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## ARTICLES

### **The Epidemic of Children’s Dental Diseases: Putting Teeth into the Law**

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## INTRODUCTION

Children in the United States suffer from an epidemic of poor dental health. The Surgeon General issued a detailed report on dental health in 2000, explaining the epidemic of pediatric tooth decay and cavities.<sup>1</sup> Unfortunately, such problems persist.<sup>2</sup> This epidemic is almost entirely preventable, costly to society, and cost-effective to remedy. Dental disease is a problem ripe for the use of societal resources. While some progress in controlling this health crisis has occurred since the Surgeon General issued his report, many remaining problems appear intractable in the current healthcare system. Addressing them requires substantive changes. Because these changes are partly legal in nature, this dental epidemic cries out for action and requires altering the legal framework of pediatric dental care by implementing the following changes: (1) expanding licensing for alternative caregivers; (2) simplifying reimbursement procedures for Medicaid; and (3) creating regulatory structures that educate and encourage parents to provide the necessary preventive care. Furthermore, U.S. policymakers need to consider providing dental care in schools, especially for children who live in poverty. This policy would make it easier for families to obtain access to care and has been adopted in New Zealand with great success in outcomes and cost-effectiveness, receiving noteworthy attention worldwide.<sup>3</sup>

Children's dental health is critically important to their overall health and successful development into high-functioning adults.<sup>4</sup> Protecting it is straightforward and cost effective.<sup>5</sup> When left untreated, dental disease undermines a child's well-being.<sup>6</sup> Diseases such as tooth decay and cavities are debilitating in themselves and can lead to other problems such as constant pain, malnourishment, loss of teeth, and in adulthood, increased risk of cardiac problems and diabetes.<sup>7</sup> If severe enough, dental decay and cavities cause

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1. See U.S. PUBLIC HEALTH SERVICE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ORAL HEALTH IN AMERICA: A REPORT FROM THE SURGEON GENERAL 1 (2000) [hereinafter REPORT FROM THE SURGEON GENERAL], available at <http://silk.nih.gov/public/hck1ocv.@www.surgeon.fullrpt.pdf>.

2. See Regina Benjamin, *Oral Health: The Silent Epidemic*, 125 PUB. HEALTH REP. 158 (2010), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2821841>.

3. D.A. Nash et al., *Dental Therapists: A Global Perspective*, 58 Int'l Dental J. 61, 63 (2008). Currently, fifty-three countries utilize dental therapists in programs modeled, at least in part, on New Zealand's system. *Id.*

4. See Benjamin, *supra* note 2, at 158 (stating that carried and periodontal disease, left untreated, "may cause pain, dysfunction, poor appearance, loss of self-esteem, absence from school or work, and difficulty concentrating on daily tasks").

5. *Id.* (calling dental carries and periodontal disease "largely preventable").

6. Dental decay and cavities are the most common unmet medical needs of children. See Paul W. Newachek et al., *The Unmet Health Needs of America's Children*, 105 PEDIATRICS 989 (2000), as cited in CENTERS FOR MEDICARE & MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, GUIDE TO CHILDREN'S DENTAL CARE IN MEDICAID 2 (2004), available at <http://www.cms.gov/MedicaidDentalCoverage/Downloads/dentalguide.pdf>.

7. See discussion accompanying *infra* notes 40-52.

infections that can even result in death.<sup>8</sup> Pain itself may overshadow childhood, making it difficult to learn, attend school,<sup>9</sup> and develop socially.<sup>10</sup>

A consensus exists regarding the proper steps for adequate preventive care, and there is very little risk to children from receiving this care.<sup>11</sup> These steps are simply not taken for many children. The problems caused by inadequate pediatric preventive dental care are well-known in public health spheres.<sup>12</sup> The federal government, numerous state governments, and the American Dental Association (ADA) have funded research and pilot programs at federal, state, and local levels.<sup>13</sup> This work has continued for some time, sustained by the promulgation of the Surgeon General's report in 2000, the issuance of the Oral Health Initiative 2010,<sup>14</sup> and a child's widely reported death from tooth decay in 2007.<sup>15</sup> The prospective oral health objectives for Healthy People 2020, under development by the Department of Health and Human Services (HHS), will further increase public awareness. Yet, even as a multitude of interested stakeholders attempt to ameliorate these problems, the statistics remain poor.<sup>16</sup> The dental health infrastructure in the United States is still not getting dental care to children in a consistent and timely manner.

From a legal perspective, this epidemic makes little sense, which may explain why it is so rarely discussed in the legal literature. When one thinks of dental care for children, certain simple steps come to mind, such as brushing, flossing, and seeing a dentist twice a year. The problems associated with acquiring regular tooth cleanings can seem minor, uninteresting, and not difficult to overcome. Most affluent children are raised with adequate access to preventive care, and the families of such children certainly have the resources to access necessary treatment if preventive care is not provided and a problem arises. Moreover, for children living in poverty, the federal laws and regulations that

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8. See PEW CTR. ON THE STATES, THE COST OF DELAY: STATE DENTAL POLICIES FAIL ONE IN FIVE CHILDREN 2 (2010), available at [http://www.pewcenteronthestates.org/uploadedFiles/Cost\\_of\\_Delay\\_web.pdf](http://www.pewcenteronthestates.org/uploadedFiles/Cost_of_Delay_web.pdf).

9. See CENTERS FOR MEDICARE & MEDICAID SERVICES, *supra* note 6, at 3. A REPORT FROM THE SURGEON GENERAL, *supra* note 1, at 158, as cited in AM. ACAD. PEDIATRIC DENTISTRY, POLICY ON ABSENCES FROM SCHOOL FOR DENTAL APPOINTMENTS 31 (2010), available at [http://www.aapd.org/media/Policies\\_Guidelines/P\\_SchoolAbsences.pdf](http://www.aapd.org/media/Policies_Guidelines/P_SchoolAbsences.pdf).

10. See PEW CTR. ON THE STATES, *supra* note 8, at 2.

11. See discussion *infra* Part I.

12. See, e.g., REPORT FROM THE SURGEON GENERAL, *supra* note 1, at 63-67 (describing the prevalence of periodontal diseases, tooth loss, and racial and socioeconomic disparities).

13. See *id.* at 249.

14. See U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, HHS ORAL HEALTH INITIATIVE 2010, at 3 (2010), available at <http://www.hrsa.gov/publichealth/clinical/oralhealth/hhsinitiative.pdf>.

15. See Mary Otto, *For Want of a Dentist*, WASH. POST, Feb. 28, 2007, at B01.

16. See GENERAL FROM THE SURGEON GENERAL, *supra* note 1, at 63-64. This is not meant to deny that improvements have occurred in the last twenty years, as will be discussed below, but rather that the problem is still quite large even in light of these improvements.

govern the Medicaid program require states to provide coverage for all necessary preventive dental care.<sup>17</sup> On the surface, this would seem to solve the problem of inadequate dental care for children.

Unfortunately, the challenges of maintaining dental health in many children's lives are significant, and the current legal framework for the provision of pediatric dental care is insufficient to ensure adequate delivery. There is a serious shortage of dentists qualified to treat children.<sup>18</sup> Public and private dental insurance do not function well, and the federal government has committed significant financial resources to addressing the problem of poor parental understanding of the importance of adequate preventive care for children.<sup>19</sup> These problems explain the persistence of the epidemic and also hint at the laws that may be supporting the continuation of this inadequate system. It is unlikely that the United States will achieve the ideal of universal treatment without significant legal changes, and this Article delineates areas where these changes need to occur.

Data indicate that there is a greater incidence of pain from decay and cavities in children from families who are financially disadvantaged or of certain racial or ethnic backgrounds.<sup>20</sup> Furthermore, for these vulnerable children, the twin diseases of dental decay and cavities can cause or compound other problems. For example, children whose families earn less than \$10,000 a year have twelve times more "restricted activity days" (including days missed from school) due to dental pain than children from wealthier families.<sup>21</sup> Additionally, such children will suffer through many more days in pain while attending school, which negatively affects their in-school performance.<sup>22</sup> These issues have a predictable, detrimental impact on children's lives. Untreated dental disease can cripple a child's efforts to function well and undermine societal efforts to improve these children's lives.

While much of this Article, like most research in this area, is focused on children from impoverished families or those from historically disadvantaged ethnic backgrounds, all people have an increased vulnerability to dental diseases

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17. See CENTERS FOR MEDICARE & MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, THE STATE MEDICAID MANUAL 9 (2005), available at <http://www.cms.gov/Manuals/PBM/itemdetail.asp?itemid=CMS021927>.

18. See Michelle R. McQuistan et al., *General Dentists' Referrals of 3- to 5-Year-Old Children to Pediatric Dentists*, 137 J. AM. DENTAL ASS'N 653, 653 (2006).

19. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 399, 124 Stat. 119 (2010) [hereinafter PPACA].

20. See generally UNITED STATES GENERAL ACCOUNTING OFFICE, REPORT TO CONGRESSIONAL REQUESTERS: ORAL HEALTH: DENTAL DISEASE IS A CHRONIC PROBLEM AMONG LOW-INCOME POPULATIONS 4 (2000) [hereinafter ORAL HEALTH], available at <http://www.gao.gov/new.items/he00072.pdf>; PEW CTR. ON THE STATES, *supra* note 8, at 14-15.

21. See *id.* at 9.

22. See PEW CTR. ON THE STATES, *supra* note 8, at 2.

when they do not receive adequate preventive care,<sup>23</sup> change should not focus solely on those from known vulnerable groups. Children are, by definition, dependent and vulnerable to choices adults make for their lives. Studies show that even in the most financially privileged families, nearly 30% of children ages six to eighteen have not seen a dentist in the past year, and that almost 60% of children ages two to five have not seen a dentist in the past year.<sup>24</sup> Though the wealthiest children miss few days from school due to dental problems, the cumulative effects of poor dental care in childhood can lead to expensive and potentially debilitating costs in their adult lives.<sup>25</sup> This is especially unsettling given how preventable this damage is.

There are other causes for dental problems besides access to preventive care. Two examples are the high amounts of sugar in children's diets<sup>26</sup> and the lack of fluoride in some community water systems.<sup>27</sup> In addition, preventive care cannot entirely avert the occurrence of periodontal diseases. This Article primarily focuses on preventive care, but systematic approaches to addressing all of these harms require further study from a legal perspective.

This epidemic is ripe for legal analysis in light of recent legislation to broaden health care coverage. The Patient Protection and Affordable Care Act (PPACA) contains significant potential new funding streams for providing dental care to children and educating parents about dental care's importance.<sup>28</sup> If there are structural, legal impediments to achieving universal care, the opportunity presented by this funding will not be utilized properly. The challenge of achieving universal pediatric preventive dental care at this time of broader reform offers an opportunity to create a model of how access and quality can be achieved in a cost-effective manner.

Part I of this Article explains the elements of good pediatric preventive dental care, the known problems caused by a failure to receive this care, and the prevalence of children failing to receive it. It also identifies the particularly vulnerable populations that suffer from these problems in greater numbers than the general population of children. Part II explains the current dental infrastructure, focusing on structural problems that impede children's access to timely care. Part III examines current reform activity, and Part IV contains proposals for further reform, focusing on the necessary legal changes and

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23. See Benjamin, *supra* note 2.

24. See ORAL HEALTH, *supra* note 20, at 15.

25. See, e.g., PEW CTR. ON THE STATES, *supra* note 8, at 2.

26. The effect of high consumption of sugar on dental disease is actually quite limited in developed countries with access to fluoridated water, with the exception of a significant correlation between increased risk of dental cavities and high consumption of sugar in drinks, such as soda or sweetened fruit drinks at age 3. See Teresa A. Marshall et al., *Comparison of the Intakes of Sugars by Young Children With and Without Dental Caries Experience*, 138 J. AM. DENTAL ASS'N 39, 42 tbl.1 (2007).

27. See *infra* Section II.A.

28. See PPACA, Part T-Oral Healthcare Prevention Activities, 124 Stat. 550 (2010).

corresponding impediments. Part V discusses impediments to adoption of the Article's proposal. Part VI concludes by arguing for a significant change to the infrastructure for providing dental care in order to achieve universal preventive care for all children.

## I. THE COSTS OF POOR DENTAL HEALTH IN CHILDREN

### A. Defining Good Dental Health and Proper Pediatric Preventive Care

As medical science progresses, it is increasingly clear that dental health is intrinsically bound to overall health. A basic program of preventive dental care for children consists of twice yearly examinations and tooth cleanings when teeth start to emerge,<sup>29</sup> fluoridated drinking water supplies in the community,<sup>30</sup> and brushing and flossing twice daily.<sup>31</sup> Studies show that this program's effectiveness is enhanced by the use of both professional topical fluoride applications provided to children (who are at moderate risk) by a dentist during the biannual visit<sup>32</sup> as well as "pit and fissure sealants" on emerging molars to prevent decay or cavity development.<sup>33</sup> While some mouths require expensive orthodontia and interventions to fix damage due to accidental injuries, adhering to this basic plan in childhood may greatly reduce tooth decay, cavities, and loss of adult teeth throughout a person's life.<sup>34</sup> If preventive care is effective, it logically follows that universal adherence to it will greatly reduce these problems for an entire population. Medicaid's Early Periodic Screening, Diagnosis, and Treatment (EPSDT) standards, which describe a package of healthcare benefits that must be provided to children enrolled in Medicaid, include the recommendations described above, and every state's Medicaid program fully covers these preventive measures for all Medicaid-eligible children.<sup>35</sup> Most State Children's Health Insurance Programs (SCHIP), created to provide insurance for children of the working poor with family incomes above the level of Medicaid

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29. AM. ACAD. PEDIATRIC DENTISTRY, CLINICAL AFFAIRS COMM., GUIDELINE ON PERIODICITY OF EXAMINATION, PREVENTIVE DENTAL SERVICES, ANTICIPATORY GUIDANCE/COUNSELING, AND ORAL TREATMENT FOR INFANTS, CHILDREN, AND ADOLESCENTS 96 (AM. ACAD. PEDIATRIC DENTISTRY 2009) (1991), available at [http://www.aapd.org/media/Policies\\_Guidelines/G\\_Periodicity.pdf](http://www.aapd.org/media/Policies_Guidelines/G_Periodicity.pdf).

30. *Id.* at 94.

31. See REPORT FROM THE SURGEON GENERAL, *supra* note 1, at 8.

32. AM. ACAD. PEDIATRIC DENTISTRY, *supra* note 29, at 94.

33. Jean Beauchamp et al., *Evidence-based Clinical Recommendations for the Use of Pit-and-Fissure Sealants: A Report of the American Dental Association Council on Scientific Affairs*, 139 J. AM. DENTAL ASS'N 257, 257 (2008).

34. See Paul S. Casamassimo et al., *Beyond the DMFT: The Human and Economic Cost of Early Childhood Caries*, 140 J. AM. DENTAL ASS'N 650 (2009).

35. CTNS. FOR MEDICARE & MEDICAID SERVICES, *supra* note 7, at 6.

eligibility,<sup>36</sup> also cover this care.<sup>37</sup> The American Academy of Pediatric Dentistry publishes a “Periodicity Schedule,” which provides a detailed, age-tailored set of standards that is in full accord with the EPSDT standards.<sup>38</sup>

The statistics show a deep, persistent failure to meet these preventive care recommendations. While the numbers are not close to universal provision of care for any group, issues such as income disparities, racial and ethnic identity, and homelessness greatly increase the likelihood that a child is not receiving the proper care.<sup>39</sup>

### *B. Problems Caused by Poor Dental Health in Children*

#### *1. Death from Infection and Increased Risk of Other Serious Medical Conditions*

Death in a developed country from an entirely preventable and easily treatable problem such as dental decay may seem absurd, but it is a real risk when children do not receive appropriate preventive dental care.<sup>40</sup> Dental decay and cavities, if left untreated, often lead to infections in the mouth. Moreover, without treatment, these infections may spread to other parts of the body. Deaths have occurred when infections that start in the mouth spread to the brain.<sup>41</sup> While fatalities caused by dental infections are rare, it has been hypothesized that the incidence of these deaths in children are most likely under-reported, with the cause of death listed as a brain infection rather than the underlying dental infection that caused it.<sup>42</sup> The tragic case of Deamonte Driver, a twelve-year-old boy who died on February 25, 2007, from a brain infection caused by an infected

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36. For a discussion of the SCHIP program and its history, see generally Sara Rosenbaum, Anne Markus, & Colleen Sonosky, *Public Health Insurance Design for Children: The Evolution from Medicaid to SCHIP*, 1 J. HEALTH & BIOMEDICAL L. 1 (2004).

37. See generally Letter from Cindy Mann, Director of the Center for Medicaid and State Operations, to State Health Official[s], Re: Dental Coverage in CHIP 2 (Oct. 7, 2009), available at <http://www.cms.gov/smdl/downloads/SHO100709.pdf>. SCHIP (State Children’s Health Insurance Program) and CHIP (Children’s Health Insurance Program) are joint federal/state programs designed to provide health care to children who are from financially stressed families but who are not entitled to Medicaid. See Rosebaum, Markus, & Sonosky, *supra* note 39, at 17.

38. See American Academy of Pediatric Dentistry, Guideline on Periodicity of Examination, Preventative Dental Services, Anticipatory Guidance/Counseling, and Oral Treatment for Infants, Children, and Adolescents, 31 AAPD REFERENCE MANUAL 118, 118 (1991, rev. 1992, 1996, 2000, 2003, 2007, 2009), available at [http://www.aapd.org/media/Policies\\_Guidelines/G\\_Periodicity.pdf](http://www.aapd.org/media/Policies_Guidelines/G_Periodicity.pdf).

39. See REPORT FROM THE SURGEON GENERAL, *supra* note 1, at 74.

40. See SHELLY GEHSAN ET AL., FILLING AN URGENT NEED: IMPROVING CHILDREN’S ACCESS TO DENTAL CARE IN MEDICAID AND SCHIP 1 (2008), available at <http://www.kff.org/medicaid/upload/7792.pdf>.

41. For example, the mouth does not exist in isolation and is particularly close to the brain; infections of the sinuses, ear canals, and dental structures can all result in brain infections. See Itzhak Brook, *Topical Review: Brain Abscess in Children: Microbiology and Management*, 10 J. CHILD NEUROLOGY 283, 283 (1995).

42. See Casamassimo et al., *supra* note 34, at 652-53.

tooth, is perhaps the best-known example of this type of fatality.<sup>43</sup> His tooth decay was entirely preventable. A tooth extraction, once the decay had reached a serious level, would have cost eighty dollars<sup>44</sup> Left untreated, Deamonte's cavity led to an abscess in his mouth, and the bacteria from the abscess spread to his brain.<sup>45</sup> The infection became serious enough before any medical treatment was provided that, despite extensive brain surgery and a lengthy hospitalization, the damage proved irreparable, leading to the young boy's death.<sup>46</sup>

The risk of death and other health dangers spring from the intimate relationship between the mouth and the rest of the body's functioning. Wounds to teeth and gums from decay and the loss of permanent teeth create portals by which bacteria enter the body.<sup>47</sup> This is a well-established fact in medical literature.<sup>48</sup> Dental decay, poor gum health, and untreated cavities place stress on the body's immune system, making it more vulnerable to many unrelated illnesses.<sup>49</sup> Medical research is currently finding many instances where poor oral health has a serious effect on other health problems such as heart disease, diabetes,<sup>50</sup> and obesity.<sup>51</sup> Thus, the health of the mouth is intertwined with the general health of a person, and dental problems that begin in childhood have long-term, negative effects throughout a person's life.<sup>52</sup>

## 2. Pain and Its Known Costs

For children, the persistent pain of untreated dental problems is particularly poignant and costly. Pain decreases the quality of a child's life, interrupting her

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43. See Otto, *supra* note 15. While Deamonte's case is probably the best-known recent example of a child dying from untreated dental decay, unfortunately, there have been other reports of similar tragic occurrences. For instance, Alexander Callender, a six-year-old boy who lived in Mississippi, died in 2007 from sepsis caused by an infected tooth. It is suspected that many more children have died from dental problems, but the reporting is not accurate, since dental decay directly leads to, but is not the ultimate "cause" of, the death. See Casamassimo et al., *supra* note 34, at 652.

44. See Otto, *supra* note 15.

45. *Id.*

46. *Id.*

47. See REPORT FROM THE SURGEON GENERAL, *supra* note 1, at 104.

48. *Id.*; see also L. Feldman & I.M. Trace, *Subacute Bacterial Endocarditis Following the Removal of Teeth or Tonsils*, 11 ANNALS INTERNAL MED. 2124 (1938), available at <http://annals.org/content/11/12/2124.extract>.

49. See *Linkages with General Health, The Mouth as a Portal of Entry for Infection*, in REPORT FROM THE SURGEON GENERAL, *supra* note 1, at 104.

50. See REPORT FROM THE SURGEON GENERAL, *supra* note 1, at 95; PEW CTR. ON THE STATES, *supra* note 8, at 2.

51. See Univ. Buffalo, News Release, *Decay of Baby Teeth May be Linked to Obesity, Poor Food Choices, Study Suggests*, (June 22, 2010), available at <http://www.buffalo.edu/news/11463>; see also Brita Willerhausen et al., *Association Between Body Mass Index and Dental Health in 1,290 children of Elementary Schools in a German City*, 11 CLINICAL ORAL INVESTIGATIONS 195 (2007).

52. See ORAL HEALTH, *supra* note 20, at 9–11.

ability to learn, play, eat, and sleep.<sup>53</sup> While children who suffer from chronic pain can live fulfilling and productive lives,<sup>54</sup> it is certainly more difficult for them to do so. Persistent dental pain from untreated decay and cavities comes, first and foremost, from inattention to a child's medical needs. It is both preventable and treatable; this may indicate that the child already suffers from a lack of appropriate, effective attention and care giving.<sup>55</sup> In these circumstances, it is highly unlikely that the child will have access to additional support that can limit the pain's impact.

Dental pain causes children to stay home from school.<sup>56</sup> For those children whose parents are unable to gain access to timely dental interventions, these missed days add up. However, even when pain does not result in time away from school, the time spent in school is markedly less productive.<sup>57</sup> Pain interferes with a child's ability to concentrate, reducing the value of time spent in school.<sup>58</sup> It is exhausting and diminishes a child's energy for the difficult tasks of a full day of school. Furthermore, pain in the mouth leads to a decreased ability to eat healthy foods.<sup>59</sup> For children who are not properly fed at home, the free-food programs in school are of greatly reduced value when the food is not consumed because of dental problems.<sup>60</sup> Poor food intake exacerbates the effects of pain on concentration and energy and leads to malnutrition.<sup>61</sup>

Pain also disrupts the development of a child's intellectual capacity that takes place apart from schooling.<sup>62</sup> Developmental psychiatry has long

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53. See PEW CTR. ON THE STATES, *supra* note 8, at 2 (explaining that poor dental health has adverse effects on growth and development as well as overall health).

54. For a discussion of the way children lead full lives while suffering from chronic pain, see Tonya Mizell Palermo, *Impact of Recurrent and Chronic Pain on Child and Family Daily Functioning: A Critical Review of the Literature*, 21 J. DEVELOPMENTAL & BEHAV. PEDIATRICS 58, 58 (2000).

55. See, e.g., Alfred M. Burns, Parental Stress as a Co-Morbidity of Severe Early Childhood Caries (2009) (unpublished M.S. thesis, The Ohio State University), available at <http://etd.ohiolink.edu/send-pdf.cgi/Burns%20Alfred%20M.pdf?osu1241624634> ("Extensive literature has proven decay and poor oral health is high among children with a history of abuse or neglect.").

56. See ORAL HEALTH, *supra* note 20.

57. See *id.* at 9-10.

58. See *id.* at 7; REPORT FROM THE SURGEON GENERAL, *supra* note 1, at 2.

59. See generally REPORT FROM THE SURGEON GENERAL, *supra* note 1. Supporting the idea that dental disease can lead to problems eating, see Martha Clarke et al., *Malnourishment in a Population of Young Children with Severe Early Childhood Caries*, 28 PEDIATRIC DENTISTRY 254 (2006), available at <http://www.ingentaconnect.com/content/aapd/pd/2006/00000028/00000003/art00006> (showing a correlation between high levels of cavities in children and malnutrition).

60. These food programs are provided with funding from the federal government. See The Healthy, Hunger-Free Kids Act of 2010, Pub. L. No. 111-296, 124 Stat. 3183 (codified as amended at 42 U.S.C. § 1751).

61. See NATIONAL MATERNAL & CHILD ORAL HEALTH RESOURCE CENTER, ORAL HEALTH AND LEARNING: WHEN CHILDREN'S HEALTH SUFFERS, SO DOES THEIR ABILITY TO LEARN 2 (2003), available at <http://www.mchoralhealth.org/PDFs/learningfactsheet.pdf>.

62. See PEW CTR. ON THE STATES, *supra* note 8, at 2.

recognized the importance of play and other childhood activities for the development of intelligence and other social skills.<sup>63</sup> Often, pain greatly interferes with a child's ability to play, thus detracting from a child's ability to garner the intellectual development provided by this activity.<sup>64</sup>

It is through play and school involvement that children develop social skills, and pain diminishes a child's ability to cultivate these skills. Furthermore, untreated dental decay and cavities may result in disfigurement, ranging from misshapen smiles to foul odors. Apart from the problems caused by pain and discomfort, these effects likely have a detrimental effect on a child's social development.

### 3. Poor General Health into Adulthood

Lack of proper preventive care in childhood greatly increases an adult's risk of losing permanent teeth during adulthood.<sup>65</sup> There is a significant association between the number of missing permanent teeth and an adult's increased risk of developing heart disease.<sup>66</sup> This association holds true even when the numbers are adjusted to accommodate numerous other factors, such as age, race, alcohol use, obesity, and hypertension.<sup>67</sup>

The adult dental care required to fix the problems caused by poor childhood dental care is more expensive than providing the preventive care prior to the development of decay. Replacing a lost tooth with an implant, for example, may cost thousands of dollars<sup>68</sup> and requires surgery.<sup>69</sup> The failure to provide care in childhood leads to an increased burden of reduced education, reduced social development skills, and the social stigma of having missing teeth. Finally, adults with significant untreated dental problems are often in a great deal of pain, thus

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63. Kenneth R. Ginsburg et al., *The Importance of Play in Promoting Healthy Child Development and Maintaining Strong Parent-Child Bonds*, 119 PEDIATRICS 182, 191 (2007); Lev Vygotsky, *Play and Its Role in the Mental Development of the Child*, 6 VOPROSY PSIKHOLOGII (Nate Schmolze trans., 2002) (1966), available at <http://www.marxists.org/archive/vygotsky/works/1933/play.htm> (cited more than 700 times).

64. For example, in a study assessing the effect of cancer on a child's ability to play, on a scale of 1 to 100 (100 being normal, measured by siblings without cancer and other children), the mean for children with cancer was 75.4, compared to 97.4 for other children. See Shirley B. Lansky et al., *The Measurement of Performance in Childhood Cancer Patients*, 60 CANCER 1651, 1651 (1987).

65. See ORAL HEALTH, *supra* note 20, at 9-11 (explaining that decay and gum disease lead to tooth loss).

66. See Catherine A. Okoro et al., *Tooth Loss and Heart Disease: Findings from the Behavioral Risk Factor Surveillance System*, 29 AM. J. PREVENTIVE MED. 50 (2005).

67. See Okoro et al., *supra* note 66, at 50.

68. See Greg Johnstone, *Dental Implants Cost and Candidacy: Is Implant Dentistry Worth It?*, CONSUMER GUIDE TO DENTISTRY, <http://www.yourdentistryguide.com/implant-procedures> (updated Mar. 25, 2011).

69. See *id.*

suffering from a decreased ability to function properly in their own lives.<sup>70</sup>

Approximately 22% of adults in the United States experienced dental pain in early 2003.<sup>71</sup> Fifty-three million Americans currently have decay in adult teeth.<sup>72</sup> For adults aged nineteen to sixty-four with family incomes of less than \$10,000 a year, “nearly one in two had at least one decayed tooth that had not been treated.”<sup>73</sup> Tooth loss, which has been closely correlated with increased risk of heart disease,<sup>74</sup> is prevalent in adults at all income levels, though at increased rates for those who live in poverty. For those with family incomes of \$35,000 or more a year, for example, only 51% have all of their teeth, 34% have lost one to five teeth, and 13% have lost six or more of their teeth.<sup>75</sup> For poorer Americans, the problem increases in severity. For those family incomes of less than \$15,000 a year, 34% have all of their teeth, 30% have lost one to five teeth, and 34% have lost six or more teeth.<sup>76</sup>

### *C. Prevalence of Dental Disease Increases Among Vulnerable Populations of Children*

While it is easy to explain, in theory, how important preventive dental care is for children, a call for widespread legal reform would be unjustified without evidence of the substantial “real life” problems caused by failures in pediatric dental care. Unfortunately, this evidence is too easy to find. As is often stated, there is an epidemic of untreated dental decay and cavities in children of the United States, and the epidemic’s prevalence in this population exceeds any other single health threat, including asthma, diabetes, and obesity.<sup>77</sup> Generally, access to preventive dental care is far from universal, and there are vulnerable subsets, primarily identifiable by poverty level and ethnicity, with an increased risk of harm.

Untreated dental pain can have harsh consequences for the children not receiving care. As discussed above, it may diminish quality of life and schoolwork<sup>78</sup> as well as lead to other health problems throughout the body,<sup>79</sup>

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70. See ORAL HEALTH, *supra* note 20 (describing how poor dental health and tooth decay can negatively impact activities like going to work).

71. See Richard H. Carmona, U.S. Surgeon Gen., National Oral Health Call to Action (Apr. 29, 2003), available at <http://www.surgeongeneral.gov/news/speeches/oralhealth042903.htm>.

72. DIVISION OF ORAL HEALTH, CTRS. FOR DISEASE CONTROL AND PREVENTION, *Oral Health: Preventing Cavities, Gum Disease, and Tooth Loss* (2010), available at <http://www.cdc.gov/nccdphp/publications/aag/doh.htm>.

73. See ORAL HEALTH, *supra* note 20, at 10.

74. See Hsin-Chia Hung et al., *The Association Between Tooth Loss and Coronary Heart Disease in Men and Women*, 64 J. PUB. HEALTH DENTISTRY 209, 209 (2004).

75. See ORAL HEALTH, *supra* note 20, at 11 tbl.2.

76. *Id.*

77. ORAL HEALTH, *supra* note 20, at 7; REPORT FROM THE SURGEON GENERAL *supra* note 9, at 2.

78. PEW CTR. ON THE STATES, *supra* note 8, at 2.

including death from infection.<sup>80</sup> Tooth decay and dental cavities are the most common chronic diseases of childhood<sup>81</sup> and are almost entirely preventable with simple treatments such as water fluoridation, dental sealants, fluoride toothpaste, and professionally applied topical fluorides.<sup>82</sup> Yet, as the statistics discussed below show, untreated dental problems are the single most prevalent unmet health need of children in the United States.<sup>83</sup> The lack of care is most obvious in children from low-income families, where as few as 20% of Medicaid-eligible children receive the bare minimum of dental care to which they are entitled.<sup>84</sup> However, even the wealthiest families fail to provide their children with appropriate preventive care.<sup>85</sup>

### 1. Family Income

Data regarding children's access to dental care are grim. Though the numbers of children who are suffering the ill effects of poor access to preventive dental care are quite large across the population, such numbers are largest in groups who already suffer from poverty or are historically less privileged. However, the problem of access to preventive pediatric dental care is not entirely explained by differences in family wealth. The group of children who receive care at the highest percentage of the population consists of children in families that are relatively well-off financially. But even in this segment of the population, preventive dental care is not universal. As of 2004, studies have shown that for families with incomes over \$75,000 a year, 14% of children had not seen a dentist in the past year.<sup>86</sup> The numbers receiving care then drop steadily with family income levels. Among all families with income that exceeds 200% of the federal poverty level, some reports show as few as 82% of those aged two to seventeen have seen a dentist in the past year. Twenty percent of children aged two to eleven had never seen a dentist.<sup>87</sup>

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79. GEHSAN ET AL., *supra* note 40, at 3.

