practice, make mistakes" but noting that other literature focuses on how to reduce mistakes).

⁸⁰ See, e.g., *id.* at 569 ("[M]istakes occur when *one* makes choices that result in negative or less than desirable outcomes." (emphasis added)).

⁸¹ See Bertram F. Malle, Steve Guglielmo & Andrew E. Monroe, *Moral, Cognitive, and Social: The Nature of Blame, in* SOCIAL THINKING AND INTERPERSONAL BEHAVIOUR 313, 316 (Joseph P. Forgas, Klaus Fieldler & Constantine Sedikides eds., 2012) ("Genuine blame requires [finding] meaning of a particular kind—one that involves agents who caused the negative event."); id. at 325-26 ("People treat not only individuals as moral agents; they also treat groups that way if the group has the abilities of forming reasons and acting intentionally in light of these reasons.").

⁸² See JENICEK, supra note 26, at 173 (asserting that medical decision making is detailed, complex, and not suited to easily ascribe blame); Andrew A. White & Thomas H. Gallagher, *Medical Error and Disclosure, in* 118 HANDBOOK OF CLINICAL NEUROLOGY: ETHICAL AND LEGAL ISSUES IN NEUROLOGY 107, 108 (James L. Bernat & H. Richard Beresford eds., 2013) (noting that most errors are not attributable to individual failures but to "a combination of individual and systems failures").

⁸³ See White & Gallagher, *supra* note 82, at 115 (discussing emotional impact of errors on clinicians); Crigger, *supra* note 79, at 572 (discussing negative effects that blaming an individual for an error can have on health care professionals).

In the context of medical error, instead of the emphasis being on the patient and how to create safer systems, the focus is too often on who is at fault and who we can blame.⁸⁴ In the legal system, we look to the tort regime in how we assign blame.⁸⁵ Tort law has three major objectives—"[c]ompensation, corrective justice, and deterrence."⁸⁶ Of these three, compensation is often seen as tort law's most significant function.⁸⁷ Compensation is largely predicated on a finding of fault, as only once fault is found can damages be awarded to the plaintiff.⁸⁸ This is meant to indemnify the plaintiff for all losses, as far as money can do so.⁸⁹ The requirement for a finding of fault is based on the idea that "wrongdoers bear personal responsibility for the harm they have caused others."⁹⁰ In order to redress this harm, the wrongdoer should pay damages to restore the victim.⁹¹

Despite this traditional response within tort law, in the aftermath of a medical error, it is key to move away from assigning blame and instead focus on a system-oriented approach that de-emphasizes individual fault finding. Our treatment of error in healthcare and within the tort system creates a dangerous system of finger pointing, instead of identifying the harm and making changes. The desire to create change around medical error has fueled harsh responses from healthcare institutions, including forms of surveillance and punishment.⁹² Instead, when medical errors do arise, the reaction should be to learn from them, rather than trying to assign blame and punish someone.

Resorting to punitive action is ineffective for several reasons. First, swift and harsh punishment fails to create an environment where healthcare professionals will feel comfortable to bring forth an error or to discuss what went wrong.⁹³ Second, human instinct may be to find someone to blame, but in reality, when an error occurs, it is often the result of systematic failures and various missteps.⁹⁴ Very rarely is a single person or entity entirely to blame for the occurrence of an

⁹² See Berwick & Leape, *supra* note 84, at 136 (noting some efforts towards creating safer healthcare systems are "channelled into harsh forms of surveillance and punishment").

⁸⁴ See Donald M. Berwick & Lucian L. Leape, *Reducing Errors in Medicine: It's Time to Take This More Seriously*, 319 BRIT. MED. J. 136, 136 (1999).

⁸⁵ See B. Sonny Bal, An Introduction to Medical Malpractice in the United States, 467 CLINICAL ORTHOPAEDICS & RELATED RSCH. 339, 340 (2009) ("Medical malpractice is a specific subset of tort law that deals with professional negligence.").

⁸⁶ See Joan M. Gilmour, Patient Safety, Medical Error and Tort Law: An International Comparison 8 (2006).

⁸⁷ See id.

⁸⁸ See id. at 4, 8-9.

⁸⁹ *Id.* at 9.

⁹⁰ Id.

⁹¹ Id.

⁹³ See White & Gallagher, *supra* note 82, at 115 ("Shame, fear of litigation or punishment, and misguided advice to speak with nobody also prompt many healthcare workers to cope in isolation.").

⁹⁴ See supra note 82 and accompanying text.

error.⁹⁵ This punitive culture and the assignment of blame do not fix the problem or reduce the occurrence of error. Assigning blame simply demoralizes physicians and healthcare professionals without resolving the underlying problem.⁹⁶ Research indicates that when organizations are dealing with "complex systems, safety depends not on exhortation, but rather on the proper design of equipment, jobs, support systems, and organisations."⁹⁷ So, not only is focusing on blame harmful, but it also does not solve the problem. Most medical errors are caused by problems in the system—not human error alone.⁹⁸ What we need to recognize is that in order to have safer care, we need to design safer care systems, as opposed to emphasizing reactionary penalties.⁹⁹

Dr. Milos Jenicek describes the causal factors of medical error as follows:

Any medical error is a product of various "external" circumstances, including the environment, working conditions, and pressures; rapidly evolving technology; and managerial, administrative, or system functioning. These external factors only contribute to the essence (the internal factors) behind the medical error, namely, the physician's own faulty reasoning, logic, critical thinking, and decision making.¹⁰⁰

An emphasis on punishment to address errors within medicine and the health care system will not work. Healthcare professionals are concerned about the overall institutional culture of blame.¹⁰¹ There is an emphasis placed on fault finding without a full recognition or understanding of the complexity of the healthcare environment.¹⁰² The individuals involved in a medical error likely already suffer from guilt and shame about the error¹⁰³ and this culture of blame will only serve to lower morale and present further challenges as healthcare professionals set out to address the mistake and improve patient safety.

⁹⁹ See Berwick & Leape, *supra* note 84, at 136 ("If we truly want safer care we will have to design safer care systems.").

¹⁰⁰ See JENICEK, supra note 26, at xvi.

⁹⁵ See White & Gallagher, *supra* note 82, at 108-09 (describing several causes of medical error which do not depend on a single person).

⁹⁶ See id. at 115.

⁹⁷ Berwick & Leape, *supra* note 84, at 136.

⁹⁸ See Kristen R Salvatore, *Taking Pennsylvania Off Life Support: A Systems-Based Approach to Resolving Pennsylvania's Medical Malpractice Crisis*, 109 PENN ST. L. REV. 363, 385 (2004) (finding reports in Pennsylvania "indicat[ing] that errors are occurring due to particular system failures" rather than individual errors alone).

¹⁰¹ Ann Hendrich, Christine Kocot McCoy, Jane Gale, Lora Sparkman & Palmira Santos, *Ascension Health's Demonstration of Full Disclosure Protocol for Unexpected Events During Labor and Delivery Shows Promise*, 33 HEALTH AFFS. 39, 39 (2014) (arguing that placing blame hinders "open communication" with patients about errors).

 $^{^{102}}$ *Id.* (explaining how searching for someone to blame overshadows recognition of health care's complexities).

¹⁰³ See ROSEMARY GIBSON & JANARDAN PRASAD SINGH, WALL OF SILENCE: THE UNTOLD STORY OF THE MEDICAL MISTAKES THAT KILL AND INJURE MILLIONS OF AMERICANS 11 (2003) (describing medical errors as "devastating" to medical professionals).

Particularly within the case of diagnostic errors, clinicians are reluctant and often defensive about judging themselves or their colleagues for potentially missing or delaying diagnosis.¹⁰⁴ Further, even when they do judge their colleagues, clinicians are reluctant to speak out for fear of jeopardizing their professional standing or job security.¹⁰⁵ By some accounts, clinicians will actively "cover[] up or ignore [mistakes], and it's back to business as usual."¹⁰⁶ This reluctance to hold one another accountable just contributes to the problem.¹⁰⁷ While many medical errors may be due to faulty systems and systematic breakdowns, this does not mean that individuals should be allowed to be careless, without reproach. Instead, each person involved in the healthcare system should maintain a level of vigilance and responsibility for their actions.

The question is not how to keep bad physicians from harming patients but rather how to keep *all* physicians from harming patients.¹⁰⁸ Part of creating a safer system means moving away from a culture of blaming individuals. Developing a systems-based approach to medical error removes the focus from finding fault and blaming bad actors and instead prioritizes individuals who are trying to do the right thing within an imperfect system.¹⁰⁹ Even when these individuals try to do right, within our current system, errors still happen.¹¹⁰ It does not matter how experienced or careful healthcare providers are; mistakes will happen.¹¹¹ But, creating safer systems and reducing systemic errors can reduce the number of mistakes that are made.

The use of fear, reprisal, and punishment do not produce safety but rather defensiveness, secrecy, and enormous human anguish. This approach when error occurs has evidently created an environment of fear, hostility, and defensiveness. When faced with an error, the medical field has traditionally doubled down and chosen to "deny and defend"¹¹² the actions taken in the case

¹⁰⁴ Schiff et al., *supra* note 30, at 1881 (arguing that because of the unpredictable nature of medical conditions and the limitations of testing, clinicians are "justifiably reluctant" to judge potential missed diagnoses).

¹⁰⁵ See GIBSON & SINGH, supra note 103, at 11 ("Many doctors and nurses privately express deep concern about medical mistakes, yet they remain silent. If they speak out publicly, their jobs and professional standing may be at risk.").

¹⁰⁶ *Id.* at 10.

¹⁰⁷ See id. (noting clinicians will not find medical errors if they do not seek errors' sources nor will they correct systematic errors they do not find).

¹⁰⁸ See id. at 13-14 ("It is not enough to improve surgical procedures or enhance medical knowledge. Even weeding out incompetent health care professionals won't solve the problem. Making health care safer requires changing how health care is organized and how health professionals work together and communicate.").

¹⁰⁹ See Bryan A. Liang, The Adverse Event of Unaddressed Medical Error: Identifying and Filling the Holes in the Health-Care and Legal Systems, 29 J.L. MED. & ETHICS 346, 346-47 (2001).

¹¹⁰ See id.

¹¹¹ See JAMES REASON, HUMAN ERROR 17 (1990) (describing how all people are prone to different types of errors in the "normal course of daily life").

¹¹² See infra notes 116-18 and accompanying text.

of the harm.¹¹³ The persistence of harm indicates that the current approach does not work and that something must change.

B. Current Responses to Medical Error

Our system for dealing with medical error in the United States is abysmal. Traditionally, when faced with a sentinel event—an unexpected occurrence involving death or the risk of permanent or severe temporary physical or psychological harm¹¹⁴—patients and their families are offered little to no information and virtually no recourse for how to handle the occurrence of a medical error.¹¹⁵ Patients are left searching for information with little understanding as to what happened and who is at fault. Traditionally, when a medical professional or hospital makes a mistake, that person or institution opts for what is known as "deny and defend," whereby health institutions simply deny that a mistake was made and seek to avoid responsibility.¹¹⁶ In this approach, "[physicians] deny that mistakes happened and vigorously defend against malpractice claims."¹¹⁷ This tactic of denial and stonewalling achieves very little, except to anger patients and their families.¹¹⁸

¹¹³ See White & Gallagher, *supra* note 82, at 112 (discussing how physicians typically do not fully disclose medical errors to patients).

¹¹⁴ Sentinel Event, JOINT COMM'N, https://www.jointcommission.org/resources/patient-safety-topics/sentinel-event/ [https://perma.cc/R979-YSLN] (last visited Jan. 19, 2022).

¹¹⁵ See GIBSON & SINGH, supra note 103, at 10 ("[W]hen a patient dies from a medical mistake, the mistake is either covered up or ignored"); Thomas H. Gallagher, David Studdert & Wendy Levinson, *Disclosing Harmful Medical Errors to Patients*, 356 NEW ENG. J. MED. 2713, 2713 (2007) (noting lack of uniform guidance on disclosure procedures); T. B. McDonald, L. A. Helmchen, K. M. Smith, N. Centomani, A. Gunderson, D. Mayer, W. H. Chamberlin, *Responding to Patient Safety Incidents: The "Seven Pillars*," 19 QUALITY & SAFETY HEALTH CARE e11, e14 (2010) (concluding that disclosure of medical errors is rare despite the "seven pillars" safety incident response program); White & Gallagher, *supra* note 82, at 112 ("Multiple studies indicate that physicians disclose less than half of harmful errors to patients. When error disclosure does occur, physicians often do not present all of the content desired by patients." (citation omitted)).

¹¹⁶ See Daniel Rocke & Walter T. Lee, *Medical Errors: Teachable Moments in Doing the Right Thing*, 5 J. GRADUATE MED. EDUC. 550, 550 (2013) (describing "deny and defend" practice); White & Gallagher, *supra* note 82, at 112 (finding many physicians are advised by risk management teams to "deny and defend" errors).

¹¹⁷ Rocke & Lee, *supra* note 116, at 550.

¹¹⁸ See Albert W. Wu, Layla McCay, Wendy Levinson, Rick Iedema, Gordon Wallace, Dennis J. Boyle, Timothy B. McDonald, Marie M. Bismark, Steve S. Kraman, Emma Forbes, James B. Conway & Thomas H. Gallagher, *Disclosing Adverse Events to Patients: International Norms and Trends*, J. PATIENT SAFETY 43, 46 (2017) ("[D]isclosing only generalities to patients and avoiding open discussion about why specific clinicians acted or spoke as they did not only cause patients anger and frustration but may induce them to file complaints, take legal action, or go to the media."); McDonald et al., *supra* note 115, at e14 (noting that delays in disclosure can be perceived as "subterfuge" by patients).

"Deny and defend" results in poor outcomes for both sides—the physician misses an opportunity to address an error and improve overall patient safety,¹¹⁹ and the patient and their family are left totally in the dark as to what happened.¹²⁰ This adversarial stance moves "the physician-patient relationship from one of intimacy and trust to one of distance and opposition."¹²¹ Consequently, patients and their families are then left alone to deal with the resulting harm and to figure out how to move forward and what steps need to be taken.¹²² In the wake of an error, some patients will simply sever all ties with their physician and that healthcare institution, or will avoid health care as a whole.¹²³ Many patients are simply looking for an apology, to understand what happened, and to enact change—"deny and defend" deprives them of this opportunity.¹²⁴

Without this opportunity to discuss the error and resolve their concerns, some patients will turn to the legal system to find recourse. Data indicates that the "deny and defend" practice transforms the physician-patient relationship into an adversarial one and is one of the main reasons malpractice lawsuits are filed.¹²⁵ Patients are generally more focused on how the error is handled instead of the

¹²² See Gallagher et al., *supra* note 120, at 898-902 (discussing case studies with patient experiences that show the resulting confusion patients and their families deal with).

¹²³ See BETSY LEHMAN CTR. REPORT, *supra* note 41, at 1 ("Individuals report that they have lost trust in the health system and some avoid not only the clinicians and facilities responsible for their injuries, but health care entirely.").

¹²⁴ See Rocke & Lee, *supra* note 116, at 550 ("[T]he top reasons patients sue [are] to prevent the error from happening again, to get an explanation, to get an admission of error, and to have the physician realize how the victim felt."); *see also* Bruce L. Lambert, Nichola M. Centomani, Kelly M. Smith, Lorens A. Helmchen, Dulal K. Bhaumik, Yash J. Jalundhwala & Timothy B. McDonald, *The "Seven Pillars" Response to Patient Safety Incidents: Effects on Medical Liability Processes and Outcomes*, 51 HEALTH SERVS. RSCH. 2491, 2494-95 (2016) (discussing strategy for resolving medical errors including apology and disclosure); McDonald et al., *supra* note 115, at 3 (suggesting apology and rapid remediation to resolve patient concerns after a medical error); White & Gallagher, *supra* note 82, at 110 ("Ethicists, physicians, and patients agree that patients harmed by errors should receive prompt, open disclosure and a full apology.").

¹²⁵ See Rocke & Lee, supra note 116, at 550 ("Data suggest that this relational shift is central to why most malpractice lawsuits are filed."); see also Jennifer K. Robbennolt, *Apologies and Legal Settlement: An Empirical Examination*, 102 MICH. L. REV. 460, 462 (2003) (arguing that more apologies would reduce litigation generally).

¹¹⁹ See David M. Studdert, Michelle M. Mello, William M. Sage, Catherine M. DesRoches, Jordon Peugh, Kinga Zapert & Troyen A. Brennan, *Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment*, 293 J. AM. MED. Ass'N 2609, 2609, 2617 (2005) (finding defensive medicine—where "physicians alter their clinical behavior because of the threat of malpractice liability"—may reduce access to care and risk physical harm).

¹²⁰ See, e.g., Thomas H. Gallagher, Sigall K. Bell, Kelly M. Smith, Michelle M. Mello & Timothy B. McDonald, *Disclosing Harmful Medical Errors to Patients: Tackling Three Tough Cases*, 136 CHEST 897, 898 (2009) (describing case study where medical error was not disclosed to patient who did not ask).

¹²¹ Rocke & Lee, *supra* note 116, at 550.

error itself.¹²⁶ One study found the following as the top reasons patients decide to sue: (1) "prevent the error from happening again," (2) receive an explanation as to what happened, (3) "get an admission of error," and (4) help the physician understand how the patient felt because of the harm.¹²⁷ When patients were asked what could have prevented them from filing suit, the most common response was that they may not have filed suit had they received an explanation and an apology.¹²⁸ This is because "apologies benefit injured parties by restoring their sense of dignity and power."¹²⁹ They also benefit "apologizers by affirming their self-worth and morality."¹³⁰ Further, research indicates that when those harmed by an error receive an explanation and a chance to discuss the adverse event openly, it helps to mitigate their emotions and allows them to emotionally process what occurred.¹³¹

Four main themes emerged from the analysis as the basis for litigation.¹³² First, patients expressed concerns with the standard of care. Both patients and their families wanted to know the institution had learned from their experiences and that this same harm would not occur again in the future. Second, patients sought an explanation for the error. Patients wanted to know how the injury happened and why. Third, patients wanted compensation. This money could be used to redress their actual losses and pain and suffering. Compensation could also be used to ensure and cover future care for the injured person. Finally, patients desired accountability. Patients felt that the staff or organization should be held accountable for their actions.¹³³ The decision to take legal action often stemmed from patients' desire for greater honesty and a genuine understanding of the harm and trauma they suffered.¹³⁴ Litigation involving adverse events

¹²⁶ See Rocke & Lee, *supra* note 116, at 550 ("Indeed, the main reasons that patients sue physicians are more related to the handling of the mistake than to the actual mistake itself."); *see also* Robbennolt, *supra* note 125, at 463 ("Survey research suggests that claimants desire apologies and that some would not have filed suit had an apology been offered.").

¹²⁷ Rocke & Lee, *supra* note 116, at 550 (citing Charles Vincent, Magi Young & Angela Phillips, *Why Do People Sue Doctors? A Study of Patients and Relatives Taking Legal Action*, 343 LANCET 1609, 1611 tbl.3 (1994)).

¹²⁸ *Id.* (citing Vincent et al., *supra* note 127, at 1612 tbl.5).

¹²⁹ Jennifer Wimsatt Pusateri, *It Is Better to Be Safe When Sorry: Advocating a Federal Rule of Evidence That Excludes Apologies*, 69 KAN. L. REV. 201, 202 (2020).