80. *Id.*

81. Burton L. Edelstein, *Disparities in Oral Health and Access to Care: Findings of National Surveys*, 2 *AMBULATORY PEDIATRICS* 141, 141 (Supp. 2002).

82. Wendy E. Mouradian et al., *Disparities in Children's Oral Health and Access to Dental Care*, 284 *JAMA* 2625, 2625 (2000).

83. *Id.*; Newacheck et al., *supra* note 7, at 989.

84. Mouradian et al., *supra* note 82, at 2625.

85. CHILD TRENDS DATA BANK, UNMET DENTAL NEEDS tbl.1 (2004), available at [http://www.childtrendsdatabank.org/pdf/82\\_PDF.pdf](http://www.childtrendsdatabank.org/pdf/82_PDF.pdf).

86. *Id.*

87. Bruce A. Dye et al., *Trends in Oral Health Status: United States, 1988-1994 and 1999-2004*, CDL VITAL AND HEALTH STATISTICS SERIES II, at 28 tbl.19 (2007). These data include children ages 2 to 5—individuals who are far less likely to see a dentist than older children, which may skew the numbers in a negative direction. Still, according to the same study, almost 7% of all children ages 6 to 11 have never seen a dentist (from 1999–2004 data). *Id.* As described above, children should be seeing a dentist every 6 months, whereas this study only looks at whether a child has seen a dentist in the past 12 months. It simply does not tell us if the children who are seeing a

When family income is below 100% of the federal poverty level, the percentage of children ages six to eighteen that have not seen a dentist in the previous year is 64%.<sup>88</sup> For children with family incomes between 100% and 200% of the poverty level, the percentage is even worse, with 69% not having seen a dentist in the past year.<sup>89</sup> For those with family incomes between 200% and 400% of the poverty level, the percentage of children who have not seen a dentist drops to slightly below 50%.<sup>90</sup> Data show “eighty percent of untreated c[avities] in permanent teeth are found in roughly 25% of children who are five to seventeen years old, mostly from low income and other vulnerable groups.”<sup>91</sup>

While these numbers are truly awful, it is far too optimistic to use these as placeholders for percentages of children who are, or are not, receiving adequate preventive dental care. The studies cited in this Article only measure whether there was at least one visit to the dentist in a given calendar year, rather than the two annual dental examinations that are recommended. They also do not specify whether these dental visits were for preventive care or to treat a problem. As a result, these data do not give percentages of children who are receiving care that fully comply with an adequate preventive care schedule. However, if a child has not seen a dentist in the last calendar year, as measured here, that child is clearly not getting appropriate dental care. Subsequently, these studies most likely underreport the extent of the problem that is the focus of this Article, meaning that the number of children who are not getting appropriate care is most likely greater than any percentage the data provides.

## 2. Ethnicity

Income is not the sole determinant of increased risk of untreated tooth decay or cavities. Studies that have looked at the prevalence of these dental diseases show that, while they are widespread in the general pediatric population, there are also distinct patterns of increased vulnerability based on ethnicity. For example, looking at the population of children aged six to eight, 29% of all these children have untreated tooth decay.<sup>92</sup> For Native American children, the number soars to 69%, and for Asian and Pacific Islander children, 71%.<sup>93</sup> African American children report 36%, Mexican Americans 43%, and white children,

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dentist, as reported here, are getting the full benefit of recommended preventive care; so we do not know, for a fact, how many children within the 72% are being treated properly. In short, the problem is at least as bad as these numbers suggest, but could be much worse.

88. See ORAL HEALTH, *supra* note 20, at 15 fig.5.

89. *Id.*

90. *Id.*

91. *Id.* at 7.

92. See ORAL HEALTH, *supra* note 20, at 12. This number by itself is inexcusable given that decay is almost entirely preventable and entirely treatable.

93. *Id.*

26%.<sup>94</sup> Interestingly, these numbers dip for all reported ethnic groups by age fifteen then rise again by age thirty-five.<sup>95</sup> For example, 29% of African American children at fifteen have untreated tooth decay, while 46% of African American adults aged thirty-five to forty-four have the same problem.<sup>96</sup> While the study that reported these data does not offer an explanation for this dip and subsequent rise in dental decay, it is perhaps explained by the growth over the course of childhood of new, healthy adult teeth, which then gradually decay.

*D. The Measurable Effects of Untreated Dental Pain on Vulnerable Children: Educational Deficits*

Ethically, it is difficult to design an observational study that measures the number of children in pain from dental problems and the effect of this pain on their activity levels, learning, socialization, etc. The pain and other negative effects from dental decay and cavities are so easily treatable; thus, it is ethically unjustifiable to identify a child who is suffering from treatable pain and then deny the child access to treatment while a study is conducted. In the absence of this type of study, other information may be used to identify the costs of lack of dental care. A potentially useful focal point is education, with respect to both a child's school attendance and her ability to focus in school. While school performance is not, by itself, the same as a wholesale measure of a child's well-being, a child's functioning in school can be illuminating as to whether the child is thriving.

For children living in poverty, dental problems lead to an astonishingly high number of "missed activity days," such as missing school. For children with family incomes less than \$10,000 a year, it has been estimated that they miss twelve times the number of days compared with wealthier children due to dental problems.<sup>97</sup> For those children with family incomes between \$10,000 and

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94. *Id.*

95. *Id.* (The table reports 195% for white children aged 15. Presumably the source means 19%).

96. *Id.*

97. Jihong Liu et al., *Disparities in Dental Insurance Coverage and Dental Care among U.S. Children: The National Survey of Children's Health*, 119 PEDIATRICS S13 (2007) ("Poor children experience nearly 12 times as many restricted activity days from dental diseases as do children from higher income families." (citing ORAL HEALTH, *supra* note 20, at 9)). This is a complicated number to both assess and comprehend. It most likely represents the terrible impact something as simple as dental care can have on a family stressed by poverty and by whatever circumstances led to the poverty. As will be seen later in this Article, parents in the lowest income groups have a consistently difficult time finding dentists who will treat their children, as well as difficulties in actually getting their children to dental appointments once one is successfully made. The circumstances that lead to missed school days for this population are most likely as deep and complex as poverty, itself. The author would like to thank David Owen for his insightful questions about this statistic about missed school days.

\$20,000, the number is still quite high— eleven times that of wealthier children.<sup>98</sup> For those with family incomes above \$20,000, the number of missed activity days due to dental problems drops dramatically.<sup>99</sup> In total, as of 1989, the last year for which data is available, the accumulated burden of missed school days for dental problems amounted to fifty-two million school hours, or eight million school days.<sup>100</sup>

These numbers are breathtaking, especially when considered in light of ongoing debates about measuring school and teacher performance and the costs and benefits of extending the school year or increasing the hours in the school day to improve children's performance. The infrastructure pays for these missed hours of school, whether the children attend school or not. When these children do not attend, the money and teaching time is simply wasted.

Tens of millions of school hours are being missed, surely with some effect on overall school performance. From a school system's perspective, these absences will likely lead to a gross distortion of quality assessment. Comparisons between schools are also likely to be inaccurate if the schools have different levels of dental disease in their respective student populations. The statistics that show an increased prevalence of dental diseases in poorer populations imply a problem for assessing the comparative performance between schools that might have disparate rates of dental health. Given that a high proportion of dental diseases in a school population has the potential to distort student performance, data should be collected so that its role can be more clearly ascertained or else conclusions about a school's success in teaching are likely to be inaccurate.

## II. THE INFRASTRUCTURE OF THE PEDIATRIC DENTAL CARE SYSTEM

A well-planned infrastructure for providing preventive dental care seems to be a sensible goal of social policy given the importance of preventive dental care for children, its cost-effectiveness from a medical perspective, and the other significant costs detailed above caused by failing to provide it. As data in Part I show, the infrastructure currently in place is failing to ensure that children have this preventive care, as well as often failing egregiously in providing treatment for the twin diseases of decay and cavities. The pediatric dental infrastructure consists of three distinct arms: fluoridation of drinking water, providers, and payment systems. It requires the cooperation of dentists and other care providers, payers, and parents to function properly.

### *A. Fluoridation of Public Water Supplies*

Adding fluoride to water supplies is both cost effective and very helpful in

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98. See ORAL HEALTH, *supra* note 20, at 9 fig.2.

99. *Id.*

100. *Id.*

preventing dental decay and cavities.<sup>101</sup> According to an analysis of CDC data conducted by the Pew Center, roughly 88% of Americans get water from a community system, and more than one quarter of these people do not get water that is properly fluoridated.<sup>102</sup> If all Americans were supplied with properly treated water, it has been estimated that the country could save as much as \$1 billion per year in dental costs.<sup>103</sup> The current widespread availability of fluoridated water in many areas of the country is a critical part of dental care for children, and increasing access is a continuing project for numerous federal agencies.<sup>104</sup>

### B. Providers

There is a significant shortage of dentists who are trained to treat children.<sup>105</sup> This shortage has an effect on every aspect of the dental care infrastructure in the United States, making it harder for patients to find dentists and allowing dentists to be more selective in the populations they treat. Dentists work predominantly in private practices, a high proportion of which are solo or small groups, and they retain significant autonomy in practice decisions.<sup>106</sup> These practices are

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101. A study conducted by the Center for Disease Control found that every \$1 spent on adding fluoride to the water supply generated \$38 in savings on dental care. DIV. FOR ORAL HEALTH, CTRS. FOR DISEASE CONTROL AND PREVENTION, *Cost Saving of Community Water Fluoridation* (2009), [http://www.cdc.gov/fluoridation/fact\\_sheets/cost.htm](http://www.cdc.gov/fluoridation/fact_sheets/cost.htm). The use of fluoride in drinking water has been found to be useful in reducing tooth decay for children and adults in a number of different studies, with reductions ranging from 18% to 40%. PEW CTR. ON THE STATES, *supra* note 8, at 21.

102. *See id.* at 22..

103. *See id.* at 21.

104. *See, e.g.* CTRS. FOR DISEASE CONTROL AND PREVENTION, *Community Water Fluoridation*, <http://www.cdc.gov/fluoridation> (last visited Jan. 25, 2010). This concern is also highlighted in PPACA.

105. According to data collected in 2000, there are 4 pediatric dentists for every 100,000 children in the United States, with roughly 2900 total in private practice. *See* S.M. Hashim Nainar & Robert J. Feigal, *Geographic Distribution of Pediatric Dentists in Private Practice in the United States*, 26 PEDIATRIC DENTISTRY 526, 528 (2004). These few dentists are not evenly distributed geographically, with Connecticut having twice the national average and Maine having only one quarter of the national average. *See id.* at 527-28. There is also an overall shortage of general dentists and the problem has been growing over the last two decades. In the last twenty-five years, six national dental schools have closed, whereas only one new one has opened, resulting in far fewer new dentists each year. *See* Richard W. Valachovic, *Dental Workforce Trends and Children*, 2 ACADEMIC PEDIATRICS 154, 154 (2001). Furthermore, dental practices are more likely to suffer in a bad economy than medical practices, making it a less secure profession unless one is planning on building a practice that primarily serves the most well-off, which is, not coincidentally, where most new pediatric dentistry practices have been located. *Id.* It is unclear what an adequate ratio of dentists to children should be. There are roughly 2000 people for every practicing dentist, which is merely descriptive and not a reflection of what is adequate. To equal this ratio for dentists trained in treating children, the numbers would need to be increased by 1200%.

106. There are also some clinics of varying types, some of which hire dentists on salary. But this represents a very small proportion of dentists, overall. *See, e.g., Federally Supported Dental Health Programs*, FEDERAL DENTAL HEALTH, <http://www.federaldentalhealth.com>.

extremely profitable and tend to be located where patients can afford their services, such as in more well-off suburban areas.<sup>107</sup>

While the small number of dentists is highly problematic, this does not present an insurmountable impediment to achieving universal care. Studies have shown that full training in the field of dentistry may not be necessary in order to provide the preventive care that children need and that a different type of professional can be utilized to address the problem.<sup>108</sup> In a number of countries including New Zealand, the United Kingdom, Australia and the United States, dental care providers, called dental health aid therapists (DHATs), have been trained to clean, examine, and fill cavities in children's teeth; they have proven to be as good as or better than dentists at performing these tasks if one measures quality by reduction in the incidence of dental diseases, improvement in dental health generally, and patient satisfaction.<sup>109</sup> The DHAT concept is slowly gaining traction in the United States, with Minnesota recently becoming the first state to create a system for training dental therapists and allowing them to practice.<sup>110</sup> It has not, however, been free of controversy within the dental community, and the United States is far behind other countries in embracing this newer model for providing preventive care.<sup>111</sup> The American Dental Association filed suit in Alaska (unsuccessfully) in an effort to stop a limited dental therapist program

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107. See Alex Berenson, *Boom Times for Dentists, but Not for Teeth*, N.Y. TIMES, Oct. 11, 2007, at A1. See generally R. Andrew Allison & Richard J. Manski, *The Supply of Dentists and Access to Care in Rural Kansas*, 23 J. RURAL HEALTH 198, 198 (2007).

108. See, e.g., W.K. Kellogg Foundation, *New Report Details Training of New Dental Professionals To Ease Dental Care Crisis*, Aug. 10, 2010, available at <http://www.wkkf.org/news/Articles/2010/08/New-Report-Details-Training-of-New-Dental-Professionals-to-Ease-Dental-Care-Crisis.aspx>.

109. See David A. Nash, *Developing and Deploying a New Member of the Dental Team: A Pediatric Oral Health Therapist*, 65 J. PUB. HEALTH DENTISTRY 48, 48 (2005); David A. Nash, *Developing a Pediatric Oral Health Therapist to Help Address Oral Health Disparities Among Children*, 68 J. DENTAL EDUC. 8, 8 (2004); see also Kenneth Anthony Bolin, *Assessment of Treatment Provided by Dental Health Aide Therapists in Alaska: A Pilot Study*, 139 J. AM. DENTAL ASS'N 1530, 1530 (2008); David A. Nash & Ron J. Nagel, *Confronting Oral Health Disparities Among American Indian/Alaska Native Children: The Pediatric Oral Health Therapist*, 95 AM. J. PUB. HEALTH 1325, 1326 (2005).

110. See BURTON L. EDELSTEIN, TRAINING NEW DENTAL PROVIDERS IN THE U.S. 1 (2009), available at <http://www.cdhp.org/system/files/Dental%20Therapy%20Policy%20Brief%202012-16-09.pdf>; see also Press Release, UNIV. OF MINNESOTA SCH. OF DENTISTRY, Minnesota to Become First U.S. Dental School to Educate Dental Therapists (2009), available at <http://www.dentistry.umn.edu/news/DentalTherapists/home.html>, as cited in Patricia Glasrud et al., Minnesota Dental Ass'n, *A History of Minnesota's Dental Therapist Legislation* 6 (2009), available at [http://www.mndental.org/client\\_files/documents/DENTAL\\_THERAPIST\\_FINAL.pdf](http://www.mndental.org/client_files/documents/DENTAL_THERAPIST_FINAL.pdf). Alaska, as described *infra*, also allows dental therapists to practice on indigenous populations, though the therapists are trained in Oregon, where they cannot practice.

111. The full scope of this controversy is outside the scope of this Article. In brief, it mirrors the controversies surrounding nurse practitioners and physician assistants and many other similar movements within health care that threaten any one professional group's monopoly control of a specific type of care.

among Native Americans and has been adamantly opposed to the adoption of the model.<sup>112</sup>

The ADA's opposition to the widespread use of DHATs is unsurprising. A new model of healthcare professional such as the DHAT presents a direct challenge to the monopoly that dentists currently hold over the provision of specific types of dental care. Dentists currently work closely with dental hygienists, who, as a rule, only work under the direct supervision of a licensed dentist. The current model, then, consists of the care provider and an assistant. DHATs work without the direct supervision of dentists and can hire and utilize hygienists themselves. To further complicate the effect of the DHAT model on current norms, many hygienists with a bachelor's degree would likely pursue advanced training to become DHATs. The model, then, is arguably transformed from rigid groups relating within strict hierarchies to one that more closely resembles a ladder, with some mobility possible between the rungs.<sup>113</sup>

### C. Payment Systems

Private practice dentists are generally paid directly by patients or through a fee-for-service arrangement with patients and insurance companies, though a small percentage of dental professionals work under managed care contracts. A fee-for-service arrangement means that dentists are paid for each procedure that they provide to the patient. Money to pay these fees comes from private insurance plans, public insurance plans, or individuals paying for care out-of-pocket. Private dental insurance policies are purchased by employers or by individuals in the open market. These policies are less prevalent than health insurance, with only 73% of those with health insurance having dental coverage.<sup>114</sup> There is a significant correlation between having dental insurance of some kind and an increased likelihood that a child will see a dentist in any given year. The cost of a child's biannual cleanings and exams are fully covered by many of these plans. However, even among those children with private dental

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112. See Michael C. Alfano, *Dentistry: Circle Back? Circle the Wagons? Or Circle the Moment?*, GLOBAL HEALTH NEXUS 1, Summer 2010, at 10-11 for a discussion of this opposition.

113. There is a distinct gender subtext to this discussion. Dentists in the United States have historically been men; currently, men make up 75% of this group. The dental hygienist profession is considered a predominantly feminine one. To quote from an article recently published in a dental hygienist magazine, "I believe part of our struggle is because of dental hygiene's predominantly female gender in the male-dominated, patriarchal setting of dentistry." Heidi Emmerling Jones, *The Softer, Gentler Side Leads to Traditions where Gender Differences are Misunderstood*, RDH Sept. 1996, available at <http://www.rdhmag.com/index/display/articledisplay/122882/articles/rdh/volume-16/issue-10/columns/thinking-sharply/the-softer-gentler-side-leads-to-traditions-where-gender-differences-are-misunderstood.html>. Any change that has financial, hierarchical, and gender implications is bound to face opposition from those who risk losing power on all three fronts.

114. See BARBARA BLOOM & ROBIN A. COHEN, *Dental Insurance for Persons under Age 65 Years with Private Health Insurance: United States, 2008*, at 1 (2010), available at <http://www.cdc.gov/nchs/data/databriefs/db40.pdf>.

insurance, 42% did not receive annual dental care in 2008.<sup>115</sup> Clearly, cost is not the sole barrier to care in these cases. The poor statistics may be related to the structure of the benefits in these plans, or due to different problems with accessing care, such as lack of parental commitment or a shortage of dentists, as discussed further in this Article.

Dental plans are not the same as medical insurance. Many of the plans are actually discount arrangements with dentists, where the patient is responsible for paying the full, negotiated cost.<sup>116</sup> Those that function as traditional insurance plans have strikingly low caps on annual reimbursements. For example, the most generous benefit provided to federal employees under the Aetna dental plan for 2010 has an in-network cap of \$3,000 a year per patient, with co-payments for any major dental work ranging from 40% to 60% of the cost for in-network providers.<sup>117</sup> In short, a patient with dental insurance can still bear a substantial financial cost when getting care.

#### *D. Private Practice and Medicaid*

For those children whose families do not have private dental insurance or the financial ability to pay for care with their own money, the most significant source of payment for preventive dental care is through public plans, primarily Medicaid and SCHIP. More than 40% of children in the United States live in poverty or low-income families.<sup>118</sup> Of these, twenty-eight million are enrolled in these programs, and roughly five million are eligible, but are not enrolled;<sup>119</sup> so these plans play a significant role in the infrastructure of pediatric dental care. Medicaid provides dental insurance to children from impoverished families and, through its regulations, defines the elements of adequate care. Federal law created Medicaid in 1965, and the minimum schedule of benefits that children are entitled to receive under Medicaid is tightly controlled, specifically through the language of the Early Periodic Screening, Diagnosis and Treatment (EPSDT) benefit, which defines the basic care to which all children enrolled in Medicaid

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115. See ALISON BORCHGREVINK ET AL., THE EFFECTS OF MEDICAID REIMBURSEMENT RATES ON ACCESS TO DENTAL CARE 26 (2008), available at [http://nashp.org/sites/default/files/CHCF\\_dental\\_rates.pdf](http://nashp.org/sites/default/files/CHCF_dental_rates.pdf).

116. *Id.*

117. See AETNA DENTAL, A NATIONWIDE DENTAL PPO PLAN 13, 17, 20 (2010), <http://custom.aetna.com/fehbp/pdf/2010FedBrochure-FEDVIP.pdf>.

118. Nineteen percent of children live in poverty, as defined by the United States government, and 41% are part of low-income families, which means with family incomes at or below 200% of the federal poverty levels. See VANESSA R. WIGHT & MICHELLE CHAU, BASIC FACTS ABOUT LOW-INCOME CHILDREN, 2008: CHILDREN UNDER AGE 18, at 1 (2009), available at [http://www.nccp.org/publications/pdf/text\\_892.pdf](http://www.nccp.org/publications/pdf/text_892.pdf).

119. KAISER COMMISSION ON MEDICAID AND THE UNINSURED, ENROLLING UNINSURED LOW-INCOME CHILDREN (2007); see also KAISER COMMISSION ON MEDICAID AND THE UNINSURED, HEALTH COVERAGE OF CHILDREN: THE ROLE OF MEDICAID AND CHIP I (2010).

are entitled.<sup>120</sup> However, Medicaid is administered by the individual states, with joint state and federal funding. Also, while complying with EPSDT is mandatory, the details of the state plans vary.

Medicaid pediatric dental coverage promises much, but often fails to provide that which it promises. In theory, under its language, EPSDT provides the full schedule of preventive dental care, described above,<sup>121</sup> at no cost to families. Biannual cleanings, exams, and prophylactic treatments (such as fluoride and sealants) are all covered. Medicaid prohibits states from requiring co-payments from parents for these basic preventive services.<sup>122</sup> The benefits provided by SCHIP plans in every state are similar.<sup>123</sup> In reality, roughly one-third of children enrolled in Medicaid actually receive dental services in any given year.<sup>124</sup> The difference between theoretical coverage and access for this population has been extensively studied, and there appear to be few surprises or disagreements about what causes the discrepancy.<sup>125</sup> For a number of reasons, it is neither easy nor routine for a child covered by Medicaid or SCHIP to see a dentist.

### 1. Low Reimbursement Rates

The problems with low-income children's access to preventive dental care begin with the low reimbursement rates that are paid to dentists who accept Medicaid patients. Families in poverty suffer far more than well-off families from the significant shortage of pediatric dentists in the United States.<sup>126</sup> Even for families with money, it may be difficult to find a properly trained dentist to

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120. See CTRS. FOR MEDICARE & MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, THE STATE MEDICAID MANUAL 5-9 (2005), available at <http://www.cms.gov/Manuals/PBM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS021927&intNumPerPage=10>.

121. See *supra* Part I.

122. See UNITED STATES GENERAL ACCOUNTING OFFICE, MEDICAID AND SCHIP: STATES' PREMIUM AND COST SHARING REQUIREMENTS FOR BENEFICIARIES (2004), available at <http://www.gao.gov/new.items/d04491.pdf>.

123. See CTRS. FOR MEDICARE & MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, OVERVIEW CHIP DENTAL COVERAGE, <http://www.cms.gov/CHIPDentalCoverage> (last visited Apr. 14, 2011).

124. See PEW CTR. ON THE STATES, *supra* note 8, at 2. As of 2007, a full 75% of children on Medicaid received no dental care at all in three states, Delaware, Florida and Kentucky. *Id.* at 22.

125. See, e.g., OFFICE OF INSPECTOR GENERAL, U.S. DEP'T OF HEALTH & HUMAN SER., CHILDREN'S DENTAL SERVICES UNDER MEDICAID: ACCESS AND UTILIZATION (1996) [hereinafter MEDICAID: ACCESS AND UTILIZATION], available at <http://oig.hhs.gov/oei/reports/oei-09-93-00240.pdf>.

126. This problem has been growing over the last two decades. In the last twenty-five years, six national dental schools have closed, whereas only one new one has opened, resulting in far fewer new dentists each year. See Richard W. Valachovic, *Dental Workforce Trends and Children*, 2 AMBULATORY PEDIATRICS 154, 154 (2001). Dental practices are more likely to suffer in a bad economy than medical practices, and that a less secure profession unless one is planning on building a practice that primarily serves the most well-off, which is, not coincidentally, where most new pediatric dentistry practices have been located. *Id.*

provide regular care. For Medicaid patients, this shortage is compounded by Medicaid's meager reimbursement rates in most states.

The division of responsibility within the Medicaid system leads to individual states being responsible for setting the reimbursement rates for pediatric care that dentists are entitled to for treating children on Medicaid in that state. Only one state pays for Medicaid pediatric dental care at a rate that is 100% of dentists' national median retail fees.<sup>127</sup> Using median fees as a stand-in for adequate reimbursement rates, Medicaid rates fall far below this, averaging 60% of the median, with twenty-six states reimbursing at far lower rates.<sup>128</sup> Dentists are not compelled to treat Medicaid patients, but must actively choose to do so if they are to participate in the program. Given the shortage of dentists, coupled with the usual law of supply and demand, any dentist that treats Medicaid patients in the many states with extremely low reimbursement rates is likely choosing to do so for reasons other than financial gain.

Hard data have emerged showing access to dental care for Medicaid-enrolled children increases in proportion to the amount that states increase their reimbursement rates.<sup>129</sup> For example, Alabama increased its Medicaid reimbursement rates in 2001.<sup>130</sup> In 2000, roughly 72,000 children in Alabama used Medicaid dental services.<sup>131</sup> The number of Alabama children increased to 155,000 by 2004.<sup>132</sup> At the same time as the number of children using the services increased by 115%, the amount paid for these services increased by 288%.<sup>133</sup> In South Carolina during the same time frame, and with similar increases, the number of enrollees utilizing dental services increased by 58% and the costs by 85%.<sup>134</sup>

Even in states with the most generous reimbursement rates, however, the percentage of children actually receiving the proper care is still less than children who have private insurance, and not close to 100%. Currently, financial strains are driving many states to cut government programs as much as possible, likely making it difficult for states to sustain their commitments to increasing, or maintaining already increased, reimbursement rates. The Medicaid model of utilizing private practice dentists and paying them through fee-for-service reimbursements may not be feasible for pediatric dental care, if the goal is to provide preventive care to all children.

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127. See PEW CTR. ON THE STATES, *supra* note 8, at 7.

128. *Id.* at 7. The lowest four states report reimbursement rates that are lower than 40% of the median retail fees. *Id.*

129. See BORCHGREVINK ET AL., *supra* note 120, at 17.

130. See *id.* at 6.

131. *Id.* at 18.

132. *Id.*

133. *Id.*

134. *Id.*

## 2. Bureaucratic Burdens

If a dentist chooses to see Medicaid patients, they must undertake the bureaucratic burden of organizing their office to handle the claims process. It can actually be less expensive for a practice to treat these children for free than to incur the expense of filing claims for reimbursement.<sup>135</sup> In surveys and individual interviews, many dentists have reported that the cost of paying support staff to become trained in Medicaid claims processes, as well as paying staff for the tasks associated with submitting the claims, often exceeds the proceeds of treating a Medicaid patient, without any money left to go toward the cost of the treatment itself.<sup>136</sup> It is critical that a dentist's support staff are properly trained in Medicaid billing processes because errors in Medicaid billing are subject to possible criminal prosecution as Medicaid fraud.<sup>137</sup> While these prosecutions are not as common as those against physicians, the fear of prosecution is surprisingly widespread among dentists.<sup>138</sup> The combination of these burdens and fears leads to either reluctance to actually submit claims to Medicaid for treatment that is provided or a refusal to accept any Medicaid patients at all.

## 3. Missed Appointments

If a parent or guardian with a child on Medicaid can find a dentist and secure an appointment for their child, it has been argued that a substantial percentage of the patients do not actually keep the appointments that have been successfully made.<sup>139</sup> As a result, many pediatric dentists who do take Medicaid double- or triple-book their Medicaid patients in an effort to ensure that at least one patient will actually appear for the time allotted.<sup>140</sup>

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135. See, e.g., MEDICAID: ACCESS AND UTILIZATION, *supra* note 125, at 7.

136. *Id.*

137. *Id.*

138. As an example of the high level of concern, see *Dentists not Impressed with Medicaid*, THE WEALTHY DENTIST (2009), <http://www.thewealthydentist.com/SurveyResults/084-Dental-Medicaid-Patients.htm> (last visited Aug. 25, 2010). See also S. Rocke, *The War on Fraud and Its Effect on Dentistry*, 131 J. AM. DENTAL ASS'N 241 (2000).

139. While most information supporting this claim is anecdotal, coming from interviews with dentists conducted as part of studies concerning Medicaid and access problems, there have been studies that substantiate the dentists' oft-repeated complaint. For example, a study that measured missed appointments for Medicaid and non-Medicaid children in a University-based orthodontic practice in Virginia found that Medicaid patients failed to keep 15.4% of their appointments, while non-Medicaid patients failed to keep 8.3%. See Bryan P. Horsley et al., *Appointment Keeping Behavior of Medicaid vs Non-Medicaid Orthodontic Patients*, 132 J. ORTHODONTICS & DENTOFACIAL ORTHOPEDICS 49, 49 (2008). This study does not reveal a level of missed appointments that is commensurate with the claims made by many of the interviewed dentists, but still presents a substantial problem for the children who are not receiving care.

140. See Emily Hohenwarter, *Finding Dental Care is Still Tough for Medicaid Clients*, TIMES-NEWS, July 7, 2008, available at <http://www.thetimesnews.com/news/clients-15341-dental->

#### 4. Poor Parental Education

The low rates of children's utilization of proper dental care might imply that parents are undereducated about the importance of dental care for their young children and how painless proper care can be. In the current dental infrastructure, parental commitment to children receiving proper care has been found to be a critically important element of preventive care.<sup>141</sup> Parents supervise brushing and flossing, minimize processed sugars in the diet, and make sure children visit the dentist twice a year. Interestingly, parental attitudes about dental care also influence the success of their children's visits to the dentist, measured by children's behavior at the dentist's office, cooperation with the examination process, and experience of pain and discomfort.<sup>142</sup> For parents who do not have healthy teeth and were not raised with regular and effective preventive care, visiting the dentist can be a frightening and anxiety-producing experience; it has been theorized that this is communicated to their children, making visits to the dentist more difficult for all concerned, including the dental professionals.<sup>143</sup> While these problems, poor education, and high levels of anxiety may be more common in the Medicaid and SCHIP populations, they are not exclusive to them. Many adults simply do not fully comprehend what is at stake with preventive dental care, and dental anxiety is widespread in the general population.<sup>144</sup>

Substantial data are unavailable to support that parents are uneducated about children's dental needs, but recent legislative activity suggests the perception that this is a problem is widely shared. For example, PPACA includes funding for a five-year campaign to improve parental education regarding the importance of children receiving timely preventive dental care.<sup>145</sup>

### III. CURRENT REFORM ACTIVITY

Preventive dental care for children has been shown to be cost-effective in light of both the extremely expensive and damaging problems that poor dental care can cause during childhood and the long-term negative effects of poor

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finding.html; see also *The Fray, The American Way of Dentistry, Important Point on Medicaid*, THE SLATE.COM (Oct. 1, 2009, 09:37 EST), <http://www.slate.com/discuss/forums/thread/3278953.aspx> (containing various postings of a heated discussion of this issue among dentists).