¹³⁰ *Id.*

¹³¹ BETSY LEHMAN CTR. REPORT, *supra* note 41, at 15 ("For people who receive it, open communication is associated with lower levels of adverse emotional health impacts and heath care avoidance.").

¹³² See Vincent et al., *supra* note 127, at 1612 (noting the four themes as standards of care, explanation, compensation, and accountability).

¹³³ See id. at 1612-13.

¹³⁴ See id. (describing the importance of communication in contemplating litigation).

cannot simply be viewed as a legal and financial problem¹³⁵—it is a human problem, and it must be dealt with as such.

It is clear that the approach of "deny and defend" is destructive for several reasons. First, the clinician's avoidance of responsibility completely severs the physician-patient relationship.¹³⁶ Second, this tactic destroys the faith or trust the patient and their family had held with that institution.¹³⁷ Third, it removes the opportunity to learn from that mistake and make changes to the system to prevent against that error and make it safer for patients in the future.¹³⁸ Fourth, the "deny and defend" approach may actually cause a patient to pursue legal action,¹³⁹ and once in court, the doctor and hospital will continue with their denial and develop a case to defend their actions.¹⁴⁰ The "deny and defend" practice creates a circular system where both medical professionals and patients are unable to learn from the error and move forward.¹⁴¹

C. How to Respond to Medical Error

Disclosure is one of the most important steps that a medical professional faces after a medical error.¹⁴² Despite its previous prevalence, the tide is turning: "deny and defend" is no longer an appropriate response when a medical error occurs.¹⁴³ Even with this shift in how errors should be treated, barriers to the disclosure process remain.

Despite the fact that most physicians agree that errors should be disclosed, there is no consistent approach and little guidance on how this should be done.¹⁴⁴

¹³⁸ See id. (encouraging disclosure as a part of the learning process).

¹³⁹ See Rocke & Lee, supra note 116, at 550 (alluding that "deny and defend" is one of the reasons why patients sue physicians).

¹⁴⁰ See infra notes 350-59 and accompanying text (explaining why doctors are hesitant to admit fault in court).

¹⁴¹ See Gallagher et al., *supra* note 120, at 898-902 (discussing case studies where physicians failed to disclose adequate details about medical errors).

¹⁴² See White & Gallagher, *supra* note 82, at 110 ("How physicians explain medical mistakes to patients may have significant emotional and legal consequences for the patient, family, doctor, and healthcare system.").

¹⁴³ See Lorens A. Helmchen, Michael R. Richards & Timothy B. McDonald, Successful Remediation of Patient Safety Incidents: A Tale of Two Medication Errors, 36 HEALTH CARE MGMT. REV. 114, 114-15 (2011) (discussing rise of patient safety culture); Rocke & Lee, supra note 116, at 550 (describing recent adoption of mistake disclosure protocols at major health systems).

¹⁴⁴ See Gallagher et al., *supra* note 115, at 2713 ("Until recently, virtually no guidance was available to health care professionals regarding how or when to disclose errors").

¹³⁵ See id. at 1612 ("The legal system is being used . . . for a variety of reasons, some of which it is not intended to serve. Patients and relatives are hoping for more than compensation when they embark on a legal action.").

¹³⁶ See supra notes 125-26 and accompanying text.

¹³⁷ See McDonald et al., *supra* note 115, at e14 (arguing open communication is the only way to retain "trust in the process and mak[e] the patient and family key partners in the process").

Research in this area echoes this confusion and lack of consistency. In one study, 19% of physicians admitted to making what they considered to be a minor error and not disclosing it to the patient and their family.¹⁴⁵ Of those surveyed, 4% had even made a major error and not disclosed it.¹⁴⁶ Additional research has found "that only 24% of trainees and 21% of physicians disclosed the most significant error they made in the past year."¹⁴⁷ Based on this research and physician confusion around how and when to disclose an error, there appears to be a gap between *best practices* and physicians' *actual attitudes and practices* in error disclosure.¹⁴⁸

While there is a recognized necessity for providing patients and their families with full error disclosures, healthcare professionals still face several barriers to error disclosure.¹⁴⁹ In addition to those barriers, healthcare professionals often avoid disclosing errors because they do not know what to say or how to say it.¹⁵⁰ There has been little training invested in teaching healthcare professionals how to communicate a medical error.¹⁵¹ Instead, "deny and defend" has historically monopolized these conversations, leaving healthcare institutions and physicians unsure of how to handle medical errors.¹⁵² Due to this lack of training and insufficient guidance on how to handle the occurrence of errors, healthcare providers understandably feel uncomfortable with having to reveal that someone under their care suffered harm because of a seemingly simple mistake. This fear of how to properly engage in a dialogue without worsening the error, alongside the lack of guidance or training on how to do so, deters many healthcare professionals from participating in effective error disclosure.¹⁵³

¹⁴⁸ See Kaldjian et al., supra note 145, at 994.

¹⁴⁹ See Hendrich et al., *supra* note 101, at 39 (listing various barriers to error disclosure); Rocke & Lee, *supra* note 116, at 551 (listing sources of barriers to error disclosure).

¹⁵⁰ See Rocke & Lee, *supra* note 116, at 551 ("Most medical trainees do not receive education on how to disclose medical errors despite an overwhelming interest by physicians in having this training.").

¹⁵¹ See Hendrich et al., supra note 101, at 40-42 (describing novel disclosure training initiative).

¹⁵² See Gallagher et al., *supra* note 120, at 902 (concluding that lingering challenges to disclosure from "deny and defend" era should be addressed before disclosure policies or systems are implemented); Gallagher et al., *supra* note 115, at 2713-14 (surveying some initial pushes to increase disclosure).

¹⁵³ See Gallagher et al., *supra* note 115, at 2717 (noting that physicians are likely to have "concerns" in the face of new disclosure requirements); Lambert et al., *supra* note 124, at

¹⁴⁵ Lauris C. Kaldjian, Elizabeth W. Jones, Barry J. Wu, Valerie L. Forman-Hoffman, Benjamin H. Levi & Gary E. Rosenthal, *Disclosing Medical Errors to Patients: Attitudes and Practices of Physicians and Trainees*, 22 J. GEN. INTERNAL MED. 988, 991 tbl.2 (2007).

¹⁴⁶ *Id*.

¹⁴⁷ Rocke & Lee, *supra* note 116, at 550 (citing Kathleen M. Mazor, Steven R. Simon & Jerry H. Gurwitz, *Communicating with Patients About Medical Errors: A Review of the Literature*, 164 ARCHIVES INTERNAL MED. 1690, 1690-91 (2004) (reviewing 17 articles with "original empirical data on disclosure of medical errors to patients and families")).

Moreover, healthcare professionals are concerned about the legal consequences of revealing and taking responsibility for medical errors.¹⁵⁴ Physicians fear that revealing an error, or even apologizing, will make them liable—and thus increase their likelihood of being sued.¹⁵⁵ They also fear that disclosure will lead to an increase in their malpractice premiums or lead to a termination of their malpractice insurance coverage.¹⁵⁶ In fact, these concerns are valid: some health insurance providers attempt to block institutions from apologizing or admitting to fault in the event of an error.¹⁵⁷ If a medical provider violates their insurer's "cooperation clause," they "risk[] the possibility that the insurer will refuse to cover whatever associated costs" arise from a lawsuit or costs that may occur to the insured after the error.¹⁵⁸

Poor or inadequate disclosures are directly linked with increased malpractice litigation,¹⁵⁹ but the court is not an appropriate place for patients and their families to find out about a medical error and the harm that they suffered. CRPs move this process out of the courtroom and encourage healthcare professionals to have honest and frank conversations with their patients about what happened and how to move forward.¹⁶⁰ But rather than placing the duty of revealing an error on the courts or waiting for hospitals to formally adopt a CRP approach, healthcare institutions need to be better prepared and equipped with resources to effectively implement disclosure standards. The courtroom functions as a poor arbiter of medical error. The court can award the plaintiff damages, but money

¹⁵⁹ See supra notes 125-28 and accompanying text.

^{2495-96 (}citing actions Department of Safety and Risk Management took to increase trust with physicians as disclosure programs were implemented).

¹⁵⁴ See Hendrich et al., *supra* note 101, at 39 (noting physician fear of both litigation and increases in malpractice insurance premiums as a result of error disclosure); Michelle M. Mello, Richard C. Boothman, Timothy McDonald, Jeffrey Driver, Alan Lembitz, Darren Bouwmeester, Benjamin Dunlap & Thomas Gallagher, *Communication-and-Resolution Programs: The Challenges and Lessons Learned from Six Early Adopters*, 33 HEALTH AFFS. 20, 24 (2014) (noting physician fear of increased liability from disclosures and settlement offers).

¹⁵⁵ See Wu et al., *supra* note 118, at 45 ("There is concern internationally about the impact that increasing disclosure may have on litigation."); *see also* Kaldjian et al., *supra* note 145, at 990 ("Of the faculty and resident physicians, 10% reported that on at least 1 occasion they had chosen not to tell a patient that a medical mistake had occurred because of concerns about legal liability.").

¹⁵⁶ See Hendrich et al., supra note 101, at 39.

¹⁵⁷ See John D. Banja, *Does Medical Error Disclosure Violate the Medical Malpractice Insurance Cooperation Clause?*, in 3 ADVANCES IN PATIENT SAFETY: FROM RESEARCH TO IMPLEMENTATION 371, 371 (K. Henriksen, J. B. Battles, E. S. Marks & D. I. Lewin eds., 2005) (concluding that despite insurer attempts, "the legally sanctioned reasons for denying coverage . . . address factors other than an insured's *truthful and honest disclosure* of what happened to a claimant" (emphasis added)).

¹⁵⁸ *Id.* at 373.

¹⁶⁰ See discussion infra Section IV.B.

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is often not enough. Patients and their families want an understanding of what happened to them and an apology for the hurt and pain caused by the mistake.¹⁶¹

While filing a lawsuit and relying on the court to address the harm done is often insufficient, the expanded use of CRPs presents an opportunity to address many patients' key concerns following a medical error. The goal with using CRPs is not to pin down liability in a courtroom but to elicit transparency from healthcare organizations.¹⁶² CRPs create an open conversation where the healthcare institution discusses the error, apologizes when harm is caused by inappropriate care, handles the emotional state of the patient and their family, and makes changes to the system to prevent this type of error from occurring again.¹⁶³ Through a series of conversations and systematic changes, healthcare institutions can address the error, help the patient and their family through this process, and implement safeguards for the future. Patients want an assurance that changes will be made and that safeguards will be put in place to prevent the reoccurrence of this harm.¹⁶⁴ Some patients even want to be involved in making changes to the system.¹⁶⁵ As CRPs involve a series of conversations between the patient and healthcare provider, through the use of CRPs, the patient should have the opportunity to work with the hospital to make suggestions and institute safeguards to prevent this type of harm from happening again in the future.¹⁶⁶ The current system of response to medical errors is inadequate.

III. SOCIAL TRUST IN THE MEDICAL SYSTEM

The now infamous IOM Report, *To Err Is Human*, focused widespread attention on the fact that patients are not always safe in the healthcare system.¹⁶⁷

¹⁶¹ See McDonald et al., *supra* note 115, at e13 (describing the importance of apology and explanation to patients in the disclosure process).

¹⁶² See COLLABORATIVE FOR ACCOUNTABILITY & IMPROVEMENT, COMMUNICATION AND RESOLUTION PROGRAMS (CRPs): WHAT ARE THEY AND WHAT DO THEY REQUIRE? 1 [hereinafter COMMUNICATION AND RESOLUTION PROGRAMS], https://communicationandresolution.org/pix/Collaborative_CRP_Essentials.pdf [https://perma.cc/UE99-6F3X] (last visited Jan. 19, 2022).

¹⁶³ See *id.* at 2 (describing steps in CRP process); McDonald et al., *supra* note 115, at e14 (noting the importance of opening a line of communication early to maximize value of disclosure).

¹⁶⁴ Vincent et al., *supra* note 127, at 1613 (noting prevalence of patient desire to know that the mistake will not be repeated on others in the future).

¹⁶⁵ Helmchen et al., *supra* note 143, at 117 (describing instance where patient's family wanted to be involved in future patient safety improvements at the hospital).

¹⁶⁶ See COMMUNICATION AND RESOLUTION PROGRAMS, *supra* note 162, at 2 (listing step in CRP process as "[m]onitor[ing] and respond[ing] to the patient's and family's needs, questions and concerns and share factual (as differentiated from speculative) information about the event as it becomes available" and then "[u]ndertak[ing] a rigorous, human-factors-based event analysis that incorporates information and perspectives from the patient and family").

¹⁶⁷ See TO ERR IS HUMAN, supra note 1, at 26 (finding as many as 98,000 people die every year from errors in hospitals).

For the public, the finding that doctors, nurses, and other healthcare professionals make errors that injure people was revolutionary.¹⁶⁸ Doctors have a specialized relationship with patients and their families, which places an enormous amount of trust in them and the healthcare system.¹⁶⁹ Unfortunately, it is impossible to prevent all error and harm to patients and their families. Though some harm is inevitable, patients maintain a level of expectation about the nature and standard of care they will receive in a hospital.¹⁷⁰ As medicine is a highly specialized and technical field, patients often rely on their doctors and their recommendations for treatment.¹⁷¹ In the context of this vital relationship of trust, it is important to recognize the research that has revealed that inequities exist in patients' experiences. Historically, racial and ethnic minorities, women, and the transgender community have faced implicit bias and experienced mistreatment, discrimination, and unequal access to health care.¹⁷² Further, research indicates that these communities bear a disproportionate amount of the harm of medical errors.¹⁷³ Everyone is harmed by medical error and unsafe systems, but efforts to reduce medical error and increase patient safety should consider the unique and disproportionate harm done to vulnerable communities.

The U.S. Department of Health and Human Services ("HHS") has stated a commitment to making progress toward protecting the rights of every American to access quality care and recognizing diverse populations and their distinctive needs.¹⁷⁴ In discussing the HHS commitment to protecting LGBTQ populations,

¹⁷¹ Kao et al., *supra* note 169, at 681 ("Even well-informed and knowledgeable patients have to rely on their physicians"); *cf.* Timothy E. Quill & Howard Brody, *Physician Recommendations and Patient Autonomy: Finding a Balance Between Physician Power and Patient Choice*, 125 ANNALS INTERNAL MED. 763, 763 (1996) (describing history of patient reliance on physicans to make complex medical decisions and recent shift toward patient autonomy).

¹⁶⁸ Raper, *supra* note 27, at 272 (noting that the report garnered widespread attention from "the public, the media, and legislators").

¹⁶⁹ See Audiey C. Kao, Diane C. Green, Nancy A. Davis, Jeffrey P. Koplan & Paul D. Cleary, *Patients' Trust in Their Physicians: Effects of Choice, Continuity, and Payment Method*, 13 J. GEN. INTERNAL MED. 681, 681 (1998).

¹⁷⁰ Nadia N. Sawicki, *Judging Doctors—The Person and the Professional*, 13 VIRTUAL MENTOR 718, 718 (2011) (describing society's expectation that physicians be "beyond reproach" and "strive for success at all costs, despite the fact that medicine is an inherently imperfect science").

¹⁷² See supra notes 14-15 and accompanying text; see also Joanne Doroshow & Amy Widman, *The Racial Implications of Tort Reform*, 25 WASH. U. J.L. & POL'Y 161, 164 (2007) ("[C]redible studies have also uncovered evidence that race and ethnicity influence a patient's chance of receiving specific procedures and treatments.").

¹⁷³ Doroshow & Widman, *supra* note 172, at 187 ("Minorities are frequently forced to bear a disproportionately large share of this country's health and safety problems.").

¹⁷⁴ See, e.g., DEP'T OF HEALTH & HUM. SERVS., HHS ACTION PLAN TO REDUCE RACIAL AND ETHNIC HEALTH DISPARITIES: A NATION FREE OF DISPARITIES IN HEALTH AND HEALTH CARE 11, https://www.minorityhealth.hhs.gov/assets/pdf/hhs/HHS_Plan_complete.pdf [https://perma.cc/G6RM-E89N] (last visited Jan. 19, 2022) (discussing action plan to

the HHS broadly asserted that "[s]afeguarding the health and well-being of all Americans requires a commitment to treating all people with respect while being sensitive to their differences."¹⁷⁵ Despite this broad proclamation, vulnerable groups, such as women, sexual and gender minorities, and racial and ethnic minorities continue to experience disparate experiences in health care, access to care, and bodily autonomy.¹⁷⁶

It is well recognized that health disparities and biases persist within our healthcare system.¹⁷⁷ "[T]he landmark 2003 [IOM] Report, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*, found compelling evidence that providers' racial bias, discrimination, and stereotyping contribute to treatment disparities."¹⁷⁸ Despite decades of legislation banning discrimination on the basis of race, gender, and other protected characteristics, research continues to show ongoing discrimination and bias within society—and the healthcare field is no exception.¹⁷⁹ There are many confounding factors that result in disparate access to and treatment within the healthcare system, but research indicates that implicit bias contributes to the difference in treatment and in the health care received.¹⁸⁰

Everyone may have implicit biases, but it is important to consider how healthcare providers' unconscious biases may influence patients and their health

¹⁷⁶ See supra notes 14-15 and accompanying text.

¹⁷⁷ See, e.g., supra notes 14-15; see also, e.g., Mary Crossley, Black Health Matters: Disparities, Community Health, and Interest Convergence, 22 MICH. J. RACE & L. 53, 55-56 (2016) (describing history of reports of racial disparity in health care, starting with Heckler Report in 1985 and tracing to present).

¹⁷⁸ Crossley, *supra* note 177, at 63.

[&]quot;reduc[e] racial and ethnic health disparities"); LGBT POL'Y COORDINATING COMM., U.S. DEP'T OF HEALTH & HUM. SERVS., ADVANCING LGBT HEALTH & WELL-BEING 1 (2016) [hereinafter ADVANCING LGBT HEALTH] (discussing actions to improve "health and wellbeing of all lesbian, gay, bisexual, and transgender . . . communities").

¹⁷⁵ LGBT Health and Well-Being U.S. Department of Health and Human Services Recommended Actions to Improve the Health and Well-Being of Lesbian, Gay, Bisexual, and Transgender Communities, U.S. DEP'T OF HEALTH AND HUM. SERVS. [hereinafter LGBT Health], https://www.hhs.gov/programs/topic-sites/lgbt/enhanced-resources/reports/healthobjectives-2011/index.html [https://perma.cc/T7NQ-UYAV] (last reviewed June 4, 2014).

¹⁷⁹ See, e.g., Eliza K. Pavalko, Krysia N. Mossakowski & Vanessa J. Hamilton, *Does Perceived Discrimination Affect Health? Longitudinal Relationships Between Work Discrimination and Women's Physical and Emotional Health*, 44 J. HEALTH & SOC. BEHAV. 18, 19 (2003) (describing survey research demonstrating remaining discrimination in health care).