141. See Peter Milgrom et al., *A Community Strategy for Medicaid Child Dental Services*, 114 PUB. HEALTH REP. 528, 528 (1999).

142. See, e.g., M. O. Folayan et al., *Parental Anxiety as a Possible Predisposing Factor to Child Dental Anxiety in patients Seen in a Suburban Dental Hospital in Nigeria*, 12 INT'L J. PEDIATRIC DENTISTRY 255, 255 (2002).

143. *Id.*

144. See George C. Economou, *Dental Anxiety and Personality: Investigating the Relationship Between Dental Anxiety and Self-Consciousness*, 67 J. DENTAL EDUC. 970, 970 (2003).

145. PPACA, § 399LL(a).

pediatric dental care into adulthood.<sup>146</sup> The Surgeon General signaled the extraordinary importance of childhood access to preventive dental care in the 2000 report.<sup>147</sup> Yet, even with this apparent agreement among stakeholders, the epidemic of preventable dental disease has proven resistant to fairly aggressive attempts at amelioration by health care providers, government officials, and school systems.

Given the depth of the problems described above, and how well-known these problems are, it makes sense that there are numerous pilot programs that are being utilized to determine how best to resolve them. The pilot programs are being developed by many different stakeholders, including governments at both state and federal levels, school boards, dental licensing organizations, and assorted non-profit organizations concerned with children's well-being. These pilot programs can be grouped into different approaches, which will be discussed below. First are efforts to address problems that are especially prevalent among low-income families, such as low Medicaid reimbursement rates for children's dental care. Second, in order to address the persistent shortage of dentists, there are efforts to increase the number of people who are qualified to provide preventive care to children. Third are programs that focus on providing children with specific interventions, such as sealants. Fourth are movements to require proof of an annual dental screening before a child can begin school, much as children must show proof of proper vaccines. In an effort to contain the analysis here, this short list highlights the dominant approaches that are presently utilized. Also, programs exist that provide full access to dental care in schools, with great measurable success.

Part II of this Article describes the weakness of the dental care infrastructure; in light of this weakness, it is difficult to see how any reform steps taking place within this existing infrastructure can hope to achieve the substantive changes necessary to achieve dental care for all children. There is a shortage of dentists. The funding for public insurance is not rich enough to attract a sufficient number of dentists. And while some parents arrange for dental care for their children, many others do not provide for this care, even when resources appear adequate.

#### *A. Medicaid Reform*

As stated above, the primary problems with Medicaid dental care are low reimbursement rates, missed appointments, poor parental education, and few

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146. See CHILDREN'S DENTAL HEALTH PROJECT, CDHP POLICY BRIEF: COST EFFECTIVENESS OF PREVENTIVE DENTAL SERVICES (2005), available at [http://www.cdc.gov/oralhealth/publications/library/burdenbook/pdfs/CDHP\\_policy\\_brief.pdf](http://www.cdc.gov/oralhealth/publications/library/burdenbook/pdfs/CDHP_policy_brief.pdf) (collecting numerous studies showing different aspects of preventive dental care cost-effectiveness, both for children's healthcare costs and into adulthood).

147. REPORT FROM THE SURGEON GENERAL, *supra* note 1, at 249.

pediatric dentists who accept Medicaid patients. The numerous Medicaid reform pilot programs that are currently taking place are certainly focused on increasing the number of children who see a dentist on a regular basis. However, the success of Medicaid's dental coverage is dependent on private practice dentists choosing to treat Medicaid patients, so a realistic goal of reform must also include making children on Medicaid more attractive to dentists as patients.

The low reimbursement rates for Medicaid patients create a major problem. There have been two distinct approaches to addressing this issue. Over time, a series of successful lawsuits have been brought on behalf of Medicaid-eligible children that have forced states to as much as double their reimbursement rates.<sup>148</sup> While these represent substantial successes and required sophisticated lawyering to achieve, doubling some of these rates still resulted in shockingly low reimbursements that came nowhere close to the national commercial rate charged for the same services.<sup>149</sup> More recently, as the costs of failing to provide this care have become better understood, a number of states, with assistance from the federal government, have voluntarily increased reimbursement rates.<sup>150</sup> As described earlier, these increases have resulted in increased utilization, but have not managed to budge the number of children being treated to a number above 50% in any state and the improvements are proving difficult to sustain in the current recession. Certainly, the United States Medicaid system, as a whole, is nowhere near the national retail average in its Medicaid dental reimbursements. For a dentist to treat a child on Medicaid, the practice must decide to dedicate its time to what is in essence a charitable act, which is not a firm foundation for providing the necessary care that millions of children require. As was noted in a recent article by the dean of the New York University College of Dentistry, high compensation is emerging as a "key driver in the selection of an occupation" for the new generation of dental students,<sup>151</sup> making it even less likely that care will be provided to children on Medicaid in the future.

The problem of missed appointments also has received attention, and reform programs have achieved a degree of success. Some states offer transportation reimbursements for families on Medicaid.<sup>152</sup> This is helpful if such money is beyond the means of those on Medicaid. In order to create an incentive for parents to not inconvenience dental care providers, it could be argued that parents

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148. See generally Sean Jessee, Comment, *Fulfilling the Promise of the Medicaid Act: Why the Equal Access Clause Creates Privately Enforceable Rights*, 58 EMORY L.J. 791-830 (2009) (discussing the challenges in bringing these actions).

149. See *Carr v. Wilson-Coker*, No. 3:00 CV 1050 (AVC) (D. Conn. Apr. 29, 2008). This class action lawsuit in Connecticut was settled in 2008, after eight years of litigation. *Id.*

150. See BORCHGREVINK ET AL., *supra* note, at 120.

151. See Charles Bertolami, *Message from the Dean*, 12 GLOBAL HEALTH NEXUS 2, at 5 (2010).

152. See, e.g., Delaware's Medicaid program, <http://dhss.delaware.gov/dhss/assc/dentaltns.html>.

should suffer a financial penalty for missing their children's appointments by being billed for the cost of that appointment, as this could be an effective incentive for non-Medicaid patients—causing them to more often attend or provide notice when cancelling their appointments, and helping to offset dental practice costs for an empty appointment slot. This type of penalty is not permitted under the current Medicaid claims structure for parents whose children are enrolled in Medicaid.<sup>153</sup> But this could be an effective incentive for non-Medicaid parents. Under Medicaid, actual medical care must be provided to a patient for any billing to take place, which leaves no mechanism for billing a parent when the care is skipped. The dentist is allowed to refuse to see the child in the future in response to a missed appointment or for any other reason, but she cannot financially punish the parent. To address this problem in the Medicaid population, studies are now documenting the promising potential of Medicaid programs hiring dental case managers, whose purposes are the following: to find dentists for Medicaid children; make appointments; and remind parents that the appointments have been made, are necessary, and that the children need to go.<sup>154</sup>

Many Medicaid programs now actively encourage parents to bring children to the dentist sometime in the child's first year of life in an effort to catch any early problems, but more importantly, so that the dentist can educate parents about what will be necessary as the child's teeth begin to develop and to create a "dental home" for the child that will be a source of regular care and continuing education.<sup>155</sup>

### *B. Increasing the Number of Pediatric Dental Care Providers*

Any change in the current system must take into account the shortage of dentists, given that there are not enough dentists trained in treating young children. Furthermore, dental practices are not evenly spread across the country and tend to be concentrated in more densely populated areas.<sup>156</sup>

There were 40% fewer graduates of dental schools in 2000 than in 1986,<sup>157</sup>

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153. See UNITED STATES GENERAL ACCOUNTING OFFICE, REPORT TO CONGRESSIONAL REQUESTERS—MEDICAID: STATE AND FEDERAL ACTIONS HAVE BEEN TAKEN TO IMPROVE CHILDREN'S ACCESS TO DENTAL SERVICES, BUT GAPS REMAIN 1 (2009), available at <http://www.gao.gov/new.items/d09723.pdf> (billing parents for missed appointments is expressly prohibited by the language of CMS).

154. See Barbara J. S. Greenberg et al., *Dental Case Management: Increasing Access to Oral Health Care for Families and Children With Low Incomes*, 139 J. AM. DENTAL ASS'N 1114, 1114 (2008).

155. See, e.g., CTRS. FOR MEDICARE & MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, GUIDE TO CHILDREN'S DENTAL CARE IN MEDICAID 5 (2004), available at <http://www.cms.gov/MedicaidDentalCoverage/Downloads/dentalguide.pdf>.

156. See Louis Susi & Ana Karina Mascarenhas, *Using a Geographical Information System To Map the Distribution of Dentists in Ohio*, 133 J. AM. DENTAL ASS'N 636, 642 (2002) (analyzing the location of dental practices in Ohio).

157. Valachovic, *supra* note 126, at 154.

though one can see signs that this may be slowing. Between 1982 and 2000, seven dental schools closed.<sup>158</sup> Three new dental schools opened since 2000, and a number of other new dental schools are being planned.<sup>159</sup> In raw numbers, the academic world of dentistry will soon be graduating an increasing number of students.<sup>160</sup> Even with this increase, in the future a significant problem is likely to be caused by the current age of practicing dentists, with more than one-third of dentists in the United States over the age of fifty-five and “edging towards retirement.”<sup>161</sup> There are roughly 248,000 dentists practicing in the United States,<sup>162</sup> which means more than 75,000 will have to be replaced in the next decade to stay even with current numbers. There were 4500 new graduates from dental schools in 2006, which is simply not enough to keep pace with expected retirements.<sup>163</sup>

The geographic disparities in the locations where dentists practice present a serious challenge to providing access to care, particularly for low-income families. A conservative method for measuring those areas that suffer from a shortage of dentists is to count the areas that have successfully applied to the federal government to be designated as Dental Health Professional Shortage Areas (DHPAs). This designation triggers federal assistance in attracting dentists. But the application is a lengthy process that many areas do not have the resources to complete, making it likely that the actual shortages are under-reported.<sup>164</sup> Using DHPAs’ numbers, more than 46 million people live in DHPAs, and more than 30 million of those people have no access to a dentist.<sup>165</sup> And it has been calculated “that more than 10 percent of the nation’s population has no reasonable expectation of being able to find a dentist.”<sup>166</sup>

Two distinct approaches for addressing the problem have emerged. The first identifies the skills that a professional must have to meet the preventive dental care needs of children and creates a distinct class of professional, the dental therapist, who is trained in those exact skills. The second approach utilizes people who currently have interactions with children, training them to administer any part of preventive dental care that they can comfortably handle.

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158. Bertolami, *supra* note 151, at 5.

159. *Id.*

160. Two things have occurred that might be encouraging this new vigor. First is the Surgeon General’s eloquent “Call To Action” to reduce oral health disparities, made in 2000. Second, recent science has changed how we assess the role of dental health in overall health, due to a steady series of studies that consistently show dental health is related to a slew of other conditions, and concurrently, good oral health can play a critical role in reducing the incidence of other problems. See REPORT FROM THE SURGEON GENERAL, *supra* note 1.

161. PEW CTR. ON THE STATES, *supra* note 8, at 24.

162. *Number of Dentists 2009*, STATEHEALTHFACTS.ORG, available at <http://www.statehealthfacts.org/comparemtable.jsp?ind=442&cat=8> (last visited June 25, 2011)

163. PEW CTR. ON THE STATES, *supra* note 8, at 24.

164. PEW CTR. ON THE STATES, *supra* note 8, at 24.

165. *Id.*

166. See *id.* at 24.

For pediatric preventive dental care, the necessary skills are a subset of those acquired by dentists and dental hygienists, with additional training to treat young children. A dental therapist is a professional who is trained to clean children's teeth, take x-rays of their mouths, fill cavities, and recognize problems that require referral to a dentist. It requires between two and four years of post-secondary education, depending on the program, to complete a dental therapy program,<sup>167</sup> making it far easier to train dental therapists to provide the necessary care to all children than it is to train more dentists.<sup>168</sup> Alaska has one of the few dental therapist programs in the United States, which was created and is currently being utilized to provide care for American Indian and Alaskan Native people. The training occurs in Alaska and is supervised by staff from the University of Washington, in partnership with the University of Otago in New Zealand.<sup>169</sup> New Zealand, as discussed more fully below, has been the international leader in expanding access to dental care for its children to near universal levels, and one of the primary means for it accomplishing this has been the development and support of dental therapist training in that country.

Dental therapy programs have not been as readily adopted in the United States as in other countries. The American Dental Association (ADA) has been adamantly opposed to these programs, and employment for any graduates will require the political will to create dental therapist licensing structures in every state they practice in.<sup>170</sup> Only Oregon has a training program for dental therapists, and this program is quite new. This program was created to provide dental therapists to rural Alaskan children and came into existence only after a bruising political battle between its proponents and the ADA, as detailed below. However, the success of the program in New Zealand has not gone unnoticed in the United States, and pressure is clearly building for a broader move towards this caregiver model in the United States.<sup>171</sup>

Utilizing the second approach and focusing on those who already have contact with children, many medical groups have begun to promote the training of primary care physicians and their nurses to perform dental screenings, educate

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167. See AHRQ HEALTH CARE INNOVATION EXCHANGE, *Dental Health Aide Program Improves Access to Oral Health Care for Rural Alaska Native People*, (June 9, 2008) [hereinafter *Rural Alaska Native People*], available at <http://www.innovations.ahrq.gov/content.aspx?id=1840>.

168. A related approach is to allow licensed dental hygienists to practice without immediate dental supervision, which could increase children's access to dental cleanings, though without the added benefit of diagnosis and treatment of cavities.

169. *Rural Alaska Native People*, *supra* note 167.

170. For example, during the legislative debate in Minnesota about creating a dental therapist training program, the ADA provided funding to the Minnesota Dental Association, which lobbied in opposition to the legislation.

171. For a discussion of the momentum and conflict within the profession, see Alfano, *supra* note 112, at 10-15.

parents and children about oral hygiene, and apply fluoride to teeth.<sup>172</sup> While these steps are not as effective as receiving the full menu of preventive care, most children do see their pediatricians with some regularity. In addition, studies have shown that parents are more likely to be given a referral to see a specific dentist if a pediatrician is involved in caring for a child's teeth.<sup>173</sup>

### *C. Dental Sealants in Schools*

Dental sealants are thin plastic coatings that are applied to molars in children's mouths.<sup>174</sup> A painless and brief procedure, applying a sealant can protect teeth from decay for as much as ten years.<sup>175</sup> They are most effective if applied soon after the mature molar erupts in a child's mouth. The Surgeon General's Report on Oral Health in 2000 reported that sealants can reduce decay in children's mouths by as much as 70%.<sup>176</sup> Sealants are very inexpensive, far less than the cost of filling cavities,<sup>177</sup> and can be applied by a dental technician.<sup>178</sup>

School-based sealant programs have been developed to provide this type of preventive care to children who are otherwise less likely to receive proper preventive dental care; such programs have been successful in the areas that have adopted this approach.<sup>179</sup> The Centers for Disease Control (CDC) and the Task Force on Community Preventive Services are strong proponents of these programs, and funding and support for them has been provided by the Maternal and Child Health Bureau, Health Resources and Services Administration, Department of Health and Human Services.<sup>180</sup> The CDC developed a software program, known as Sealant Efficiency Assessments for Locals and States (SEALS), for tracking the results of the school-based sealant programs, and this software continues to provide evidence of the effectiveness of this public health program.<sup>181</sup>

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172. See *Integrating Oral Health into Primary Medical/Pediatric Care*, 14 COLGATE ORAL CARE REP. 1, 1 (2004).

173. See Georgia G. dela Cruz et al., *Dental Screening and Referral of Young Children by Pediatric Primary Care Providers*, 114 PEDIATRICS e642, e652 (2004).

174. *Dental Sealants*, CDC, [http://www.cdc.gov/oralhealth/publications/factsheets/sealants\\_faqs.htm](http://www.cdc.gov/oralhealth/publications/factsheets/sealants_faqs.htm) (last visited August 25, 2010).

175. *Id.* at 1.

176. *Id.*

177. See Rocio B. Quiñonez et al., *Assessing Cost-Effectiveness of Sealant Placement in Children*, 65 J. PUB. HEALTH DENTISTRY 82, 82 (2005).

178. See PEW CTR. ON THE STATES, *supra* note 8, at 27.

179. *Id.* at 26–28.

180. See, e.g., NANCY CARTER, SEAL AMERICA: THE PREVENTION INVENTION (2007), available at <http://www.mchoralhealth.org/seal> (providing guidance to school districts assisting them in implementing these programs hosted by the Maternal and Child Health Resource Center).

181. See Barbara F. Gooch et al., *The Role of Evidence in Formulating Public Health Programs To Prevent Oral Disease and Promote Oral Health in the United States*, 6 J. EVIDENCE-BASED DENTAL PRAC. 85, 88 (2006).

*D. Dental Screenings as a Condition of School Attendance*

In an effort to address parental failure to care for children's teeth, many school districts have begun requiring proof of a dental screening before children can be enrolled in school.<sup>182</sup> Unfortunately, studies have shown that a dental screening alone has no correlation to increased dental health for a pediatric population.<sup>183</sup> There is a significant difference between the occasional screening, which can be nothing more than a cursory glance in a child's mouth every few years to satisfy a school district's requirements, and the recommended twice yearly dental exam and cleaning that children should receive. Screenings can serve to inform a child (or the parents) that a problem exists, but the child is still left adrift in the current dental infrastructure with no guaranteed referral source available to provide any treatments that the screening reveals are necessary. Furthermore, while a screening may reveal that a problem has occurred, it does nothing to provide the preventive care that will inhibit the problems from happening. Finally, given the insufficient number of pediatric dental care providers that are available, if the person performing the screening is trained in dentistry, an interaction that is limited to merely screening for the presence of a dental problem wastes one of the limited times a child might have this access. It would appear that in an apparent rush to adopt this requirement, many school districts appear unaware of the data proving its lack of effectiveness.<sup>184</sup> A more robust screening program, coupled with treatment, could be more effective.

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182. As of 2007, twelve states had this requirement. See Association of State and Territorial Dental Directors, *Emerging Issues in Oral Health: State Laws on Dental "Screening" for School-Aged Children* (2008), available at <http://www.astdd.org/docs/FinalSchoolScreeningpaper10-14-08.pdf>. In addition, Kentucky began this program in 2010.

183. See, e.g., K. Milsom et al., *School Dental Screening Does Not Increase Dental Attendance Rates or Reduce Disease Levels*, 8 EVIDENCE-BASED DENTISTRY 5, 5 (2007) (noting that data support that no improvement results from screening); see also K. Milsom et al., *The Effectiveness of School Dental Screening: A Cluster-randomized Control Trial*, 85 J. DENTAL RES. 924, 924 (2006).

184. See *School Dental Screenings*, IOWA DEPARTMENT OF PUBLIC HEALTH, [http://www.idph.state.ia.us/hpcdp/oral\\_health\\_school\\_screening.asp](http://www.idph.state.ia.us/hpcdp/oral_health_school_screening.asp) (last visited Apr. 14, 2011) ("All children newly enrolling in an Iowa elementary or high school are required to have a dental screening. This requirement was passed by the 2007 legislature and became effective July 1, 2008. The purpose of the dental screening requirement is to improve the oral health of Iowa's children. Dental screenings help with early detection and treatment of dental disease; reduce the incidence, impact, and cost of dental disease; inform parents and guardians of their children's dental problems; promote the importance of oral health for school readiness and learning; and contribute to statewide surveillance of oral health."). It bears noting that this requires two screenings over the course of a child's education. This is not meant to single out Iowa. England has long required all school children to have screenings, and many other school districts in the United States are also implementing these requirements.

#### IV. A PROPOSAL FOR SCHOOL-BASED DENTAL CARE: TOWARD UNIVERSAL PEDIATRIC PREVENTIVE CARE

This Article argues that the infrastructure for providing preventive dental care for children should be reassessed and changed for all children. As it is currently structured, it does not, and most likely cannot, provide the level of care required for the entire population of children. Given the range of problems that stand in the way of lower income children receiving timely and adequate access to preventive care, this segment of the population emerges as the most pressing target for immediate reform. This statement is made in light of the fact that the strong commitment of many stakeholders to improving the current system for these children has not been enough to raise the penetration of care anywhere close to 100%. There have been many federal block grants made to states to assist them in providing access to dental care for their children. Even this has not been enough to improve care so that the epidemic is controlled.<sup>185</sup> One must be cautious in shaping calls for reform in language that relates exclusively to income disparity. While family income clearly plays a significant role in this problem, ethnicity also has a measurable correlation with access to care. Furthermore, the significant percentage of relatively well-off children not receiving adequate care implies that there are other impediments to access beyond wealth and ethnicity that have not yet been defined properly. If the goal is providing care to all children, these impediments must be identified.

The solution called for in this Article is to provide all children in the United States with preventive dental care in their schools from a fully trained and plentiful group of professionals, specifically dental therapists. In the short term, however, this outcome seems unlikely because of the sheer scale of the changes that would be required. In the short term, the focus should be on children who are impoverished. Family income identifies children highly likely to be at risk for receiving substandard dental care and schools with high concentrations of these students can be readily identified by using the percentage of children who receive federally funded lunch and breakfast (the school lunch programs) since these programs are based on the family income of individual students. This focus should, however, take into account the children in school districts who are receiving appropriate care and support them accordingly.

The current system focuses on dentists as the primary caregivers and private practices as the location for that care to be provided. Working within this system as it now stands, another solution to providing care to children living in poverty would be to train numerous pediatric dentists to work in private practices that are geographically widespread and welcoming of Medicaid patients. However, this is

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185. For a detailed description of these grants, see NATIONAL MATERNAL & CHILD ORAL HEALTH RESOURCE CENTER, MCHB-FUNDED PROJECTS, *available at* <http://www.mchoralhealth.org/Projects/index.html>.

not likely to occur, as it would require a substantial increase in the number of dental schools to train the necessary number of dentists and a significant change in how dentists who treat Medicaid children are paid in order to create a financial incentive for them to treat this group in large numbers.

For children who are not living in poverty, there are stop-gap measures that are likely to increase the utilization of care while using fewer societal resources. These proposals are delineated below. These measures should be created to not only improve children's access to care, but to help identify the impediments to this occurring. The overall percentage of children who receive all recommended care is well below one hundred, including those whose parents can afford to provide it. This could be caused by a simple access problem, given that dental practices are not dispersed equally throughout the country, and there are some locations where it is difficult for even committed parents to find appropriate care for their children. However, it is likely that some of the same problems that have been studied and documented in lower income families, such as poor parental understanding of the importance of preventive dental care, parental anxiety about seeing a dentist, and the difficulties of making time to take a child (or children) to the required biannual appointments are present in all socioeconomic groups and are detrimental to children's care. The answer is unknown and needs to be identified.

#### *A. School-Based Care*

For children from lower income families, particularly those who go to schools that have a significant percentage of children receiving free lunches and breakfasts, it may make sense to begin providing preventive dental care in those schools, at no cost to the students. Providing twice yearly cleanings, examinations, sealants, cavity and decay treatment and fluoride rinses builds on the proven success of the dental sealant programs that have focused on reaching children in their schools.<sup>186</sup> Recognizing the shortage of dentists who are available to treat significant numbers of poor children, and the expense of paying national retail rates to attract dentists to these patient populations, dental therapists, or similar professionals, should be utilized to provide basic care and make referrals to dentists for anything outside the scope of their expertise that is discovered during examinations. School-based clinics staffed with dental therapists should both increase access and reduce the cost of providing it from current levels.

Given the need to refer patients to dentists for the treatment of particularly serious conditions, the clinics should have an assigned caseworker who manages children's referrals to dentists. This will ensure that more serious problems are

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186. See PEW CTR. ON THE STATES, *supra* note 8 (resulting in an impressive increase in the number of children who receive dental sealants).

properly handled, which is important for two reasons. First, as discussed above, these caseworkers have a proven record of increasing children's utilization of appropriate care. Second, the use of a caseworker may calm some concerns dentists might have with the introduction of a new form of dental professional that may be competitive with the dental business model. The caseworkers can build up relationships with dentists, providing a steady source of referrals from their schools as well as ensuring that the children who need care do, in fact, arrive at scheduled appointments.

This type of in-school clinic should ensure close to universal care for this population, extrapolating from the experiences in Boston and New Zealand, whose very similar program is discussed below. Furthermore, there have been numerous studies showing the cost effectiveness of preventive dental care, implying that this will eventually save money for the states that implement it, as Medicaid dental costs for these children's care are reduced over time.<sup>187</sup>

A case study that proves this model can have an important positive effect on children's dental health is a program called ForsythKids, which has operated in Massachusetts over the last six years.<sup>188</sup> This program uses dentists and hygienists to provide care to children, with parental permission, during the school day in the public school.<sup>189</sup> The schools initially chosen for this study all have substantial at-risk populations with high levels of poverty, as evidenced by more than 50% student enrollment in free or reduced cost lunch programs.<sup>190</sup> The program has proven so successful that it has since been expanded to fifty-three schools, from the original six.<sup>191</sup>

In the initial screenings, "77% of the children had untreated cavities and 13% had acute infections or abscesses."<sup>192</sup> After two rounds of the full schedule of preventive care, the children are now "virtually free of new tooth decay."<sup>193</sup> The average time away from class per year was less than one hour, and the only adverse event was a single abscess that formed after treatment, a rate of less than .05%.<sup>194</sup>

As this case study shows, providing the full scope of preventive care in schools solves myriad problems. First and foremost, schools are where the children are. As described earlier, dentists who do treat Medicaid patients routinely complain about the large number of children on Medicaid who fail to

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187. See CHILDREN'S DENTAL HEALTH PROJECT, *supra* note 146, at 1.

188. See Richard Niederman et al., *A Model for Extending the Reach of the Traditional Dental Practice: The ForsythKids Program*, 139 J. AM. DENTAL ASS'N. 1040 (2008).

189. *Id.* at 1040.

190. *Id.* at 1042.

191. See FORSYTHKIDS ELEMENTARY SCHOOL-BASED CAVITIES PREVENTION PROGRAM, available at <http://www.aap.org/oralhealth/summit/ForsythKids.pdf>.

192. *Id.*

193. *Id.*

194. See *id.* at 1044; NIEDERMAN ET AL., *supra* note 188.

show up for their scheduled appointments, which implies there are substantial logistical hurdles that impoverished parents face in getting their children to the dentist's office. Providing care in schools will do away with many of these logistical hurdles, making it far more likely that children will receive regular and timely preventive care. Second, the population of schools is relatively easy to predict, as is the time required for providing preventive care. This makes planning for staffing and scheduling in a school-based clinic relatively straightforward.

Third, funding this care through a single entity, such as a school district, and basing that funding on a set population, such as the number of students enrolled in that school, creates a simplified model of financing, compared to the current, more burdensome process.<sup>195</sup> This, too, is likely to increase the number of children who receive care on a consistent basis, and reduce the cost of providing the care to each person who receives it. Innovative programs created to provide dental care to low-income children often have little on-going funding, instead relying on determining the insurance status of specific children, and then submitting claims for reimbursement to any third-party payer that is discovered.<sup>196</sup> This is laborious, risky, and can cause problems for the care providers, judging from dentists' other problems with Medicaid billing and claims processes. All of these issues may dissuade dentists from providing these services. As described in Part III, above, given the threat of criminal fraud prosecution, the process of submitting Medicaid claims is, by itself, time consuming and somewhat stressful for dental professionals. Perhaps more importantly, many children have sporadic enrollment in Medicaid or SCHIP, and some do not enroll at all, even though they are technically entitled.<sup>197</sup> If treatment were dependent on Medicaid-enrollment status, a significant and important portion of these children would not receive care. If treatment were not dependent on enrollment, but funding were dependent on claims reimbursements, a funding mechanism incorporated into some school sealant programs would make it difficult to develop consistent funding streams for the dental care that is provided, since varying portions would be offset by Medicaid reimbursements.

Some school districts currently provide dental care to their students and

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195. See *supra* Section II.D for a discussion of current problems with claims processing.

196. See, for example, Colorado's "Be Smart and Seal Them" school-based, dental sealant program. This program's central mechanism for providing care is dental hygienists going to schools and applying sealants. The hygienist is expected to submit Medicaid claims for all eligible children, and this is the only source of funding for these programs that is explicitly delineated in the program's guidelines, beyond one time seed money provided by the state public health department. See COLORADO DEPARTMENT OF PUBLIC HEALTH & ENVIRONMENT, BE SMART AND SEAL THEM! A SCHOOL-BASED DENTAL SEALANT MANUAL, at section titled "Budget," available at <http://www.cdph.state.co.us/pp/oralhealth/BeSmartandSealThem.pdf> (last visited Aug. 26, 2010).

197. "Nearly two-thirds of uninsured children are eligible for public coverage." ENROLLING UNINSURED LOW-INCOME CHILDREN IN MEDICAID AND SCHIP 2 (2009), available at [http://www.kff.org/medicaid/upload/2177\\_06.pdf](http://www.kff.org/medicaid/upload/2177_06.pdf).

anecdotal evidence of the success of these programs appears highly favorable. At the present time, there are no large-scale studies conducted in the United States that have examined this closely, but it appears that much of the care is provided by dental hygienists, who then bear the responsibility of submitting Medicaid claims for reimbursement.

### *B. Increased Use of Dental Therapists*

This Article argues in favor of using dental therapists to provide preventive care to children, and this is an area that will require significant changes to the existing legislative and regulatory structure. This profession is emerging as a competent,<sup>198</sup> easily trained,<sup>199</sup> and relatively inexpensive resource.<sup>200</sup> Currently, there are not enough dentists, and the marketplace of dental care is stacked against children from low-income families. The overall demand for dental care nationwide exceeds the supply, making it relatively simple for dentists to fill their practices with those who can afford the national retail rate for their services.<sup>201</sup> As discussed in Part III, Medicaid and SCHIP reimbursement rates are generally far below the retail rate to purchase care from dentists. For lower-income children, it is well documented that it is exceedingly difficult to find a private practice dentist who will treat them, and their inability to pay the market rate for the required services is a primary cause.<sup>202</sup> Dental therapists have been successfully utilized to resolve this shortage in other countries, as well as in certain areas of Alaska.<sup>203</sup>

A new profession requires creating the legal structure to sustain it. Currently, only Minnesota and Alaska have created a structure for licensing dental therapists, and in Alaska the licensing is limited so that dental therapists can only work within specific geographic areas and only treat indigenous populations. Every other state will have to create a licensing structure for this emerging profession, as well as setting parameters for the types of care they can provide for patients. Licensing by itself will not create a market for dental therapists, but the

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198. See BURTON L. EDELSTEIN, TRAINING NEW DENTAL PROVIDERS IN THE U.S. 2 (2009), available at <http://www.cdhp.org/system/files/Dental%20Therapy%20Policy%20Brief%2012-16-09.pdf>.

199. In New Zealand and Great Britain, this is a two-year, post-high school degree, though the first general program in the United States is a forty-month-combined dental therapy and bachelor of science degree offered at the University of Minnesota School of Dentistry.

200. See *Rural Alaska Native People*, *supra* note 167. The total cost of training a dental therapist from Alaska in New Zealand was between \$50,000 and \$60,000 including all travel and books.