¹⁸⁰ See, e.g., Irene V. Blair, John F Steiner & Edward P Havranek, Unconscious (Implicit) Bias and Health Disparities: Where Do We Go from Here?, 15 PERMANENTE J. 71, 72-73 (2011) (citing studies that have shown presence of implicit biases in healthcare providers); FitzGerald & Hurst, supra note 14, at 1 (surveying research of implicit bias in health care and finding "healthcare professionals exhibit the same levels of implicit bias as the wider population"); see also Balakrishnan & Arjmand, supra note 14, at 42 (discussing experimental studies finding implicit biases "measurably affect clinical assessments and treatment decision making").

care outcomes. Research repeatedly suggests that providers' implicit attitudes about race contribute to racial and ethnic disparities in health.¹⁸¹ One study assessing implicit bias among healthcare providers found all providers across the respondent physicians' races and genders—aside from African American providers—showed a significant implicit bias for White patients over Black patients.¹⁸² This implicit preference for one group over another can have detrimental effects on treatment and quality of care.

Implicit bias may also erode trust in the physician-patient relationship; this is significant as trust "may be closely related to the degree to which patients seek routine medical care, adhere to prescribed medications, and maintain long-term relationships with medical providers and health insurers."¹⁸³ Different levels of trust in healthcare providers among African Americans have been connected to racial disparities in health, access to health care, and lower rates of satisfaction with physician visits among African Americans.¹⁸⁴ Further, research has found that racial minorities tend to be less satisfied with various aspects within the healthcare system than their White counterparts.¹⁸⁵ One study found that "Latinos rated physicians' accessibility less favorably than did whites."¹⁸⁶ Other data also suggest that "Asian Americans have the lowest satisfaction of any ethnic or racial group."¹⁸⁷ Research has suggested that "[r]acial variation in trust of different healthcare entities may reflect divergent cultural experiences that affect the domains of both interpersonal and institutional trust."¹⁸⁸

Because of the foundational importance of trust in a physician-patient relationship, these inherent and unconscious biases, and their effect on patient

¹⁸⁴ Boulware et al., *supra* note 183, at 359.

¹⁸⁷ Doescher et al., *supra* note 183, at 1157 (discussing studies finding low Asian American satisfaction rate).

¹⁸⁸ Boulware et al., *supra* note 183, at 362.

¹⁸¹ See, e.g., Janice A. Sabin, Brian A. Nosek, Anthony G. Greenwald & Frederick P. Rivara, *Physicians' Implicit and Explicit Attitudes About Race by MD Race, Ethnicity, and Gender*, 20 J. HEALTH CARE FOR POOR & UNDERSERVED 896, 897-98 (2009) (discussing two research studies showing implicit physician attitudes are partly responsible for inequitable health outcomes based on race).

¹⁸² See id. at 901-02.

¹⁸³ L. Ebony Boulware, Lisa A. Cooper, Lloyd E. Ratner, Thomas A. LaVeist & Neil R. Powe, *Race and Trust in the Health Care System*, 118 PUB. HEALTH REPS. 358, 359, 362-64 (2003) (finding White patients more likely than other racial groups to trust physicians); *see also* Mark P. Doescher, Barry G. Saver, Peter Franks & Kevin Fiscella, *Racial and Ethnic Disparities in Perceptions of Physician Style and Trust*, 9 ARCHIVES FAM. MED. 1156, 1158 (2000) (finding White patients trust physicians more than other racial groups at a statistically significant level).

¹⁸⁵ See Doescher et al., *supra* note 183, at 1159 tbl.1 (showing relationships between race/ethnicity and satisfaction with physician).

¹⁸⁶ Jann L. Murray-García, Joe V. Selby, Julie Schmittdiel, Kevin Grumbach & Charles P. Quesenberry, Jr., *Racial and Ethnic Differences in a Patient Survey: Patients' Values, Ratings, and Reports Regarding Physician Primary Care Performance in a Large Health Maintenance Organization*, 38 MED. CARE 300, 300 (2000).

trust, matter.¹⁸⁹ It is clear that levels of trust vary across racial groups, with racial and ethnic minorities generally expressing lower levels of trust and retaining a deep sense of mistrust and wariness of the healthcare system.¹⁹⁰ Yet, patients who trust their doctors may experience higher levels of satisfaction as their health care more closely aligns with their "wants, needs, and preferences."¹⁹¹ This increased satisfaction leads to effective communication with their doctor, which in turn improves adherence to treatment regiments and overall health outcomes.¹⁹² Trust lays the foundation for effective communication. To communicate effectively, a doctor must "listen to and understand [their] patients and then communicate their understanding back to [their] patients."¹⁹³ Just like trust, effective communication and active listening are necessary in an ideal physician-patient relationship.

A. Women as a Vulnerable Community

[G]ender is an institutionalized system of social practices for constituting people as two significantly different categories, men and women, and organizing social relations of inequality on the basis of that difference.¹⁹⁴

Historically, medical education and research have been male-focused, specifically on the White cis-gendered male.¹⁹⁵ Within medicine there exists a foundation of research conducted on the White cis-gendered male, with the assumption that this data could simply be extrapolated to women and other racial and ethnic minorities.¹⁹⁶ Research has found sex-based differences¹⁹⁷ as an

¹⁹⁴ Cecilia L. Ridgeway & Shelley J. Correll, *Unpacking the Gender System: A Theoretical Perspective on Gender Beliefs and Social Relations*, 18 GENDER & Soc'Y 510, 510 (2004).

¹⁹⁶ See Gabrielle Jackson, *The Female Problem: How Male Bias in Medical Trials Ruined Women's Health*, GUARDIAN (Nov. 13, 2019, 12:08 PM), https://www.theguardian.com/lifeandstyle/2019/nov/13/the-female-problem-male-bias-in-medical-trials.

¹⁹⁷ Importantly, researchers have often used the terms "gender" and "sex" interchangeably. More recent studies distinguish between *gender*, which "refers to a person's self-representation" and *sex*, which "refers to the classification of living things, generally as male or female." *See, e.g.*, Emmanuel O. Fadiran & Lei Zhang, *Effects of Sex Differences in the Pharmacokinetics of Drugs and Their Impact on the Safety of Medicines in Women, in*

¹⁸⁹ See Doescher et al., supra note 183, at 1157.

¹⁹⁰ See Boulware et al., *supra* note 183, at 358 ("Patterns of trust in components of our health care system differ by race."); Doescher et al., *supra* note 183, at 1159 tbl.1 (showing African Americans, Latinos, and other racial minorities expressing less trust for physicians than White respondents).

¹⁹¹ Doescher et al., *supra* note 183, at 1156.

¹⁹² See id.

¹⁹³ Id.

¹⁹⁵ See Elinor Cleghorn, Opinion, Medical Myths About Gender Roles Go Back to Ancient Greece. Women Are Still Paying the Price Today, TIME (June 17, 2021, 5:46 PM), https://time.com/6074224/gender-medicine-history/ (describing how the male body has always been at the forefront of medicine).

important variable that affects health and illness.¹⁹⁸ For example, there are significant sex-based differences in various bodily functions, including those of the liver, kidneys, and the digestive system.¹⁹⁹ Thus, how women respond to a disease or react to treatment will likely be different than men.²⁰⁰ Consequently, it is not enough to study White cis-gendered men in medicine and assume the findings for treatment are applicable to women, the transgender population, or other racial groups. In 2016, the American Heart Association issued a statement acknowledging sex-specific differences in the causes and symptoms of heart attacks.²⁰¹ Research has found that doctors misdiagnose heart attacks in women because they have been trained to look for more common heart attack symptoms among in male victims and may not recognize serious heart attack symptoms among

MEDICINES FOR WOMEN 41, 42 (Mira Harrison-Woolrych ed., 2015). For the purposes of this Article, I focus on sex-based differences and their resulting effects on health care.

¹⁹⁸ See generally id. (discussing sex differences in pharmacokinetics); COMM. ON UNDERSTANDING BIOLOGY OF SEX & GENDER DIFFERENCES, INST. OF MED., EXPLORING THE BIOLOGICAL CONTRIBUTIONS TO HUMAN HEALTH: DOES SEX MATTER? 45 (Theresa M. Wizemann & Mary-Lou Pardue eds., 2001) [hereinafter DOES SEX MATTER] (discussing biological differences in sex and effects on health care).

¹⁹⁹ DOES SEX MATTER, *supra* note 198, at 72 ("[W]omen, but not men, undergo fluctuations associated with the reproductive condition (such as the ovarian cycle and pregnancy) that influence numerous bodily functions (e.g., gastrointestinal transit time, urinary creatinine clearance, liver enzyme function, and thermoregulation), including brain function.").

²⁰⁰ See Nathan Huey, Treating Men and Women Differently: Sex Differences in the Basis of Disease, SCI. IN THE NEWS (Oct. 30, 2018), https://sitn.hms.harvard.edu/flash/2018/treating-men-and-women-differently-sex-differences-in-the-basis-of-disease/ [https://perma.cc/G5AZ-KNJA] (examining several mechanisms by which sex influences disease and reaction to treatment); see also Virginia M. Miller, Walter A. Rocca & Stephanie S. Faubion, Commentary, Sex Differences Research,

Precision Medicine, and the Future of Women's Health, 24 J. WOMEN'S HEALTH 969, 969 (2015) (discussing need "to better diagnose and treat conditions, both acute and chronic, that are specific to women, occur more frequently in women than men, or that present with different symptoms and outcomes for women compared to men").

²⁰¹ See Laxmi S. Mehta, Theresa M. Beckie, Holli A. DeVon, Cindy L. Grines, Harlan M. Krumholz, Michelle N. Johnson, Kathryn J. Lindley, Viola Vaccarino, Tracy Y. Wang, Karol E. Watson & Nanette K. Wenger, Acute Myocardial Infarction in Women: A Scientific Statement from the American Heart Association, 133 CIRCULATION 916, 916, 922 (2016) (observing that "recent data have suggested a greater role of microvascular disease in the pathophysiology of coronary events among women" and that "[c]ompared with men, women are more likely to have high-risk presentations and less likely to manifest central chest pain"). The American Heart Association also published informational notices as early as 2015 with similar sentiments. See, e.g., Heart Attack Symptoms in Women, AM. HEART ASS'N (July 31, 2015), https://www.heart.org/en/health-topics/heart-attack/warning-signs-of-a-heart-attack/heart-attack-symptoms-in-women [https://perma.cc/52SE-3VV8] ("We've all seen the movie scenes where a man gasps, clutches his chest and falls to the ground. In reality, a heart attack victim could easily be a woman, and the scene may not be that dramatic.").

women.²⁰² This is significant because heart attacks are the leading cause of death among women in the United States.²⁰³

Differences in the perception and treatment of women within health care also extend to pharmaceuticals and prescribed dosages of drugs. The research and study of sex differences is now a regular part of drug development.²⁰⁴ Despite this shift, there are still clear failures to account for the sex-based differences in pharmacology.²⁰⁵ In the early 2010s, a series of news outlets reported various incidents of individuals—primarily women—who had crashed their cars after falling asleep at the wheel upon taking the drug zolpidem—commonly called Ambien—to help with insomnia.²⁰⁶ In 2013, the Federal Drug Administration ("FDA") issued an unprecedented advisory reducing the recommended dosage of zolpidem.²⁰⁷ The FDA took this stance after research found women clear zolpidem from their system more slowly than men—at almost half the rate.²⁰⁸ Despite the more recent emphasis on including women in drug research, major gaps persist as to the sufficient inclusion of women in clinical studies—particularly for drug development.²⁰⁹

²⁰⁶ See, e.g., Kai Falkenberg, *While You Were Sleeping*, MARIE CLAIRE (Sept. 27, 2012), https://www.marieclaire.com/culture/news/a7302/while-you-were-sleeping/

²⁰⁷ U.S. FDA, RISK OF NEXT-MORNING IMPAIRMENT AFTER USE OF INSOMNIA DRUGS; FDA REQUIRES LOWER RECOMMENDED DOSES FOR CERTAIN DRUGS CONTAINING ZOLPIDEM (AMBIEN, AMBIEN CR, EDLUAR, AND ZOLPIMIST) 1 (2013).

²⁰² See supra notes 63-75 and accompanying text.

²⁰³ Women and Heart Disease, supra note 72; Mehta et al., supra note 201, at 916.

²⁰⁴ Fadiran & Zhang, *supra* note 197, at 41.

²⁰⁵ See Offie P. Soldin & Donald R. Mattison, Sex Differences in Pharmacokinetics and Pharmacodynamics, 48 CLINICAL PHARMACOKINETICS 143, 145 (2009) ("[T]he FDA has suggested that women experience more adverse [drug] events than men and that adverse [drug] events are more serious in women.").

[[]https://perma.cc/5SYE-UMEG]; Colleen Curry & Aaron Katersky, Kerry Kennedy Says Ambien 'Overtook' Her, Causing Car Crash, ABC NEWS (Feb. 26, 2014, 10:15 AM), https://abcnews.go.com/US/kerry-kennedy-ambien-overtook-causing-car-

crash/story?id=22679672 [https://perma.cc/P3KU-8GCK]; *see also* David J. Greenblatt, Jerold S. Harmatz, Thomas Roth, *Zolpidem and Gender: Are Women Really at Risk*?, 39 J. CLINICAL PSYCHOPHARMACOLOGY 189, 198 (2019) (questioning subsequent FDA reaction to car crashes; postulating that "reduc[ing] dosage may in fact increase the public health risk due to undertreatment of insomnia in women, and the consequent impaired automobile operation as a result of sleep deprivation").

²⁰⁸ Fadiran & Zhang, *supra* note 197, at 47 ("Women cleared zolpidem tartrate from the body after sublingual administration of a 3.5 mg dose of Intermezzo at a lower rate than men (2.7 mL/min/kg vs. 4.0 mL/min/kg)."); Ronald H. Farkas, Ellis F. Unger & Robert Temple, *Zolpidem and Driving Impairment — Identifying Persons at Risk*, 369 NEW ENG. J. MED. 689, 690 (2013) ("In some patients — particularly women, who clear zolpidem more slowly than men — blood levels the morning after taking the recommended bedtime doses could be considerably higher than 50 ng per milliliter.").

²⁰⁹ Soldin & Mattison, *supra* note 205, at 144.

Research has also found "physicians and medical institutions fail to offer equitable, unbiased, appropriate medical care for women."²¹⁰ One reason for this failure is the presumption that women are "overly emotional."211 Within our culture, women have long suffered from unfair stereotypes and dismissal of their concerns as hysteria or emotion.²¹² These societal assumptions and stereotypes may influence women's health and the care they receive as healthcare providers carry implicit biases into their work and into interactions with their patients.²¹³ Given this stereotype of women as emotional, a doctor may brush aside a woman's symptoms and attribute them to depression, anxiety, or stress.²¹⁴ Further, once a woman has an anxiety diagnosis in her chart, her doctor may use this as an explanation for some of her other symptoms.²¹⁵ Consequently, women's pain and symptoms are not taken seriously; this refusal to acknowledge pain or listen to women results in misdiagnoses and often long-term health concerns.²¹⁶ Within society—and all too often in medicine—the perception of women is that they are not accurate judges of their own bodies or when something is wrong.²¹⁷

²¹³ See Homan, supra note 210, at 487.

²¹⁴ See Laura Kiesel, Women and Pain: Disparities in Experience and Treatment, HARV. HEALTH BLOG (Oct. 9, 2017), https://www.health.harvard.edu/blog/women-and-pain-disparities-in-experience-and-treatment-2017100912562 [https://perma.cc/H5A9-UA2Q].

²¹⁵ See, e.g., Zawn Villines, *What to Know About Gender Bias in Healthcare*, MED. NEWS TODAY (Oct. 25, 2021), https://www.medicalnewstoday.com/articles/gender-bias-inhealthcare [https://perma.cc/35EJ-P7YN] (discussing study finding "doctors were more likely to treat women's pain as a product of a mental health condition, rather than a physical condition").

²¹⁶ See id. (listing potential consequences of gender bias in health care as including results such as "[a]voidance of medical care" and "[a]buse, neglect, and death").

²¹⁷ Katarina Hamberg, *Gender Bias in Medicine*, 4 WOMEN'S HEALTH 237, 242 (2008) ("The gender order, often implying that women are less valued and influential than men, helps explaining gender bias [in medicine]."); *see, e.g.*, A. Pawlowski, *The Invisible Woman? The Challenge at the Doctor's Office Every Woman Needs to Know About*, TODAY (May 13, 2019, 7:56 AM), https://www.today.com/health/gender-bias-doctor-how-women-s-heart-disease-chronic-pain-t147692 [https://perma.cc/4A8N-7V93] ("It's not malice but a pervasive, implicit sex and gender bias in medicine that's leading female patients to be misdiagnosed, neglected, . . . or told their symptoms are all in their heads "); *see also* Ashley Fetters, *The Doctor Doesn't Listen to Her. But the Media Is Starting To.*, ATLANTIC (Aug. 10, 2018),

²¹⁰ Patricia Homan, Structural Sexism and Health in the United States: A New Perspective on Health Inequality and the Gender System, 84 AM. SOCIO. REV. 486, 487 (2019).

²¹¹ See Lisa Feldman Barrett & Eliza Bliss-Moreau, *She's Emotional. He's Having a Bad Day: Attributional Explanations for Emotion Stereotypes*, 9 EMOTION 649, 654-55 (2009) ("[T]he stereotype of the overly emotional female is linked to the belief that women express emotion because they are emotional creatures, but men express emotion because the situation warrants it.").

²¹² See Maria Cohut, The Controversy of 'Female Hysteria,' MED. NEWS TODAY (Oct. 13, 2020), https://www.medicalnewstoday.com/articles/the-controversy-of-female-hysteria [https://perma.cc/T5W6-6V5X].

The passage of the Affordable Care Act ("ACA") in 2010 is arguably "the most important advance in women's health policy since 1965."²¹⁸ The ACA "increases the number of American women who can get health insurance, lowers the cost of health care for many women, and improves the quality of the health care women receive."²¹⁹ Beyond this, the ACA "improves preventative services for women" in critical areas such as "annual mammograms, well-woman visits, birth control, and breastfeeding support."²²⁰ Under the ACA, providers cannot charge women "more simply because they are women"—nor can they "den[y] health insurance coverage because of a pre-existing women's health condition, such as breast cancer, pregnancy, or depression."²²¹ Despite the advancements made in women's health due to the passage of the ACA, women continue to experience significant disparities in their treatment and access to care.

B. The LGBTQ Community as a Vulnerable Community

Every person should be treated with respect and dignity and should be able to live without fear, no matter who they are or whom they love. . . . People should be able to access healthcare and secure a roof over their heads without being subjected to sex discrimination. All persons should receive equal treatment under the law, no matter their gender identity or sexual orientation.²²²

"Antigay and antitransgender attitudes in medicine have long affected health providers."²²³ These attitudes have persisted for decades even after "the 1973 decision to remove homosexuality from the *Diagnostic and Statistical Manual of Mental Disorders*."²²⁴ In recent years, society has made great strides in the

²¹⁹ See Affordable Care Act Improves Women's Health, supra note 218.

²²¹ Id.

²²⁴ Id.

https://www.theatlantic.com/family/archive/2018/08/womens-health-care-

gaslighting/567149/ ("That many women have stories of medical practitioners dismissing, misdiagnosing, or cluelessly shrugging at their pain is, unfortunately, nothing new."); *Gaslighting in Women's Health: No, It's Not Just in Your Head*, NORTHWELL HEALTH: KATZ INST. FOR WOMEN'S HEALTH, https://www.northwell.edu/katz-institute-for-womens-health/articles/gaslighting-in-womens-health [https://perma.cc/HQV4-MAJ7] (last visited Jan. 19, 2022) (interviewing specialists to examine why gaslighting of female patients occurs so often).

²¹⁸ Affordable Care Act Improves Women's Health, OFF. ON WOMEN'S HEALTH, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.womenshealth.gov/30-achievements/31 [http://perma.cc/MP86-7JXL] (last updated Apr. 1, 2019); see also Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, 124 Stat. 119 (2010).

²²⁰ Id.

²²² Exec. Order No. 13988, 86 Fed. Reg. 7023, 7023 (Jan. 20, 2021).

²²³ Matthew Mansh, Gabriel Garcia & Mitchell R. Lunn, *From Patients to Providers: Changing the Culture in Medicine Toward Sexual and Gender Minorities*, 90 ACAD. MED. 574, 575 (2015).

perceptions of these communities, but more work is necessary.²²⁵ In particular, "[t]ransgender people encounter interpersonal and structural barriers to healthcare access."²²⁶ Alongside these barriers, the fear or expectation of experiencing discrimination remains a factor as to why transgender people postpone or avoid health care.²²⁷ Unfortunately, barriers to access and avoidance of health care result in "poorer physical and mental health outcomes" within the transgender community.²²⁸

Further, sexual and gender minorities continue to face "unique health and healthcare disparities."²²⁹ These disparities include "poor access to health care" and "increased incidence of a number of diseases" (including HIV, certain cancers, and mental health disorders).²³⁰ Further, the "lack of inclusion and even explicit exclusion of [LGBTQ individuals and transgender people] from clinical trials . . . has inhibited the study of these health disparities."²³¹ In order "[t]o achieve change for and improve the health of these communities, we must adopt and prioritize practices that enhance transparency and understanding of the presence, magnitude, and root causes of [the existing health] inequities."²³²

A recent study found that 31% of transgender Americans do not have access to regular health care.²³³ This number does not occur in a vacuum—many vulnerabilities exist within our society and healthcare system that leave transgender people exposed to homelessness, rape, and assault.²³⁴ This raises the question as to what "regular" health care means for transgender people.²³⁵ Ruby Corado, a transgender woman who runs a group home for transitioning teens and young adults, responded to that question: "Preventable."²³⁶ Yet, preventable

²²⁵ Id.

²²⁶ Luisa Kcomt, Kevin M. Gorey, Betty Jo Barrett & Sean Esteban McCabe, *Healthcare Avoidance Due to Anticipated Discrimination Among Transgender People: A Call to Create Trans-Affirmative Environments*, 11 SSM - POPULATION HEALTH 1, 1 (2020).

²²⁷ See id. at 4 (finding "transgender stigma" results in "healthcare avoidance").

²²⁸ Id. at 1.

²²⁹ Mansh et al., *supra* note 223, at 574.

²³⁰ Id.

²³¹ Id.

²³² Id.

²³³ NAT'L PUB. RADIO, ROBERT WOOD JOHNSON FOUND. & HARV. T.H. CHAN SCH. OF PUB. HEALTH, DISCRIMINATION IN AMERICA: EXPERIENCES AND VIEWS OF LGBTQ AMERICANS 2 (2017) [hereinafter EXPERIENCES OF LGBTQ AMERICANS] ("Nearly a quarter [of transgender people] say they have avoided doctors or health care out of concern they would be discriminated against (22%), and 31% say they have no regular doctor or form of health care.").

²³⁴ See Neda Ulaby, Health Care System Fails Many Transgender Americans, NPR (Nov. 21, 2017, 4:29 PM), https://www.npr.org/sections/health-shots/2017/11/21/564817975 /health-care-system-fails-many-transgender-americans [https://perma.cc/L8A8-MN3M].

 ²³⁵ See id.
 ²³⁶ Id.

concerns such as HIV infections and certain cancers continue to run rampant within the transgender population.²³⁷

Among the reasons that transgender people are unable to access preventable care is the fact that transgender people face difficulty in securing jobs, which in turn, makes it more difficult for them to find healthcare coverage.²³⁸ Setting social stigma aside, transgender people face great difficulty in securing jobs when their genders do not match the ones on their legal IDs.²³⁹ A 2015 survey found that the unemployment rate among transgender people in the United States was 15%—three times the national average at the time.²⁴⁰

Aside from a lack of health insurance, transgender people face the fear of what may happen during an interaction while they are seeking medical care. An NPR poll found that 22% of transgender people said "they ... avoided doctors or health care [for fear that] they would be discriminated against."241 Many of these individuals feel that their "trans[gender] status is on display and on parade for other people to make fun of [them,]" including "insensitive medical professionals who [ask] such questions as, 'What are you?'" 242 For transgender individuals, "find[ing] a primary care provider who's willing to work with them" can also be difficult.²⁴³ Even among those who can find a regular provider, many "insurance companies will not cover care related to gender transition, such as hormones or surgery."244 Lack of access to gender-affirming care may also contribute to mental health concerns among transgender people. They often feel that their external presentation does not align with their true identity, but do not have the healthcare coverage or financial means to address this.²⁴⁵ As of 2015, 40% of transgender people attempted suicide within their lifetime;²⁴⁶ as of 2018, "between 30% and 51% of transgender adolescents" had attempted suicide within their lifetime.²⁴⁷ Historically, transgender people have been "more likely

²³⁷ See id.

²³⁸ See EXPERIENCES OF LGBTQ AMERICANS, *supra* note 233, at 11 fig.5 (showing 20% of all respondent LGBTQ people and 32% of LGBTQ people of color experienced discrimination applying for jobs).

²³⁹ See Ulaby, supra note 234.

²⁴⁰ SANDY E. JAMES, JODY L. HERMAN, SUSAN RANKIN, MARA KEISLING, LISA MOTTET & MA'AYAN ANAFI, NAT'L CTR. FOR TRANSGENDER EQUAL., THE REPORT OF THE 2015 U.S. TRANSGENDER SURVEY 5 (2016) (finding transgender population's high rate of unemployment likely a "major contributor to the[ir] high rate of poverty").

²⁴¹ EXPERIENCES OF LGBTQ AMERICANS, *supra* note 233, at 2.

²⁴² Ulaby, *supra* note 234 (first internal quotation marks omitted).

²⁴³ Id.

²⁴⁴ Id.

²⁴⁵ See id.

²⁴⁶ JAMES ET AL., *supra* note 240, at 5 (noting that the transgender population attempted suicide rate is "nearly nine times the attempted suicide rate in the U.S. population (4.6%)").

²⁴⁷ Russell B. Toomey, Amy K. Syvertsen & Maura Shramko, *Transgender Adolescent Suicide Behavior*, 142 PEDIATRICS 1, 5-6 (2018) (noting that study's findings are "consistent with some previous research revealing suicide risk among transgender populations").

to slip through the cracks of the healthcare system."²⁴⁸ Unfortunately, many doctors and health insurance companies continue to "treat them as though their bodies don't make any sense."²⁴⁹

Given the various challenges facing women within the healthcare system, it is important also to recognize the intersectional needs of lesbian, bisexual, and transgender women. Members of the LGBTQ community have consistently faced denial of the services they deserve, particularly within health care.²⁵⁰ Lesbian, bisexual, and transgender women face health disparities that research has "linked to social discrimination and denial of their civil and human rights."251 For example, research has found that "[1]esbians are less likely to get preventative services for cancer."252 Lesbians and bisexual women "are [also] more likely to be overweight or obese."²⁵³ Transgender women are "at [greater] risk for HIV and sexually transmitted infections, violence, mental health issues, and suicide."254 Additional research has found that transgender women have higher rates of HIV mortality in comparison with non-transgender persons.²⁵⁵ Further, Black and Latina transgender women are disproportionately affected by HIV.²⁵⁶ In particular, 19% of Black transgender women are HIV positive in comparison with 0.3% of the general population.²⁵⁷ If you are a transgender woman of color, you are more likely to contract HIV, receive poorer care, face stigmatization and discrimination, be exposed to physical harassment and violence, and suffer from a lack of access to appropriate care, all of which make this population potentially more likely to die from HIV.²⁵⁸ Bisexual women face

²⁵⁶ Ronald A Brooks, Alejandra Cabral, Omar Nieto, Anne Fehrenbacher & Amanda Landrian, *Experiences of Pre-exposure Prophylaxis Stigma, Social Support, and Information Dissemination Among Black and Latina Transgender Women Who Are Using Pre-exposure Prophylaxis*, 4 TRANSGENDER HEALTH 188, 188 (2019).

²⁵⁷ JAMES ET AL., *supra* note 240, at 6.

²⁵⁸ See Brooks et al., supra note 256; Bridget M. Kuehn, Higher Mortality Risk Among Transgender People, 326 J. AM. MED. ASS'N 1471, 1471 (2021); Poteat et al., supra note 255,

²⁴⁸ Ulaby, *supra* note 234.

²⁴⁹ Id.

²⁵⁰ See generally Mansh et al., *supra* note 223 (acknowledging the pervasive anti-LGBTQ attitudes in the health care regime).

²⁵¹ Recognizing the Needs of Lesbian, Bisexual, and Transgender Women, OFF. ON WOMEN'S HEALTH, U.S. DEP'T OF HEALTH & HUM. SERVS. [hereinafter *LGBT Women*], https://www.womenshealth.gov/30-achievements/29 [https://perma.cc/U4SN-WBD8] (last updated Apr. 1, 2019).

²⁵² Id.

²⁵³ Id.

²⁵⁴ Id.

²⁵⁵ See Tonia Poteat, Sari L. Reisner & Anita Radix, *HIV Epidemics Among Transgender Women*, 9 CURRENT OP. HIV & AIDS 168, 170 (2014) ("In San Francisco, transgender women living with HIV have been found to have higher HIV-related mortality and a higher community viral load than nontransgender persons, consistent with both a lack of adequate HIV treatment and late presentation of disease." (citation omitted)).

"greater risk of rape, physical violence, and stalking than lesbian and heterosexual women."²⁵⁹

Due to these disparities, the U.S. Department of Health and Human Services ("HHS") developed "the first-ever Lesbian, Gay, Bisexual, and Transgender (LGBT) Issues Coordinating Committee in 2010. The committee developed a set of recommendations, first released in 2011 and updated annually."²⁶⁰

The ACA was also significant in addressing the health disparities facing the LGBTQ community—as it provides improved access to health coverage.²⁶¹ This change was critical because studies have shown that "health disparities related to sexual orientation and gender identity are due in part to lower rates of health insurance coverage."²⁶² The ACA also began to tackle discrimination that same-sex couples face in the medical system.²⁶³ In the past, many same-sex couples faced denial of the opportunity to see their loved ones at the hospital.²⁶⁴ In November 2010, the Centers for Medicare & Medicaid Services ("CMS") issued new rules for hospitals participating in Medicare and Medicaid to respect the rights of all patients to be able to choose who visits them at the hospital.²⁶⁵

Despite the progress made through the ACA in improving access to health care for all Americans, the Trump Administration made significant rollbacks that disproportionately influenced women and members of the LGBTQ community. Specifically, the Trump Administration made significant changes to the scope of section 1557 of the ACA,²⁶⁶ which prohibits health programs and

- ²⁵⁹ LGBT Women, supra note 251.
- ²⁶⁰ Id. (citations omitted).
- ²⁶¹ See ADVANCING LGBT HEALTH, supra note 174, at 3-4.
- ²⁶² LGBT Health, supra note 175.

²⁶³ See ADVANCING LGBT HEALTH, supra note 174, at 2 (explaining that for health care, "states are required to treat spouses in a marriage between a same-sex couple the same as spouses in a marriage between an opposite-sex couple"); see also Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, § 1557, 124 Stat. 119, 260 (2010) (codified as amended at 42 U.S.C. § 18116).

²⁶⁴ See generally Meredith Fileff, Comment, *Hospital Visitation: The Forgotten Gay Rights Struggle*, 45 J. MARSHALL L. REV. 939 (2012) (describing controversy over hospital visitation for same-sex partners).

²⁶⁵ ADVANCING LGBT HEALTH, *supra* note 174, at 2.

²⁶⁶ Katie Keith, *HHS Strips Gender Identity, Sex Stereotyping, Language Access Protections from ACA Anti-Discrimination Rule*, HEALTH AFFS. BLOG (June 13, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200613.671888/full/ (summarizing new

at 169; *HIV Death Rate in the U.S. in 2019, by Ethnicity*, STATISTICA, https://www.statista.com/statistics/731823/hiv-death-rate-united-states-by-ethnicity/

[[]https://perma.cc/6WZQ-LDHA] (last visited Jan. 19, 2022) (showing that Black, multiracial, and Latinx people died at much higher rates from HIV than White people); *see also* JAMES ET AL., *supra* note 240, at 10 ("HIV rates were higher among transgender women (3.4%), especially transgender women of color. Nearly one in five (19%) Black transgender women were living with HIV, and American Indian (4.6%) and Latina (4.4%) women also reported higher rates." (emphasis omitted)).

facilities that receive federal funds from discriminating based on race, color, national origin, age, disability, or sex.²⁶⁷ The new rule "remove[d] protections against discrimination based on sex stereotyping [or] gender identity."²⁶⁸ Specifically, the new rule eliminates "definitions of key terms such as 'covered entity' and 'on the basis of sex."²⁶⁹ It also removes "[s]pecific nondiscrimination protections based on sex, gender identity, and association."²⁷⁰ In short, changes to section 1557 function to remove the protections instituted by the Obama Administration.²⁷¹

In January 2021, the Biden Administration issued an Executive Order ("EO") entitled *Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation.*²⁷² This EO sets a new tone and establishes protections for the transgender community, directly referencing efforts to address disparities in the healthcare system. ²⁷³ Early efforts within this Administration suggest its willingness to do more for the transgender community, but the Biden Administration's support is not enough to address the past harm curtailing transgender individuals' civil and healthcare rights. Within health care, the LGBTQ community evidently needs more protection and stronger efforts to address the health disparities that persist. It is expected that the Biden Administration will issue another EO to address the changes made to section 1557 under the Trump Administration.²⁷⁴

Alongside these legal developments, there has been an increase in public awareness of transgender as an identity over the past two decades.²⁷⁵ However,

²⁶⁷ See Sidney D. Watson, Section 1557 of the Affordable Care Act: Civil Rights, Health Reform, Race, and Equity, 55 How. L.J. 855, 859 (2012).

²⁷¹ See id. (explaining that the June 12, 2020, rule change to section 1557 revises Obamaera rule protecting against sex and gender discrimination).

²⁷² See generally Exec. Order No. 13988, supra note .86 Fed. Reg. 7023 (Jan. 20, 2021).

²⁷³ See id., at 7023 (establishing "[p]rohibitions on [s]ex [d]iscrimination on the [b]asis of [g]ender [i]dentity or [s]exual [o]rientation").

²⁷⁴ See Maddie Mason, *Quick Take: Biden Administration Health Care and Health Equity Executive Actions*, NAT'L HEALTH COUNCIL: PUTTING PATIENTS FIRST BLOG (Feb. 12, 2021), https://nationalhealthcouncil.org/blog/quick-take-biden-administration-health-care-and-health-equity-executive-actions/ [https://perma.cc/KCP7-ZHRX] ("The [National Health Council] believes President Biden may issue an EO soon on section 1557 of the ACA, which is the provision that prohibits discrimination based on race, color, national origin, sex, age, and disability in health programs.").

²⁷⁵ See Christoph Hanssmann, Counting Us In: Problems and Opportunities in Health Research on Transgender and Gender-Nonconforming Communities, 8 SEATTLE J. SOC. JUST.

rule adopted on June 12, 2020, by Department of Health and Human Services revising interpretation of section 1557); *see also* Nondiscrimination in Health and Health Education Programs or Activities, 85 Fed. Reg. 37,160 (June 19, 2020) (to be codified in scattered sections of 42 C.F.R. pts. 438, 440, 460 and 45 C.F.R. pts. 86, 92, 147, 155, 156).

²⁶⁸ Keith, *supra* note 266.

²⁶⁹ Id.

²⁷⁰ Id.

as the transgender community has increased in visibility, there has been resistance against the community, including public debates as to their rights, treatment, and place within society. This conversation has recently moved into the healthcare space, and the transgender community now faces increased adversity in access to health care and gender-affirming care.²⁷⁶

This year alone there have been at least thirty-five bills in twenty states focused on targeting the transgender community and their ability to seek health care.²⁷⁷ States across the United States are seeking to impose penalties against doctors²⁷⁸—and parents²⁷⁹—for gender-affirming care among transgender youth. The recent uptick in legislation significantly curbing access to health care and gender-affirming care within the transgender community further highlights the vulnerability of this community. Despite this resistance, research has reflected the attitude that "trans health is important and valid, [and] that all transgender and gender-nonconforming people are entitled to exceptional healthcare."²⁸⁰

Our society should have the expectation "that none of us should encounter barriers to primary or specialty care that we require."²⁸¹ Despite this expectation, the prevalence of medical error and the continued harm to vulnerable LGBTQ communities indicate that more needs to be done both to address these errors and to protect these historically disadvantaged and marginalized communities.

^{541, 541 (2010) (}examining how increase in public awareness of those who identify as transgender has changed research and health care).

²⁷⁶ Health & HIV, NAT'L CTR. FOR TRANSGENDER EQUAL., https://transequality.org/issues/health-hiv [https://perma.cc/K9A3-KYN3] (last visited Jan. 19, 2022) (summarizing barriers and stigma that transgender people face in health care).

²⁷⁷ Ella Schneiberg, *These Are the States Attempting to Pass Anti-Trans Health Care Bills*, HUM. RTS. CAMPAIGN (Feb. 12, 2021), https://www.hrc.org/news/these-are-the-statesattempting-to-pass-anti-trans-health-care-bills [https://perma.cc/B6SV-QQ9E] (recording state legislation introduced in 2021 that targets transgender people and their access to health care).

²⁷⁸ See, e.g., H.B. 1, 2021 Leg., Reg. Sess. (Ala. 2021) (prohibiting gender-affirming treatment to children under eighteen by punishing doctors who provide puberty-blocking medication, hormone doses, and surgery); S.B. 10, 2021 Leg., Reg. Sess. (Ala. 2021) (prohibiting gender-affirming treatment to children under eighteen by punishing doctors who provide puberty-blocking medication, hormone doses, and surgery); S.B. 1511, 55th Leg., Reg. Sess. (Ariz. 2021) (criminalizing medical treatment of children under eighteen with gender-affirming treatments including puberty-blocking medication, hormone doses, and surgery); H.B. 68, 87th Leg., Reg. Sess., at 3 (Tex. 2021) (prohibiting "attempt[s] to change or affirm a child's perception of the child's sex, if that perception is inconsistent with the child's biological sex[,]" among a list of actions that constitute child abuse).

²⁷⁹ See, e.g., Tex. H.B. 68.

²⁸⁰ Hanssmann, *supra* note 275, at 543.

²⁸¹ Id.