201. See Berenson, *supra* note 107.

202. See discussion *supra* Part III.

203. For a discussion of the Alaska program, see Erik Bruce Smith, Note, *Dental Therapists in Alaska: Addressing Unmet Needs and Reviving Competition in Dental Care*, 24 ALASKA L. REV. 105 (2007). For a study of different countries' uses of dental therapists, see Nash et al., *supra* note 4.

absence of a licensing process is a significant impediment to the emergence of this profession. Further actions, such as establishing more schools to train dental therapists, creating liability insurance programs, and changing third party payer arrangements so that dental therapists can be reimbursed are additional necessary steps to altering the infrastructure so that it can incorporate this new model.

### C. The New Zealand Model

A model that should be looked at as one way of ending the epidemic of children's dental diseases in the United States is the system in New Zealand that provides school-based dental care to its children. New Zealand recently faced its own crisis of pediatric dental care and adopted a program similar to the one called for here. New Zealand's program covers its entire population, rather than only low-income children, who are the focus of this Article's initial proposal. While New Zealand has been providing some dental care in its schools for more than ninety years, it has recently modernized its system.<sup>204</sup> All New Zealand children up to the age of eighteen are entitled to receive preventive dental care free of charge.<sup>205</sup> For children through age twelve, care is provided in dental clinics that are located in the schools that the children attend, or for preschool children, the school closest to where they live.<sup>206</sup> In the school clinics, dental therapists—salaried employees of the government—provide the care.<sup>207</sup> For adolescents, care is provided in private dental offices and paid for by the government; the parent selects a dentist or dental therapist, and the family is responsible for taking the child to that office.<sup>208</sup>

The statistics from this new program, while not perfect, are impressive. In 2002, for children ages five to six, 93.4% received proper preventive care; for those ages seven to ten, 97% did. There is a drop for children ages eleven to fourteen, down to 88.2%.<sup>209</sup> This decline is most likely due to inclusion of thirteen- and fourteen-year-olds, who do not receive their dental care at school clinics—which reinforces how important the location is to achieving universal care. Within the small percentages of children who do not receive appropriate care, less privileged minorities are over-represented, much as they are in the United States. But the overall numbers are still extremely positive.

This model faces significant hurdles to adoption in the United States. This type of program, with broadly available care at no cost to the patient, requires a significant re-envisioning of the healthcare system. Even without the political

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204. See Nash et al., *supra* note 4, at 63.

205. *Id.*

206. *Id.*

207. *Id.*

208. *Id.*

209. See Lisa M. Jamieson & Pauline I. Koopu, *Child Use of Dental Services and Receipt of Dental Care in New Zealand*, 43 J. PAEDIATRICS & CHILD HEALTH 732 (2008).

impediments such as the opposition of the ADA, programs for training therapists have to be created. Licensing procedures in every state must be enacted, requiring the creation of numerous appropriate regulatory bodies to govern the process.

New Zealand is a small country, with roughly six million citizens. Historically, the government has provided centralized services in many different areas. The tax burden to support the services is far more equally distributed than in the United States, because the income disparities across the population are far smaller. It may be entirely unrealistic to anticipate the United States developing a commitment to a communal sense of responsibility for children's health such as exists in countries with more centralized healthcare systems. On the other hand, the language of Medicaid presumptively provides this high level of care to poor children, and this is a proposal to do so in a way that may be less expensive and more effective than what currently occurs.

#### *D. Certificates of Preventive Care Compliance*

In pursuit of the goal of universal adherence to preventive dental care for all children, those children who live in families with more resources should not be forgotten. To ensure that these children receive care, it may be necessary to require proof of full compliance with the ADA's preventive care schedule as a prerequisite to school attendance. The current dental screening requirements adopted by some school districts described in Part III provide useful information to parents who choose to take advantage of it, but do not appear to have solved the underlying problem of getting all children preventive care on a regular basis. The effect of the requirement proposed here should be relatively minor for the majority of families, as the dentist they already see can simply complete any necessary form when the student is in the office. For those families that do not get necessary care for their children on a regular basis, this requirement will make it extremely difficult to continue to neglect doing so.

It may be that requiring all children to show proof of proper dental care will be extremely burdensome and perhaps impossible for some parents who do not fit current profiles for at-risk families. A significant, known risk for many families is lack of access to a dentist. Requiring that all children receive adequate preventive care should rapidly expose any true shortages of dentists, and will create momentum for the adoption of alternative dental professionals. Requiring proof of compliance may also expose other impediments that are causing problems for families, which will be extremely helpful for purposes of identifying systemic problems in the dental healthcare infrastructure. Learning about the parents who, while earning family incomes above the poverty line, still have serious challenges in accessing appropriate care, is necessary to design a program that will meet their needs. On the other hand, given the apparent ability of these families to acquire dental care when a problem presents itself, it may be

that failure to provide proper preventive care is caused by a lack of commitment, and this program should rectify that problem.

## V. IMPEDIMENTS TO CHANGE

The New Zealand approach is attracting attention around the world, but it faces substantial hurdles to being adopted in the United States. The primary problem is the cost of training and licensing of dental therapists and building new clinics. New Zealand uses schools to provide care, but its pre-reform infrastructure already included dental clinics in many schools, so the reform there could build on this.<sup>210</sup> This infrastructure does not exist in most schools in the United States and will require a significant investment to develop. The secondary problem is political and societal. The dental profession, while divided, overall appears reluctant to readily embrace the dental therapist as a profession. Furthermore, providing care in schools may alarm parents, who may perceive it as a loss of control over their children's health care.

### A. Cost of New Infrastructure

Change can be expensive to implement, and this type of program requires the construction of numerous clinical environments in schools for providing dental care.<sup>211</sup> This means a high initial outlay of funds to generate long-term cost savings, a difficult argument to make in difficult financial times. Furthermore, while the model proposed here would be almost certainly cost-effective by measure of overall cost to society, the current system is sufficiently diffuse as to make it difficult to develop specific evidence of calculable savings for any single participant. Funding sources for dental care currently include individuals, employers, multiple governments and school districts, as well as taxpayers. The cost of poor dental care, including the increased prevalence of dental diseases and other health problems caused by the diseases, is borne primarily, but not exclusively, by individuals. It is also borne by the following: healthcare payers who must fix the eventual problems that develop as a result of poor care; the education system; and society, which suffers the cost of less happy, less productive members.<sup>212</sup>

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210. See generally Rhys B. Jones, *The School-Based Dental Care Systems of New Zealand and South Australia—A Decade of Change*, 44 J. PUB. HEALTH DENTISTRY 120 (1984) (discussing the history of this program).

211. For a rough cost estimate for these clinics, see CARTER, *supra* note 180. There are two primary approaches to building space for providing care in schools: building a clinic center at the school itself or using a bus or truck that has been outfitted as a travelling dental office. Either approach would appear to require a significant investment, especially considering the sheer number of schools that would need access.

212. For an example of the diffuse cost, see PEW CTR. ON THE STATES, *supra* note 8, at 14 ("In 2007, California counted more than 83,000 visits to emergency departments for both children and adults for preventable dental conditions.").

The state Medicaid programs are an exception to this problem, as studies have shown significant cost savings for these programs when children receive timely preventive dental care.<sup>213</sup> Unfortunately, while a program such as the one used in New Zealand should offer significant cost savings for state Medicaid programs, these programs are not currently structured to allow for investments in infrastructure and salaried payments to care providers. Medicaid pays when care is provided. Changing this will most likely require coordinated action from Congress, different state governments, and school boards. A model could be based on contracts that Medicaid programs have negotiated with managed care plans, where a flat fee is paid for each child's care. But the proposal here is still a substantial change from current Medicaid practices.

There are a small number of federally funded dental clinics, and perhaps reform could be modeled on the existing financing structure for these, leaving aside the Medicaid programs entirely. However, using dental therapists and providing care in schools would be a significant enhancement to how these clinics are currently structured. PPACA does include funding for increasing the provision of care in schools,<sup>214</sup> and does not exclude dental care from that funding.<sup>215</sup> This may create working models that can serve to prove cost effectiveness and assuage state government concerns.

### *B. The Dental Profession's Opposition*

It is likely that any change of the scope envisioned here will arouse concerns in the dental profession, which has been profitable and successful for decades.<sup>216</sup> And organizations such as the American Dental Association (ADA) have already proven their power in slowing the adoption of any models that might challenge this profitability.<sup>217</sup> This opposition, however, is not uniform. Several states have or are considering adopting legislation that would allow for dental therapists, and some state dental organizations are meeting privately, without ADA involvement, to organize approaches to what they term "mid-level practitioners."<sup>218</sup> Furthermore, influential schools of dentistry are showing support for reform.<sup>219</sup> On the other hand, other state dental organizations are meeting to formulate plans to oppose the same model,<sup>220</sup> signaling serious discord within the profession. It is likely that significant opposition from organizations like the ADA will continue to present problems for adopting

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213. See CHILDREN'S DENTAL HEALTH PROJECT, *supra* note 146, at 1.

214. PPACA, Pub. L. No. 111-148 § 4101 (a), 124 Stat. 119, 546 (2010).

215. *Id.*

216. See Berenson, *supra* note 107.

217. See Alfano, *supra* note 112, at 12 (criticizing the "dysfunctional" and reflexive opposition of the ADA to new caregiver models).

218. *Id.* at 13.

219. *Id.* at 10.

220. *Id.* at 13.

reforms. Perhaps signaling its recognition of this obstructionist mindset, the federal government has recently excluded the ADA from committees that are studying the delivery of dental care in the United States.<sup>221</sup>

The potential effect on private dental practices of providing preventive dental care in schools or in private practices of dental therapists should not be overestimated. As described earlier, dental practices are operating at maximum capacity and are not serving the entire population. Furthermore, the number of graduates from dental schools, at current rates, will not come close to equaling the number of dentists who are likely to retire in the next two decades. Focusing initial changes on populations who are currently not served by traditional dentists may ease concerns created by the introduction of this form of care-giving model, but the ADA's previous reaction to dental therapist proposals, such as the one in Alaska, implies otherwise. Given that much of Alaska has no dentists, and that the population of dental therapists consisted almost entirely of Native Americans from Alaska, it seemed to have presented no threat to the ADA. Yet its opposition was fierce.<sup>222</sup>

Data generated by the successful ForsythKids program, described above in Section IV.A, shows a program where the traditional dentist-hygienist team were successful in treating at-risk children, and could be used as an argument for why the dental therapist model is unnecessary.<sup>223</sup> However, it is unclear whether any increased efficiency gained by providing care in schools will offset the terrible shortage of dentists now and into the future.

### *C. Parental Concerns*

It is not difficult to imagine that a parent might feel frightened at the thought of a stranger providing medical care to her child, especially when she may have no opportunity to meet the caregiver or supervise the interaction. While the provision of dental care in schools may be perceived as a significant convenience to some parents, all parents must be given the option of providing the care themselves at their own cost and with the care provider they have chosen. Preventive dental care is a low-risk medical interaction, and the benefits of providing the care in schools seem to outweigh any theoretical parental concerns. But mandating such care significantly and unjustifiably diminishes parental authority.

This Article's proposal calls for an initial focus on lower income families, who may not have the resources to pay for a private dentist of their choosing. So as not to unjustly impose a burden of lesser parental authority on less well-off

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221. *Id.*

222. According to Dr. Alfano, the governing board of the ADA aggressively opposed the Alaskan program in an effort to "nip this approach in the bud." Alfano, *supra* note 112, at 13.

223. See Niederman et al., *supra* note 193, at 1048 (discussing how a program like ForsythKids may increase efficiency for dental practices).

parents than on those with greater financial resources, Medicaid should continue to reimburse for care provided to children by dentists in private practice. The parents thus suffer no loss of any choice they may have under the current system, limited as it may be. If care is provided to the bulk of lower income children in their schools, it should make it far easier for lower income families to have access to private practice dentists when necessary.

Finally, parents may be concerned about the loss of classroom time when a student is being treated. As was shown in the discussion of the program in Boston, the average time away from class is an hour, which is less than the time children usually spend away from school when going to the dentist. However, the parents' ability to seek private care outside of normal school hours should lessen this concern, if not entirely relieve it.

### CONCLUSION

Preventive care is absolutely necessary for protecting children from dental decay and cavities. Currently, there is an epidemic of both diseases in children due to the failure to adequately provide this care. This is an inexcusable problem, as the basic requirements for pediatric preventive dental care are well-known, generally low-risk, and cost effective. The problem exists across all income levels, with many children from even upper middle class families failing to receive recommended preventive care.

Certain identifiable groups of children are particularly vulnerable, affected by this epidemic, and suffer dental diseases at a far greater rate than the general population. Low family income, vulnerable racial or ethnic identities, and homelessness all increase a child's risk. Many of these children already carry an overwhelming number of burdens, including poor nutrition and lack of parental involvement in their lives. The failure to receive preventive dental care in childhood exacerbates these problems. First, dental decay and cavities can cause pain. This pain alone may then lead to lower educational achievements, poor socialization, and an inability to eat proper foods. Furthermore, suffering the diseases of decay and cavities increases a child's vulnerability to other infections, and at its worst, leads to death from infection.

The problems that spring from poor childhood preventive care persist into adulthood. For example, receiving proper preventive care in childhood can reduce the number of adult teeth lost over a lifetime. Concrete connections exist between missing teeth in adulthood and increased risk of cardiac disease and diabetes. It is likely that the list of health problems linked to dental decay, cavities, and the oral problems they cause will grow, as all evidence leads researchers to believe that the connection between oral health and general health is far more pervasive than had been realized before. Poor oral health in adults, including missing or rotting teeth, also may be unattractive and painful, leading to difficulties in acquiring and keeping employment. Dental problems are

expensive to fix properly, and there is little or no public funding to provide this care to adults, making the burdens of poor oral health beginning in childhood potentially crippling later in adulthood. Finally, childhood impairment of educational and social development caused by dental pain and disfigurement has negative consequences on an adult's ability to thrive.

As shown here, the current infrastructure for providing preventive dental care to children is not capable of providing this care to all children who need it. Few dentists are available to treat all children, and these professionals are not distributed evenly, leading to geographic areas that contain almost no dental care for people who live there. Medicaid, the primary public insurance plan for children living in poverty, lacks adequate funding to compete for the scarce good of pediatric dental care in this marketplace.

This Article argues that the infrastructure for providing dental care to children needs to be changed, and that much of the necessary change requires fundamental legal reform. Comparatively, dental therapists are easy to train and can begin to fill the gaps in children's care caused by the shortage of dentists. However, this will require the development of legal structures for training and licensing this profession.

Preventive dental care should be provided to children in schools, ensuring that most children receive it in a consistent manner. New Zealand currently provides preventive dental care to its children in this way, having dental therapists administer the care in schools for children up to age twelve. This program has achieved close to universal treatment for these children, and it is a useful model for the development of a similar system in the United States. Given both the costs associated with a change of this magnitude and the disproportionate suffering borne by children who live in poverty, this program should begin in schools where a large percentage of children receive free or reduced cost meals. But ideally, all children will eventually either receive care in schools or be required to submit proof of having received proper care elsewhere. Providing care in schools requires the development of systems to both pay for the care and administer it.

Many stakeholders have been actively involved in the reform of the dental system, but they all have sought to achieve reform while avoiding wholesale change of the structure itself. The epidemic that children currently face has proven resistant to current reform efforts, and it is time to consider what the legal and regulatory infrastructure of pediatric dental care should look like in the future. It must be designed to reach *all* children, to have the capacity to care for all children on a regular basis, and to do so at a sustainably affordable cost. The proposal described here will help to accomplish these goals.



# No Role for Apology: Remedial Work and the Problem of Medical Injury

Steven E. Raper\*

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*[A]nd there are those who seem so outraged by injury that they become greedy for revenge, and thus they must ready harm for others.*

- Dante, as Vergil<sup>1</sup>

## INTRODUCTION

Many commentators endorse apologizing after injuring someone in the course of medical treatment. The sentiment has been stated in its most elemental form: “Say you’re sorry when you hurt somebody.”<sup>2</sup> However, an apology has special linguistic weight: it is an admission of regret, remorse and responsibility. As such, apologies may prove a case of medical negligence. In an attempt to decrease the potential harms of saying “I’m sorry” in the healthcare setting, some state legislatures have enacted statutes intended to protect physicians. The thesis of this Article is that apologies should not be issued in the medical setting, and that apology laws are misguided. These laws work against the important social policy goal of improving patient safety by discouraging healthcare workers from openly acknowledging and correcting systematic errors and deficiencies in human performance. Apology laws are also misguided because they bolster the failed litigation regime of deterrence and corrective justice of medical injuries. Lastly, these laws may require individual physicians to apologize for the actions (or inactions) of a complex healthcare delivery system over which physicians have little authority or control, rendering the apologies contrived and insincere.

Modern health care is a complex enterprise with a large and varied cast. A non-exhaustive *dramatis personae* would include state and national accreditation bodies, federal and third-party payers, hospital-wide committees, administrators, credentialed general care and specialty physicians, advanced practitioners, nurses, and support personnel. When there is a medical injury ascribed to error, many—indeed most—of the above-mentioned groups often play roles.

Over the past decade, medical injuries have been a significant societal problem jeopardizing patients who undergo medical treatment. The Institute of Medicine, in a landmark book called *To Err is Human: Building a Safer Health System*, called national attention to the fact that medical errors were among the top ten leading causes of death, and that the cost of preventable medical injuries

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1. DANTE ALIGHIERI, *THE DIVINE COMEDY OF DANTE ALIGHIERI: PURGATORIO*, 282 (Robert M. Durling ed. & trans., Oxford University Press 2003) (1314):

*ed è chi per ingiuria par ch'aonti  
si che si fa de la vendetta ghiotto,  
e tal convien che 'l male altrui impronti:*

2. ROBERT FULGHUM, *ALL I REALLY NEED TO KNOW I LEARNED IN KINDERGARTEN 6* (Random House 2003) (1988).

was between \$17 and \$29 billion.<sup>3</sup> Although complex, healthcare systems are amenable to the same systems analyses as other organizational systems. Similarly, principles of human performance as elucidated by cognitive psychology are also adaptable to healthcare professionals and other workers.<sup>4</sup> The types of adverse events that may contribute to excessive cost, preventable injury, and death include diagnostic errors, treatment errors, and preventive errors.<sup>5</sup> Other types of errors, such as equipment failures and failures to communicate, also occur.<sup>6</sup> It is therefore imperative to use modern principles of systems analysis and human performance to understand why medical errors take place and to develop a methodology for identifying and preventing errors from happening in the future.<sup>7</sup>

Surgical procedures are common causes of medical injury.<sup>8</sup> For most procedures, the long list of potential harms includes bleeding, infection, operative site or other organ injury, disability, and death. The likelihood of various complications is increased by pre-existing conditions such as heart disease, emphysema, or diabetes—all widely recognized as lifestyle illnesses.<sup>9</sup> Policies designed to prevent the wrong operation, medication errors, and hospital acquired infections are required for all facilities that perform operations and other invasive procedures.<sup>10</sup> The transfusion of blood and blood products can also cause injuries, such as cardiovascular collapse and death,<sup>11</sup> even though the discipline of transfusion medicine is subject to rigorous safeguards in laboratory testing, patient identification, and administration. Diagnostic and therapeutic radiologic procedures are also fraught with the potential for injury—delayed diagnosis can

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3. INST. OF MED., *Executive Summary*, in *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 2* (Linda T. Kohn et al. eds., 2000).

4. MARILYN SUE BOGNER, *Introduction* to *HUMAN ERROR IN MEDICINE 1, 4* (Marilyn Sue Bogner ed., 1994).

5. Lucian L. Leape et al., *Preventing Medical Injury*, 19 *QUALITY REV. BULL.* 144, 145 (1993) (listing types of errors seen in healthcare systems).

6. *Id.*

7. See JAMES REASON, *HUMAN ERROR* 17 (1990) (explaining that hindsight alone does not equal foresight).

8. Knowing surgery best, and the consequences of medical injury in the perioperative setting, the focus of the present analysis will be on injuries in surgical patients. Although the precise types of injury may vary in other medical disciplines, the principles are the same.

9. CENTERS FOR DISEASE CONTROL AND PREVENTION, U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *THE BURDEN OF CHRONIC DISEASES AND THEIR RISK FACTORS NATIONAL AND STATE PERSPECTIVES 34-39* (2004), available at [http://www.cdc.gov/nccdphp/burdenbook2004/pdf/burden\\_book2004.pdf](http://www.cdc.gov/nccdphp/burdenbook2004/pdf/burden_book2004.pdf).

10. THE JOINT COMMISSION ACCREDITATION PROGRAM: *HOSPITAL NATIONAL PATIENT SAFETY GOALS*, [http://www.jointcommission.org/assets/1/6/2011\\_NPSGs\\_HAP.pdf](http://www.jointcommission.org/assets/1/6/2011_NPSGs_HAP.pdf) (effective Jan. 1, 2011).

11. Eleftherios C. Vamvakas & Morris A. Blajchman, *Transfusion-Related Mortality: The Ongoing Risks of Allogeneic Blood Transfusion and the Available Strategies for Their Prevention*, 113 *BLOOD* 3406, 3406 (2009).

arise from a missed finding or a delay in receipt of information by the responsible treating physician. Contrast agents and inaccurate dosages of ionizing radiation also pose risks. Lastly, every medication has side effects, ranging from mild to lethal. In addition, medications pass through physicians, nurses, and pharmacists on their way to patients. At each step along the way—from ordering to transcription to dispensing to administration—the potential for injury is present.

Advising against apology does not mean blocking communication of adverse events to patients. Modern emphasis on patient autonomy means that the patient must be informed of adverse events for the purpose of making informed decisions regarding future care.<sup>12</sup> Better approaches to patient disclosure include institutional use of careful *accounts*—a type of remedial work—by the responsible healthcare organization and legislative assistance in strengthening privileged communications regarding documents generated in the pursuit of improved patient safety, which would otherwise be admissible as business records under applicable rules of evidence. Concerns of creating moral hazard in physicians emboldened by the absence of a need to apologize when error occurs are abated by increased oversight from government and non-governmental organizations, greater emphasis on credentialing and maintenance of competencies, accountability in medical staff affairs, and identification and management of the impaired physician. Lastly, there is an evolving understanding of professional commitment to the principles of patient safety and improved quality of care.<sup>13</sup>

## I. THE COMPLEXITIES OF MODERN MEDICINE

### A. *Risks of Injury in Contemporary Medical Care*

During one year-old Jeanella Aranda's surgery for a liver tumor, damage to blood vessels left her in a non-survivable condition without a new liver. Her parents were told that one of them might be able to donate part of their own liver to save their daughter's life. A laboratory error led Baylor University surgeons to surgically remove and transplant half of the father's liver into Jeanella when in fact the mother should have been the donor.<sup>14</sup> The father survived his unnecessary operation, but the infant died 20 days later. At another hospital in Rhode Island, surgeons operated on the wrong side of the brain in three separate

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12. JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* 104-29 (2002).

13. Troyen A. Brennan, *Physicians' Responsibility To Improve the Quality of Care*, 77 *ACAD. MED.* 973, 976 (2002); see also Anthony D. Whitemore, *The Competent Surgeon: Individual Accountability in the Era of "Systems" Failure*, 250 *ANN. SURGERY* 357 (2009).

14. Denise Grady & Lawrence K. Altman, *Suit Says Transplant Error Was Cause in Baby's Death*, *N.Y. TIMES*, Mar. 12, 2003, <http://www.nytimes.com/2003/03/12/us/suit-says-transplant-error-was-cause-in-baby-s-death.html>.

patients within the course of a year.<sup>15</sup>

The aphorism “first, do no harm” is well known to all physicians and surgeons.<sup>16</sup> Yet every surgeon accepts the uncomfortable fact that he or she will make errors leading to complications and death.<sup>17</sup> There is no such thing as a “mask of infallibility;”<sup>18</sup> widespread media coverage has unmasked the medical profession—revealing a fallibility that sometimes brings catastrophic results.<sup>19</sup> Each step in the medical process imposes the possibility of error and injury.

*To Err is Human*, published barely a decade ago, documented the rates of medical injury and error and suggested ways to improve patient safety.<sup>20</sup> It garnered widespread attention from the public, the media, and legislators for its finding that as many as 98,000 people die annually from medical errors in hospitals.<sup>21</sup> Errors in the delivery of medical care caused more deaths than motor vehicle accidents, breast cancer, or AIDS.<sup>22</sup>

Three seminal studies provided the support for the conclusions of *To Err is Human*. The first was the largely unheralded Medical Insurance Feasibility Study done in the early 1970s by the California Medical Association and California Hospital Association.<sup>23</sup> The second, the Harvard Medical Practice Study

15. Felice J. Freyer, *Hospital Fined in Wrong-Site Surgery*, PROVIDENCE J., Nov. 27, 2007, [http://www.projo.com/news/content/WRONG\\_Site\\_11-27-07\\_PB818Q7\\_v12.2704b40.html](http://www.projo.com/news/content/WRONG_Site_11-27-07_PB818Q7_v12.2704b40.html).

16. Cedric M. Smith, *Origin and Uses of Primum Non Nocere—Above All, Do No Harm!*, J. CLINICAL PHARMACOLOGY 371, 372 (2005) (reviewing the likely origin of the phrase and concluding prominent English physician Thomas Sydenham, not Hippocrates, was the author).

17. Charles L. Bosk, FORGIVE AND REMEMBER: MANAGING MEDICAL FAILURE 50 (1979) (citing an anonymous surgeon: “It would look suspicious if you are doing major surgery and, week after week, you have no deaths and complications. You’re going to have these, especially deaths, if you do major surgery.”).

18. Marlynn Wei, *Doctors, Apologies, and the Law: An Analysis and Critique of Apology Laws*, 40 J. HEALTH L. 107, 147 (2007).

19. RICHARD I. COOK ET AL., A TALE OF TWO STORIES: CONTRASTING VIEWS OF PATIENT SAFETY (1998), available at [www.npsf.org/rc/tts/npsf\\_w97.doc](http://www.npsf.org/rc/tts/npsf_w97.doc) (documenting a comprehensive bibliography of “celebrated” cases of medical errors leading to injury or death that have attracted a great deal of attention from the public, regulators, the media, and the courts). Willie King (Florida) had the wrong leg amputated. Betsy Lehman (Massachusetts) and Vincent Gargano (Illinois) died of cancer chemotherapy overdoses. Ben Kolb (Florida) died receiving a syringe full of epinephrine rather than a local anesthetic. Libby Zion (New York) died of a drug-drug interaction allegedly due to decisions made by overworked resident doctors. *Id.*

20. INST. OF MED., *supra* note 3, at 26.

21. *Id.*

22. *Id.*

23. Don Harper Mills, *Medical Insurance Feasibility Study: A Technical Summary*, 128 W.J. MED. 360, 362-64 (1978). The intent of the study was to provide data on the type, frequency, and severity of compensable disabilities in an attempt to estimate the cost of alternatives to the existing medical malpractice regime. Review of records from 20,864 hospital admissions to twenty three California hospitals found that potentially compensable events (similar to current definitions of medical injuries) had occurred in 4.65%. Although the majority, 80%, were temporary, 10.3% were

(HMPS), reviewed 30,195 New York hospital records from the year 1984 and documented a medical injury rate of 3.7%.<sup>24</sup> The HMPS was criticized as being from one state and one year. In response, thirteen Utah and fifteen Colorado hospitals were chosen to participate in a similar study for the year 1992.<sup>25</sup> This third study, a survey of 1047 patients admitted to two intensive care units and one surgical unit at a large teaching hospital, documented a correlation between the incidence of medical injury and increasing complexity of care.<sup>26</sup> In a study of 44,603 patients who underwent surgery between 1977 and 1990 at a large medical center, 2428 patients (5.4 percent) suffered adverse events.<sup>27</sup> A study of surgical care from the Colorado and Utah data cited above found that injuries resulting in death, disability, or a prolonged hospital stay were no more likely to

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permanent, and 9.7% resulted in death. Patients aged 65 or older were statistically more likely to sustain an injury, and nearly 72% of the events occurred in the operating room. *Id.*

24. Troyen A. Brennan et al., *Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I*, 324 NEW ENG. J. MED. 370, 371-72 (1991). Although most of these adverse events gave rise to complete recovery in less than six months, 2.6% involved permanently disabling injuries and 13.6% resulted in death. Further study of these records identified 1133 patients with disabling injuries; drug complications were most common (19%), followed by wound infections (14%), and technical complications (13%). Nearly half were associated with an operation (48%), and the rate of injuries in those aged 64 and over was twice that of patients under age 45. *Id.*

25. Eric J. Thomas et al., *Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado*, 38 MED. CARE 261, 264-67 (2000) (submitting for review non-psychiatric hospital discharge records; 5,000 in Utah and 10,000 in Colorado). Five hundred eighty seven medical injuries were identified; for a rate of 2.9 % of hospitalizations in each state. The rate of injury associated with operations was again nearly half (44.9%.) More than four in five of the recorded injuries occurred in the hospital, with the rest occurring prior to admission in non-hospital settings. A lower percentage of deaths due to injuries (6.6%) were found when compared to the HMPS (13.6%). *Id.*

26. Lori B. Andrews et al., *An Alternative Strategy for Studying Adverse Events in Medical Care*, 349 LANCET 309, 311-12 (1997). Ethnographers trained in qualitative observational research integrated into physician teams for attending rounds, residents' work rounds, nursing shift changes, case conferences, and other scheduled meetings, and various departmental and section meetings. Data were collected about health-care providers' own assessments about the appropriateness of the care that patients received to assess the nature and impact of adverse events and how health-care providers and patients responded to the injury. Of the 1047 patients in the study, 185 (17.7%) were reported to have had at least one serious injury defined along a spectrum from temporary physical disability to death. The likelihood of having a medical injury was linked to the seriousness of the patient's underlying illness. Patients with long stays in hospital had more injuries than those with short stays. The likelihood of experiencing an injury increased 6% for each day of hospital stay. The most common causes of injury were individuals (37.8%), interactive causes (15.6%), or administrative decisions (9.8%). Injuries discussed in the various settings were recorded and a classification scheme was developed to code the data. A major difference was the real-time nature of the data collection in contrast to the three seminal studies. *Id.*

27. Hunter H. McGuire et al., *Measuring and Managing Quality of Surgery: Statistical vs Incidental Approaches*, 127 ARCHIVES SURGERY 733, 734-36 (1992). Somewhat less than one-half of these adverse events were considered attributable to error. During the same hospitalization, 749 patients died during; 7.5 percent of these deaths were attributed to error. *Id.*

occur with surgical care than with nonsurgical care.<sup>28</sup>

*To Err is Human* focused widespread attention on the simple fact that patients were not always *safe* in the healthcare setting. There existed a widespread problem of medical injury with and without error. To the public, documentation that doctors, nurses, and others in the healthcare setting could make errors and injure patients was a revelation. However, *To Err is Human* made the novel suggestion that improving patient safety required healthcare leadership to identify and correct faulty systems in which errors could happen, rather than a focus on punitive approaches, like malpractice litigation, when patients were injured by medical diagnosis and treatment. The main message of *To Err is Human* was later elegantly summarized:

“Most errors are committed by good, hardworking people trying to do the right thing . . . . It is far more productive to identify error-prone situations and settings and to implement systems that prevent caregivers from committing errors . . . .”<sup>29</sup>

And yet, medical injuries appear unavoidable in the healthcare delivery system and occur throughout the spectrum of medical care.<sup>30</sup> The recognition that patients are injured through error has led to an emphasis on patient safety initiatives. After the publication of *To Err is Human*, the IOM released a second medical error analysis in 2001, *Crossing the Quality Chasm*, which made further recommendations for enhancing patient safety in healthcare institutions.<sup>31</sup>

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28. Atul A. Gawande et al., *The Incidence and Nature of Surgical Adverse Events in Colorado and Utah in 1992*, 126 *SURGERY* 66, 69-71 (1999). Among surgical injuries, 54% were considered to be preventable. Fifteen common operations each accounted for 1% or more of surgical injuries. *Id.*

29. Robert M. Wachter & Peter J. Pronovost, *Balancing “No Blame” with Accountability in Patient Safety*, 361 *NEW ENG. J. MED.* 1401, 1401 (2009).