C. Racial and Ethnic Minorities as Vulnerable Communities

Despite this country's long and sordid history of race discrimination in healthcare, race remains of significant salience in medicine, and there are ways in which it is still being used that are neither widely discussed nor fully regulated.²⁸²

Systemic racism and discrimination have shaped many institutions in the United States, including the healthcare industry.²⁸³ Consequently, racial and ethnic minorities receive inferior care and treatment within the healthcare system and are often subject to high rates of preventable medical errors.²⁸⁴ Due to these systemic barriers, these communities are more likely to be uninsured than White Americans, which further contributes to substandard care and poor health consequences.²⁸⁵ Consequently, minorities often suffer a disproportionate share of health and safety issues.²⁸⁶

Research has also shown that communities of color continue to bear a "disproportionate burden of morbidity and mortality."²⁸⁷ Racial disparities in health have emerged as a major public health issue, as "[m]inority groups continue to live sicker and die younger."²⁸⁸ Broadly speaking, "people of color receive less care — and often worse care — than white Americans."²⁸⁹ It is clear that the health outcomes in communities of color are worse than those of Whites.²⁹⁰

As medicine was framed around the White cisgendered-male body, racial and ethnic minorities often have a disparate experience in health care and face discrimination in medical research.²⁹¹ Although "segregation and blatant racial

²⁸⁷ Gilbert C. Gee & Chandra L. Ford, *Structural Racism and Health Inequities: Old Issues, New Directions*, 8 DU BOIS REV. 115, 115 (2011).

²⁸⁹ Frakt, *supra* note 283.

²⁸² Kimani Paul-Emile, Patients' Racial Preferences and the Medical Culture of Accommodation, 60 UCLA L. REV. 462, 504 (2012).

²⁸³ See Austin Frakt, *Racism Is Built into Health Care*, N.Y. TIMES, Jan. 14, 2020, at B5 (discussing ways racial discrimination has shaped American healthcare institutions).

²⁸⁴ See Doroshow & Widman, supra note 172, at 164.

²⁸⁵ See id. at 167 ("[R]acial and ethnic minorities are uninsured more often than non-Hispanic whites, a status that frequently results in less than adequate care and poor health consequences.").

²⁸⁶ See id. at 187 (concluding that minorities bear a "large share of this country's health and safety problems" because of "inferior medical care, infringed civil rights, environmental pollution or any number of other indignities and injuries").

²⁸⁸ Osagie K. Obasogie, Irene Headen & Mahasin S. Mujahid, *Race, Law, and Health Disparities: Toward a Critical Race Intervention*, 13 ANN. REV. L. & Soc. Sci. 313, 314 (2017) (citation omitted).

²⁹⁰ See *id*. (explaining that health outcomes of people of color are worse than those of White people because of "lower rates of health coverage; communication barriers; and racial stereotyping based on false beliefs").

²⁹¹ See, e.g., Crossley, supra note 177, at 64 ("In [a] vicious cycle, Blacks' experiences or

discrimination are no longer the norm in medicine, numerous studies report that more subtle forms of discrimination endure."²⁹² Given the persistence of unequal and discriminatory treatment in medicine, communities of color are less likely to seek care or adhere to recommended treatment.²⁹³

As the widest health disparities are seen between Black and White Americans, this Article will focus specifically on the experiences of the Black community. Black Americans "receive lower-quality health services, including for cancer, H.I.V., prenatal care and preventative care."²⁹⁴ Black Americans are also "less likely to receive treatment for cardiovascular disease" and more likely to be recommended for amputations, rather than being given other treatment options.²⁹⁵ Research has found that "[t]here has never been any period in American history where the health of blacks was equal to that of whites[.]... Disparity is built into [our healthcare] system."²⁹⁶ Black health is poorer overall, but Black men have the worst health outcomes of any demographic group, and research indicates that this is based on a history and legacy of mistrust of the medical system.²⁹⁷ This mistrust becomes part of each interaction with the medical system:

Although most patients are sensitive to the interpersonal dynamic that occurs in medical encounters, Black patients may be acutely aware of interpersonal cues from physicians because of historical and personal experiences with discrimination in healthcare and in society at large. Research on racial stigma suggests that individuals cope with the threat of bias or discrimination by avoiding interactions with the stigmatizing group. Thus, to avoid negative encounters, racial minorities (who are more likely to experience discrimination while seeking health services) may prefer physician-patient race concordance or reject physicians who are members of a perceived stigmatizing group.²⁹⁸

awareness of discrimination in the health care system and medical research may result in mistrust, making them less likely to seek care or adhere to recommended treatment."); sources cited *supra* note 15 (discussing mistreatment of racial minorities in medical experimentation and research).

²⁹² Paul-Emile, *supra* note 282, at 499.

²⁹³ See Crossley, *supra* note 177, at 64 (finding that health care disparities between Black and White people are widened because Black people often avoid seeking health care because of past experiences with discrimination within the health care system).

²⁹⁴ Frakt, *supra* note 283.

²⁹⁵ See id.

²⁹⁶ Jeneen Interlandi, *Why Doesn't the United States Have Universal Health Care? The Answer Begins with Policies Enacted After the Civil War*, N.Y. TIMES MAG., Aug. 14, 2019, at 44 (quoting Harvard historian of science Evelynn Hammonds).

²⁹⁷ See Frakt, *supra* note 283 (finding Black men are at a particular disadvantage in health care as compared to other demographic groups and explaining this likely stems from historic discrimination and experimentation in health care which has resulted in pervasive mistrust of the health care system).

²⁹⁸ Paul-Emile, *supra* note 282, at 499 (footnotes omitted).

There is "[a] legacy of racial discrimination in medical research and the health care system[, which] has been linked to a low level of trust in medical research and medical care among African Americans."²⁹⁹ Further, this research indicates that variations in patterns of trust in the healthcare system differ by race.³⁰⁰ These differences observed in levels of trust are reflective of "divergent cultural experiences of blacks and whites [in the medical system] as well as differences in expectations for care."³⁰¹ The history of African Americans in the medical system is a treacherous one, with Black bodies often used in inhumane and cruel ways to further science and medical innovation.³⁰² The United States retains "a well-documented legacy of racial discrimination toward African Americans in medical research and clinical settings."³⁰³

The problem is not simply that African Americans and communities of color were frequently mistreated by science and the medical system in the past—it is the ways in which the past harm translates into a deep mistrust within these same communities today.³⁰⁴ This legacy of past harm has gone unaddressed, and, in many ways, these same harms are perpetuated today. Now, Black communities retain a deep sense of mistrust of healthcare providers, medicine, and the healthcare system overall.³⁰⁵

Over time, communities of color have built a deep sense of fear and suspicion of medicine. "[R]esearch has demonstrated that African Americans' knowledge of [the] history of racial discrimination is associated with reluctance to participate in medical research and may be associated with low rates of trust in medical researchers and clinicians."³⁰⁶ As racial and ethnic minorities come to understand the history of how the medical system has harmed them, this influences how they perceive the medical system and the ways in which they will choose to engage with their health care moving forward.³⁰⁷

IV. FROM APOLOGIES TO COMMUNICATION AND RESOLUTION PROGRAMS

Apology laws are critical in addressing medical error as they allow healthcare professionals to recognize harm was done and take responsibility, but on their

²⁹⁹ Boulware et al., *supra* note 183, at 358, 362 (finding through scientific study that "patterns of trust in physicians, health insurance plans, and hospitals differed by race").
³⁰⁰ See id.

See id.

³⁰¹ *Id.* at 358, 362 ("Racial variation in trust of different health care entities may reflect divergent cultural experiences that affect the domains of both interpersonal and institutional trust.").

³⁰² See, e.g., sources cited supra note 15.

³⁰³ Boulware et al., *supra* note 183, at 359.

³⁰⁴ See Doescher et al., *supra* note 183, at 1159 tbl.1 (showing respondents of color expressing lower levels of trust in physicians than White respondents).

³⁰⁵ See id.

³⁰⁶ Boulware et al., *supra* note 183, at 359.

³⁰⁷ See Frakt, supra note 283 (finding the publicization of the Tuskegee study, in which African American men with syphilis were brutally experimented on, "is frequently cited as a driver of documented distrust in the health system by African-Americans").

own, they are not enough. "The idea behind enacting [apology] laws is that, with an apology and explanation of what caused the unanticipated outcome, a patient will be less likely to seek answers through a malpractice claim–reducing anger, insurance premiums, and the cost of healthcare."³⁰⁸ Apology laws offer some legal protection to healthcare providers by preventing their sympathetic statements or apologies from being used against them in a subsequent lawsuit.³⁰⁹ Broadly, "apology statutes restrict the admissibility of statements of benevolence, sympathy, commiseration, condolence, or compassion made by a healthcare provider" in the aftermath of an adverse event.³¹⁰ Despite this general protection, "not all 'apology laws' are created equal and few provide adequate protection for the truly penitent physician."³¹¹

First, this Part addresses the variation seen across state apology laws. It discusses the problems that arise from having such disparate and varied state laws and suggests elements that create an effective apology law. This Part then advocates for federal legislation which could help states effectively implement a baseline standard that provides legal protection for apologies and disclosure of an error. Second, this Part discusses CRPs and the benefits of integrating social science research and a detailed approach in response to an occurrence of an error. CRPs provide for a multifaceted approach for hospitals and healthcare institutions to follow in the aftermath of an error. This approach often includes an apology, disclosure of the error, an investigation, open communication with the patient and their family, financial compensation as determined, internal changes to create safer systems, development of a system to track and analyze data, and education and training on medical error and patient harm.³¹² The use of CRPs may vary in accordance with the needs of an institution, but these elements reflect the core of what should be a part of responding to and addressing the resulting harms from an error.

Given the varying nature of the current existing state apology laws, the introduction of federal legislation can help states to develop a baseline protection for apologies. This legislation would more effectively protect physicians to prevent the admissibility of apologies or statements of sympathy. While instituting federal legislation designed to better support and develop apology laws is a step in the right the direction, and if done properly can lower a patient's propensity to file suit, apologies on their own are not enough to address the widespread harm that can result in the aftermath of an error. This Article advocates for combining federal legislation designed to reduce the amount of medical error, to

³⁰⁸ John Hicks & Courtney McCray, *When and Where to Say "I'm Sorry*," CLM MAG. (Feb. 16, 2021), https://www.theclm.org/Magazine/articles/apology-laws-medical-malpractice/2172 [https://perma.cc/FJR7-NTUW].

³⁰⁹ See id. (explaining function of apology laws).

³¹⁰ *Id*.

³¹¹ Id.

³¹² See COMMUNICATION AND RESOLUTION PROGRAMS, supra note 162, at 1-2.

adequately address the different forms of harm that can occur after an error, to decrease medical liability suits filed, and to start to repair the long-standing harm and social distrust among historically underrepresented communities and vulnerable populations.

A. Apology Laws

Apologizing has benefits for both the physician and the patient in the aftermath of an adverse event.³¹³ Yet, defense attorneys have historically pushed to limit their clients' apologies due to fear these admissions may be used during trial as evidence.³¹⁴ This has created a culture in which physicians have been "conditioned to avoid apologies to avoid admitting fault."³¹⁵ To circumvent this fear and to create an environment that not only allows apologies, but encourages them, many states have passed apology laws.³¹⁶ The overall goal behind most of these laws is to "reduce the risk of apologizing for defendants by making statements of apology, sympathy, and condolence inadmissible in any subsequent trial."³¹⁷ Apology laws are designed to reduce litigation and decrease the pressure defendants may face from threats of legal liability.³¹⁸ Unfortunately, these laws offer varying levels of protection,³¹⁹ which raise questions as to what extent they protect physicians or healthcare institutions or serve their underlying purpose—to allow for a human connection, to recognize the harm done, and to take responsibility.

³¹³ See Pusateri, *supra* note 129, at 202 ("[A]pologies benefit injured parties by restoring their sense of dignity and power, apologizers by affirming their self-worth and morality, and society by decreasing aggression and revenge."). For additional discussion of the benefits of apologies on the individuals involved and society generally, see *id.* at 202-16.

³¹⁴ See Benjamin J. McMichael, R. Lawrence Van Horn & W. Kip Viscusi, "Sorry" Is Never Enough: How State Apology Laws Fail to Reduce Medical Malpractice Liability Risk, 71 STAN. L. REV. 341, 344 (2019).

³¹⁵ Benjamin Ho & Elaine Liu, *What's an Apology Worth? Decomposing the Effect of Apologies on Medical Malpractice Payments Using State Apology Laws*, 8 J. EMPIRICAL LEGAL STUD. 179, 179 (2011); *see* Robbennolt, *supra* note 125, at 465-67 (noting that conventional wisdom views apologies as admissions of responsibility that can be used as evidence in court proceedings).

³¹⁶ See McMichael et al., *supra* note 314, at 344-45; *see also* Adam C. Fields, Michelle M. Mello & Allen Kachalia, *Apology Laws and Malpractice Liability: What Have We Learned?*, 30 BRIT. MED. J. QUALITY & SAFETY 64, 64 (2021) (describing apology laws as supporting efforts to "meet[] ethical obligations, promot[e] greater patient trust and foster[] patient safety").

³¹⁷ McMichael et al., *supra* note 314, at 345.

³¹⁸ See id. ("[S]tate lawmakers have been very clear that in passing these laws, they seek 'to reduce lawsuits and encourage settlements'" (footnote omitted)); Robbennolt, *supra* note 125, at 463 (noting that legal scholars suggest apologizing can help avoid litigation altogether).

³¹⁹ Hicks & McCray, *supra* note 308 (differentiating varying types of apology laws throughout the United States).

1. Framework and History of Apology Laws

The start of apology laws as we know them today developed out of legislation passed in Massachusetts in 1986, when "Massachusetts became the first state to enact apology legislation that specifically addressed accidents."320 This legislation was developed after former Massachusetts State Senator William L. Saltonstall's daughter died in a car accident.³²¹ The driver admitted he never apologized out of fear that the apology would be used against him in court.³²² Out of this, Senator Saltonstall helped propose the first apology law to alleviate this fear.³²³ Texas followed with the passage of its own apology law, although Texas's law did not protect "statements concerning negligence or culpable conduct."324 This soon led to diverse approaches to apology laws, which may help to explain some of variations we see across state apology laws today. Although Massachusetts introduced the idea of apology laws, and Texas helped to further diversify this space, "Colorado became the first state to enact a statute that specifically protected both healthcare providers and their employees."³²⁵ Colorado's statute applies explicitly to medical malpractice lawsuits, protecting expressions of sympathy or admissions of fault by medical providers who harm a patient.326

In considering the wide scope and framework that apology laws may take within states, it is helpful to consider a few examples. In 2006, Washington passed a statute barring the admissibility of evidence that a provider had furnished or offered to pay medical expenses.³²⁷ This statute also prevents the

³²⁰ Brittany Brooks Frankel, "I'm Sorry, Mississippi": An Argument for Enactment of a Physician Apology Statute by the Mississippi Legislature, 37 Miss. COLL. L. REV. 191, 192 (2019). The Massachusetts apology law retains the same as the 1986 version:

Statements, writings or benevolent gestures expressing sympathy or a general sense of benevolence relating to the pain, suffering or death of a person involved in an accident and made to such person or to the family of such person shall be inadmissible as evidence of an admission of liability in a civil action.

Act of Dec. 24, 1986, ch. 652, 1986 Mass. Acts 1199 (codified at MASS. GEN. LAWS ch. 233, § 23D (2021)).

³²¹ See Frankel, *supra* note 320, at 192-93.

³²² See id. at 193.

³²³ See id.

³²⁴ Act of Apr. 15, 1999, ch. 673, 1999 Tex. Gen. Laws 3244 (codified at TEX. CIV. PRAC. & REM. CODE ANN. § 18.061 (West 2021)); *see also* Frankel, *supra* note 320, at 193 (finding that Texas's change "began the diverse approaches to apology laws").

³²⁵ Frankel, *supra* note 320, at 193; *see* Act of Apr. 17, 2003, ch. 126, 2003 Colo. Sess. Laws 940 (codified at COLO. REV. STAT. § 13-25-135 (2021)).

³²⁶ See Frankel, supra note 320, at 193.

 $^{^{327}}$ Act of Mar. 6, 2006, ch. 8, § 101, 2006 Wash. Sess. Laws 36, 37 (codified at WASH. REV. CODE § 5.64.010(1) (2021)) ("In any civil action against a health care provider for personal injuries which is based upon alleged professional negligence, . . . evidence of furnishing or offering or promising to pay medical, hospital, or similar expenses occasioned by an injury is not admissible.").

admissibility of "expressing apology, fault, [or] sympathy."328 Vermont passed a similar statute in the same year, stating that any expression of regret or apology made by a healthcare provider is inadmissible so long as the statements were made within thirty days of when the provider should have known the consequences of the error.³²⁹ Vermont presents an interesting case in that even before the state had officially enacted "a physician apology statute, the Vermont Supreme Court was particularly [hesitant] to allow physician apologies to be used as stand-alone evidence in support of a medical malpractice claim."³³⁰ "In ... Phinney v. Vinson, the Vermont Supreme Court ruled that a physician's apology for an 'inadequate' operation is not admissible as an admission of liability."331 In fact, even "[t]en years earlier [than Phinney], the Vermont Supreme Court similarly held that an apology for a severe mistake during surgery does not in and of itself establish an element of a malpractice claim without additional evidence."332 Thus, Vermont had already established a history of reluctance to use a physician's apology in court or as the sole basis of evidence of a malpractice claim, and the 2006 statute merely codified some of those long-standing principles.

Apology laws introduced a new framework for thinking about physician culpability and their ability to take ownership over a mistake and express sympathy. In terms of addressing harm, an apology is a step in the right direction but is insufficient to fully deal with the issues that unfold after an error occurs. Some states have recognized that apology laws may have their benefits, but more needs to be done to address the harm that may result to patients and their families after an adverse event.

2. Typology of State Apology Laws

"The apology laws that have been enacted range from broad and far-reaching [coverage] to narrow and limited. The differences in these statutes have immense evidentiary and legal consequences "³³³ Many state apology laws only offer partial protection: they do not fully protect the apologizer from the admissibility of certain apologies.³³⁴ Instead, "they preserve the admissibility of apologies that

³²⁸ *Id.* (holding that statements "expressing apology, fault, sympathy, commiseration, condolence, compassion, or a general sense of benevolence" are inadmissible).

³²⁹ Act of May 15, 2006, No. 142, sec. 1, § 1912, 2006 Vt. Acts & Resolves 142-43 (codified at VT. STAT. ANN. tit. 12, § 1912(a) (2021)) ("An oral expression of regret or apology . . . that is provided within 30 days of when the provider or facility knew or should have known of the consequences of the error, does not constitute a legal admission of liability for any purpose and shall be inadmissible in any civil or administrative proceeding").

³³⁰ See Frankel, supra note 320, at 193.

³³¹ Id. (citing Phinney v. Vinson, 605 A.2d 849, 849 (Vt. 1992)).

³³² *Id.* (citing Senesac v. Assocs. in Obstetrics & Gynecology, 449 A.2d 900, 903 (Vt. 1982)).

³³³ Hicks & McCray, *supra* note 308.