30. To conform to the terminology extant in the patient safety literature, most definitions are derived from the Institute of Medicine (IOM) study “To Err is Human.” An adverse event is an injury resulting from a medical intervention, or in other words, it is not due to the underlying condition of the patient.

31. COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA INSTITUTE OF MEDICINE *CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY* (2001) (proposing improvements in six dimensions towards which all healthcare constituencies should strive). These six dimensions are: *Safe*—avoiding injuries to patients from the care that is intended to help them. *Effective*—providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively). *Patient-centered*—providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions. *Timely*—reducing waits and sometimes harmful delays for both those who receive and those who give care. *Efficient*—avoiding waste, including waste of equipment, supplies, ideas, and energy. *Equitable*—providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status. *Id.*

## B. Patient Safety: The Need for Protected Disclosure

### 1. Health System-based Approaches to Making Patients Safer

Since 2004, there has been a steady decline in the number of reported wrong-site surgeries in Pennsylvania.<sup>32</sup> Many factors could be contributing to this decrease: implementation of a universal protocol or “pause for safety,” intra-institutional confidential reporting of injuries, mandatory reporting to a state patient safety authority, and root cause analysis to prevent similar events in the future. The patient safety movement is based on concepts learned from diverse disciplines and their disasters, many of which are imprinted on the collective conscience: the nuclear reactor industry (Three Mile Island, Chernobyl),<sup>33</sup> the chemical industry (Bhopal),<sup>34</sup> the National Aeronautics and Space Administration (Challenger, Columbia),<sup>35</sup> and the airlines industry.<sup>36</sup> The overarching goals of the patient safety approach are to prevent injuries caused during medical diagnosis and treatment and to reduce errors through systemic change. Patient safety advocates push for transparency through *confidential* reporting requirements, which are required and may even be anonymous. No single data source is sufficient to gain a complete understanding of errors contributing to actual or potential medical injury, so thought has been given to the development of a culture of patient safety:<sup>37</sup> a culture reconciling professional accountability with the need to create a safe environment to report medical errors.<sup>38</sup>

Accurate reporting of outcomes is crucial to improving patient safety. Surgeons were first challenged to report procedural outcomes a century ago by Ernest A. Codman.<sup>39</sup> He chastised public—or “charity”—hospitals for not looking at patient outcomes. Codman charged individual physicians with not wanting to standardize or report how their patients fared because hospitals would

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32. *Pennsylvania Patient Safety Authority Wrong-Site Surgery Reports by Quarter*, PATIENT SAFETY AUTH. (Dec. 2010), [http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Documents/psrs\\_qreports.pdf](http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/PWSS/Documents/psrs_qreports.pdf).

33. REASON, *supra* note 7, at 189.

34. *Id.* at 191.

35. *Id.* at 192; *see also Space Shuttle Columbia and Her Crew*, NASA, <http://www.nasa.gov/columbia/home/index.html> (last visited May 5, 2011).

36. *Accidents Involving Passenger Fatalities U. S. Airlines (Part 121) 1982—Present*, NAT'L TRANSPORTATION SAFETY BOARD, <http://www.nts.gov/aviation/Paxfatal.htm> (last visited Mar. 7, 2010).

37. *Develop a Culture of Safety*, IHI.ORG, <http://www.ih.org/knowledge/Pages/Changes/DevelopaCultureofSafety.aspx> (last visited July 20, 2011).

38. AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, AHRQ'S PATIENT SAFETY INITIATIVE: BUILDING FOUNDATIONS, REDUCING RISK (2003), *available at* <http://www.ahrq.gov/qual/pscongrpt>.

39. ERNEST A. CODMAN, A STUDY IN HOSPITAL EFFICIENCY: AS DEMONSTRATED BY THE CASE REPORT OF THE FIRST FIVE YEARS OF A PRIVATE HOSPITAL 49 (1996).

not want the expense.<sup>40</sup> Codman classified sub-optimal outcomes as due to one or more of several causes: lack of technical knowledge or skill; lack of surgical judgment; lack of care or equipment; lack of diagnostic skill; the patient's "unconquerable disease;" the patient's refusal of treatment; those accidents and complications over which there was no known control; and lastly, acknowledgment of the fact that not all sub-optimal outcomes could be attributed to error—"the calamities of surgery."<sup>41</sup> Codman was blunt in his criticism of his surgical colleagues: "[Y]ou let the members of the medical staff throw away money [by causing] unnecessary deaths, ill-judged operations and careless diagnoses. . . ."<sup>42</sup> At the turn of the twentieth century, the tools necessary for systems analysis did not exist, and the basic principles of human performance and error were not well understood.

At the turn of the twenty-first century, a systems approach to improving patient safety—as advocated by the IOM in *To Err is Human*—emerged based on three principles: First, error is an inherent, unavoidable aspect of human work. Second, faulty systems allow human error to lead to adverse events. Third, systems can be designed that prevent or detect human error before such adverse events occur.<sup>43</sup> The systems approach to patient safety is supported by many groups, including professional societies, medical centers, health insurance purchasers, federal and state legislatures, and perhaps most importantly, patients.<sup>44</sup> Low rates of adverse events now rank among the public's leading measures of healthcare quality.<sup>45</sup> The results of a survey of over 2000 adults indicate that people are more concerned about mistakes in hospitals than on airplanes.<sup>46</sup> A majority (71%) of survey respondents say that information about medical errors would be one of the biggest helps in determining the quality of providers.<sup>47</sup> In sum, there is demand for transparency in medical injury. However, it is crucial for all relevant parties to understand that most medical injuries are attributable to system flaws rather than individual incompetence or neglect.

Any worthwhile effort to improve such systems is likely to require substantial collaboration among parties—with reporting used to guide

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40. *Id.* at 53.

41. *Id.* at 59.

42. *Id.* at 17.

43. REASON, *supra* note 7, at 17.

44. Thomas H. Gallagher et al., *Current Concepts: Disclosing Harmful Medical Errors to Patients*, 356 NEW ENG. J. MED. 2713, 2713 (2007).

45. *Americans as Health Care Consumers: An Update on the Role of Quality Information*, KAISER FAMILY FOUNDATION AND AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ), <http://www.ahrq.gov/qual/kffhigh00.htm> (last visited Dec. 24, 2009).

46. *Id.*

47. *Id.*

collaborative quality improvement efforts and not to punish the participants and strictly protect the identity of individual physicians and hospitals.<sup>48</sup> It is also essential to recognize that to maintain or repair public faith in the United States healthcare system, patient safety must be placed among the highest priorities of social policy setting,<sup>49</sup> and transparency must be ensured.<sup>50</sup>

Hence, it seems clear that a systems-based approach is a valuable tool in the battle for medical injury reduction. Safe systems are designed by taking into consideration appropriate credentialing of physicians and surgeons and analyzing how hospital personnel interact with each other in teams and how they use machines and equipment. Output of such analyses includes the training and integration of new staff into existing teams, a reconciliation of medications and allergies, a protocol to prevent operating on the wrong patient or body part, procedures for checking equipment and supplies prior to beginning surgery, and the provision of a blame-free environment for organizational analysis and change to prevent future adverse events.<sup>51</sup>

Physicians have taken the opportunity to improve the safety and quality of care, anticipating the expansion of Internet resources in increasing public awareness of patient safety and quality of care.<sup>52</sup> Growing concerns about patient safety have led to an increase in the percentage of patients who would choose a highly rated surgeon whom they had not seen before over a less highly rated surgeon whom had previously provided care; also a factor of publicly available information.<sup>53</sup> Thus, improving patient safety is a matter of self-interest for the provider as well as a mechanism for improving patient safety.<sup>54</sup>

Patient safety initiatives actually do make patients safer. Arguably the most advanced program for outcomes assessment and safety improvement of surgical outcomes is the National Surgical Quality Improvement Program (NSQIP),

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48. Nancy J. O. Birkmeyer et al., *Partnering with Payers to Improve Surgical Quality: The Michigan Plan*, 138 SURGERY 815, 816 (2005).

49. Thomas R. Russell, *Safety and Quality in Surgical Practice*, 244 ANNALS SURGERY 653, 653 (2006).

50. Hiram C. Polk, Jr., *Presidential Address: Quality, Safety, and Transparency*, 242 ANNALS SURGERY 293, 293 (2005).

51. INST. OF MED., *supra* note 3, at 62.

52. Andrew R. Robinson et al., *Physician and Public Opinions on Quality of Health Care and the Problem of Medical Errors*, 162 ARCHIVES OF INTERNAL MED. 2186, 2189 (2002) (demonstrating that a majority of Colorado physicians and the public believe that reduction of medical errors should be a national priority).

53. *Americans as Health Care Consumers: Update on the Role of Quality Information, Highlights of a National Survey*, KAISER FAMILY FOUND. AND THE AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (Mar. 13, 2010), [www.ahrq.gov/qual/kffhigh00.htm](http://www.ahrq.gov/qual/kffhigh00.htm).

54. Alain C. Enthoven & Laura A. Tollen, *Competition in Health Care: It Takes Systems To Pursue Quality and Efficiency*, 24 HEALTH AFF. W5-420, W5-427 (2005).

achieving a 27% decrease in thirty-day mortality after major procedures and a 45% decrease in morbidity in Veterans Affairs Medical Centers throughout the country.<sup>55</sup> One important aspect of the NSQIP is that data are coded so only the participating healthcare organizations know which data set belongs to them.<sup>56</sup> The NSQIP was responsible for identifying intraoperative processes of care and postoperative adverse events as important risk factors for prolonged hospital stay after major elective surgery.<sup>57</sup> Other notable findings were that for many common procedures, there was no significant association between case volume at a given hospital and thirty-day mortality.<sup>58</sup> NSQIP has now expanded into the broader community under the auspices of the American College of Surgeons (ACS).<sup>59</sup> It has also been used to validate the Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicators.<sup>60</sup>

Examples of successful safety improvement efforts within surgery in the private sector are also numerous, and they include formalized team training at Beth Israel Deaconess, resulting in a 53% decrease in potential adverse outcomes in high-risk patients.<sup>61</sup> Using systems principles, and relying heavily on feedback for medical injuries, the Northern New England Cardiovascular Disease Study Group was able to decrease mortality rates 24%.<sup>62</sup> Intermountain Health Systems in Utah has developed interdisciplinary care standards,<sup>63</sup> and the Maine Medical Assessment Foundation has decreased rates of spine surgery and improved

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55. Shukri F. Khuri et al., *The Department of Veterans Affairs' NSQIP The First National, Validated, Outcome-Based, Risk-Adjusted, and Peer-Controlled Program for the Measurement and Enhancement of the Quality of Surgical Care*, 228 ANNALS SURGERY 491, 507 (1998).

56. Shukri F. Khuri et al., *The Comparative Assessment and Improvement of Quality of Surgical Care in the Department of Veterans Affairs*, 137 ARCHIVES SURGERY 20, 22 (2002).

57. Tracie Collins et al., *Risk Factors for Prolonged Length of Stay After Major Elective Surgery*, 230 ANNALS SURGERY 251, 257-58 (1999).

58. Katherine S. Rowell et al., *Use of National Surgical Quality Improvement Program Data as a Catalyst for Quality Improvement*, 204 J. AM. C. SURGEONS 1293, 1293 (2007).

59. Bruce L. Hall et al., *Does Surgical Quality Improve in the American College of Surgeons National Surgical Quality Improvement Program: An Evaluation of All Participating Hospitals*, 250 ANNALS SURGERY 363, 368 (2009).

60. Patrick S. Romano et al., *Validity of Selected AHRQ Patient Safety Indicators Based on VA National Surgical Quality Improvement Program Data*, 44 HEALTH SERVICES RES. 182, 183 (2009) (comparing AHRQ Patient Safety Indicators (PSI) against NSQIP data and to show that further validation should be considered before most of the PSIs evaluated are used to publicly compare or reward hospital performance).

61. Donald W. Moorman, *On the Quest for Six Sigma*, 189 AM. J. SURGERY 253, 256 (2005).

62. Gerald T. O'Connor et al., *A Regional Intervention to Improve the Hospital Mortality Associated with Cardiopulmonary Bypass Surgery*, 275 JAMA 841, 842 (1996).

63. Judy Hougaard, *Developing Evidence-Based Interdisciplinary Care Standards and Implications for Improving Patient Safety*, 73 INT'L J. MED. INFORMATICS 615, 624 (2004).

outcomes.<sup>64</sup> These organizations demonstrate four important characteristics: first, frank reporting of adverse events in a protected manner; second, a systems approach to quality improvement rather than placing blame; third, voluntary, physician-led interventions as or more effective as external regulatory mechanisms; and fourth, participation by providers in outcomes research as a response to practice variations.<sup>65</sup> Recently, an explicit link between improvements in patient safety have been shown to result in decreased malpractice claims; an intuitive result but not one for which compelling data exist.<sup>66</sup> Considerable obstacles to improving patient safety still exist.<sup>67</sup> One institutional hindrance to making patients safer is the entrenched notion that the quality improvement methods already available are adequate to address adverse events.<sup>68</sup> The persistence of patient safety problems in the face of such methods should be a sufficient argument for the inadequacy of existing approaches. Departmental morbidity and mortality (M&M) conferences are a traditional venue for discussion of adverse events, but they frequently do not consider all complications, are not consistently well-attended, and often do not involve healthcare providers other than attending surgeons and residents.<sup>69</sup> One study that compared NSQIP data with traditional M&M conferences noted that the latter failed to consider about 75% of the complications and about 50% of the deaths.<sup>70</sup> Further, education is usually stated as an important goal of the M&M conference, which may work against full analysis of an adverse event.<sup>71</sup> Arguably, M&M

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64. Steven J. Atlas et al., *Long-Term Outcomes of Surgical and Nonsurgical Management of Lumbar Spinal Stenosis: 8 to 10 Year Results from the Maine Lumbar Spine Study*, 30 SPINE 936, 943 (2005).

65. O'Connor, *supra* note 62, at 844; Eugene H. Shively et al., *Practicing Surgeons Lead in Quality Care, Safety, and Cost Control*, 239 ANNALS SURGERY 752, 752-53, 762 (2004).

66. Michael D. Greenberg et al., *Is Better Patient Safety Associated with Less Malpractice Activity?: Evidence from California*, RAND INSTITUTE FOR CIVIL JUSTICE (2010), [http://www.rand.org/content/dam/rand/pubs/technical\\_reports/2010/RAND\\_TR824.pdf](http://www.rand.org/content/dam/rand/pubs/technical_reports/2010/RAND_TR824.pdf).

67. Michelle M. Mello & Troyen A. Brennan, *Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform*, 80 TEX. L. REV. 1595, 1597 (2002); *see also* Robert S. Galvin, *The Business Case for Quality*, 20 HEALTH AFF. 57 (2001) (identifying specific obstacles to include a perceived vulnerability to legal discovery and liability, including: a traditional medical culture based on individual responsibility (blame and shame); unreimbursed costs for patient safety initiatives and quality; evolving medical informatics; the time and expense involved in defining and implementing evidence-based practice; the local nature of health care, and the perception of the lack of a business case, or, poor return on investment).

68. Mello & Brennan, *supra* note 67, at 1598.

69. Jay D. Orlander & B. Graeme Fincke, *Morbidity and Mortality Conference: A Survey of Academic Internal Medicine Departments*, 18 J. GEN. INTERNAL MED. 656, 656 (2003).

70. Matthew M. Hutter et al., *Identification of Surgical Complications and Deaths: An Assessment of the Traditional Surgical Morbidity and Mortality Conference Compared With the American College of Surgeons-National Surgical Quality Improvement Program*, 203 J. AM. COLLEGE SURGEONS 618, 624 (2006).

71. *Id.*

conferences present an obstacle to safety improvements by creating an illusion of improvements in patient safety. One can imagine, among others, the following specific obstacles to patient safety: resistance to admitting that errors have occurred; traditional “shame and blame” medical culture based on individuals rather than systems; fears that all discussions regarding injury or error are discoverable and subject to liability; the time and expense of evidence-based practice; inadequate resources due to the perception that a focus on safety is a poor return on investment; and the local, disaggregated nature of healthcare delivery and reporting.

## 2. *Improving Human Performance*

In addition to a fuller realization of the importance of systems in the development of medical adverse events, principles of human performance are also now understood to play a role. To be successful, a human task-based performance (e.g., an operation) has three main phases: planning, storage, and execution. Errors resulting from failures in performance may be classified as *slips*, *lapses*, or *mistakes*,<sup>72</sup> depending on which phase of the performance is involved. In one sense, surgeon performance can be a system factor, but in another sense, individual cognitive and technical ability make up a large part of a system’s safety barriers. Overemphasizing an individual physician’s role retards rather than advances understanding of systems failure, evoking defensiveness rather than constructive action. A number of steps have been taken to address problems of human performance.

Continuing medical education (CME) programs attempt to bridge knowledge and quality of patient care, and are generally held confidential. Many states, as a prerequisite for re-licensure, require a certain number of hours of CME programs, yet the structural incentives associated with health care in the United States lead to highly variable patterns of care and a widespread failure to implement evidence-based practice.<sup>73</sup> There is a link between CME participation

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72. REASON, *supra* note 7, at 9. Slips are failures of the execution phase, the storage phase, or both, and lapses are failures of the storage phase both may occur regardless of whether the planned procedure was adequate. Generally, slips are obvious or overt, whereas lapses are often hard to detect, or covert. Mistakes are failures of planning, reflecting basic deficiencies or failures in selecting an objective or specifying the means to achieve it, regardless of how well the plan was executed. *Id.*

73. Molly J. Coye, *No Toyotas in Health Care: Why Medical Care Has Not Evolved to Meet Patient’s Needs*, 20 HEALTH AFF. 44, 46 (2001) (discussing lack of a business case for quality in health care, and why each of the strategies intended to improve quality has been less effective than anticipated). A business case for quality would require that purchasers, users, and providers recognize and value advancements in quality outcomes. *Id.*

and performance on board recertification examinations,<sup>74</sup> and specialty board certification is linked to improved outcomes.<sup>75</sup> A direct link between CME participation and safer patient care is not as easy to confirm. Systematic reviews of the differences in the impact various CME strategies have on actual practice change have raised serious concerns about the value of some current CME programs.<sup>76</sup> The strategies shown to be most effective for practice change (e.g., reminders, patient-mediated interventions, outreach visits, opinion leader input, and multifaceted activities) place substantial emphasis on performance change rather than simply on learning.<sup>77</sup> There is evidence to suggest that despite some methodological shortcomings, performance on cognitive examinations such as certification and re-certification examinations is related to performance in practice<sup>78</sup> and that a physician's current certification status should be among the evidence-based measures used in the quality movement.<sup>79</sup>

Legislative approaches to improvements in safety have also been tried. Congress established the Medicare Utilization and Quality Control Peer Review Program to improve the efficiency, effectiveness, economy, and quality of services delivered to Medicare beneficiaries.<sup>80</sup> Peer review organizations (PROs), were originally intended as a mechanism for professional self-evaluation but subsequently became subject to anticompetitive abuse and other undesired consequences.<sup>81</sup> The potential for inequity was a particular concern, in that physicians who relinquished privileges on their own initiative might be treated more leniently than those against whom action was initiated by a peer review

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74. Robert S. Rhodes et al., *Continuing Medical Education Activity and American Board of Surgery Examination Performance*, 196 J. AM. C. SURGEONS 604, 607 (2003).

75. Lisa K. Sharp et al., *Specialty Board Certification and Clinical Outcomes: The Missing Link*, 77 ACAD. MED. 534, 537 (2002).

76. Jack L. Dolcourt, *Commitment to Change: A Strategy for Promoting Educational Effectiveness*, 20 J. CONTINUING EDUC. HEALTH PROF. 156, 157 (2000).

77. Paul E. Mazmanian, *Institute Of Medicine Recommends a Continuing Professional Development Institute For U.S. Health Professions*, 30 J. CONTINUING EDUC. HEALTH PROF. 1, 2 (2010); see also Paul E. Mazmanian & David A. Davis, *Continuing Medical Education and the Physician as Learner: Guide to the Evidence*, 288 JAMA 1057, 1059 (2002).

78. Robyn Tamblyn et al., *Association Between Licensure Examination Scores And Practice In Primary Care*, 288 JAMA 3019, 3024 (2002); see also John J. Norcini & Rebecca S. Lipner, *The Relationship Between the Nature of Practice and Performance On A Cognitive Examination*, 75 ACAD. MED. S68, S70 (2000).

79. Troyen A. Brennan et al., *The Role of Physician Specialty Board Certification Status in the Quality Movement*, 292 JAMA 1038, 1040 (2004)

80. 42 U.S.C. § 1395 (2006). The Secretary shall, in making the determinations under paragraphs (1) and (9) of subsection (a), and for the purposes of promoting the effective, efficient, and economical delivery of health care services, and of promoting the quality of services of the type for which payment may be made under this title, enter into contracts with utilization and quality control peer review organizations pursuant to part B of title XI of this Act. *Id.*

81. Michael A. Cassidy, *Peer Review Immunity: History, Operation, and Recent Decisions—Has HCQIA Accomplished Its Goals?*, 5 HEALTH CARE L. MONITOR 3, 9 (2002).

committee—a result of the loophole created by the physician’s surrendering of clinical privileges before an investigation is started in return for not being reported to the National Practitioner Data Bank.<sup>82</sup> Moreover, the data reviewed by peer review organizations were often legally discoverable, and this lack of anonymity and confidentiality tended to deter voluntary participation. Even when peer review organizations identified problems, they were often unable to implement solutions.<sup>83</sup> Quality improvement organizations (QIO) have largely supplanted peer review organizations, but they have yet to prove effective.<sup>84</sup>

Another way to evaluate physician quality is through physician clinical performance assessment (PCPA), defined as the “quantitative assessment of physician performance based on the rates at which their patients experience certain outcomes of care and/or the rates at which physicians adhere to evidence-based processes of care.”<sup>85</sup> PCPA initiatives have been slow to win acceptance by physicians on the grounds that they could be used as evidence in malpractice litigation.<sup>86</sup> The threshold for admission of such evidence in malpractice litigation is high and the possibility that PCPA data will reach this bar seems remote, at least for the vast majority of injury types that prompt litigation.<sup>87</sup> Unfortunately, some hospitals persist in separating patient safety, risk management and quality-assurance initiatives, to the detriment of each. Hospital incident reports have much the same shortcomings as the peer review process—discoverability by plaintiffs’ attorneys.<sup>88</sup> Individuals also may be reluctant to file reports out of fear that their employment might be jeopardized or that the reported party might seek retribution. Further, such reports are generally not protected by quality assurance privilege and are considered business records.<sup>89</sup>

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82. Barry R. Furrow et al., *Professional Relationships in Health Care Enterprises Section I: Staff Privileges and Hospital-Physician Contracts*, in HEALTH LAW: CASES, MATERIALS, AND PROBLEMS 849, 859 (6th ed. 2008).

83. Ilene N. Moore et al., *Rethinking Peer Review: Detecting and Addressing Medical Malpractice Claims Risk*, 59 VAND. L. REV. 1175, 1177-86 (2006).

84. Claire Snyder & Gerard Anderson, *Do Quality Improvement Organizations Improve the Quality of Care for Medicare Beneficiaries?*, 293 JAMA 2900, 2905 (2005) (finding no statistically significant difference in fourteen of fifteen quality indicators). *But see* William Rollow et al., *Assessment of the Medicare Quality Improvement Organization Program*, 145 ANNALS INTERNAL MED. 342, 353 (2006) (finding nineteen of twenty-one hospital measures showed improvement).

85. Aaron S. Kesselheim et al., *Will Physician-Level Measures of Clinical Performance Be Used in Medical Malpractice Litigation?*, 295 JAMA 1831, 1831 (2006).

86. *Id.* at 1833 (noting, however, that PCPA actions could still be used against physicians in other circumstances, for example, in proceedings by state licensure boards, hospital review committees, and other adjudicatory bodies).

87. *Id.* at 1834.

88. Clemon W. Williams, *Guide to Hospital Incident Reports*, 10 HEALTH CARE MGMT. REV. 19, 23 (1985) (discussing the benefits of—and the limited protections available for—incident reports).

89. FED. R. EVID. 803(6).

### 3. External Oversight

Although those best able—from a policy standpoint—to enhance patient safety by decreasing adverse events are those within individual healthcare entities, it has been known for nearly a century that physicians left to themselves may not do all that can be done to maintain or improve patient care.<sup>90</sup> There is concern even in the surgical community that voluntary reporting to state licensing boards (or even local credentials committees) is inconsistent.<sup>91</sup> Psychology may also underlie these behaviors, including fear about discussions in an open forum, feelings of denial and infallibility.<sup>92</sup>

The patient safety concept of non-punitive reporting systems aimed at getting doctors and other healthcare workers to disclose has gained momentum in response to interest and pressure from a wide assortment of federal, state and private entities: AHRQ,<sup>93</sup> Centers for Disease Control and Prevention<sup>94</sup> (CDC), Centers for Medicare and Medicaid Services<sup>95</sup> (CMS), the Joint Commission<sup>96</sup> (TJC), American College of Surgeons<sup>97</sup> (ACS), American Medical Association<sup>98</sup> (AMA), American Hospital Association<sup>99</sup> (AHA), American Society of Anesthesiologists<sup>100</sup> (ASA), and the Association of Operative Registered

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90. Walter P. Bowers, *Why Medical Malpractice?*, 200 NEW ENG. J. MED. 93, 93 (1929) (“[I]n the practice of medicine, there will always be, in the nature of the art, a large field in which if the physician chooses to do wrong, no one but he will know about it until the day of Judgment.”).

91. Hutter et al., *supra* note 70, at 621.

92. *Id.* at 622.

93. Daniel R. Neuspiel et al., *Improving Error Reporting in Ambulatory Pediatrics with a Team Approach*, in 1 ADVANCES IN PATIENT SAFETY: NEW DIRECTIONS AND ALTERNATIVE APPROACHES (Kerm Henriksen et al. eds., 2008), available at [http://www.ahrq.gov/downloads/pub/advances2/vol1/Advances-Neuspiel\\_43.pdf](http://www.ahrq.gov/downloads/pub/advances2/vol1/Advances-Neuspiel_43.pdf).

94. William R. Jarvis, *Infection Control and Changing Health-Care Delivery Systems*, 7 EMERGING INFECTIOUS DISEASES 170, 171 (2001).

95. CENTER OF MEDICARE & MEDICAID SERVICES, STATE OPERATIONS MANUAL APP. A §482.25(b)(6)(2009), available at [http://www.cms.gov/manuals/Downloads/som107ap\\_a\\_hospitals.pdf](http://www.cms.gov/manuals/Downloads/som107ap_a_hospitals.pdf) (noting that to improve incident reporting the facility should adopt a non-punitive system with the focus on the system and not the involved health care professionals).

96. Betty Jessup & Michelle A. Koury, *Joint Commission Accreditation: Leadership Challenges and Advantages*, 6 GRP. PRACT. J. 26, 27 (2009), available at [www.jointcommission.org/assets/1/18/getfile.pdf](http://www.jointcommission.org/assets/1/18/getfile.pdf).

97. Christian Shalgian, *Patient Safety Initiatives Following the IOM Report*, 86 BULL. AM. C. SURGEONS 8, 9 (2001).

98. Letter from Michael D. Maves, Exec. Vice President, Am. Med. Ass’n, to the Adm’r of the AHRQ 1 (Apr. 11, 2008), available at <http://www.ama-assn.org/resources/doc/washington/patient-safety-comment-letter.pdf>.

99. AM. HOSP. ASS’N, QUALITY ADVISORY: LONG-ANTICIPATED PATIENT SAFETY ORGANIZATION PROGRAM BEGINS, available at <http://www.aha.org/aha/advisory/2008/081029-quality-adv.pdf>.

100. Robert K. Stoelting, *Response to the IOM Report*, ANESTHESIA PATIENT SAFETY FOUNDATION, [http://www.apsf.org/about\\_safety.php](http://www.apsf.org/about_safety.php) (last visited Apr. 2, 2011).

Nurses<sup>101</sup> (AORN). The rationale is that improved error reporting will make future errors less common and less severe. Unreported errors are more likely to be repeated and cause further injuries.<sup>102</sup>

Commentators within the discipline of surgery as well as the community at large have noted it is vital that physicians not use protected disclosure as an excuse for avoiding responsibility for complications.<sup>103</sup> Private accreditation, conducted by external associations, has helped alleviate concerns regarding the “self-policing” nature and lack of oversight of most individual and institutional mechanisms for enhancing patient safety.<sup>104</sup> To address the issue of medical injury, in 1995 the Joint Commission (TJC), at the time known as the Joint Commission for Accreditation of Healthcare Organizations, adopted a Sentinel Events Policy (hereinafter known as “the Policy”) for TJC-accredited healthcare organizations.<sup>105</sup> The Policy requires that healthcare organizations report certain adverse, or sentinel, events to TJC.<sup>106</sup> Although TJC representatives claim that adherence to the Policy is voluntary, accreditation and the ability to provide services to at least Medicare and Medicaid patients hinges upon adherence.<sup>107</sup> The healthcare organization must then perform a self-critical, systems-based root cause analysis (RCA) of such events, and submit a report on the RCA along with a corrective action plan to TJC for review and approval.<sup>108</sup>

There are, however, characteristics of the Policy that are significant obstacles to facilities interested in improving safety. As might be expected, the Joint Commission approach to sentinel event disclosure has raised concerns

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101. *AORN Position Statement on Creating a Practice Environment of Safety*, AORN (last revised May 5, 2011), [http://www.aorn.org/PracticeResources/AORNPositionStatements/Position\\_CreatingaPatientSafetyCulture](http://www.aorn.org/PracticeResources/AORNPositionStatements/Position_CreatingaPatientSafetyCulture).

102. THE JOINT COMMISSION, *COMPREHENSIVE ACCREDITATION MANUAL FOR HOSPITALS: THE OFFICIAL HANDBOOK* (2011), [http://www.jointcommission.org/assets/1/6/2011\\_CAMH\\_SE.pdf](http://www.jointcommission.org/assets/1/6/2011_CAMH_SE.pdf) [hereinafter *JOINT COMMISSION HANDBOOK*].

103. Wachter & Provonost, *supra* note 29; see also Keith D. Lillemoe, *To Err is Human, but Should We Expect More from a Surgeon?*, 237 *ANNALS SURGERY* 470, 471 (2003) (admonishing surgeons to take responsibility for the safe conduct surgical procedures and the consequences of errors).

104. Barry R. Furrow et al., *supra* note 82, at 191-94.

105. *JOINT COMMISSION HANDBOOK*, *supra* note 102, at SE-9.

106. *Sentinel Events Policy and Procedures*, THE JOINT COMMISSION, [http://www.jointcommission.org/Sentinel\\_Event\\_Policy\\_and\\_Procedures](http://www.jointcommission.org/Sentinel_Event_Policy_and_Procedures) (last visited Apr. 2, 2011) (defining reportable adverse events as an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof). Serious injury specifically includes loss of limb or function. The phrase, “or the risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called “sentinel” because they signal the need for immediate investigation and response. Accredited organizations have some flexibility in defining “unexpected,” “serious,” and “the risk thereof.” *Id.*

107. Bryan A. Liang, Comment, *Other People’s Money: A Reply to the Joint Commission*, 33 *J. HEALTH L.* 657, 659 (2000).

108. *JOINT COMMISSION HANDBOOK*, *supra* note 102, at SE-9.

regarding exposure during litigation and the use of information beyond its intended patient safety purpose, such as TJC sanctions against healthcare organizations.<sup>109</sup> For example, if the Joint Commission receives an inquiry about an accreditation decision of an organization that has experienced a reviewable sentinel event, the organization's accreditation decision will be reported in the usual manner without making reference to the sentinel event.<sup>110</sup> However, if an inquirer specifically references the sentinel event, the Joint Commission will acknowledge that it is aware of the event and currently is working or has worked with the organization through the sentinel event review.<sup>111</sup> If the adverse report is not made, or the root cause analysis is not considered acceptable after process has been followed, TJC may place an organization progressively on Provisional Accreditation, Conditional Accreditation, and finally, Preliminary Denial of Accreditation.<sup>112</sup> Ultimately, TJC may revoke the provider's accreditation, which has major implications for reimbursement.<sup>113</sup>

The Joint Commission's accreditation program lacks the ability to identify many patient safety problems, and it is difficult to determine whether the Joint Commission's reporting policy has prevented adverse events—assuming such prevention is the primary aim of the policy.<sup>114</sup> Since the inception of TJC's unanticipated outcomes disclosure policy in 2001, the Elements of Performance have become more exacting.<sup>115</sup> Therefore, although recognition of the systems

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109. The Joint Commission, *Sentinel Events: Approaches to Error Reduction and Prevention*, 24 J. QUALITY IMPROVEMENT 175, 175 (1998).

110. JOINT COMMISSION HANDBOOK, *supra* note 102, at SE-14.

111. *Id.*

112. *2011 Accreditation Decision Rules*, THE JOINT COMMISSION, <http://e-dition.jcrinc.com/Frame.aspx> (last visited Apr. 2, 2011).

113. *A Look at the Joint Commission: CMS Approves Continued Deeming Authority*, BULL. AM. C. SURGEONS 49, 49 (2010) (reporting that the Department of Health and Human Services' Centers for Medicare and Medicaid Services (CMS) has approved the continuation of deeming authority for TJC's accreditation program, which has held deeming authority since the inception of the Medicare program in 1965). The CMS designation means that hospitals accredited by The Joint Commission applies to be "deemed" as meeting Medicare and Medicaid certification requirements. CMS has found that The Joint Commission's standards for hospitals meet or exceed those established by the Medicare and Medicaid program. The Joint Commission's hospital accreditation program had previously been granted unique statutory deeming authority, but this unique status ended with enactment of the Medicare Improvements for Patients and Providers Act of 2008. Accreditation is voluntary and seeking deemed status through accreditation is an option, not a requirement. If hospitals seeking Medicare approval choose to be surveyed by The Joint Commission, all visits are unannounced. *Id.*

114. Marlene R. Miller et al., *Relationship Between Performance Measurement and Accreditation: Implications for Quality of Care and Patient Safety*, 20 AM. J. MED. QUALITY 239, 246 (2005) (noting few relationships between Joint Commission categorical accreditation and Inpatient Quality Indicators or Patient Safety Indicators).

115. See THE JOINT COMMISSION, COMPREHENSIVE ACCREDITATION MANUAL FOR HOSPITALS (2009), <http://e-dition.jcrinc.com/Frame.aspx> (last visited Dec. 29, 2009). Chapter on Rights and

nature of error may represent progress in theory, the shame and blame mechanisms used by the Joint Commission for enforcement represent at least one step backwards. In combination with other medical efforts, progress toward error reduction and patient safety promotion may be significantly retarded.<sup>116</sup>

In summary, three converging trends have pointed to enhancements in patient safety as a source of reform for healthcare institutions. First, systems analytic quality measurement methods are evolving as a way to quantitatively assess guidelines for care. Second, there are mature methods for analysis of the fundamentals of human performance and failures of health care as a system. Lastly, external oversight of individual healthcare institutions by organizations, such as the Joint Commission, help provide incentives to continuous patient safety goals.

### *C. Medical Malpractice as Deterrence: A Failed Approach to Patient Safety*

The present professional liability system is particularly controversial with respect to whether it facilitates or hinders improvements in patient safety. Implicit in the analysis of medical injury is a genuine desire to reduce such injuries and make patients safer. Injuries are studied not only for their effects on involved individuals, but also for the critical objective of establishing systems to prevent similar injuries. An alternative to the patient safety approach of systems analysis, improved human performance, and external oversight is medical malpractice litigation for a presumed deterrence effect. Negligence tort law claims of medical malpractice have been brought against physicians for nearly a century. In New York City in 1910, 1.1% of tort cases were for medical malpractice.<sup>117</sup> In 1929, a physician was sued for malpractice once every four

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Responsibilities, RI.01.02.01, states: "The hospital respects the patient's right to participate in decisions about his or her care, treatment, and services." See also *Id.*, Elements of Performance # 21 ("The hospital informs the patient or surrogate decision-maker about unanticipated outcomes of care, treatment, and services that relate to sentinel events considered reviewable by The Joint Commission"); *Id.* # 22 ("The licensed independent practitioner responsible for managing the patient's care, treatment, and services, or his or her designee, informs the patient about unanticipated outcomes of care, treatment, and services related to sentinel events when the patient is not already aware of the occurrence or when further discussion is needed").

116. Ed Lovern, *JCAHO's New Tell-All; Standards Require that Patients Know About Below-Par Care*, 31 MODERN HEALTHCARE 2, 3 (documenting that providers have expressed concerns regarding provider liability for this new policy: e.g., every admission has unanticipated outcomes, the standard will create awkwardness between hospitals and medical staffs, and "the hospital, by definition, is now intruding into the patient-physician relationship if there is a [TJC] documentation process required" for these disclosures).

117. LAWRENCE M. FRIEDMAN, A HISTORY OF AMERICAN LAW 521 (3d ed. 2005).

days.<sup>118</sup> In 1934 surgeons were cautioned “Secure consent before you operate.”<sup>119</sup>

The care with which clients are selected for medical malpractice litigation notwithstanding, many suits are filed which do not support allegations of negligence. In one reported study, a total of ninety-eight claims were filed against 151 healthcare providers.<sup>120</sup> Of the ninety-eight claims, only forty-seven were confirmed as due to treatment given in the given time period.<sup>121</sup> Eight claims established a negligent adverse event related to treatment, ten claims involved hospitalization that had produced injuries not thought due to physician negligence, and three cases exhibited some evidence of medical causation, but not enough to pass the study’s negligence criteria.<sup>122</sup> Thus, twenty-six claims—more than half—provided no evidence of medical injury *or* negligence.<sup>123</sup>

Lawyers are generally responsible only to their clients.<sup>124</sup> Plaintiffs attorneys generally take thirty to forty percent of damage awards, plus expenses, but nothing if the jury finds for the defendant.<sup>125</sup> Selecting the right client is therefore a critical part of a plaintiff’s firm’s survival. To be found worthy of representation, a variety of tests have been used, including a pattern of negligence on the part of the defendant, how a case would likely stand up to a jury, and the readiness of a firm to work on a case for years.<sup>126</sup>

As might be expected, the high threshold for filing a claim on behalf of clients leads to a malpractice gap.<sup>127</sup> In the Harvard Medical Practice Study, physician reviewers identified 1133 adverse events out of a sample of 31,429 medical records. Of the documented adverse events, 280 were deemed due to negligence, but in these cases, only eight malpractice claims were filed (1.53%).<sup>128</sup> Another estimate (from 1984), relying on results of the statewide

118. Bowers, *supra* note 90, at 93 (“The situation at the present time is that about once every four days some patient makes a claim against a physician seeking legal redress for alleged malpractice.”).

119. Halbert G. Stetson & John E. Moran, *Malpractice Suits, Their Cause and Prevention*, 210 NEW ENG. J. MED. 1381, 1381 (1934) (“[A]pproximately 20,000 suits have been brought against physicians in the United States in the past five years.”).

120. PAUL C. WEILER ET AL., *Patient Injury and Litigation, in A MEASURE OF MALPRACTICE: MEDICAL INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION* 70 (1993).

121. *Id.*

122. *Id.* at 71.

123. A. Russell Localio et al., *Relation Between Malpractice Claims and Adverse Events Due to Negligence: Results of the Harvard Medical Practice Study III*, 325 NEW ENG. J. MED. 245, 248 tbl. 1 (1991).

124. MODEL RULES OF PROF’L CONDUCT pmbl. (2007) (“A lawyer, as a member of the legal profession, is a representative of clients, an officer of the legal system and a public citizen having special responsibility for the quality of justice.”).

125. BARRY WERTH, *DAMAGES* 44-45 (1998).

126. *Id.* at 53.

127. WEILER ET AL., *supra* note 120, at 69.

128. Localio et al., *supra* note 123, at 247.

medical chart reviews, found that there were 3571 patient claims from 21,179 estimated negligent injuries (17%).<sup>129</sup> When the authors expressed the claims data in the form of ratios calculated from sampling weights, the chances that a claim would be filed were not 17%, but 2%.<sup>130</sup>

As confirmation of the malpractice gap noted in the HMPS study, a similar patient record review of claims filed in Utah and Colorado showed similar results: eighteen malpractice claims were filed from a sample of 14,700 hospital discharges.<sup>131</sup> Fourteen of eighteen were made in the absence of negligence, and ten in the absence of an adverse event.<sup>132</sup> The overall probability of a claim after a negligent adverse event causing significant or major disability was 3.8%.<sup>133</sup> Patients who experienced negligent adverse events but did not sue shared social and demographic factors including being poor, uninsured, beneficiaries of Medicaid or Medicare, and seventy-five years of age or over.<sup>134</sup>

Arguably, not every negligent adverse event would produce a tort claim; most physical disabilities studied in the HMPS were moderate, temporary, or occurred in persons aged seventy or older whose monetary damages would be comparatively low.<sup>135</sup> Such injuries, even if negligent, might not meet a threshold for litigation but would trigger a patient safety review when disclosed. The impetus to study and correct systematic and individual errors would be to prevent similar errors in the future—not a goal of a plaintiff's attorney—whose responsibility is to represent an individual client.<sup>136</sup> Apologies or other statements—if made and admitted into evidence—could lower one of the other major bars to successful litigation—causation—leading to decreased costs of litigation and more filed claims.

The likely outcome of more disclosure is more litigation. There is little hard data on this point, but surveys of injured patient's responses to disclosure are suggestive. A survey of sixty-five experts predicted a 95% chance that claims would increase, including a 60% chance that full disclosure of severe injuries would double the annual number of claims nationwide and a 33% chance that volume would increase at least threefold.<sup>137</sup> Among patients, deterrent impact

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129. WEILER ET AL., *supra* note 120, at 70.

130. *Id.* at 73.

131. David M. Studdert et al., *Negligent Care and Malpractice Claiming Behavior in Utah and Colorado*, 38 MED. CARE 250, 250 (2000).

132. *Id.* at 253.

133. *Id.* at 255.

134. *Id.* at 257.

135. Localio et al., *supra* note 123, at 247-48.

136. MODEL RULES OF PROF'L CONDUCT, *supra* note 124.

137. David M. Studdert et al., *Disclosure Of Medical Injury to Patients: An Improbable Risk Management Strategy*, 26 HEALTH AFF. 215, 219-21 (2007) (coining the phrase "the great unlitigated reservoir").

was perceived to be greater: Disclosure would deter an average of 57% of plaintiffs whose injuries were not due to negligence and prompt 17% of those who were not inclined to file a claim, while there would be essentially no effect on those whose injuries were adjudged due to negligence.<sup>138</sup>

There are data also to suggest that the poor, the uninsured, and the aged suffer a disproportionate impact under malpractice litigation as currently practiced.<sup>139</sup> Lest the outlook on litigation as an approach to decreasing medical injuries appear too bleak, it has been noted that the legal system operates more accurately than the data suggest.<sup>140</sup> While the absolute number of claims is considerably larger than the absolute number of valid claims, the likelihood a physician will be sued is greater if negligent treatment is believed to have occurred than if not.<sup>141</sup> Further, given the care with which clients are selected by plaintiffs' attorneys, the success of malpractice claims is modest.<sup>142</sup>

Studdert has labeled malpractice law as "punitive, individual, [and] adversarial," seeking to place blame and transform injury into money.<sup>143</sup> This system has its basis in the traditional paradigm of surgical care, which holds the individual surgeon solely accountable. The "captain of the ship" paradigm has enabled many great achievements in surgical care, but it has also probably fostered a dangerous sense of infallibility. As a consequence, errors tend to be equated with negligence, and questions of professional liability tend to involve blaming individuals. Indeed, the very willingness of professionals to accept responsibility for their actions makes it convenient to focus more on individual errors than on collective ones;<sup>144</sup> an individual surgeon is a more satisfactory target for the anger and grief of a patient or family than a nameless, faceless healthcare organization. This is certainly not to say that surgeons should avoid responsibility. Rather, the point is that focusing on the errors of individual surgeons without addressing flaws in the underlying system does little to improve health care, and increases the likelihood that errors will go under-reported. Multivariate analyses of physician's answers to hypothetical vignettes showed that a willingness to report errors was positively associated with a belief that such reports improve quality of care, knowledge of the reporting process, and,

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138. *Id.* at 219.

139. Helen R. Burstin et al., *Do the Poor Sue More? A Case-Control Study of Malpractice Claims and Socioeconomic Status*, 270 JAMA 1697, 1700 (1993).

140. WEILER ET AL., *supra* note 120, at 74.

141. *Id.*

142. THOMAS H. COHEN, TORT BENCH AND JURY TRIALS IN STATE COURTS, 2005, (2009), available at <http://bjs.ojp.usdoj.gov/content/pub/pdf/tbjtsc05.pdf> (reporting 15% of bench and jury trials disposed of in state courts in 2005 were medical malpractice cases; of these, 22.7% had verdicts for the plaintiffs, with an average verdict of \$679,000).

143. David Studdert, *Medical Malpractice*, 350 NEW ENG. J. MED. 283, 287 (2004).

144. JAMES T. REASON, *Foreword* to HUMAN ERROR IN MEDICINE, at vii (Marilyn S. Bogner ed., 1994).

importantly, an expectation of forgiveness.<sup>145</sup> Where culpable, mechanisms of discipline should be (and are) being implemented by healthcare organizations.<sup>146</sup>

Another notable flaw in the liability process is that judgments of causality or fault are backward-looking, and prone to hindsight bias, which can prejudice experts' assessments of quality of care. This tendency was illustrated by a study of anesthetic care in which knowledge of differences in outcome (temporary versus permanent disability) exerted a significant effect on the opinion rendered by the reviewer.<sup>147</sup> Hindsight bias focuses too narrowly on adverse outcomes and pays insufficient attention to the processes of care. Yet another defect of the liability process is that it can be financially devastating for physicians,<sup>148</sup> often adversely affecting their problem-solving abilities. To the extent that experience with or fear of a lawsuit deters efforts at quality improvement by encouraging defensive medicine, it adds very little value to health care and is counterproductive from a cost standpoint.<sup>149</sup> Lastly, the majority of expenditures in the malpractice system go towards litigation; "The overhead costs of malpractice litigation are exorbitant."<sup>150</sup> Many believe that major reform of the professional liability system is a prerequisite for achieving any significant improvements in quality.<sup>151</sup> Undoubtedly, tort reform is highly desirable; however, the real prerequisite for improving identification and correction of system failures is the provision of increased protection for privileged discussion of such failures.

Organized medicine has mounted vigorous resistance to financially driven controls imposed under managed care without clinical justification, but is still in the initial stages of adopting scientifically based practice guidelines and effective accountability measures.<sup>152</sup> A transparent discussion of errors, complications, and deaths was reported not to lead to an increased risk of lawsuit in the trauma setting.<sup>153</sup> The improvements in patient safety achieved by anesthesiologists

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145. Lauris C. Kaldjian et al., *Reporting Medical Errors To Improve Patient Safety: A Survey of Physicians in Teaching Hospitals*, 168 ARCHIVES INTERN MED. 40, 43 (2008).

146. Wachter & Pronovost, *supra* note 29, at 1405 tbl. 2.

147. Robert A. Caplan et al., *Effect of Outcome on Physician Judgments of Appropriateness of Care*, 265 JAMA 1957, 1960 (1991).

148. Nicholas P. Lang, *Professional Liability, Patient Safety, and First Do No Harm*, 182 AM. J. SURGERY 537, 540 (2001); see also Barry M. Manuel, *Double-Digit Premium Hikes: The Latest Crisis in Professional Liability*, 86 BULL. AM. C. SURGEONS 19, 19-20 (2001).

149. David M. Studdert et al., *Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment*, 293 JAMA 2609, 2616 (2005).

150. David M. Studdert et al., *Claims, Errors, and Compensation Payments in Medical Malpractice Litigation*, 354 NEW ENG. J. MED. 2024, 2024 (2006).

151. David M. Studdert et al., *Medical Malpractice*, 350 NEW ENG. J. MED. 283, 288. (2004).

152. Peter P. Budetti, *Tort Reform and the Patient Safety Movement: Seeking Common Ground*, 293 JAMA 2660, 2661 (2005).

153. Ronald M. Stewart et al., *Transparent and Open Discussion of Errors Does Not Increase Malpractice Risk in Trauma Patients*, 243 ANNALS OF SURGERY 645, 647 (2006) (reporting that in

argue for the benefits of such accountability. Instead of pushing for laws to protect against patients' malpractice claims, anesthesiologists focused on improving patient safety. As a result, anesthesiologists paid less for malpractice insurance, adjusted for inflation, than they did twenty years prior.<sup>154</sup>

## II. APOLOGY LAW: COMMON LAW AND STATUTE

Case law is well settled on the effect of disclosures by physicians of admissions of liability for various injuries sustained by patients. When a physician makes such an admission, the plaintiff tends to prevail.<sup>155</sup> Many states have enacted "apology laws," which are intended to mitigate the conflict that a physician faces when trying to meet the patient's desire (and perhaps need) for an apology while avoiding self-incrimination. Apology laws change the traditional rule on admissibility of evidence by declaring that apologies are inadmissible in civil actions arising from alleged medical errors.<sup>156</sup> Apology laws purport to protect apologies from being entered into evidence, but these protective laws can be separated into those that do or do not protect accompanying acknowledgments of fault. For example, Colorado's apology statute addresses all civil actions arising out of "unanticipated outcome[s] of medical care" and makes inadmissible as evidence of an admission of liability statements "expressing apology, fault, sympathy, commiseration, compassion, or a general sense of benevolence."<sup>157</sup> In contrast, an Indiana statute protects the apology, or "communication of sympathy," but not a "statement of fault," even if made within the context of the apology.<sup>158</sup>

### A. Why Apologizing Won't Work

His mother said:

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an open M&M conference, of 412 cases, only seven claims were filed and of these, six were surprises—having not been presented).

154. Brian A. Liang, *Clinical Assessment of Malpractice Case Scenarios in an Anesthesiology Department*, 11 J. CLINICAL ANESTHESIOLOGY 267, 270 (1999).

155. *Giles v. Brookwood Health Servs., Inc.*, 5 So. 3d 533 (Ala. 2008); *Quibodeaux v. Med. Center of Sw. La.*, 707 So. 2d 1380 (La. App. 3d Cir. 1998); *Woods v. Zeluff*, 158 P.3d 552 (Utah App. 2007); *Phinney v. Vinson*, 605 A.2d 849 (Vt. 1992).

156. *See, e.g.*, Del. Code Ann. tit. 10, § 4318 (b) (2006) ("Any and all statements, writings, gestures, or affirmations made by a health care provider or an employee of a health care provider that express apology (other than an expression or admission of liability or fault), sympathy, compassion, condolence, or benevolence relating to the pain, suffering, or death of a person as a result of an unanticipated outcome of medical care, that is made to the person, the person's family, or a friend of the person or of the person's family, with the exception of the admission of liability or fault, are inadmissible in a civil action that is brought against a health care provider.")

157. COLO. REV. STAT. ANN. § 13-25-135 (West 2003).

158. IND. CODE ANN. § 34-43.5-1-3 to -5 (West 2006).

—O, Stephen will apologise.

Dante said:

—O, if not, the eagles will come and pull out his eyes.<sup>159</sup>

### 1. *Apology: A Definition*

A rational use of apology in the medical care setting requires a careful consideration of what constitutes an apology, and how it is different from other acknowledgements that a patient has suffered. There is a substantial medico-legal literature on the use of apology, and the majority view is that physicians should apologize to patients who have experienced medical injury.<sup>160</sup> Commentators have treated the term “apology” rather cursorily, seemingly without a clear understanding of what the offer of an apology entails linguistically, if not morally.<sup>161</sup> To obligate clinicians to engage in such endeavors is therefore naïve and possibly counterproductive to the goal of patient safety.

Apology is defined as “a written or spoken expression of one’s regret, remorse, or sorrow for having insulted, failed, injured, or wronged another.”<sup>162</sup> Apologies have been operationally defined as “admissions of blameworthiness and regret for an undesirable event, for example, a transgression, a harmful act, an embarrassing incident.”<sup>163</sup> Such definitions leave no doubt as to the fact that apologies, as illocutionary acts, include a statement of fault.<sup>164</sup> The consensus as to the requirement of admission of fault is also confirmed by empirical studies on the uses of apology in legal settlements. Apologies in the fullest sense include acceptance of responsibility.<sup>165</sup>

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159. JAMES JOYCE, *A PORTRAIT OF THE ARTIST AS A YOUNG MAN 2* (Easton Press ed. 1977) (1914).

160 Jonathan R. Cohen, *Advising Clients to Apologize*, 72 S. CAL. L. REV. 1009, 1014-46 (1999); Deborah L. Levi, *The Role of Apology in Mediation*, 72 N.Y.U. L. REV. 1165 1167 (1997); Daniel Shuman, *The Role of Apology in Tort Law*, 83 JUDICATURE 180, 180 (2000); Lee Taft, *Apology and Medical Mistake: Opportunity or Foil?*, 14 ANNALS HEALTH L. 55, 62-67 (2005); Lee Taft, *Apology Subverted: The Commodification of Apology*, 109 YALE L. J. 1135 (2000).

161. Doug Wojcieszak et al., *The Sorry Works! Coalition: Making the Case for Full Disclosure*, 32 JOINT COMM’N J. ON QUALITY & PATIENT SAFETY 344, 345 (2006) (conflating full disclosure and apology, noting apologies can both acknowledge and disavow responsibility).

162. *Apology Definition*, DICTIONARY.COM, <http://dictionary.reference.com/browse/apology> (last visited Jan. 8, 2010).

163. Bruce W. Darby & Barry R. Schlenker, *Children’s Reactions to Apologies*, 43 J. PERSONALITY & SOC. PSYCHOL., 742, 743 (1982).

164. KENT BACH, *Speech Acts and Pragmatics*, in BLACKWELL GUIDE TO THE PHILOSOPHY OF LANGUAGE, 147 (Michael Devitt & Richard Hanley eds., 2006).

165. Jennifer K. Robbenolt, *Apologies and Legal Settlement: An Empirical Examination*, 102 MICH. L. REV. 460, 484 (2003) (defining “partial apology” as a statement that expresses sympathy,

Apologies have been described as a form of remedial work, “a gesture through which an individual splits himself into two parts: the part that is guilty of an offense and the part that dissociates itself from the delict and affirms a belief in the offended rule.”<sup>166</sup> Further, an apology brings heavy moral approbation down on the offender, and

[h]as several elements: expression of embarrassment and chagrin; clarification that one knows what conduct had been expected and sympathizes with the application of negative sanction; verbal rejection, repudiation, and disavowal of the wrong way of behaving along with vilification of the self that so behaved; espousal of the right way and an avowal henceforth to pursue that course; performance of penance and the volunteering of restitution.<sup>167</sup>

The apology performs a function by which “an individual splits himself into two parts, the part that is guilty of an offense and the part that dissociates itself from the delict and affirms a belief in the offended rule.”<sup>168</sup> In order for a “full apology” to be performed, the speaker must acknowledge responsibility for having committed some offending act, and he or she must express regret about the offense.<sup>169</sup> The admission of responsibility for the adverse event is a necessary feature of an apology because it conveys to the listener that the speaker is aware of the social norms that have been violated, and therefore conveys that the speaker will be able to avoid the offense in future interactions.<sup>170</sup>

The form of an apology is also varied; by saying “I apologize,” one makes an explicit performative utterance.<sup>171</sup> Utterances may be considered to be

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but does not admit responsibility). Partial apologies are contrasted with “full apologies,” in which the offender both expresses sympathy and accepts responsibility. *Id.*

166. Erving Goffman, *Remedial Interchanges*, in *RELATIONS IN PUBLIC: MICROSTUDIES OF THE PUBLIC ORDER* 109 (1971) (describing the function of remedial work as “to change the meaning that otherwise might be given to an act, transforming what could be seen as offensive into what can be seen as acceptable” and setting forth three types of remedial work; accounts, apologies and requests).

167. *Id.* at 113.

168. *Id.*

169. Bruce Fraser, *On Apologising*, in *CONVERSATIONAL ROUTINE* 261 (Florian Coulmas ed., 1981).

170. Steven J. Scher & John M. Darley, *How Effective Are the Things People Say To Apologize? Effects of the Realization of the Apology Speech Act*, 26 *J. PSYCHOLINGUISTIC RES.* 127, 128 (1997); see also Jeremy C. Anderson et al., *Influence of Apologies and Trait Hostility on Recovery from Anger*, 29 *J. BEHAV. MED.* 347, 348 (2006) (defining the elements of a “genuine” apology to include six verbal components: first, an explicit expression of remorse; second, a specific statement of why one feels remorse and being sorry for the right thing; third, one must accept responsibility for one’s actions; fourth, a truthful explanation for the offensive behavior without trying to excuse the offence and shirk responsibility; fifth, a promise of forbearance—a statement that the offensive behavior is not reflective of the offender’s true character, therefore the victim can trust the behavior will not recur— and, sixth, an offer of restitution).

171. BACH, *supra* note 164, at 148.

apologies without the benefit of an explicit statement.<sup>172</sup> Apology utterances have been further classified into three distinct levels of action beyond the act of utterance itself: the act of saying something (I apologize), what one does *in* saying it (conveying the adverse event to the patient), and the outcome effected *by* saying it (patient accepts or does not accept the apology). These are dubbed *locutionary*, *illocutionary*, and *perlocutionary* acts, respectively.<sup>173</sup>

Apologies are therefore different from other statements expressing responsibility, liability, sympathy, commiseration, condolence, compassion or a general sense of benevolence that may be rendered inadmissible as admissions or statements against interest in some state statutes. Psycholinguistic experts have classified apologies and suggested a number of elements which may be included in an apology: illocutionary force indicating devices (for example, “I’m sorry,” or “I apologize”), an explanation of the cause which brought about the wrong, an offer of repair, a promise of forbearance, and an expression of the speaker’s responsibility for the offense.<sup>174</sup>

## *2. Points to Consider in Offering Apologies: Not as Easy as One Might Think*

Coulmas has described apologies as reactive, making reference to an object of regret.<sup>175</sup> All apology strategies are intended to convey important information to the hearer (e.g., patient or family) about the speaker (e.g., the physician), improving perceptions about the speaker, reducing the intended sanctions, increasing emotions of remorse or regret attributed to the speaker, and enhancing the appropriateness of the apology.<sup>176</sup> Apologies with no acknowledgement of responsibility are not indebteding and can merge into other statements, such as expressions of sympathy.<sup>177</sup>

There are several strategies for apologizing in which the speaker explicitly

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172. *Id.* at 149 (noting one can apologize without explicitly using the performative phrase “I apologize” as a “*force-indicating device*”). Accordingly, Bach believes here is no theoretically important difference between apologizing explicitly (by saying, “I apologize”) and doing it inexplicitly. *Id.*

173. JOHN LANGSHAW AUSTIN, *HOW TO DO THINGS WITH WORDS* 94 (2d ed. 1962).

174. Scher & Darley, *supra* note 170, at 130.

175. Florian Coulmas, “*Poison to Your Soul*”: *Thanks and Apologies Contrastively Viewed*, in *CONVERSATIONAL ROUTINE*, 75-76 (Florian Coulmas ed., 1981) (distinguishing objects of regret as “a kind of damage, annoyance, or inconvenience which is predictable vs. unpredictable; indebteding vs. not indebteding”). All medical adverse events occur *ex post* and it is only these with which the current paper is concerned.

176. Scher & Darley, *supra* note 170, at 130.

177. Coulmas, *supra* note 175, at 76.

states that an apology is at issue.<sup>178</sup> Apology strategies that actually use the word “apology” leave little likelihood that the speaker’s intentions are other than to apologize although only in the first, the performative form (e.g., “I hereby apologize . . .”), does she actually say that what she is doing is apologizing. Other choices, such as expressing the obligation to apologize, offering to apologize, or requesting the hearer accept one’s apology do not technically mean the speaker is *apologizing*.<sup>179</sup> Notice that in none of these four strategies does the speaker explicitly *say* that she is responsible for or that she regrets or is remorseful for the object of regret, though these two points are certainly contained in the meaning of the words *apology* or *apologize*. Although an illocutionary force indicating device, an apology such as “I apologize” or “Pardon me,” unaccompanied by an expression of remorse, does not convey the required information about the emotional state of the speaker.

Remorse, responsibility, and regret are the primary information conveyed by an apology.<sup>180</sup> Expressing regret for the offense with phrases such as “I’m sorry for . . .” or “I regret that I . . .” the speaker explicitly expresses regret for the offense as well as explicitly acknowledges responsibility for the object of regret itself.<sup>181</sup> Goffman has said as much: “Whether one runs over one’s sentence, time, dog or body, one is more or less reduced to saying some variant of ‘I’m sorry.’”<sup>182</sup> Remorse also serves to deflect negative personality judgments and other reactions from the transgressor.<sup>183</sup>

Other strategic decisions are whether to request forgiveness for the offense or to explicitly acknowledge responsibility.<sup>184</sup> By acknowledging responsibility alone or requesting forgiveness the speaker is *not* explicitly expressing regret. An offer of compensation has an obvious connection to the remedial function of an apology. The speaker certainly implies, but does not make explicit, that she has some responsibility and feels regret by saying “what can I do to amend?”<sup>185</sup> It is

178. Fraser, *supra* note 169, at 263 (describing four forms of explicit apology: first, announcing that one is apologizing “I (hereby) apologize for . . .”; second, stating one’s obligation to apologize “I must apologize for . . .”; third, offering to apologize “I (hereby) offer my apology for . . .”; “I would like to offer my apology to you for . . .”; fourth, requesting the hearer accept an apology (e.g., “Please accept my apology for . . .”; “Let me apologize for . . .”; “I would appreciate it if you would accept my apology for . . .”).