³³⁴ See id.

admit fault" while protecting statements that simply apologize for injuries.³³⁵ "This partial protection . . . restricts the communication between the physician and the injured party."³³⁶ While there is valid legislative intent behind this partial protection, as "[i]t is reasonable that many states want to avoid such a broad protection that a full admission of liability would be excluded from evidence[,]" the partial protection contravenes the aim of these laws: "to [encourage] open communication."³³⁷ The nature of this partial protection is likely to induce a scenario where a physician wants to apologize, but also wants to avoid liability, and thus, the apology will seem "insincere or suspicious."³³⁸ An insincere apology may potentially raise more questions, rather than actually addressing the concerns of the patient.³³⁹

"In contrast to states offering only a partial protection, a number of jurisdictions offer total protection of an apology made by a healthcare provider."³⁴⁰ Total protection apology laws offer broader protection to the apologizer and remove the fear that a statement of apology or fault will be admissible in court. Consequently, these types of laws are more effectively designed to encourage open communication and transparency between apologies.³⁴¹

Finally, some states have "generic apology laws that apply beyond the scope of the healthcare field."³⁴² As opposed to stating "that the benevolent or sympathetic statement or gesture must be made by a healthcare provider, [these laws] allow the statute to be expanded to any 'accident."³⁴³

Thirty-eight states, the District of Columbia, and Guam have adopted an apology law, leaving twelve states that allow the admission of statements of fault or apologies into evidence.³⁴⁴ The twelve states with no apology law presently

³³⁹ See Hicks & McCray, supra note 308.

³⁴⁰ Id.

³⁴¹ See *id.* (explaining how "total protection" apology laws provide "broader protection for the apologizer," which then "promot[es] more open communication and transparency between the parties").

³⁴³ Id.

³⁴⁴ See Hicks & McCray, *supra* note 308 (finding that since 1986 a total of thirty-eight states and the District of Columbia have adopted some version of an apology law); Heather Morton, *Medical Professional Apologies Statutes*, NAT'L CONF. OF STATE LEGISLATURES (Aug. 2, 2021), https://www.ncsl.org/research/financial-services-and-commerce/medical-professional-apologies-statutes.aspx [https://perma.cc/8UW5-EB8B] (noting "[t]hirty-nine states, the District of Columbia and Guam" have some "provisions" regarding apology laws

³³⁵ See id.

³³⁶ Id.

³³⁷ See id.

³³⁸ See *id.*; Robbennolt, *supra* note 125, at 462 ("[A]pologies that avoid the legal consequences of apologizing — whether because the apology is merely an expression of sympathy or because it is protected by statute and is inadmissible — are devoid of moral content and likely ineffectual.").

³⁴² *Id.*

in place are Alabama, Arkansas, Illinois, Kansas, Kentucky, Minnesota, Mississippi, New Jersey, Nevada, New Mexico, New York, and Rhode Island.³⁴⁵ As discussed above, not all state apology laws are created equal—nor do they offer physicians the same amount of protection. Many physicians may be unaware that their state has apology laws and others may not understand what is actually covered under the law in their state.³⁴⁶ Further, some physicians may be dubious as to the law's ability to protect them from malpractice liability—and thus be unwilling to apologize.³⁴⁷ This skepticism is warranted, as thirty-five out of the thirty-eight states with apology laws "only cover statements of sympathy, or . . . sympathy and explanations" whereas "only four protect [against] statements of fault" in legal proceedings.³⁴⁸ Regardless of the benefit of apologies, the unfortunate reality is that a simple "I'm sorry" may be used against the offending party in court, depending on the individual state's apology law. Yet, despite the varying level of protection that state laws may provide for physicians, these laws still serve an important overarching purpose.

Though the legislation discussed above is far from covering all state laws that currently exist, the statutes discussed help illustrate the history behind apology laws, and the framework that these laws were developed out of. They reflect the importance of legally allowing an apology or an expression of sympathy in the aftermath of an adverse event. Healthcare providers should be allowed to take responsibility and apologize when an error occurs, and apology laws, though incomplete, are an important part of the process to address the harm caused by medical errors. The above legislation allows physicians—to a certain extent—to recognize their actions and apologize. While this is a good first step, more is needed to address the harm that patients and their families face in the aftermath of an error. CRPs offer a new framework to go beyond the initial apology and to create a space of transparency and open communication that can help to reduce errors, the resulting harm, the number of lawsuits filed, and save money for healthcare institutions.

3. Proposal for Federal Legislation

Thus far, states can choose to implement an apology law to protect physicians and healthcare institutions. There is no federal support or standard for apology

but counting Massachusetts twice); *see also* Fields et al., *supra* note 316, at 64 (noting that thirty-nine states have passed apology laws).

³⁴⁵ Hicks & McCray, *supra* note 308 (finding that these states historically dealt with apology laws differently, from overturning old laws to never having passed a law).

³⁴⁶ See Fields et al., *supra* note 316, at 65 (hypothesizing that apology laws may not increase apologies because physicians may not be aware these laws exist).

³⁴⁷ See *id.* ("Physicians . . . may know [the laws] exist but be uncertain or sceptical about their scope of coverage."); *see also* McMichael et al., *supra* note 314, at 386-88 (discussing cases where doctors knew about apology law but made statements not specifically protected by law).

³⁴⁸ Fields et al., *supra* note 316, at 65 (finding that skepticism is also warranted because some statutes provide exceptions to covered statements in various circumstances).

laws. Given that thirty-eight states have chosen to introduce an apology law in some form,³⁴⁹ this suggests both an interest in federal legislation and a need for it. Existing state laws also reflect problems with our current system of responding to medical error and addressing the ensuing harm. The extent and scope of what each apology law covers varies widely, leaving physicians unsure of what and how much to say, while exposing them to potential liability in court.³⁵⁰ Various states have adopted inconsistent protections that generally protect partial apologies or none at all.³⁵¹

Apologies are a part of our daily lives.³⁵² Children are taught early in life that, if you hurt another person or make a mistake, it is important to apologize and take responsibility. Unfortunately, when dealing with medical error, apologies have moved beyond a human acknowledgment of harm done and potentially incur legal liability. Despite how apologies are treated when it comes to patient safety, there is an underlying misconception that apologies actually speak to a defendant's fault, and thus liability.³⁵³ There are many reasons to question this assumption, as psychological studies have found that individuals often feel guilt and even regret when they are not at fault.³⁵⁴ Apologies are often made for many reasons besides legal fault, including "social custom, feelings of shame, feelings of sympathy or empathy, or [desire] to restore a relationship with an injured party."³⁵⁵

Within the healthcare context, apologies have in fact been taken as admissions of fault, leaving an "I'm sorry" or expression of sympathy open to scrutiny and a potential finding of liability in court.³⁵⁶ Allowing apologies as evidence of fault is particularly damaging because apologies and open communication could help patients and their families cope emotionally and resolve harm outside of court.³⁵⁷ Under state laws that offer partial or no protection, doctors are left at odds as to how to apologize, or whether they should apologize at all, given little—if

³⁵⁵ *Id.* at 202.

³⁴⁹ See id. at 64 (noting that thirty-eight states have passed apology laws); see also supra text accompanying note 344.

³⁵⁰ See discussion supra Sections IV.A.1-2.

³⁵¹ See Pusateri, supra note 129, at 240 ("Without a federal rule, protection is spotty and inconsistent in state courts").

³⁵² See McMichael et al., supra note 314, at 344.

³⁵³ See Pusateri, *supra* note 129, at 223 (noting that legal actors, including lawyers, judges, and juries, often assume an apology implies guilt).

³⁵⁴ See *id.* ("Neither guilt nor blameworthiness are necessary ingredients to apologies. It is common to feel guilt in the absence of blameworthiness, and it is common to apologize in the presence (and absence) of feelings of guilt." (footnotes omitted)).

³⁵⁶ See, e.g., McMichael et al., *supra* note 314, at 387 (discussing case where physician's apology was construed as "admission of fault and not simply a statement of condolence" (citing Davis v. Wooster Orthopaedics & Sports Med., Inc., 2011-OH-3199, 952 N.E.2d 1216, at ¶¶ 2-15)).

³⁵⁷ See Pusateri, supra note 129, at 202 (discussing benefits of apologies for both parties involved).

any—of what they say will be protected from a lawsuit.³⁵⁸ This could lead to half-hearted or poor apologies, which do little to address the harm and resolve the error.³⁵⁹ This fear of liability prevents doctors and providers from effectively addressing harm and creating safer systems for patients.

States have recognized this tension between the fear of liability and the desire to create safer systems for patients but have inconsistently addressed it through apology laws. ³⁶⁰ Because the coverage and intent of existing state laws is so wide and varied, introducing federal legislation to support apology laws provides a much stronger and more seamless approach to tackling the harm done by an adverse event.³⁶¹

Apology laws have gained some attention at the federal level.³⁶² In 2005, Hillary Clinton and Barack Obama, during their time as U.S. Senators, proposed legislation that included a federal apology law.³⁶³ The purpose of this bill was to establish the National Medical Error Disclosure Compensation ("MEDiC") Program for "the confidential disclosure of medical errors and patient safety events."³⁶⁴

The establishment of the MEDiC Program called for the following:

Establishment.—The Secretary, acting through the Director of the Office, shall establish a National Medical Error Disclosure and Compensation (MEDiC) Program to provide for the confidential disclosure of medical errors and patient safety events in order to improve patient safety and health care quality, reduce rates of preventable medical errors, ensure patient access to fair compensation for medical injury due to medical error, negligence, or malpractice, and reduce the cost of medical liability for doctors, hospitals, health systems, and other healthcare providers.³⁶⁵

To successfully promote a culture of safety, the MEDiC Program had four main goals:

³⁵⁸ See Hicks & McCray, *supra* note 308 ("The line where the inadmissible apology ends and the statement of fault begins is not often black and white.").

³⁵⁹ See *id.* (finding that partial apology laws "restrict[] the communication between the physician and the injured party").

³⁶⁰ See Pusateri, supra note 129, at 240 (noting inconsistency of state statutes designed to facilitate apologies).

³⁶¹ See Hicks & McCray, supra note 308.

³⁶² See National Medical Error Disclosure and Compensation Act, S. 1784, 109th Cong. (2005); see also Hillary Rodham Clinton & Barack Obama, *Making Patient Safety the Centerpiece of Medical Liability Reform*, 354 NEW ENG. J. MED. 2205, 2206 (2006).

³⁶³ McMichael et al., *supra* note 314, at 346 ("Then-Senators Barack Obama and Hillary Clinton introduced legislation that included a federal apology law."). *See generally* Clinton & Obama, *supra* note 362 (discussing MEDiC program).

³⁶⁴ S. 1784, § 3.

³⁶⁵ Id.

(1) improve the quality of health care by encouraging open communication between patients and healthcare providers about medical errors and other patient safety events;

(2) reduce rates of preventable medical errors;

(3) ensure patients have access to fair compensation for medical injury due to medical error, negligence, or malpractice; and

(4) reduce the cost of medical liability insurance for doctors, hospitals, health systems, and other healthcare providers.³⁶⁶

To put this program into action, Clinton and Obama indicated the MEDiC Program should be established within a newly created Office of Patient Safety and Health Care Quality under the Department of Health and Human Services.³⁶⁷ The MEDiC program would allow participants, including doctors, hospitals, and health systems, to receive grants and technical assistance for disclosing medical errors and offering compensation for injuries.³⁶⁸ As a condition for joining the program, "[p]articipants would submit a safety plan and designate a patient-safety officer, to whom these disclosures and notices of related legal action would be reported."³⁶⁹ Under the MEDiC Program, apologies offered by healthcare providers who joined the program would "be kept confidential and could not be used [as evidence] in . . . legal proceedings."³⁷⁰

Further, the bill described several hospital systems and medical liability insurance companies that adopted policies of disclosing medical errors, apologizing, and compensating patient injury early, noting the overall benefits seen in these institutions.³⁷¹ The Department of Veterans Affairs hospital in Kentucky, the University of Michigan Health System, and Copic Insurance Company in Colorado each reported significantly decreased legal expenses and smaller claim payouts after adopting such policies.³⁷² Overall, these policies resulted in "fewer numbers of malpractice suits being filed, more patients being compensated for injuries, greater patient trust and satisfaction, and significantly

³⁶⁶ *Id*; *see also* Clinton & Obama, *supra* note 362, at 2205 (explaining the four goals for the MEDiC Act).

³⁶⁷ Clinton & Obama, *supra* note 362, at 2206.

³⁶⁸ See id.

³⁶⁹ Id.

³⁷⁰ Id.

³⁷¹ *See id.* at 2207-08 (describing changes to apology policy that several institutions have made that significantly reduced liability costs).

³⁷² National Medical Error Disclosure and Compensition Act, S. 1784, 109th Cong. § 2 (2005) (listing "hospital systems and private medical liability insurance companies" that benefited from "a policy of robust disclosure of medical errors"); *see also* Clinton & Obama, *supra* note 362, at 2207-08 (finding that VA hospital had average settlements of "\$15,000 per claim as compared with more than \$98,000 at other VA institutions" and that the University of Michigan Health system cut annual litigation costs by \$2 million).

reduced administrative and legal defense costs for providers, insurers, and hospitals where such policies are in place."³⁷³

However, the aforementioned institutions benefitted not only from reducing medical malpractice claims but also from greater trust and satisfaction among patients.³⁷⁴ The benefits these institutions reaped reflect the power of disclosing an error, apologizing when an error has occurred, and providing compensation in addressing an error. Thus, while apologies are important for addressing medical error, they should be combined with other policies, such as early compensation and disclosure of the error, to be more effective.³⁷⁵ Additionally, while apologies in and of themselves may not be enough, instituting federal legislation is a step in the right direction and allows apologies to be a part of improving patient safety as opposed to finding of liability.

In introducing federal legislation like the MEDiC Program to encourage the development of clearer standards within apology laws, one consideration is the scope of coverage that should be covered within the law. As previously discussed, there is wide variation in existing state laws in terms of protection and what is admissible in court.³⁷⁶ This Article contends that the purpose behind introducing this type of federal legislation is to introduce continuity, provide a clear set of standards for healthcare providers, and encourage the use of apologies and open communication before litigation. For apology laws to provide sufficient protection, this Article advocates designing federal legislation that proposes a baseline that offers total protection for an apology made by a healthcare provider. The current apology law in Colorado provides a good example of thorough protection to encourage apologies:

In any civil action brought by an alleged victim of an unanticipated outcome of medical care, or in any arbitration proceeding related to such civil action, any and all statements, affirmations, gestures, or conduct expressing apology, fault, sympathy, commiseration, condolence, compassion, or a general sense of benevolence which are made by a healthcare provider or an employee of a healthcare provider to the alleged victim, a relative of the alleged victim, or a representative of the alleged victim and which relate to the discomfort, pain, suffering, injury, or death of the alleged victim as the result of the unanticipated outcome of medical care shall be inadmissible as evidence of an admission of liability or as evidence of an admission against interest.³⁷⁷

Encouraging the adoption of federal legislation that provides total protection—like the current law in Colorado—will not only provide clear protection for healthcare providers, but it will also allow the human element of

³⁷³ S. 1784, § 2.

³⁷⁴ Id.

³⁷⁵ See, e.g., Lambert et al., *supra* note 124, at 2494 (explaining approach that includes apologies as one of seven separate "pillars" to respond to patient safety incidents).

³⁷⁶ See discussion supra Sections IV.A.1-2.

³⁷⁷ Colo. Rev. Stat. § 13-25-135(1) (2021).

apologies to be a part of the conversation on increasing patient safety. While these apology laws, and a federal solution, are a positive step towards remediating adverse events, apologies are not enough to adequately address patient harm and create safer systems.

4. Apology Law Efficacy

Research over the past two decades has indicated the benefits of apologizing and open communication as including the potential to produce better outcomes for patients, reduce errors, and create a safer system overall. ³⁷⁸ In addition to the growing social science research and literature on addressing medical error, the American Medical Association ("AMA") has also weighed in on how doctors should respond when a patient is harmed and if an apology is warranted.³⁷⁹ According to the AMA, healthcare institutions should compassionately communicate with patients who experience harm:

Physicians must offer professional and compassionate concern toward patients who have been harmed, regardless of whether the harm was caused by a health care error. An expression of concern need not be an admission of responsibility. When patient harm has been caused by an error, physicians should offer a general explanation regarding the nature of the error and the measures being taken to prevent similar occurrences in the future. Such communication is fundamental to the trust that underlies the patient-physician relationship, and may help reduce the risk of liability.³⁸⁰

Yet, despite this promising research as to the medical and administrative benefits of open communication after an error,³⁸¹ there is still some debate that apologizing and admitting to an error may function as incentive for a patient to sue.³⁸² Research has been mixed as to whether apology laws reduce medical liability litigation or the occurrence of medical errors.³⁸³ Some scholars have

³⁷⁸ See generally Pusateri, *supra* note 129, at 202-16 (encouraging the use of apologies as a means to redress harm).

³⁷⁹ See The AMA Code of Medical Ethics' Opinions on Patient Safety, 13 VIRTUAL MENTOR 626, 627 (2011).

³⁸⁰ Id.

³⁸¹ See McDonald et al., *supra* note 115, at e13 (finding increase in incident reports, investigations, system improvements, and disclosures tied to implementation of CRP principles); Mello et al., *supra* note 154, at 24 (citing anecdotal evidence of high defense costs and patient safety incidents that could have been avoided through CRPs).

³⁸² Compare McMichael et al., *supra* note 314, at 385 ("[A]pologies contain signals of malpractice that encourage patients to pursue lawsuits and larger indemnity payments."), *with* Ho & Liu, *supra* note 315, at 195 (acknowledging that it is an "unlikely" possibility that apologies "could actually create more lawsuits" because they inform patients of injuries of which the patients may have been otherwise unaware).

³⁸³ See Ho & Liu, *supra* note 315, at 181 (synthesizing prior studies providing "a comprehensive psychological overview of why and how apologies could be effective in reducing patients' likelihood to litigate" but recognizing that litigation changes "could be attribut[able] to factors besides the apology program").

advocated against using apology laws and using apologies to address harm, arguing that the lack of protection for apologies does not block open communication.³⁸⁴ Considerable research has linked the protection of apologies to more expressions of sympathy, admissions of fault, and opportunities for open communication in lieu of a lawsuit.³⁸⁵

In contrast, other research has also suggested that offering an apology increases litigation—if the apology was either done poorly³⁸⁶ or if it alerted the patient to the fact that an error occurred.³⁸⁷ One scholar argues that once a patient becomes aware of the occurrence of a medical error, their incentive to pursue a claim may increase, even if the apology offered may not be introduced as evidence.³⁸⁸ However, as opposed to apologies acting as the catalyst for a lawsuit, patient surveys have indicated that a primary reason for filing suit was the *lack* of an apology.³⁸⁹ Patients often want to know what happened and want the institution to take responsibility for the error. Allowing healthcare providers to apologize and explain what happened can reduce the number of malpractice

³⁸⁴ See Raper, supra note 27, at 271 (assuring that "[a]dvising against apology does not mean blocking communication of adverse events to patients" because disclosure could occur through "careful *accounts*" that do not incorporate apology).