179. Fraser, *supra* note 169, at 263-64.

180. Scher & Darley, *supra* note 170, at 129-30.

181. Fraser, *supra* note 169, at 264.

182. GOFFMAN, *supra* note 166, at 117.

183. Scher & Darley, *supra* note 170, at 130.

184. Fraser, *supra* note 169, at 263 (giving examples of requesting forgiveness for the offense such as “Please excuse me for . . .” “Pardon me for . . .” “I beg your pardon for . . .” “Forgive me for . . .” and examples acknowledging responsibility for the offending act such as “That was my fault” or “Doing that was a dumb thing to do”).

185. Fraser, *supra* note 169, at 264.

an offer to try to correct the situation, to try to partially restore the patient to her pre-adverse event condition, which is often difficult if not impossible, and in which case some form of monetary compensation is all that can be provided (for example, cost-free care of the complicating injury). Rarely, however, does the physician have the fiduciary authority on behalf of the healthcare system to make such an offer to repair things so that it is as if the transgression had not occurred. As the physician has no ability to obligate an offer of compensation, one of the purported reasons for the apology to serve as a form of symbolic function of punishment of the “guilty self” cannot take place.<sup>186</sup>

### *3. Malpractice Insurance Coverage and the Physician as Independent Contractor*

Among the practical issues that must be understood prior to any consideration of an apology for medical adverse events are the effect on a physician’s malpractice coverage, and any risks to the physician as an independent contractor. Rarely in the healthcare setting is sustaining an adverse event as simple as *A* injures *B*, so *A* must apologize to *B*. Does the making of an apology void the physician’s malpractice insurance coverage? Does apologizing place the physician at risk to be fired at will?

The concept of moral hazard suggests that insured physicians might feel free to apologize, or worse, take fewer precautions to protect patient safety. Why not? The insurance company, not the physician, may be perceived as liable under such circumstances. However, liability insurance may impose upon the insured a *general duty of cooperation* with the insurance company to defend claims.<sup>187</sup> Some liability insurance policies also specifically prohibit the insured from voluntarily assuming liability.<sup>188</sup> Cohen suggests two questions need be answered prior to the giving of an apology, both of which are part of a “full apology,” as noted above.<sup>189</sup> First, is an insured’s apology considered a breach of the insured’s general duty of cooperation? Second, would the insured’s apology be taken as assuming liability, again leading to breach?<sup>190</sup>

For the insurer to prevail in assertions of breach in the general duty of cooperation, the insurer must show bad faith—hard to prove in the absence of some collusion between the physician and patient (such as an attempt to defraud and share profits).<sup>191</sup> If, instead of apologizing, the insured simply recounts the

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186. Scher & Darley, *supra* note 170, at 130.

187. Jonathan R. Cohen, *Advising Clients To Apologize*, 72 S. CAL. L. REV. 1009, 1025 (1999).

188. *Id.* at 1025 (citing KENNETH ABRAHAM, *INSURANCE LAW AND REGULATION* 450 (1990)).

189. *Id.*

190. *Id.*

191. *Id.*

facts as known, the insured is offering only evidence that she would likely have to disclose in deposition or at trial.<sup>192</sup> A harder case for the insured wishing to apologize is when the insurance contract specifically forbids the insured from accepting liability. Would a physician who apologizes and assumes liability without the insurance company's approval void coverage? There are few cases on this, usually arising from automobile accidents, and the law is not well settled.<sup>193</sup> One distinction that has been drawn by courts is that statements by the insured that truthfully admit fault may not void coverage, while statements that assume financial liability will void coverage.<sup>194</sup>

### B. Case Law

Case law on the legal liability of apologies and whether physicians' statements to patients may be admitted as party admissions is variable.<sup>195</sup> On balance such statements are more likely to be admitted into evidence against physicians to reverse a non-suit than not:

Under well-established rules we must . . . resolve every conflict in their testimonies in favor of plaintiff, consider every inference which can reasonably be drawn and every presumption which can fairly be deemed to arise in support of plaintiff, and accept as true all evidence adduced direct and indirect which tends to sustain plaintiff's case.<sup>196</sup>

Physician statements have been allowed in as evidence based on hearsay exceptions, or out of court statements issued to prove the truth of the matter asserted; establishing medical malpractice as defining the standard of care, breach of the standard, and causation, as discussed below. In *Colbert v. Georgetown*, statements attributed to, but denied by the defendant, were held to be admissions establishing a prima facie case of malpractice, to demonstrate that the standard of care was breached, and to reverse a summary judgment in favor of the defendants.<sup>197</sup> In *Snyder v. Pantaleo*, statements by the physician defendant

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192. *Id.*

193. See, e.g., Annotation, *Validity, Construction, and Effect of "No-Consent-To-Settlement" Exclusion Clauses in Automobile Insurance Policies*, 18 A.L.R. (1982) (citing cases where courts have variously upheld and rejected such clauses).

194. 8 JOHN A. APPLEMAN & JEAN APPLEMAN, *INSURANCE LAW AND PRACTICE* § 4780 (1981) (admonishing "a policy provision [against assuming liability] does not prohibit the insured from giving the injured person a truthful explanation of the accident and circumstances thereof").

195. Wei, *supra* note 18, at 110.

196. *Lashley v. Koerber*, 156 P.2d 441, 442 (Cal. 1945) (considering whether the judgment of nonsuit was proper).

197. *Colbert v. Georgetown Univ.*, 623 A.2d 1244, 1253 (D.C. 1993), *rev'd en banc*, 641 A.2d 469 (D.C. 1994) (citing statements such as decision first to perform lumpectomy rather than a mastectomy caused an "enhanced risk of a very high nature;" that defendant conceded to plaintiff

to another were used as expert testimony as to breach of standard of care.<sup>198</sup>

In a California wrongful death suit, *Sheffield v. Runner*,<sup>199</sup> the defendant stated, regarding a patient with bacterial pneumonia, “I should have put her in the hospital.”<sup>200</sup> The court held that a physician’s statements could not only prove liability, but also be used as expert testimony demonstrating breach of standard of care. According to the testimony of the plaintiff’s husband, the defendant then told plaintiff “to . . . have an X-ray taken, stating that he *should* have done it in the beginning . . . I know, it is not your *fault*, Mrs. Lashley, it is *all my own*.”<sup>201</sup> An Oklahoma case, *Robertson v. LaCroix*, also held that a surgeon’s statements communicated more than mistaken judgment and constituted an admission of negligence during an operation.<sup>202</sup> In *Woronka v. Sewall*, the plaintiff filed suit for burns she received on her buttocks while giving birth.<sup>203</sup> The defendant doctor examined the patient two days later and allegedly said, “My God, what a mess; my God, what happened here . . . It is a darn shame to have this happen,” and sympathized with the patient for a “very hard delivery and it was a burning shame to get that on top of it, and it was because of negligence when they were upstairs.”<sup>204</sup> In *Wickoff v. James*, the court held that defendant doctor’s statement to the plaintiff’s husband “Boy, I sure made a mess out of things today, didn’t I, Warren?” could be interpreted to establish a prima facie case of negligence, and a nonsuit in favor of the defendants was reversed.<sup>205</sup>

In *Greenwood v. Harris*, a gynecologist, upon finding that a presumed tumor

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that he had performed “the wrong operation;” and that he “had forgotten” lumpectomy was inappropriate for multicentric cancer); see also *Abbey v. Jackson*, 483 A.2d 330, 333-34 (D.C. 1984) (holding that plaintiffs may elicit from the defendants or their agents the expert opinion necessary to establish a prima facie case of malpractice).

198. *Snyder v. Pantaleo*, 122 A.2d 21, 23 (Conn. 1956) (holding that defendant radiologist’s statement to the deceased’s family physician was expert testimony of the standard of care and its breach).

199. *Sheffield v. Runner*, 328 P.2d. 828, 829 (Cal. Dist. Ct. App. 1958) (finding that the case was sufficient to reverse a nonsuit judgment by the trial court and submit to the jury).

200. *Id.*

201. *Lashley v. Koerber*, 156 P.2d at 442 (finding that a jury could reasonably conclude that the alleged admission of the defendant physician to plaintiff constituted breach of the standard of care).

202. *Robertson v. LaCroix*, 534 P.2d 17, 22 (Ct. App. Okla. 1975) (holding that physician’s statement that he “just made a mistake and got over too far” during surgery was prima facie evidence of the standard of care and its breach).

203. *Woronka v. Sewall*, 69 N.E.2d 581, 582 (Mass. 1946) (“[The defendant’s] mere use of the word ‘negligence’ does not supply the essential elements to justify a necessary finding of liability on his part,” and that “much more is contained in the admissions than the mere use of that word.”).

204. *Id.*

205. *Wickoff v. James*, 324 P.2d 661, 663-64 (Cal. Dist. Ct. App. 1958) (defining “mess,” the court looked to Webster’s New International Dictionary, Roget’s Thesaurus, and A. Partridge, Dictionary of Slang and Unconventional English in deciding the term connoted negligence).

was in fact a three-and-one-half months pregnancy, earnestly disclosed the following: “Your wife is approximately three to three and a half months pregnant, this is a terrible thing I have done, I wasn’t satisfied with the lab report, she did have signs of being pregnant. I should have had tests run again, I should have made some other tests,” and, “I am sorry.” The Supreme Court of Oklahoma found that these statements indicated a prima facie case of malpractice and reversed the trial court’s decision sustaining a demurrer.<sup>206</sup>

The use of physician statements not only serves to allow appellate courts to reverse pre-trial judgments for the defense, but also to reverse directed verdicts or have a case remanded for re-trial after a jury has returned a verdict. In *Wooten v. Curry*, a plaintiff’s husband, on finding his wife’s vagina closed after a hysterectomy, related the following statement regarding a conversation with the gynecologist defendant: “That is the only thing I have to go by, just what he told me. That was the only thing that looked like it caused it. He said he was sorry it happened and could have probably have avoided it if he had checked on her as he should.”<sup>207</sup> In *Woods v. Zeluff*, statements made by defendant to the plaintiff during a post-operative visit were excluded as unfairly prejudicial by the trial court: “I jumped the gun,” “I’ve missed something,” and “I don’t think we should have done this surgery.”<sup>208</sup>

Some courts have found that a physician’s out of court statements, including apologies, are insufficient to establish the standard of care or its breach, as discussed below. Unfortunately, statements made by physicians that are not held sufficient to establish the standard of care—or its breach—are extremely difficult to distinguish from those which are sufficient. In general, courts seem divided on whether expert testimony beyond that of statements attributed to the defendant can establish negligence, standard of care, or breach. In *Jeffries v. Murdock*, the plaintiff’s statement regarding his conversation with a defendant physician included the following: “And I said, ‘Well, how did this all happen?’ He said, ‘I’m sorry, I accidentally cut the nerve to your vocal cord.’”<sup>209</sup> The court held that the significance of the defendant’s alleged statement was negated by the testimony of defense expert witnesses and by the plaintiff’s failure to present any evidence to the contrary. In *Senesac v. Associates in Obstetrics & Gynecology*, the plaintiff testified that shortly after the operation the defendant “admitted that

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206. *Greenwood v. Harris*, 362 P.2d 85, 88 (Okla. 1961).

207. *Wooten v. Curry* 362 S.W.2d 820, 822 (Tenn. Ct. App. 1962) (holding that the statement of the defendant in the absence of any explanation made a prima facie case of negligence and proximate cause, and reversing a directed verdict for the defense).

208. *Woods v. Zeluff*, 158 P.3d. 552, 554 (Utah Ct. App. 2007) (holding that the trial court erred by excluding, as unfairly prejudicial, post-operative statements allegedly made by Dr. Zeluff and that such error warranted a new trial).

209. *Jeffries v. Murdock*, 701 P.2d. 451, 453 (Or. Ct. App. 1985).

she had made a mistake.”<sup>210</sup> The Supreme Court of Vermont affirmed a defendant’s motion for summary judgment by holding that, while a defendant’s statement might have been admissible, it alone was insufficient to meet plaintiff’s burden of production.<sup>211</sup> A plaintiff alleged the defendant said he was told by a second doctor after re-operation on the plaintiff’s prostate gland that the defendant had performed an “inadequate resection” and apologized to plaintiff “for his failure to do so.”<sup>212</sup> In *Giles v. Brookwood Health Services, Inc.*, the defendant was sued for removing a normal right rather than a diseased left ovary.<sup>213</sup> The defendant admitted that the plaintiff’s husband Giles “was absolutely right, that it was the left side that should have been removed. [He said] ‘I am so sorry . . . .’”<sup>214</sup> However, on appeal, the court held:

Giles submitted no expert testimony indicating that Dr. Perry was in any way negligent with regard to her medical care and treatment . . . . Therefore, no genuine issue of material fact exists as to Giles’s malpractice claims against Dr. Perry, and Dr. Perry is entitled to judgment as a matter of law on those claims.<sup>215</sup>

In *Airasian v. Shaak*, evidence of both the doctor’s observation and his statement admitting fault was ruled inadmissible at trial under a statute precluding admission of statements or conduct expressing regret, apology, mistake, or error.<sup>216</sup>

Some courts have held that physicians’ out-of-court statements describing adverse events as “mistakes” or “accidental” are not enough to establish a prima facie case in the absence of expert testimony. In *Maxwell v. Women’s Clinic, P.A.*, the court held that, in the absence of expert testimony, the plaintiff’s statement and act of non-billing for the surgery together would not be sufficient

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210. *Senesac v. Assocs. in Obstetrics & Gynecology*, 449 A.2d 900, 903 (Vt. 1982) (holding that the asserted statements of defendant “made a mistake, that she was sorry, and that it [the perforation of the uterus] had never happened before” did not establish a departure from the standard of care).

211. *Phinney v. Vinson*, 605 A.2d 849, 849 (Vt. 1992) (holding that while defendant’s statement may have been admissible, it was insufficient by itself to meet plaintiffs’ burden under 12 V.S.A. § 1908 (1975)).

212. *Id.*

213. *Giles v. Brookwood Health Services, Inc.*, 5 So. 3d 533, 540 (Ala. 2008) (holding that in the light most favorable to plaintiff, defendant’s apologies did not constitute expert testimony that he injured Giles by breaching the standard of care).

214. *Id.* at 540.

215. *Id.* at 548-49.

216. *Airasian v. Shaak*, 657 S.E.2d 600, 601 (Ga. Ct. App. 2008) (disallowing a defendant physician’s apology to as barred by statute from establishing negligence).

to create the required inference about failing to meet the community standard.<sup>217</sup> In *Locke v. Pachtman*, a gynecology resident acting under the supervision of an attending surgeon, who was not present, broke a needle in the plaintiff's tissues. The resident defendant made statements that plaintiff argued established a prima facie case of negligence: "I knew that needle was too small when the new scrub nurse handed it to me. It wasn't her fault because she was new, but I chose to use it anyway and it's my fault and I am really sorry . . . ."<sup>218</sup> In a federal diversity case, *Sutton v. Calhoun*, the appellate court held it proper for the lower court to refuse to give an instruction to the jury that if the "mistake" statement was made it was an admission of negligence.<sup>219</sup> Lastly, in *Quickstad v. Tavenner*, the appellate court held that the defendant's statements were not enough to support a prima facie case for the plaintiff after a needle was retained in the chest cavity during thoracentesis.<sup>220</sup> In some instances, written documents or statements provided by the physician—whether spontaneously or in response to a patient's request after an "apology" or other verbal act is made—have been held inadmissible.<sup>221</sup>

In some of the cases discussed above, statements attributed to defendant physicians were denied, but still admitted into evidence. In some circumstances the statements were admitted as proofs of negligence, and in some cases, not. As a result, circumspection in disclosure to patients is still advised. The idea is that this should reassure physicians and allow them to feel safer in apologizing to patients. But to follow this logic is to ignore the much deeper problem that the kind of apologies that these laws seek to protect are ones that are given in the context of adverse events and medical errors. Apology laws will not make case law more predictable by barring admission of apologies into evidence; as the cases cited above show, there is a particularized fact assessment that is difficult to reconcile with any given state statute.

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217. *Maxwell v. Women's Clinic, P.A.*, 625 P.2d 407, 408 (Idaho 1981) (quoting the plaintiff's husband as testifying, "[A]nd he said, the way I remember it, he said, *I obviously messed up on the first one, and another surgery has to be done to repair the damage*").

218. *Locke v. Pachtman*, 521 N.W.2d 786, 789 (Mich. 1994) (holding that while the statements may have indicated defendant's belief that she made a mistake, a jury could not reasonably infer from those statements alone that defendant's actions did not conform to standards of professional practice).

219. *Sutton v. Calhoun*, 593 F.2d 127, 127 (10th Cir. 1979) (involving family members of the plaintiff who alleged that after the operation the defendant came to them and said he had "made a mistake," that he should not have cut the common bile duct).

220. *Quickstad v. Tavenner*, 264 N.W. 436, 437 (Minn. 1936) (involving a plaintiff who alleged the doctor stated that "he broke the needle"; he "should have used a stronger needle"; he "shouldn't have done it"; and would "never try it again").

221. *Smith v. Karen S. Reisig, M.D., Inc.*, 686 P.2d 285, 289 (Okla. 1984) (holding that the defendant doctor's statement in the medical record that injury to plaintiff's bladder was "inadvertent" was not an admission of negligence).

Further, apology laws are not necessary to enable doctors to deliver statements of empathy and understanding in the everyday situation; physicians frequently and without hesitation may say to their patients that they are sorry that their patients are experiencing pain or suffering. These are not the scenarios with which the apology laws are concerned. By attempting to bar the introduction of statements by physicians communicating with patients who have been injured, apology laws are supposed to encourage doctors to speak up when medical errors occur—to push doctors to engage in apologies as part of disclosure. In this way, apology laws do not tackle the more fundamental issue: that physicians and healthcare institutions are obliged to disclose of medical errors.

### *C. How Exactly Does “Sorry” Work?*

The concept of disclosure and apology gained momentum based on reports from the Lexington Veterans Affairs Medical Center (LVAMC) a decade ago. After LVAMC lost two major malpractice cases in the mid-1980s, to the tune of \$1.5 million, its leadership started taking a more proactive approach in identifying and investigating incidents that could result in litigation. The shift in focus evolved into an organization-wide full disclosure policy and procedure.<sup>222</sup> The policy is excerpted in part:

The [disclosure] meeting is with the chief of staff, the facility attorney, the quality manager, the quality management nurse, and sometimes the facility director. At the meeting, all of the details are provided as sensitively as possible, including the identities of persons involved in the incident (who are notified before the meeting). Emphasis is placed on the regret of the institution and the personnel involved and on any corrective action that was taken to prevent similar events.<sup>223</sup>

An analysis of claims experience at LVAMC, compared to thirty-five other similar VAMCs, showed that Lexington was in the top quartile of claims but the bottom quartile in payments.<sup>224</sup> Recently, out of seven veterans who were notified by VA of substandard eye care, three have filed suit.<sup>225</sup> The LVAMC experience was also tried in the academic setting at the University of Michigan, and reported survey results suggest physicians and plaintiffs’ attorneys alike were

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222. Steve S. Kraman et al., *John M. Eisenberg Patient Safety Awards, Advocacy: The Lexington Veterans Affairs Medical Center*, 28 JOINT COMM’N J. QUALITY IMPROVEMENT 646, 647 (2002).

223. Steve S. Kraman and Ginny Hamm, *Risk Management: Extreme Honesty May Be the Best Policy*, 131 ANNALS INTERNAL MED. 963, 967 (1999).

224. *Id.* at 965.

225. John Maa & Kristen Hedstrom, *College Advocates for Ensuring Quality Eye Care for America’s Veterans*, 95 BULL. AM. C. SURGEONS 8, 9 (2010).

satisfied with the approach.<sup>226</sup> Recent experience with the Michigan data further suggests that a disclosure-with-offer policy has decreased both claims and payments; however, the precise role of apology is not clearly defined.<sup>227</sup> The authors note that causality was not established due to study design,<sup>228</sup> but during the latter part of the study malpractice claims in Michigan generally declined.<sup>229</sup> The authors also note that the University of Michigan Health System has a closed staff with a captive insurance company that assumes legal responsibility; the findings might not apply to other health systems.<sup>230</sup> Settlements were generally made in the institution's name; consequently, reporting of individual caregivers to the National Practitioner Data Bank was rare.<sup>231</sup>

Another recent private sector medical center also has touted a disclosure policy with the following recommendations given to staff: "Avoid words such as *error*, *mistake*, *fault*, and *negligence* unless you are absolutely certain that an error or mistake has occurred. Don't confess. Apologies for having caused the outcome should be avoided unless responsibility is unmistakably clear."<sup>232</sup>

One of the most strident voices for requiring physicians to say "I'm sorry" is that of the "Sorry Works!" coalition.<sup>233</sup> "Sorry Works!" has proposed that after patients experience adverse events, root cause analyses would need to be performed—presumably by a panel of members of the healthcare organization—to determine if the standard of care was met. The performance of root cause analysis for sentinel events is not controversial; The Joint Commission requires similar actions for all accredited facilities.<sup>234</sup> "Sorry Works!" does not define which events or outcomes would require such analysis; if all such events were to be subject to root cause analysis, the effort would be staggering.<sup>235</sup>

A more troubling aspect of the "Sorry Works!" agenda is the requirement for determining whether the appropriate standard of care was met. The Coalition notes such analysis may take weeks to months and may involve the assistance of

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226. Richard C. Boothman et al., *Notes and Comments: A Better Approach to Medical Malpractice Claims? The University of Michigan Experience*, 2 J. HEALTH & LIFE SCI. L. 125, 145-46 (2009).

227. Allen Kachalia et al., *Liability Claims and Costs Before and After Implementation of a Medical Error Disclosure Program*, 153 ANNALS INTERNAL MED. 213, 215-17 (2010).

228. *Id.* at 220.

229. *Id.*

230. *Id.*

231. *Id.* at 214.

232. Randolph R. Peto et al., *Patient and Family Involvement: One System's Journey in Creating a Disclosure and Apology Program*, 35 JOINT COMM'N J. ON QUALITY & PATIENT SAFETY 487, 492 (2009).

233. Doug Wojcieszak, John Banja, & Carole Houk, *The Sorry Works! Coalition: Making the Case for Full Disclosure*, 32 JOINT COMM'N J. ON QUALITY & PATIENT SAFETY 344, 345 (2006).

234. JOINT COMMISSION HANDBOOK, *supra* note 102, at SE-2.

235. JOINT COMMISSION HANDBOOK, *supra* note 102, at SE-1.

“outside experts.” A root cause analysis showing that the standard of care was *not* met due to medical error or negligence<sup>236</sup> would require providers to admit fault, apologize to the patient and/or family, fully disclose the sequence of actions which led to the event, describe changes in hospital policy and procedure made to try and prevent the same event from happening to other patients, and make a fair offer of up-front compensation.<sup>237</sup> The attorneys representing the plaintiffs and providers would negotiate the compensation. Conversely, if the root cause analysis finds that the standard of care was met, the providers would not admit fault or offer to negotiate up-front compensation. In all respects, the “Sorry Works!” approach is that of an extrajudicial legal proceeding.

The “Sorry Works!” approach suggests that each healthcare organization should develop a “panel” to investigate each occurrence of an adverse event. Struve has given considerable attention to the use of such panels, albeit in a more formal extra-institutional setting, and has concluded that such screening panels are unlikely to provide meaningful assistance in the analysis and disposition of claims, concluding that: “[N]either theory nor experience strongly supports proponents’ optimistic view of screening panels.”<sup>238</sup> Further, a significant number of the states that adopted screening panel provisions subsequently repealed or invalidated them.<sup>239</sup> Although her study is somewhat dated when compared to the current malpractice climate, Patricia Danzon analyzed insurance company data on claims closed throughout the 1970s in response to a previous malpractice crisis in 1975.<sup>240</sup> She found that pretrial screening panels had no significant effect on malpractice claims frequency or severity.<sup>241</sup> The use of such panels would not be expeditious (weeks to months as conceded by “Sorry Works!”) or low-cost. Panels would need to hold meetings, and conduct discovery (documents, participants, witnesses, and experts) in order to gather the facts. In jurisdictions where such findings are admissible as evidence trials,

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236. Breach of standard of care is one element of negligence, a legal term which can only be determined by finders of fact in a court of law.

237. Wojcieszak et al., *supra* note 233, at 345.

238. CATHERINE T. STRUVE, EXPERTISE IN MEDICAL MALPRACTICE LITIGATION: SPECIAL COURTS, SCREENING PANELS, AND OTHER OPTIONS (2003), available at [http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/](http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Medical_liability/medical_malpractice_101603.pdf)

Medical\_liability/medical\_malpractice\_101603.pdf.

239. *Id.* at 57.

240. PATRICIA M. DANZON, THE FREQUENCY AND SEVERITY OF MEDICAL MALPRACTICE CLAIMS (1982); Patricia M. Danzon, *The Frequency and Severity of Medical Malpractice Claims*, 27 J.L. & ECON. 115, 118 (1984); Patricia M. Danzon & Lee A. Lillard, *Settlement Out of Court: The Disposition of Medical Malpractice Claims*, 12 J. LEGAL STUD. 345, 377 (1983).

241. Patricia M. Danzon, *The Frequency and Severity of Medical Malpractice Claims: New Evidence*, 49 L. & CONTEMP. PROBS. 57, 78 (1986) (concluding that the effect of screening panels on claim severity is not consistent across the different equations, but there is no evidence that screening panels consistently reduce claim severity).

panels are likely to “entail the costs and delay that panels are intended to prevent.”<sup>242</sup>

#### *D. Statutory Approaches: The “Apology” Laws*

Federal Rule of Evidence 408, which has been widely adopted into state law, generally prevents an offer of consideration to compromise a claim from being admitted.<sup>243</sup> Rule 408, however, is limited to offers of settlement, and apologies are not specifically included. Even in this setting, an apology could be taken as evidence of an admission of fault while other aspects of the negotiation would be protected. A survey of states enacting apology laws identified thirty-four states and the District of Columbia as having some protected disclosure of certain statements made by putative offenders to victims.<sup>244</sup> Of the thirty-five identified statutes, twenty-five explicitly mention the word “apology.”<sup>245</sup> Only Montana defines apology and includes in this definition expressions of regret, but not responsibility. That the Montana legislature chose to exclude responsibility from its definition suggests that the remaining states, in their statutes, *intended* to keep the term “apology” as expressing responsibility, regret, and remorse; this is evidence of a desire to keep apologies separate from other statements, as admissions of fault.<sup>246</sup>

Eight states do not explicitly mention healthcare providers or patients,<sup>247</sup>

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242. Patricia M. Danzon, *Costs of Litigation*, in *MEDICAL MALPRACTICE: THEORY, EVIDENCE, AND PUBLIC POLICY* 199 (1985).

243. FED. R. EVID. 408 (“Compromise and Offers to Compromise(a) Prohibited uses.—Evidence of the following is not admissible on behalf of any party, when offered to prove liability for, invalidity of, or amount of a claim that was disputed as to validity or amount, or to impeach through a prior inconsistent statement or contradiction:(1) furnishing or offering or promising to furnish—or accepting or offering or promising to accept—a valuable consideration in compromising or attempting to compromise the claim; and (2) conduct or statements made in compromise negotiations regarding the claim, except when offered in a criminal case and the negotiations related to a claim by a public office or agency in the exercise of regulatory, investigative, or enforcement authority.”).

244. For a detailed list of states that were identified as having disclosure statutes, see *infra* app. I. The state, identifying statute section, types of inadmissible statements, by whom the statements can be made, to whom they can be made, and additional notes on specific aspects of the individual state laws are also provided. For purposes of the text, the states will be identified by name, not individual statute section numbers.

245. Arizona, Colorado, Connecticut, Delaware, Georgia, Idaho, Illinois, Indiana, Louisiana, Maine, Maryland, Montana, Nebraska, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, South Carolina, Utah, Vermont, Virginia, Washington, West Virginia, and Wyoming.

246. Fraser, *supra* note 169, at 262; Coulmas, *supra* note 175, at 76; Scher & Darley, *supra* note 170, at 129. See also Lee Taft, *Apology Subverted: The Commodification of Apology*, 109 *YALE L.J.* 1135, 1139-43 (2000).

247. CAL. EVID. CODE § 1160 (West 2001); FLA. STAT. ANN. § 90.4026 (West 2001); HAW. REV. STAT. § 626-1 (2007) IND. CODE ANN. § 34-43.5-1-3 (West 2006); MASS. GEN. LAWS ch. 233

instead choosing to use the same standard of disclosure for medical adverse events as for car accidents or any other civil action. The Vermont legislature saw fit to limit apologies and other statements to those made orally,<sup>248</sup> while most states have expanded such statements to include gestures and writings.

The state statutes also differ in who can make statements that are protected. Most state statutes allow healthcare providers or healthcare professionals, as well as employees or agents of healthcare providers or healthcare professionals to make protected statements.<sup>249</sup> Oregon requires the person by or on whose behalf statements are made to be a licensed professional. North Carolina and Louisiana restrict the making of protected statements only to healthcare providers.<sup>250</sup> Vermont and Washington statutes require that for statements—including apologies—to be deemed inadmissible, they have to be made within thirty days of when the provider knew, or should have known, about the consequences of the adverse event.<sup>251</sup> Utah awaits the bringing of a claim, and limits protective statements made by, or on behalf of, defendants who are healthcare providers.<sup>252</sup> Only New Hampshire is completely silent, which presumably means any individual is able to make a protected statement.<sup>253</sup>

States also vary in defining to whom protected statements may be made. In all cases the alleged injured individual is included, as are those persons defined as relatives and/or family members.<sup>254</sup> A subgroup of states has also included a variety of other representatives.<sup>255</sup> South Carolina requires that, in order to be protected, the statements must be made during a designated meeting to discuss the unanticipated outcome.<sup>256</sup>

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§ 23D (West 2000); MO. REV. STAT. § 538.229 (West 2005); TENN. R. EVID. 409.1; TEX. CIV. PRAC. & REM. CODE ANN. § 18.061 (Vernon 1999).

248. VT. STAT. ANN. tit. 12 § 1912 (West 2005).

249. ARIZ. REV. STAT. ANN. § 12-2605 (2009); COLO. REV. STAT. ANN. § 13-25-135 (West 2003); CONN. GEN. STAT. ANN. § 52-184d (West 2006); DEL. CODE ANN. tit. 10 § 4318 (2006); D. C. CODE § 16-2841 (2007); GA. CODE ANN. § 24-3-37.1 (West 2006); IDAHO CODE ANN. § 9-207 (2006); ME. REV. STAT. ANN. tit. 24 § 2907 (2009); NEB. REV. STAT. § 27-1201 (2007); N. D. CENT. CODE § 31-04-12 (2007); OHIO REV. CODE ANN. § 2317.43 (West 2004); OKLA. STAT. ANN. tit. 63 § 1-1708.1H (West 2009); S.C. CODE ANN. § 19-1-190 (2006); VA. CODE ANN. § 8.01-52.1 (West 2009); W. VA. CODE ANN. § 55-7-11a (West 2005); WYO. STAT. ANN. § 1-1-130. (2009).

250. N. C. GEN. STAT. ANN. § 8C-1 (West 2004); LA. REV. STAT. ANN. § 3715.5 (2005).

251. VT. STAT. ANN. tit. 12, § 1912 (West 2005); WASH. REV. CODE ANN. § 5.64.010 (West 2006). Illinois had shortened the time frame to 72 hours but this statute was, as noted in Table 1, declared unconstitutional.

252. UTAH CODE ANN. § 78B-3-422 (West 2006).

253. N.H. STAT. ANN. § 507-E:4 (West 2006).

254. States use, variously, the term victim, patient, plaintiff, or person.

255. Various states includes “health care decision-maker,” “representative,” “friend,” “any individual who claims damages by or through that victim,” “legal representative,” or “decision maker for plaintiff.” Utah defines patient as “any person associated with the patient.”