³⁸⁵ See, e.g., Fields et al., *supra* note 316, at 65 (delving into reasons why reduction in lawsuits caused by apologies may not be discovered by traditional data sets or analytical methods); Helmchen et al., *supra* note 143, at 116-17 (anecdotally connecting medical center's prompt apology to resolution of case without formal lawsuit and with maximum closure); Lambert et al., *supra* note 124, at 2504 (finding reduction of lawsuits and statistically significant reduction of liability costs following CRP intervention at the University of Illinois Hospital and Health Sciences System); McDonald et al., *supra* note 115, at e12-e13 (including apology and communications as pillars of CRP, although not directly linking those pillars to reductions in lawsuits); Mello et al., *supra* note 154, at 26 (noting practitioner intention to avoid lawsuits by settling "any case in which they admitted error"). *But see* David M Studdert, Michelle M. Mello, Atul A. Gawande, Troyen A. Brennan & Y. Claire Wang, *Disclosure of Medical Injury to Patients: An Improbable Risk Management Strategy*, 26 HEALTH AFFS. 215, 219 (2007) (computing "[ninety-five] percent chance that [total claim volume] would increase" if medical center switched away from "deny and defend" tactics).

³⁸⁶ Robbennolt, *supra* note 125, at 500 (finding along many indicators that partial apologies were not nearly as effective as "full apologies," as defined in the literature).

³⁸⁷ See McMichael et al., *supra* note 314, at 361 ("[P]atients may sue more often and demand higher settlements when they receive apologies, as they learn of malpractice they otherwise would not have recognized."); *see also* discussion *supra* notes 353-56.

³⁸⁸ See McMichael et al., *supra* note 314, at 385 ("[A]pologies contain signals of malpractice that encourage patients to pursue lawsuits and larger indemnity payments.").

³⁸⁹ See Ho & Liu, *supra* note 315, at 179 (summarizing patient surveys indicating "that a main reason patients decide to litigate is due to the lack of an apology"); Hicks & McCray, *supra* note 308 (proposing that, after apology and explanation, "a patient would be less likely to seek answers through a medical malpractice claim" and noting study where "37 percent of respondents said an explanation and an apology would have prevented the lawsuit" (citing Vincent et al., *supra* note 127)).

claims filed.³⁹⁰ Indeed, while a patient may file a lawsuit after being notified of an error that they otherwise may not have known about,³⁹¹ the overwhelming literature still reflects the benefits of apologies in repairing harm, creating safer systems, and reducing lawsuits.³⁹²

Even considering the potential benefits of apologies, offering apologies on their own will not resolve the harm caused by medical errors. An analysis of medical errors indicates that it is important to use both "modern principles of systems analysis and human performance to understand why medical errors take place."³⁹³ Further, it is necessary to "develop a methodology for identifying and preventing errors from happening in the future."³⁹⁴ Providing an apology—particularly when done poorly³⁹⁵ or in a half-hearted manner³⁹⁶—is not enough to address the underlying harm, reduce the occurrence of error, or lower medical liability litigation.³⁹⁷

Aside from poorly made apologies, there are several reasons why we have not seen a reduction in liability despite the widespread implementation of apology

³⁹³ Raper, *supra* note 27, at 270.

³⁹⁴ Id.

³⁹⁰ See Hicks & McCray, supra note 308 (noting that apologies can increase "patient safety and satisfaction" as well as reduce litigation); see also Lambert et al., supra note 124, at 2503 (finding "significant declining trend in . . . claims" after CRP intervention); Mello et al., supra note 154, at 20 (examining early, anecdotal indications that CRPs can "substantially reduce liability costs"). But see Studdert et al., supra note 385, at 215-16, 219 (conceding the "emerging view" among experts that apologies reduce the number of claims filed but finding the opposite result through statistical simulation).

³⁹¹ See McMichael et al., *supra* note 314, at 31; *supra* note 387.

³⁹² See AM. MED. ASS'N, COMMUNICATION AND RESOLUTION PROGRAMS 1 (2017), https://www.ama-assn.org/system/files/2019-01/ama-issue-brief-communication-and-resolution-programs.pdf.pdf [https://perma.cc/A9XR-QDV7] (discussing the benefits of

resolution-programs.pdf.pdf [https://perma.cc/A9XR-QDV/] (discussing the benefits of Communication and Resolution Programs); *see also* BETSY LEHMAN CTR. REPORT, *supra* note 41, at 15 (finding that only 7% of patients who openly discussed an error felt angry versus 50% of those who did not openly discuss an error); Richard C. Boothman, Amy C. Blackwell, Darrell A. Campbell, Jr., Elaine Commiskey & Susan Anderson, *A Better Approach to Medical Malpractice Claims? The University of Michigan Experience*, 2 J. HEALTH & LIFE SCIS. L. 125, 125 (2009) (studying the University of Michigan Health System's approach to dealing with medical malpractice, which "illustrates how an honest, principle-driven approach to claims is better for all"); Helmchen et al., *supra* note 143, at 114-15 (comparing two cases of preventable medical error and finding disclosure-based approach more successful at reconciling harm); McDonald et al., *supra* note 115, at e11 (finding that a policy of transparency "translated into close to 200 system improvements" at University of Illinois Medical Center at Chicago ("UIMCC")).

³⁹⁵ See McDonald et al., *supra* note 115, at e11 ("Given its complexity, providers understandably fear that inadequate or poorly executed disclosure only frustrates practitioners").

³⁹⁶ Robbennolt, *supra* note 125, at 462 (finding that "safe" apologies which try to reap benefits of apologizing while minimizing risk are "likely ineffectual").

³⁹⁷ See supra notes 338-39 and accompanying text.

laws in thirty-eight states.³⁹⁸ First, the existing evaluations of apology laws have their limitations. To start, data constraints are a major issue. For most researchers the National Practitioner Data Bank ("NPDB") presents the best available source of information on malpractice claims.³⁹⁹ Unfortunately, this information is limited to paid claims and is known to have missing claims settled on behalf of healthcare institutions.⁴⁰⁰ A deeper issue within the existing studies is that they measure the association between the state where the physician practices (with or without an apology law) and the physician's experience with malpractice claims.⁴⁰¹ A physician may or may not experience an adverse event, choose to disclose it and apologize, communicate the occurrence of the error, and have an insurer willing to offer compensation or another remedial gesture.⁴⁰² Each of these factors likely influences whether a physician experiences malpractice litigation-but unfortunately, they go unmeasured. Further, no study has measured the influence of apology laws on the actual frequency of apologies. We need more information about the rates of occurrence of adverse events along with information on how physicians and institutions react when these events occur. Without this information we cannot accurately gauge whether, and the ways in which, apology laws actually influence malpractice liability.⁴⁰³

Second, it is quite possible that apology laws do not result in more apologies from physicians. While thirty-eight states currently have an apology law in place in some form, physicians may not be aware of these laws or they may know they exist but are unclear or are warrantably skeptical as to the scope of their coverage.⁴⁰⁴ Further, "[m]any laws provide that even covered statements can be admissible if the physician later says something contradictory."⁴⁰⁵ "Some [apology laws] only apply in certain circumstances, such as serious adverse events or communications made within a particular time frame."⁴⁰⁶ Given the

³⁹⁸ These reasons and this discussion are drawn primarily from those suggested in Fields et al., *supra* note 316, and are explained fully in that article. For an additional discussion on the potential reasons why empirical analyses show that apology laws have not reduced physician liability, see McMichael et al., *supra* note 314, at 371, 386-90.

³⁹⁹ See Ho & Liu, supra note 315, at 184-85 (finding that NPDB data "has been widely used in many studies related to medical malpractice").

⁴⁰⁰ See McMichael et al., *supra* note 314, at 371 (discussing the "shortcomings" of NPDB data); *see also* Ho & Liu, *supra* note 315, at 185 (acknowledging the NPDB "corporate shield' loophole, through which settlement payments made on behalf of a practitioner by an institution are not recorded in NPDB").

⁴⁰¹ Fields et al., *supra* note 316, at 65 ("A more fundamental problem is that all existing studies measure the association between two quite distally situated measures: the fact that a physician practices in a state with (or without) an apology law and the physician's malpractice claims experience.").

⁴⁰² Id.

⁴⁰³ See id.

⁴⁰⁴ See supra notes 346-48 and accompanying discussion (discussing physicians' lack of awareness of and warranted skepticism of apology laws).

⁴⁰⁵ Fields et al., *supra* note 316, at 65.

⁴⁰⁶ Id.

potential gaps in apology laws' legal protection, physicians might not be willing to apologize, and liability insurers may focus more on what the laws do not cover, as opposed to encouraging their insured physicians to take advantage of the protections that do exist.⁴⁰⁷

Third, there is mixed analysis on the role that apology laws play in reducing lawsuits and medical liability.⁴⁰⁸ On one side, the apology laws may deter patients from suing; on the other, it may spur patients to sue based on information they otherwise would not have known but for the apology.⁴⁰⁹ It is possible that these two sides work to "cancel one another out."⁴¹⁰ "If that were the case, [then] the laws would be working as intended, in the sense that they would be fostering resolution of incidents that would otherwise escalate to litigation."⁴¹¹ Still, this confounding factor remains because many other patients may not have pursued litigation if their providers had successfully concealed an error, however unethical that may be.⁴¹²

Fourth, apology laws "may inspire physicians to apologise"; but there is still the possibility that they "execute these apologies poorly," which could potentially do more harm than good.⁴¹³ Because some physicians may be aware that their state's apology law offers only limited protection, for example, only covering statements of sympathy, this can influence the extent of their apology.⁴¹⁴ Apologizing or disclosing an error is very difficult for anyone and this type of task requires a skilled communicator. As such, physicians may handle apologies poorly and may unintentionally offend the patient as opposed to providing key information about what transpired.⁴¹⁵ In fact, a poorly executed apology may cause patients or affected families to become more incensed "rather than alleviat[ing] their anger."⁴¹⁶

Finally, apologies must be directly accompanied by efforts to remediate the harm done, and where they fail to do so, they mean little. Over the past two decades there has been a growing focus on patient safety and providing patients and their families with an apology and more transparency as to the error that occurred.⁴¹⁷Despite this well-meaning intention to apologize and offer

⁴⁰⁷ *Id*.

⁴⁰⁸ See *id*.; see also McMichael et al., supra note 314, at 386-90 (analyzing the probability of apology laws reducing malpractice disputes and affecting malpractice payments).

⁴⁰⁹ See Fields et al., supra note 316, at 65.

⁴¹⁰ *Id*.

⁴¹¹ Id.

⁴¹² See id.

⁴¹³ Id.

⁴¹⁴ See id. at 66.

⁴¹⁵ See discussion supra notes 150-53 (discussing physicians' difficulty communicating with patients about errors).

⁴¹⁶ Fields et al., *supra* note 316, at 66.

⁴¹⁷ See Helmchen et al., *supra* note 143, at 114-15 (noting recent increase in patient safety culture); Rocke & Lee, *supra* note 116, at 550 (noting recent adoption of mistake disclosure protocols at certain healthcare institutions).

transparency, many families dealing with medical injuries have practical needs—needs that an apology alone cannot address. Research indicates that most people affected by medical errors will experience financial stress in the aftermath and will want compensation.⁴¹⁸ This is where apology laws have fallen short—an apology or admission of the error that occurred can create an environment of greater transparency, but it does little to address the harm that occurred or deal with the patient's most immediate and pressing needs. In addition to a well-meaning and sincere apology, the use of CRPs can provide an effective means to both address and reduce the occurrence of medical errors.

B. Communication and Resolution Programs

CRPs are key to reducing medical error and resounding harm to patients and their families. Apology laws are important in redressing a medical error as they allow physicians and healthcare institutions to recognize a mistake was made and offer human empathy without the fear of legal liability. ⁴¹⁹ Despite their benefits, apology laws do not address all harm, such as the persistence of bias and discrimination within the medical system and the systematic breakdowns that allowed the error to occur. Nor do they offer a system for addressing the harm and preventing the reoccurrence of the error.⁴²⁰ Thus, additional systems are necessary to address these issues.

1. Benefits of CRPs

Broadly speaking, CRPs "are a principled, comprehensive, and systematic approach to responding to patients who have been harmed by their healthcare."⁴²¹ CRPs introduce a successful framework for open communication with patients and their families that incorporates apologies.⁴²² This open communication presents a unique opportunity to begin to rebuild trust and start to address the unique harm suffered by vulnerable populations.⁴²³ Further, CRPs

⁴¹⁸ BETSY LEHMAN CTR. REPORT, *supra* note 41, at 7 (noting that many people experience financial stress from medical errors, including a 33% decrease in income, a 50% increase in medical expenses, and a 33% increase in household expenses).

⁴¹⁹ See supra text accompanying note 317; see also Pusateri, supra note 129, at 202-16 (discussing the benefits of apologies on the individuals involved and society generally).

⁴²⁰ See discussion supra Section IV.A.

⁴²¹ COMMUNICATION AND RESOLUTION PROGRAMS, *supra* note 162, at 1.

⁴²² See McDonald et al., supra note 115, at e13 (discussing apology as a pillar of CRPs).

⁴²³ Helmchen et al., *supra* note 143, at 120-22 (identifying benefits of CRP approach over "deny and defend" in remediating patient harm, while recognizing that mere study of two patient safety incidents is "not definitive"); *see also* B. A. Liang, *A System of Medical Error Disclosure*, 11 QUALITY & SAFETY HEALTH CARE 64, 67 (2002) (calling for apology and disclosure from entire system, rather than individual practitioner, "after a thorough review of the relevant [apology] law in the provider's locality"); McDonald et al., *supra* note 115, at 3 (finding that adoption of CRP principles by UIMCC led to 189 system improvements over two years); Mello et al., *supra* note 154, at 27-29 (drawing lessons from six medical centers

focus on improving communication between patients and healthcare professionals.⁴²⁴ This communication extends beyond a simple apology and can help to mitigate the various feelings during the aftermath of a medical error, including sadness, betrayal, and anger. ⁴²⁵ All too often, patients and their families have no opportunity to process what happened, and many carry the effects of the event over several years.⁴²⁶

CRPs help physicians move away from "deny and defend" and implement a transparent approach, which produces better outcomes for all parties involved.⁴²⁷ Despite the existing research and better predicted outcomes, there is a deep history of "deny and defend."⁴²⁸ Fear of legal liability, distrust in the process, and lack of institutional support act as barriers against open disclosures, and may similarly act as barriers against adopting CRPs.⁴²⁹ Implementing federal legislation to protect apologies should help to allay the fear of legal liability, but more work needs to be done to reform the culture within healthcare institutions and develop support for this new process. While there may be resistance to CRPs, these programs are focused on patient safety and sufficiently addressing patient harm, which is key in the successful reduction of medical error.⁴³⁰

2. Examples of Successful CRPs in Healthcare Institutions

Given the history of "deny and defend" in the medical field, the resistance to CRPs, which require taking responsibility and admitting fault, is no surprise.

that adopted CRPs, but cautioning that "understanding the full effects of a CRP requires longer observation than was possible" in this instance).

⁴²⁴ See McDonald et al., *supra* note 115, at e12-e13 (discussing open communication as a pillar of CRPs).

⁴²⁵ See BETSY LEHMAN CTR. REPORT, *supra* note 41, at 15 ("For people who receive it, open communication is associated with lower levels of adverse health impacts and health care avoidance[.]"); McDonald et al., *supra* note 115, at e13 (discussing apology as a pillar of CRPs).

⁴²⁶ See BETSY LEHMAN CTR. REPORT, *supra* note 41, at 11 ("Medical errors are associated with long-lasting physical and emotional impacts[.]").

⁴²⁷ See Helmchen et al., *supra* note 143, at 117-18 (contrasting outcomes from "deny and defend" hospital with those from more transparent hospital showing how transparency benefited both the victim's family and the hospital); Hendrich et al., *supra* note 101, at 43-44 (exploring benefits of full communication with patients and observing barriers such as divergent goals of liability insurers and of hospitals and providers); Lambert et al., *supra* note 124, at 2511-12 (concluding that CRP-like program "which emphasizes a culture of transparency" correlated with "reductions in claims, legal fees . . . settlement costs, and self-insurance costs"); McDonald et al., *supra* note 115, at e14 (discussing transparency as organizing concept for "seven pillars" of UIMCC's response to patient safety incidents).

⁴²⁸ See supra Section II.B (discussing reasons for "deny and defend" practices and their shortcomings).

⁴²⁹ See supra notes 149-53 and accompanying text (touching on resistance caused by fear of legal liability and lack of knowledge of best practices in communication).

⁴³⁰ See To ERR IS HUMAN, supra note 1, at 18 (discussing patient safety as important goal and "domain" of quality).

Within the past two decades, though, some states and institutions have moved away from "deny and defend" to embrace approaches that incorporate transparency and disclose adverse events to patients and their families.⁴³¹ Massachusetts was not only the first state to propose an apology law⁴³²—it was also on the forefront of integrating strategies that moved beyond apologies to a more open and transparent approach within the healthcare space.

In 2012—twenty-six years after developing the first legislation around apology laws—Massachusetts developed the "Betsy Lehman center for patient safety and medical error reduction."⁴³³ As a Massachusetts state agency, the Betsy Lehman Center "supports providers, patients, and policymakers working together in order to advance the safety and quality of health care."⁴³⁴ The Betsy Lehman Center presents a good example of the application of CRP principles, as it was developed to help evaluate and disseminate information related to the sponsorship of training and education programs for best practices in patient safety and medical error reduction.⁴³⁵ This center was given a number of responsibilities, including coordinating the efforts of healthcare institutions to meet their responsibilities of "patient safety and medical error reduction[,]" assisting organizations to work as part of a total patient safety system, and creating appropriate mechanisms for consumers to be included in a statewide program of patient safety.⁴³⁶

New research from the Betsy Lehman Center indicates that effective communication can help to address the emotional damage patients and their families experience after an adverse event.⁴³⁷ A study out of the Betsy Lehman Center found that among individuals who had experienced a medical error, fifty percent of those who received no communication following the event were still angry years later, whereas only seven percent of those who were able to openly discuss with the care team were still angry.⁴³⁸ This study indicates that in the aftermath of an error, patients and their families often want to understand what

⁴³¹ See supra note 143 and accompanying text.

⁴³² See supra note 320 and accompanying text (highlighting Massachusetts's role in history of apology laws).

⁴³³ Act of Aug. 6, 2012, ch. 224, § 15, 2012 Mass. Acts 1053, 1104-05 (codified at MASS. GEN. LAWS ch. 12(C), § 15 (2021)).

⁴³⁴ BETSY LEHMAN CTR., https://betsylehmancenterma.gov/ [https://perma.cc/2ZFZ-JDRQ] (last visited Jan. 16, 2022).

⁴³⁵ Act of Aug. 6, 2012, § 19, at 1104 (stating purpose of the new center is "to serve as a clearinghouse for [such] . . . evaluation and dissemination").

⁴³⁶ See id. (laying out responsibilities to coordinate state participation in federal reports and establish patient safety and medical errors reduction board).

⁴³⁷ BETSY LEHMAN CTR. REPORT, *supra* note 41, at 15 (noting importance of communication for emotional damage even if communication could not undo physical impacts of error).

⁴³⁸ See *id.* (finding similarly dramatic differences among percentages of patients still depressed (four percent versus thirty-three percent) and still avoiding that health care facility (twenty-one percent versus eighty percent)).

happened.⁴³⁹ Creating a space that allows transparency and open communication can help patients process emotionally,⁴⁴⁰ but it also gives the healthcare institution an opportunity to recognize and address an error and ultimately create a safer system overall.⁴⁴¹

In addition to the work done in Massachusetts, one of the most notable examples of the development and use of a CRP in addressing medical error is the University of Michigan Health System ("UMHS"). Once among the institutions that thoroughly embraced the approach of "deny and defend," UMHS drastically changed its approach in 1996.⁴⁴² Instead of stonewalling and resisting admission or taking responsibility, UMHS would do the opposite:

When an unintended outcome occurs, the case is quickly reviewed. If the care was inappropriate, a thorough explanation is given, and an apology is made. This has led to surprising results. During a 7-year period, litigation costs were cut in half, annual new claims were down more than 50%, and claim processing time was decreased by 60%.⁴⁴³

Though changes to UMHS began in the mid-1990s, it more formally adopted a CRP approach in July 2001; since then, the UMHS has disclosed errors and offered compensation for the ensuing harm.⁴⁴⁴ Given these major changes made over 20 years ago, the UMHS program "has become a model for other health systems to replicate."⁴⁴⁵ The UMHS program is a full-scale program that starts "before a medical error occurs," and it emphasizes "process improvement along with the risk management aspects of an adverse event."⁴⁴⁶

Though CRPs have taken different forms to adapt to the needs of particular institutions, fundamentally, these programs should incorporate the following elements.⁴⁴⁷ First, once the medical error has been discovered, the incident

⁴⁴² Rocke & Lee, *supra* note 116, at 550 (using UMHS as an example of a system that has "adopted an approach of mistake disclosure").

⁴⁴³ *Id.* (endnotes omitted).

⁴³⁹ See *id.* at 14 (specifically asking study participants whether medical practitioners "[spoke] about the error in an easy to understand way").

⁴⁴⁰ See *id.* at 15 ("[O]pen communication is associated with lower levels of adverse emotional health impacts and health care avoidance[.]").

⁴⁴¹ Boothman et al., *supra* note 392, at 143 ("Perhaps most importantly, commitment to [CRP] principles . . . opens the door to immediate and decisive quality improvement measures and peer review opportunities."); Mello et al., *supra* note 154, at 24 (highlighting how internal investigations in CRPs "would identify opportunities to improve safety").

⁴⁴⁴ Allen Kachalia, Samuel R. Kaufman, Richard Boothman, Susan Anderson, Kathleen Welch, Sanjay Saint & Mary A.M. Rogers, *Liability Claims and Costs Before and After Implementation of a Medical Error Disclosure Program*, 153 ANNALS INTERNAL MED. 213, 213 (2010) ("In 2001, . . . [UMHS] launched a comprehensive claims management model with disclosure at its centerpiece." (endnote omitted)).

⁴⁴⁵ AM. MED. Ass'N, *supra* note 392, at 1.

⁴⁴⁶ Id. at 7.

⁴⁴⁷ These elements are drawn from the "seven pillars" of UIMCC's process for responding

should be promptly reported to the safety and risk management department.⁴⁴⁸ At the University of Illinois Medical Center at Chicago ("UIMCC")—an institution that has successfully transformed their approach to medical errors and based their approach on UMHS—staff who promptly report patient safety incidents are applauded and receive recognition in the UIMCC's patient safety newsletter.⁴⁴⁹ Further, at UIMCC, clinical departments are "financially penalised through medical malpractice premium allocations for failing to report patient safety incidents involving patient harm."⁴⁵⁰

Second, after reporting the error, the institution should investigate the incident and determine what led to the occurrence of the harm.⁴⁵¹ As aforementioned, medical errors can have varying effects on patients and can range in severity.⁴⁵² If a preliminary investigation reveals that harm occurred, then a full investigation team should be assembled to determine whether the care taken during the incident was reasonable.⁴⁵³ Additionally, investigating the error can determine if the event that occurred was a serious "near miss"—an act "that could have harmed the patient but did not cause harm as a result of chance, prevention, or mitigation"⁴⁵⁴—warranting further analysis.⁴⁵⁵

Third, now that the error has been discovered, reported, and an investigation has begun, the healthcare institution should focus on open communication and disclosure of the error with the patient.⁴⁵⁶ "The UIMCC maintains ongoing communication with the patient and [their] family" about the error, the status

⁴⁵⁰ See id. (indicating that UIMCC's new "reporting culture" led to doubling of patient safety incident reports).

⁴⁵³ See McDonald et al., *supra* note 115, at e12 (combining "preliminary review" and "investigation" into one pillar).

to patient safety incidents. The seven pillars are themselves derived from five principles, three of which were borrowed from UMHS. *See* McDonald et al., *supra* note 115, at e11-e13 (introducing the pillars before describing them in detail).

⁴⁴⁸ COMMUNICATION AND RESOLUTION PROGRAMS, *supra* note 162, at 2 (listing the first key step in the CRP process as "[i]mmediately report[ing] the adverse event to the institution or organization (within 30 minutes of the event's discovery)"); McDonald et al., *supra* note 115, at e11 ("Reporting is the first pillar and triggers the process.").

⁴⁴⁹ McDonald et al., *supra* note 115, at e11 (informing that such "[r]eports can be made by telephone, hand-written, online . . . , [or] in person").

⁴⁵¹ See id. at e12.

⁴⁵² See supra notes 38-40 and accompanying text (discussing variety of ways medical errors can cause harm).

⁴⁵⁴ INST. OF MED. OF THE NAT'L ACADS., PATIENT SAFETY: ACHIEVING A NEW STANDARD OF CARE 34 (Philip Aspden, Janet M. Corrigan, Julie Wolcott & Shari M. Erickson eds., 2004); see also Abbas Sheikhtaheri, Letter to the Editor, *Near Misses and Their Importance for Improving Patient Safety*, 43 IRANIAN J. PUB. HEALTH 853, 853 (2014) (reviewing "more than 20 definitions" of a "near miss").

⁴⁵⁵ See McDonald et al., *supra* note 115, at e12 (calling for "future determination" of near miss status if no patient harm occurred).

⁴⁵⁶ See id.

and findings of the investigation, and the institution's work toward resolution.⁴⁵⁷ Communication with the patient should be driven by facts found during the investigation, encouraging an approach of transparency. Full and transparent disclosure is a process that requires commitment from the provider, as communicating the details of the adverse event often involves a series of meetings.⁴⁵⁸

Fourth, the institution should apologize when harm is caused by inappropriate care and provide a remedy for that harm.⁴⁵⁹ Healthcare providers have found that "saying 'we are sorry' without any subsequent action is inadequate" because apologies do not fully address the underlying harm and are not a sufficient remedy.⁴⁶⁰ At this stage, in addition to the investigation, the open ongoing communication, and the apology, the institution should provide "rapid remediation" by "waiving hospital bills once [a] consensus on the failure to provide reasonable care has been reached."⁴⁶¹ Additional financial compensation may be needed depending on the nature of the incident and the harm suffered.⁴⁶²

Fifth, the institution should focus on improving its healthcare system to make it safer for patients and to prevent the same harm from reoccurring in the future.⁴⁶³ To make this process more effective and create meaningful change, the patient and their family should be actively invited to participate in the process, as is seen at UIMCC.⁴⁶⁴ Involving patients in this manner is critical for several reasons. Implicit biases, discrimination, and unequal treatment pervade the healthcare system and affect the health and health outcomes of patients.⁴⁶⁵ Vulnerable communities, including racial and ethnic minorities,⁴⁶⁶ women,⁴⁶⁷ and transgender people,⁴⁶⁸ have historically been harmed and left out of the medical system. Further, these communities are more likely to experience an

⁴⁵⁷ *Id.* at e12-e13 (cautioning that generally, "only the findings surrounding the incident that are reasonably certain and unlikely to change as the investigation proceeds are communicated to the patient").

 ⁴⁵⁸ See id. at e13 (calling disclosure "a process, not an event" requiring continuous steps).
 ⁴⁵⁹ See id.

⁴⁶⁰ See *id. But see* Robbennolt, *supra* note 125, at 487 (finding a full apology to be "more sufficient than either a partial apology or no apology").

⁴⁶¹ See McDonald et al., supra note 115, at e13.

⁴⁶² See id. (calling for "early offer of compensation" to be made concurrently with holding and waiving hospital bills).

⁴⁶³ See id.

⁴⁶⁴ See id.

⁴⁶⁵ See supra Part III (discussing health care inequalities among vulnerable populations).

⁴⁶⁶ See supra Section III.C.

⁴⁶⁷ See supra Section III.A.

⁴⁶⁸ See supra Section III.B.

error⁴⁶⁹ and are disproportionately harmed by errors that do occur.⁴⁷⁰ Integrating patients into improving patient safety and the overall system offers a unique opportunity for diverse voices and historically marginalized groups to participate in health care. This participation offers these communities the opportunity to directly engage with the healthcare system and to start to rebuild trust, which is significant to their health and outcomes.⁴⁷¹ Further, their involvement could help to shed light on their disparate and unequal experiences within the healthcare industry. More broadly, encouraging the participation of *all* injured patients and their families allows members of these vulnerable communities to actively contribute and shape their healthcare institutions. Research has revealed the importance of developing community-based partnerships and allowing members of the community to work with healthcare institutions to identify their concerns and health care needs.⁴⁷²

Sixth, the institution should implement a system to track data and evaluate performance.⁴⁷³ To learn from past mistakes and to ensure quality, the institution needs to track and compile data after the adverse event. Collected data should include the "type of patient safety incident, investigations, disclosure, financial, legal and public relations implications of the event, system improvements, and [the] number and quality of [encounters with patient communication consultants]."⁴⁷⁴ This data can be used for various purposes, including "internal quality assurance, research, public outreach and dissemination."⁴⁷⁵

Finally, in order to improve transparency and open communication, the healthcare institution should introduce education and training on medical error and the resulting patient harm.⁴⁷⁶ For CRPs to be effective and take root in healthcare institutions, they must overcome healthcare's strong "deny and

⁴⁶⁹ See, e.g., Pope et al., *supra* note 69, at 1168 (reporting statistically significant multivariable findings that hospitals were more likely to fail to hospitalize women under fifty-five and people of color despite presenting symptoms of acute cardiac ischemia).

⁴⁷⁰ See, e.g., Doroshow & Widman, *supra* note 172, at 168-70 (noting that, aside from worse health outcomes, marginalized communities are likely to receive less money in economic damages for medical error because of generally lower wages).

⁴⁷¹ See Frakt, supra note 283 (explaining link between trust and health care outcomes for racial and ethnic minorities).

⁴⁷² See, e.g., Rachel Parrill & Bernice Roberts Kennedy, *Partnerships for Health in the African American Community: Moving Toward Community-Based Participatory Research*, 18 J. CULTURAL DIVERSITY 150, 152-53 (2011) (explaining the benefits of community-based participatory research).

⁴⁷³ See McDonald et al., supra note 115, at e13.

⁴⁷⁴ *Id.* (describing patient communication consultants more in detail in the third pillar of communication and disclosure).

⁴⁷⁵ *Id.* (continuing that this data is reported to the UIMCC administration on a quarterly basis).

⁴⁷⁶ See id. ("To improve transparency, the UIMCC has established initial and continuing training requirements for professional, administrative and support staff—the seventh pillar.").

defend" culture and focus on developing institutional buy-in and support.⁴⁷⁷ Offering education and training can help to start to raise awareness and move towards a culture that is supportive of open communication and transparency.⁴⁷⁸

These seven principles represent the core aspects that should be present when using a CRP but may be adapted or modified to best suit the needs of a particular healthcare institution.⁴⁷⁹ Introducing a CRP requires time, an institutional commitment, and the tools necessary to successfully address error. For healthcare providers interested in adopting a CRP approach, the Agency for Healthcare Research and Quality has created the Communication and Optimal Resolution ("CANDOR") toolkit.⁴⁸⁰ CANDOR (which simply adds "Optimal" to the CRP acronym) refers to a process that healthcare institutions and practitioners can use to respond to medical error in a "timely, thorough, and just way."⁴⁸¹ Programs like CANDOR that encourage apologies and disclosure within individual hospitals have been shown to produce better outcomes and yield substantial savings on ligation costs.⁴⁸²

The development of the Betsy Lehman Center, UMHS, and UIMCC shows that certain states and institutions recognized a need to step in and provide guidance and support as to how to address medical errors beyond simply enacting an apology law. However, individual state response to medical error is fragmented at best. Without federal legislation or a coordinated response, states have passed their own laws and policies to tackle the harm caused by medical error.⁴⁸³ But not all states have protected apologies, and some have chosen not to introduce an apology law.⁴⁸⁴

⁴⁷⁷ See id. (discussing wide variety of trainings to utilize including "annual competency assessments, monthly organisation-wide patient safety and [patient communication consultation] educational programmes, grand rounds, unit-specific patient safety and disclosure training, and train-the-trainer programmes").

⁴⁷⁸ See id.

⁴⁷⁹ For example, UMHS lists seven steps for addressing medical error, but they do not map directly onto these seven pillars. *The Michigan Model: Medical Malpractice and Patient Safety at Michigan Medicine*, UNIV. OF MICH. HEALTH, https://www.uofmhealth.org/michigan-model-medical-malpractice-and-patient-safety-umhs [https://perma.cc/S3PC-XN3J] (last visited Jan. 16, 2022).

⁴⁸⁰ Communication and Optimal Resolution (CANDOR), AGENCY FOR HEALTHCARE RSCH. & QUALITY, https://www.ahrq.gov/patient-safety/capacity/candor/index.html [https://perma.cc/33VY-D4FG] (last reviewed April 2018) (containing eight modules and additional case studies to assist CRP implementation).

⁴⁸¹ *Id.* (contrasting CANDOR process with "deny and defend" strategies).

⁴⁸² See Ho & Liu, *supra* note 315, at 188-89 (finding in aggregate that "cases in states with the [apology] law have payments that are \$32,342 (12.8 percent) less than cases in states before the law was passed or where the law was never passed").

⁴⁸³ See discussion supra Sections IV.A.1-2 (discussing individual state approaches to apology laws).

⁴⁸⁴ See Hicks & McCray, supra note 308.

The aforementioned research suggests the potential power and importance of both an apology and an explanation when harm occurs.⁴⁸⁵ Even so, mere half-hearted or unexplained apologies to avoid liability are not enough to address the harm that has occurred or reduce the numbers of liability claims.⁴⁸⁶ CRPs offer a more adequate approach to addressing harm, reducing errors, and decreasing medical liability litigation.⁴⁸⁷ CRPs involve communicating with patients and their families about adverse events. CRPs include an apology when an investigation reveals that inappropriate care caused the harm, handle the emotional state of patients and their families, and finally make changes within the system to prevent the reoccurrence of error.⁴⁸⁸

CONCLUSION

This Article examined the persistence of medical error within the healthcare system since the publication of *To Err Is Human*. In doing so, this Article explained how medical error went from being a "hot topic" with a burst of activity revolving around efforts to reduce error—just after the IOM's report—to a fragmented and inconsistent system burdened by a history of "deny and defend" and consistent, disproportionate harm to vulnerable communities. This Article reviewed medical error through the issue of harm—who is being harmed and why—but also explored the human nature of error and why apologizing and accepting responsibility is necessary to create a safer system overall.

In order to successfully address medical error, there needs to be federal legislation to support strong state apology laws and the availability of federal funds for states to develop and encourage more widespread use of communication and resolution programs. Federal support to supplement or preempt state apology laws is needed to ensure that healthcare providers are able to apologize, admit fault, and take responsibility for their errors. Despite the benefits of apologies, and the importance that healthcare providers are protected from liability, apologies alone will not sufficiently reduce rates of medical error. Alongside this federal support of apology legislation, federal funds should be made available to encourage and expand the use of CRPs within the healthcare field. CRPs do not just help healthcare professionals apologize and recognize harm but create a structure to adequately address the harm that occurred, allow for open communication with patients and their families, determine what led to

⁴⁸⁵ See discussion supra Section IV.A.4 (discussing efficacy of apology laws).

⁴⁸⁶ See Robbennolt, *supra* note 125, at 485-90 (finding that partial apologies often fail to achieve significantly different results from no apology at all but that full apologies achieve significantly different results with high frequency).

⁴⁸⁷ See Boothman et al., *supra* note 392, at 158 (observing decreased litigation costs caused by forcing patient's counsel to assume conversational, not adversarial, role in negotiations through use of CRP principles); Mello et al., *supra* note 154, at 27-29 (discussing reduction of liability costs, insurance premiums, and harmful errors).

⁴⁸⁸ See generally BETSY LEHMAN CTR. REPORT, *supra* note 41 (summarizing effectiveness of CRPs at managing emotional damage and leading to concrete changes in medical process).

the error, and make changes to the healthcare system to prevent the reoccurrence of the harm. Passing federal guidelines or recommendations for apology legislation and expanding the use of CRPs offers a one-two punch to ensure that the various harms caused by error are addressed. It is not enough to simply apologize; the underlying and existing harms must be addressed.

It is impossible to eliminate all medical error or even the role-however slight-that healthcare professionals play in their occurrence. Errors will occur and patients will be harmed. Consequently, it is important to handle this harm appropriately-to disclose what happened, acknowledge the harm done, and start to rebuild trust. Considerable research has shown that not only is the traditional approach of "deny and defend" ineffective, but it results in poorer outcomes for both sides.⁴⁸⁹ More recent studies reflect the importance of using CRPs, transparency, and open communication when faced with medical errors.⁴⁹⁰ A major barrier to implementing CRPs or revealing an error is fear of a lawsuit or liability. Despite these fears, emerging research indicates that disclosing an error and using a CRP helps to reduce malpractice suits.⁴⁹¹ CRPs also contain the potential to salvage-and even strengthen-the physicianpatient relationship and produce better outcomes for all those involved. The ability to rebuild trust in the physician-patient relationship is critical, particularly for vulnerable communities who frequently bear a disproportionate share of health and safety problems.⁴⁹² As society strives to create safer healthcare systems overall, it is key to keep in mind that error is a human problem, that vulnerable populations disproportionately suffer and often have the most to lose within the healthcare space, and that the successful reduction of error depends on integrating approaches—like CRPs—that treat patients with openness, honesty, and respect.

⁴⁸⁹ See, e.g., Boothman et al., *supra* note 392, at 129 ("Deny and defend is an incredibly inefficient and costly (financially, emotionally, and otherwise) response to patient complaints."); Helmchen et al., *supra* note 143, at 115 (noting that "deny and defend" creates worse outcomes by erroneously assuming zero-sum nature of negotiations between medical center and aggrieved patient); Mello et al., *supra* note 154, at 24 (illustrating economic and psychological harms to hospital and physicians caused by "deny and defend" approach).

⁴⁹⁰ See, e.g., Lambert et al., *supra* note 124, at 2507-08 (summarizing findings of increased event reports and decreased settlement costs (overall and on a per claim basis) in connection with implementation of CRP); Lauren E. Lipira & Thomas H. Gallagher, *Disclosure of Adverse Events and Errors in Surgical Care: Challenges and Strategies for Improvement*, 38 WORLD J. SURGERY 1614, 1617-19 (2014) (implying the importance of improved disclosure in surgical care settings); Mello et al., *supra* note 154, at 27-29 (drawing concrete lessons from successful CRPs including the importance of internal "committed champions" for the idea).

⁴⁹¹ See Lambert et al., *supra* note 124, at 2508 (finding decrease in number of malpractice claims following implementation of CRP); McDonald et al., *supra* note 115, at e13 (observing that since adoption of CRP principles, hospital "has seen no increase in lawsuits and no increase in payouts . . . related to full disclosure").

⁴⁹² See supra note 173 and accompanying text.