256. S.C. CODE ANN. § 19-1-190 (2006).

The circumstances under which statements are rendered admissible or inadmissible have also been addressed. Most states have limited the admissibility of statements—or their content—only when such statements constitute admissions of liability or admissions against interest. These are narrow restrictions; in fact, given the rarity with which a declarant (i.e. defendant) is unavailable in a malpractice action as required for a statement against interest, the only real function of such statutes is to preclude statements as admissions of liability.<sup>257</sup> Idaho and Montana specifically exclude statements as evidence, including apologies, for any reason.<sup>258</sup> Oregon, by law, precludes depositions of Oregon Medical Board licensed practitioners or those making statements on their behalf that have made expressions of regret or apology.<sup>259</sup> Vermont has similar provisions.<sup>260</sup> Virginia protects the making of such statements only if death has occurred.<sup>261</sup>

Thirteen states allow various admissions of liability, fault, negligence, or culpable conduct.<sup>262</sup> Delaware, Indiana, Louisiana, Maine, and Nebraska are particularly problematic, as in these states apologies may be protected as statements, but may also be admitted as admissions of fault in part or in whole.<sup>263</sup> In summary, apology holds a special place in the universe of statements that are intended to express some form of sympathy towards a patient who has sustained a medical care related injury. The stance of commentators and other interested parties covers a wide spectrum of views on whether or not to apologize as a specific form of remedial work. Taft would argue that the avoidance of consequences by protective statutes strips the apology of a moral dimension: “What elevates [an apology] to a truly moral and corrective communication is the offending party’s willingness to accept the consequences that flow from the

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257. FED. R. EVID. 804 (“Hearsay Exceptions: Declarant Unavailable (b)(3) *Statement against interest*. A statement which was at the time of its making so far contrary to the declarant’s pecuniary or proprietary interest, or so far tended to subject the declarant to civil or criminal liability, or to render invalid a claim by the declarant against another, that a reasonable person in the declarant’s position would not have made the statement unless believing it to be true.”).

258. IDAHO CODE ANN. § 9-207 (2006); MONT. CODE ANN. § 26-1-814 (2005).

259. OR. REV. STAT. ANN. § 677.082 (West 2003).

260. VT. STAT. ANN. tit. 12 § 1912 (West 2005).

261. VA. CODE ANN. § 8.01-52.1 (West 2009).

262. CAL. EVID. CODE § 1160 (West 2001); DEL. CODE ANN. tit. 10, § 4318 (2006); FLA. STAT. ANN. § 90.4026 (West 2001); HAW. REV. STAT. § 626-1 (2007); IND. CODE ANN. § 34-43.5-1-3 (West 2006); LA. REV. STAT. ANN. § 3715.5 (2005); ME. REV. STAT. ANN. tit. 24, § 2907 (2009); MO. REV. STAT. § 538.229 (West 2005); NEB. REV. STAT. § 27-1201 (2007); N. H. STAT. ANN. § 507-E:4 (West 2006); TENN. R. EVID. 409.1; TEX. CIV. PRAC. & REM. CODE ANN. § 18.061 (West 1999); VA. CODE ANN. § 8.01-52.1 (West 2009).

263. DEL. CODE ANN. tit. 10, § 4318 (2006); IND. CODE ANN. § 34-43.5-1-3 (West 2006); LA. REV. STAT. ANN. § 3715.5 (2005); ME. REV. STAT. ANN. tit. 24, § 2907 (2009); NEB. REV. STAT. § 27-1201 (2007).

wrongful act.”<sup>264</sup> Any of a number of commentators have casually assumed that apology is equivalent to other statements.<sup>265</sup> Robbenolt has put forth empirical evidence that a “partial apology”<sup>266</sup> may be an acceptable compromise between circumspection and disclosure. However, “the effects of partial apologies on settlement decision making appear to be much more complicated than the effects of full apologies.”<sup>267</sup> Lastly, Jesson and Knapp have noted that the patchwork of apology laws throughout the United States has led to the need to involve legal counsel in the decision of what to disclose and who to tell.<sup>268</sup> Precisely defining the contours of healthcare apologies would create at least three types of problems for effective communication between physicians and patients or their families.<sup>269</sup> Trying to craft a healthcare apology, regardless of statutory text, should create a role for lawyers in the process of before any claims are brought or anticipated. Retaining counsel will delay and change the nature of physician-patient communication and cause delay.<sup>270</sup> The Joint Commission has maintained that effective apologies are made as quickly as possible after the adverse event occurs—within twenty-four hours.<sup>271</sup> A second problem is that the beneficial effects of apologies, whether intended to promote healing or to avoid litigation, stem from the openness of communication.<sup>272</sup> Asking the lawyer to review a proposed apology text invites revision and possible change of intended meaning. Lastly, apologies will essentially fit the contours of any statutory protection for healthcare apologies will result: “Simply put, once there is a safe harbor, all boats

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264. Lee Taft, *Apology Within a Moral Dialectic: A Reply to Professor Robbenolt*, 103 MICH. L. REV. 1010, 1012 (2005); see also Lee Taft, *Apology and Medical Error: Opportunity or Foil?*, 14 ANNALS HEALTH L. 55, 62-67 (2005).

265. MICHAEL S. WOODS, HEALING WORDS: THE POWER OF APOLOGY 14 (Joint Commission Resources 2d ed. 2007) (stating that the five “R’s” of an effective apology are recognition, regret, responsibility, remedy, and remaining engaged); Ken Braxton & Kip Poe, *How Should Hospital Policy Address Apologies to Patients?*, 9 HOSPS. & HEALTH SYS. RX 22, 22 (2007) (“Hospitals must ensure that their risk management and legal staff fully understand their applicable state law regarding ‘I am Sorry’ guidelines . . . .”); Kathy Wire, *Apology Just First Step In Event Management*, 30 MED. LIABILITY MONITOR 8, 8 (2007) (suggesting that in cases of a clear error, the *accountable party* should accept both error and responsibility. Such apologies could come from the physician, hospital representatives or, most often, both).

266. Robbenolt, *supra* note 165, at 484.

267. *Id.* at 506.

268. Lucinda E. Jesson & Peter B. Knapp, *My Lawyer Told Me To Say I’m Sorry: Lawyers, Doctors, and Medical Apologies*, 35 WM. MITCHELL L. REV. 1410, 1445 (2009) (noting that the creation of an evidentiary exclusion for medical apologies inevitably means the creation of new work for lawyers).

269. *Id.* at 1447.

270. *Id.*

271. THE JOINT COMM’N, DISCLOSING MEDICAL ERRORS: A GUIDE TO AN EFFECTIVE EXPLANATION AND APOLOGY 53 (2007).

272. Jesson & Knapp, *supra* note 268, at 1449.

will moor there.”<sup>273</sup> Once again, promptness of response and open communication will be sacrificed in attempts to protect any intended statement. In summary, apologies won’t work, and attention should be placed in other directions.

### III. RATIONAL ALTERNATIVES TO AN APOLOGY

#### *A. Promote Establishment of a National “Patient Safety Reporting System”*

Leveling fault at an individual physician or other healthcare worker for the occurrence of a complex systems error will not prevent the same or similar errors from happening again.<sup>274</sup> The physician may have not have made a mistake; or a mistake may have been made but without causation in injury or death; or a mistake was made, and causation shown, but a systems error was responsible. “[E]rror identification requires a comfortable and candid relationship among members of a healthcare team, built on trust among members that errors may be openly discussed without fear of sanction in all but the most egregious cases.”<sup>275</sup> Both mandatory and voluntary reporting systems—which complement each other—are required to make systems-based approaches to safety reporting, improved patient safety, and error prevention and effect change that contribute to decreased adverse events.<sup>276</sup>

To achieve the requisite understanding of how an adverse event occurred and how best to prevent it from happening to others, it is necessary for each institution to have a patient safety program reporting system that collects, tabulates, analyzes and reports data on the frequency and nature of adverse events as well as near misses.<sup>277</sup> The primary function of a patient safety reporting system should be to identify both real and potential adverse consequences of overt as well as latent errors and make them visible to others.<sup>278</sup>

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273. *Id.* at 1451.

274. INST. OF MED., *supra* note 3, at 4.

275. Kristen R. Salvatore, *Taking Pennsylvania Off Life Support: A Systems-Based Approach to Resolving Pennsylvania Medical Malpractice Crisis*, 109 PENN ST. L. REV. 364, 377 (2004) (citing Barry R. Furrow, *Medical Mistakes: Tiptoeing Towards Safety*, 3 HOUS. J. HEALTH POL’Y 181, 197 (2003)).

276. INST. OF MED., *supra* note 3, at 87.

277. John R. Clarke, *Making Surgery Safer*, 200 J. AM. C. SURGEONS 229, 233 (2005) (abridging recommendation 7 of the Agency for Healthcare Research and Quality (AHRQ)).

278. Lucinda Glinn, *Navigating Provider Protections for Quality of Care Reports—From Peer Review Statutes to Common Law Privileges*, 9 HOSPS. & HEALTH SYS. RX 16, 17 (2007) (advising that reports critically analyzing adverse events that show imperfect processes or failures to follow proper policies should be analyzed at the outset to ensure that the entirety of the quality review process from gathering, to investigating and drafting the resultant report, is conducted by the proper individuals and for the express purpose of quality of care, in hopes of maintaining a modicum of protection from disclosure).

Once adverse events are identified and analyzed, healthcare systems can be redesigned so as to eliminate or minimize them. The highly successful Aviation Safety Reporting System (ASRS) is good example of the type of reporting system needed in health care.<sup>279</sup> The ASRS receives, processes and analyzes voluntarily submitted reports of incidents from those in the airline industry. Submitted reports describe crashes, other unsafe occurrences and “near miss” hazardous situations.<sup>280</sup>

A successful reporting system such as the ASRS is typically nonpunitive, confidential, anonymous, independent, timely, systems oriented, and responsive to issues of human performance.<sup>281</sup> The absence of a punitive focus reduces healthcare workers’ concerns that reports might be used against them and thus minimizes underreporting.<sup>282</sup> In addition, it includes expert analysis, meaning that reports are evaluated by persons who understand the relevant circumstances and are trained to recognize underlying system-based causes. A successful reporting system usually also tabulates seemingly rare incidents (including near misses) even if there seems to be little direct or immediate benefit to doing so; in addition to their potential value in larger contexts, such analyses may help institutions predict and thereby avoid errors and system failures.<sup>283</sup> The concerns about the possible adverse consequences of a reporting system are quite strong. Andrus believes that a healthcare reporting system can succeed only if legal immunity is available: “A medical error-reporting system without absolute anonymity and nondiscoverability that does not ensure absolute immunity from punitive results for the reporter will not succeed.”<sup>284</sup>

The fear of being sued is widespread among physicians; however, the perceived risk of being sued is threefold greater than the actual risk.<sup>285</sup> Whether adverse event reporting should be voluntary or mandatory is still a matter of debate. On one hand, voluntary reporting has a high inaccuracy rate even when mandated by state or federal regulations.<sup>286</sup> However, unless strict confidentiality

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279. REASON, *supra* note 7, at vii.

280. *ASRS Concept and Mission*, AVIATION SAFETY REPORTING SYSTEM, [http://asrs.arc.nasa.gov/overview/briefing/br\\_1.html](http://asrs.arc.nasa.gov/overview/briefing/br_1.html) (last visited Feb. 27, 2011).

281. Lucian L. Leape, *Reporting of Adverse Events*, 347 *NEW ENG. J. MED.* 1633, 1633 (2002).

282. Lucian L. Leape et al., *Systems Analysis of Adverse Drug Events*, 274 *JAMA* 35, 43 (1995).

283. John W Senders, *Medical Devices, Medical Errors, and Medical Accidents*, in *HUMAN ERROR IN MEDICINE* 159 (Marilyn S. Bogner ed., 1994); *see also Error Reporting Does a Turn Around*, 23 *HOSP. PEER REV.* 121, 122 (1998).

284. Charles H. Andrus et al., *‘To Err Is Human’: Uniformly Reporting Medical Errors and Near Misses, A Naïve, Costly, and Misdirected Goal*, 196 *J. AM. C. SURGEONS* 911, 916 (2003).

285. Emily R. Carrier et al., *Physicians’ Fears of Malpractice Lawsuits are Not Assuaged by Tort Reforms*, 29 *HEALTH AFF.* 1585, 1588 (2010).

286. Patricia W. Stone et al., *Comparisons of Health Care–Associated Infections Identification Using Two Mechanisms for Public Reporting*, 35 *AM. J. INFECTION CONTROL* 145, 147 (2007)

is the standard, many surgeons fear reporting may increase the pressure to conceal errors rather than study them; that it is unworkable in the current legal regime of deterrence; and that it may result not in constructive patient safety improvement, but punishment or censure:

The current culture of blame and litigation also works against the use of voluntary error reporting. As several respondents indicated, until the legal system is changed to protect physicians' rights and hospital administrators' rights to maintain private data on errors and near-misses, it is less likely that such data will be collected and analyzed.<sup>287</sup>

### *B. Strengthen Protections for Reporting of Adverse Events*

Rather than focus on legislation that “protects” apologies from admission into evidence, a better strategy might be to strengthen protections in other rules of evidence, such as FRE 803(6), which addresses hearsay exceptions for records of regularly conducted activity.<sup>288</sup> Currently, both of these Rules allow statements to be admitted as evidence; hence most information obtained as a means to study medical errors is admissible. The systems approach of patient safety to reducing error is incompatible with the deterrence approach of medical malpractice liability. A disciplined, systematic approach of empathy, coupled with competent patient service immediately after an injury, an investigation (root cause analysis), and a resolution are all within the limits of reasonableness given the complexities of modern medicine. There are a variety of issues regarding requiring physicians to apologize as opposed to having healthcare institutions disclose an error.

Patient safety can only be enhanced in a setting of protected disclosure not only of successful initiatives but also injuries and “close calls” related to adverse events. Healthcare professionals are best positioned to make patients safer—certainly so with respect to plaintiff’s attorneys and legislators. The federal

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(noting that using each of two different reporting methods, only 8 of 89 central line associated blood stream infections were identified using both methods).

287. Lori A. Roscoe & Thomas J. Krizek, *Reporting Medical Errors: Variables in the System Shape Attitudes Toward Reporting*, 87 BULL. AM. C. SURGEONS 12, 16 (2002).

288. FED. R. EVID. 803 (“Hearsay Exceptions; Availability of Declarant Immaterial (6) *Records of regularly conducted activity.* A memorandum, report, record, or data compilation, in any form, of acts, events, conditions, opinions, or diagnoses, made at or near the time by, or from information transmitted by, a person with knowledge, if kept in the course of a regularly conducted business activity, and if it was the regular practice of that business activity to make the memorandum, report, record or data compilation, all as shown by the testimony of the custodian or other qualified witness, *or by certification that complies with Rule 902(11), Rule 902(12), or a statute permitting certification, unless the source of information or the method or circumstances of preparation indicate lack of trustworthiness.* The term ‘business’ as used in this paragraph includes business, institution, association, profession, occupation, and calling of every land, whether or not conducted for profit.”).

government appears to understand the need for a protected discussion of medical adverse events to foster a culture of safety. Congress has been cautiously moving in the direction of making patients safer by protecting those documents that result from analysis of adverse events. On December 6, 1999, President Clinton signed the Healthcare Research and Quality Act of 1999, reauthorizing the Agency for Health Care Policy and Research and changing the name to Agency for Healthcare Research and Quality (AHRQ).<sup>289</sup> AHRQ is charged with improving patient safety by promoting research on healthcare outcomes and other measures.

Of even greater import, the Patient Safety and Quality Improvement Act (PSQIA) of 2005 was enacted for the purpose of improving patient safety by encouraging voluntary, confidential reporting of events that adversely affect patients.<sup>290</sup> The act required the creation of patient safety organizations to collect, aggregate, and analyze confidential information reported by healthcare providers. PSQIA also calls for establishing a network of patient safety databases as an interactive, evidence-based management resource. However, there are shortcomings in the level of protection provided by the act. Under a number of circumstances, patient safety organizations can be compelled to produce documents otherwise protected, including information that is identified, is not work product, and “not reasonably available from another source.”<sup>291</sup> Further, any information shared with patients or families, whether a limited factual disclosure or an apology, is not protected.

In the healthcare setting, safety can be defined as freedom from accidental injury.<sup>292</sup> This definition recognizes that avoidance of accidental injury is an overarching goal from the patient’s perspective. In the past decade, the definition

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289. *Reauthorization Fact Sheet*, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, <http://www.ahrq.gov/about/ahrqfact.htm> (last visited Dec. 1, 2009) (describing AHRQ as the lead agency of the U.S. Department of Health and Human Services charged with supporting research designed to improve the quality of healthcare, reduce its cost, improve patient safety, decrease medical errors, and broaden access to essential services. AHRQ sponsors and conducts research that provides evidence-based information on healthcare outcomes; quality; and cost, use, and access).

290. Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424. (“Amends the Public Health Service Act to designate patient safety work product as privileged and not subject to: (1) a subpoena or discovery in a civil, criminal, or administrative disciplinary proceeding against a provider; (2) disclosure under the Freedom of Information Act (FOIA) or a similar law; (3) admission as evidence in any civil, criminal, or administrative proceeding; or (4) admission in a professional disciplinary proceeding”). Defines “patient safety work product” as any data, reports, records, memoranda, analysis, or written or oral statements which: (1) are assembled or developed by a provider for reporting to a patient safety organization (PSO); (2) are developed by a PSO for patient safety activities and which could result in improved patient safety or health care quality or outcomes; or (3) identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system. *Id.*

291. 42 U.S.C. § 299b-22 (2006).

292. Richardson et al., *supra* note 3, at 18.

of patient safety has been expanded to acknowledge patient safety as both emerging discipline and a process.<sup>293</sup> A number of states have begun to protect patient safety analyses from discovery or as evidence in most civil proceedings.<sup>294</sup> Individual state laws, however, can be quite different. As an example, the Oregon legislature protects patient safety data and reports, but the privilege does not apply to records of a patient's medical diagnosis and treatment or to records created in the ordinary course of business.<sup>295</sup> In Vermont, original source information, documents, and records are not immune from discovery or use in any other action merely because they were made available to the department's patient safety surveillance and improvement system.<sup>296</sup> In Virginia, no privilege to a healthcare provider, emergency medical services agency, community services board, or behavioral health authority for medical records kept in the ordinary course of business precludes or affects discovery of or production of evidence relating to hospitalization or treatment of any patient in the ordinary course of hospitalization of such patient.<sup>297</sup> However, for such reports to be comprehensive and "kept in the course of a regularly conducted business activity,"<sup>298</sup> the protections regarding discovery and admissibility should be further strengthened.

### *C. Remedial Work and Disclosure of the Adverse Event: Account, Not Apology*

As errors—injury related and “near misses”—are documented and analyzed, the disclosure of such errors to patients is being required with increasing frequency. The Joint Commission approach requires disclosure by the attending physician at the time the confidential report is submitted for patient safety and

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293. Linda Emanuel et al., *What Exactly is Patient Safety?*, INFORMED 2010-2011 PENNSYLVANIA PATIENT SAFETY UPDATE, <http://pa.cme.edu/index.aspx> (last visited July 5, 2010) (defining patient safety as “[a] discipline in the health care sector that applies safety science methods toward the goal of achieving a trustworthy system of health care delivery”). “Patient safety is also an attribute of health care systems; it minimizes the incidence and impact of, and maximizes recovery from, adverse events.” *Id.*

294. ARIZ. REV. STAT. ANN. § 36-450.01(B) (2003); COLO. REV. STAT. ANN. § 13-21-110 (2007); CONN. GEN. STAT. ANN. § 19a-127o (2004); D.C. CODE § 7-161 (2007); FL. STAT. ANN. § 395.1051 (2009); HAW. REV. STAT. § 624-25.5 (2008); ILL. COMP. STAT. ANN. § 522/10-25 (2005); IND. CODE ANN. 34-30-15-1 *and* IND. CODE ANN. 16-40-5-6 (2008); LA. REV. STAT. ANN. § 13:3715.3 (2001); ME. REV. STAT. ANN. § 8753-A (2009); MD. CODE ANN.; HEALTH OCC. § 1-401 (2008); MICH. COMP. LAWS ANN. § 331.533 (1992); NEV. REV. STAT. ANN. § 49.265 (2005) *and* NEV. REV. STAT. ANN. § 439.875 (2003); N.H. REV. STAT. ANN. § 151:38 (2010); N.J. STAT. ANN. § 26:2H-12.24 (2004); N.C. GEN. STAT. § 131-E95 (2006); 40 PA. STAT. ANN. § 1303.311 (2006); R.I. GEN. LAWS § 23-17.21-8 (2008); WASH. REV. CODE ANN. § 70.41.200 (2007); WYO. STAT. ANN. § 35-2-912 (2008).

295. OR. REV. STAT. ANN. § 442.846 (2003).

296. VT. STAT. ANN. tit. 18, § 1917 (2005).

297. VA. CODE ANN. § 8.01-581.17 (2010).

298. FED. R. EVID. 803(6).

risk management review. Pennsylvania has enacted Act 13 M-CARE legislation, which requires the disclosure of medical injury to a mandated state reporting recipient—the patient safety authority—and the affected patient and/or family. M-Care also requires the establishment of patient safety committees for each healthcare facility. In addition to the non-statutory and disclosure requirements listed above, a number of other states are also getting into the act, with at least six states enacting some form of mandatory disclosure.<sup>299</sup>

Encouraging physicians to apologize for adverse events is counterproductive to the goal of improving patient safety. Physicians should, however, be involved in a process of disclosure to ensure patients understand the medical implications of the adverse event. Such information is important so the affected patient and their families can make rational future decisions regarding their health. An explanation or account, while often given in conjunction with an apology, is not an apology. An “account,” as used in this paper, is the offering of external, mitigating circumstances and is a form of remedial work that seeks to reduce the responsibility of the transgressor for the transgression.<sup>300</sup> The reduction of responsibility entailed by an honest account of the events leading to the patient’s adverse event, may improve judgments made about the speaker and his or her relationship to the transgression, however, it does so through mechanisms that are distinct from apologies.

Accounts are intended to provide a fair analysis of the steps leading to adverse events and in an attempt to counter accusations or claims brought into courts adjudicate can usually be challenged or opposed in two ways. First, by stating the facts and correcting misperceptions which a patient may have of events which have occurred, and secondly, by leading to a frank discussion in which the healthcare providers state that although all the elements on which a claim could succeed are present, yet in the particular case of a specific patient, the claim or accusation should not succeed because other circumstances are present which makes the adverse event an exception, the effect of which is either to defeat the patient’s accusation or claim, or to ‘reduce’ it so that only a weaker claim can be sustained.<sup>301</sup> Austin has further separated such accounts, or in his

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299. FLA. STAT. ANN. § 395.1051 (2005); NEV. REV. STAT. § 439.835 (2004); N.J. STAT. § 26:2H-12.25 (2005); 40 PA. STAT. ANN. § 1303.308 (2004); VT. STAT. ANN. § 1915 (2005).

300. ERVING GOFFMAN, *RELATIONS IN PUBLIC: MICROSTUDIES OF THE PUBLIC ORDER* 109 (1971); C. R. SNYDER ET AL., *EXCUSES: MASQUERADES IN SEARCH OF GRACE* 300 (1983); Marvin B. Scott & Stanford M. Lyman, *Accounts*, 33 AM. SOC. REV. 46, 46 (1968) (defining accounts as statements made to explain untoward behavior and bridge the gap between actions and expectations).

301. H. L. A. Hart, *The Ascription of Responsibility and Rights*, in *LOGIC AND LANGUAGE (FIRST SERIES): ESSAYS BY PROFESSOR GILBERT RYLE, PROFESSOR J. N. FINDLAY, PAUL EDWARDS, MARGARET MACDONALD, G. A. PAUL, DR. F. WAISMAN* 147-60 (John Wisdom & Antony Flew eds., 1952) (noting that philosophical difficulties arise when ignoring the concept of human action as ascriptive and defeasible while searching for its necessary and sufficient conditions). The

vernacular, excuses, into several types of speech acts.<sup>302</sup> One may discuss having performed an action, but also justify, or give reasons for the action.<sup>303</sup> One may discuss that the adverse event was not a good thing to have happened, but it is not correct to say that one individual was responsible, or a slip occurred, or there was an accident, or, that the provider was doing something different than the patient perceived.<sup>304</sup> In other words, the intent is to agree the adverse event is a bad outcome, but it is not correct to think in terms of full or even partial responsibility.<sup>305</sup> Austin argues against easy solutions:

[I]f we can only discover the true meanings of each of a cluster of key terms... that we use in some particular field (as, for example, 'right', 'good' and the rest in morals), then it must without question transpire that each will fit in place into some single, interlocking, consistent, conceptual scheme. Not only is there no reason to assume this, but all historical probability is against it . . .<sup>306</sup>

The same is arguably true for the wide variety of terms that can be applied to conversations with patients who have sustained adverse events terms such as statement, affirmation, gesture or conduct expressing apology, responsibility, liability, sympathy, commiseration, condolence, compassion or a general sense of benevolence. Apology, given the charged legal nature of the term particularly seems not to fit into "some single, interlocking, consistent, conceptual scheme"<sup>307</sup> and stands alone as a strategy more harmful to patient safety and more likely to condemn healthcare providers to costly, painful and often undeserved claims of individual negligence and malpractice.

Accounts, on the other hand, can bridge the gap between adverse events and patient expectations.<sup>308</sup> The development of an account is not to be taken lightly and falls generally into one of two broad categories, both of which are

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ascription and assumption of responsibility of assertions with simple utterances such as 'I'm sorry', 'I apologize', or 'I did it' are primarily speech acts by which one confesses or admits liability. *Id.*

302. J. L. AUSTIN, *PHILOSOPHICAL PAPERS* 123 (J. O. Urmson & G. J. Warnock eds., 1961).

303. *Id.* at 124.

304. *Id.*

305. AUSTIN, *supra* note 302 (discussing a wide variety of strategies for giving accounts: use of modifying expressions; limitation of application; emphasis on negation; the "machinery of action"; listing of standards of the unacceptable; combination, dissociation, or complication; gradations of distinction; precise phrasing and style of performance; or the "trailing clouds of etymology"); *see also* GOFFMAN, *supra* note 166, at 109 (noting the purpose of remedial work is to change the meaning that might otherwise be given to an act).

306. *Id.* at 151 n.1.

307. *Id.* at 151 n.1.

308. Scott & Lyman, *supra* note 300, at 46 (noting accounts are important speech acts which can be employed whenever adverse events occur and are, inevitably, subject to "evaluative inquiry").

underutilized in modern discourse: excuses and justifications.<sup>309</sup> Accounts are particularly useful in the disclosure of an adverse event noting the ability of an account to “bridg[e] the gap between action and expectation” such as when a medical injury occurs.<sup>310</sup> Scott and Lyman have suggested five linguistic styles—intimate, casual, consultative formal, and frozen—which can be employed in the giving of accounts.<sup>311</sup> These styles are intended to represent points in a spectrum of speech that are acknowledged to merge into each other when reduced to real-world situations. Some variation of three of the styles—consultative, formal, and frozen—are likely to be useful in giving an account of an adverse event after medical injury.<sup>312</sup>

### CONCLUSIONS

Apologies—statements of regret, remorse and responsibility—do little to achieve the policy goal of making patients safer in the healthcare setting. Modern health care is delivered in a highly complex system, and medical injuries occur as a sequence of errors from blunt end to sharp. Those who work in the healthcare field are best situated to identify, report and correct system errors which injure patients; these individuals are best positioned to make patients safer. A variety of approaches are being used to improve systems and decrease errors that lead to injury: root cause analyses, peer reviews, and morbidity and mortality conferences are but a few. The principles of human performance are being used to minimize the “human factors” that are a critical part of healthcare systems. External organizations play an increasingly important role in monitoring and analyzing injuries, with the purpose of identifying common errors that lead to injury, and then establishing standards for minimizing variations in medical practice.

Essentially all of the approaches to decreasing injuries rely on protected disclosure and frank discussion regarding individual injuries and how to prevent similar injuries in the future. Apologies, by chilling the open disclosure of sensitive information and accompanying frank discussion, run counter to the

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309. *Id.* at 247 (describing excuse as “a socially approved vocabulary[y] for mitigating or relieving responsibility when conduct is questioned”). Four modal forms are described: appeal to accident, defeasibility, biologic drive, and scapegoating. *Id.* See also HART, *supra* note 301, at 160 (providing further discussions of defeasibility “the capacity of being voided”).

310. Scott & Lyman, *supra* note 300, at 46.

311. *Id.* at 55-56 (distinguishing three of the styles as: *consultative*, a verbal form ordinarily employed when the amount of knowledge available to interactants is unknown or problematic, and there is a definite element of objectivity; *formal*, often used when there are rigidly defined status (i.e., physician and patient) or when the discussant is responding to six or more; and *frozen*, occurring when immovable barriers exist (i.e., a prisoner of war giving only name, rank, and serial number to interrogators)).

312. *Id.*

goals of improving patient safety. Unlike other forms of disclosure of the events surrounding an injury, apologies also establish responsibility. In many circumstances individual assignment of “shame and blame” unfairly open up the involved individuals and organizations to liability and loss. Malpractice litigation has often been justified as a deterrent to medical injury, however the ex post nature of lawsuits, the focus of the plaintiff’s attorney upon the individual client, and the malpractice gap in which few are compensated and the high overhead costs make litigation an inefficient—if not ineffective—way to make patients safer; rather the intent of healthcare organizations to “do the right thing” coupled with the knowledge of administrative action affecting licensing or accreditation makes such an approach effective. For purposes of maintaining autonomy, the patient must be offered an account of what happened, so they can make rational decisions about their future care. However, such disclosure should be a carefully scripted interaction, with input from all relevant sources.

There are rational and achievable alternatives to the use of apology in the setting of medical injury. First, the development of a “Patient Safety Reporting System” modeled along the lines of the Airline Safety Reporting System (ASRS) should be developed. Such national reporting will be able to assess trends at a macro level that would be difficult to discern within individual institutions. A second alternative is to strengthen protections for FRE803(6) business records. Other than peer review documents, essentially all medical documents are discoverable under the business records exception. By increasing protection for frank, open discussions of what went wrong and how to fix it, lines of communication can be opened. Many states, through mandatory disclosure statutes and private accreditation bodies, such as The Joint Commission, are increasingly able to maintain oversight and encourage widespread participation.

Lastly, although apologies should be avoided, for purposes of maintaining individual autonomy the patient must be offered an account of what happened, so they can make rational decisions about their future care. Such accounts are a second kind of remedial work that has not received enough study in the setting of medical injury disclosure to patients. However, such disclosure should be a carefully scripted interaction, with input from all relevant sources. In the vast majority of injuries, it will not be possible to lay the blame upon one individual. Attempts at assigning such blame will—counter to the need for open discussion to decrease errors that lead to injury—drive the causes of error underground. An account provided to the injured individual is morally praiseworthy, but in a complex, imperfect system such as that of modern healthcare, there is no role for apology.

APPENDIX 1

State/Statute	Considered Inadmissible	By whom	To whom	Notes
<b>ARIZ. REV. STAT. ANN. § 12-2605 (2009) Evidence of admissions; civil proceedings; unanticipated outcomes; medical care</b>	any statement, affirmation, gesture or conduct expressing apology, responsibility, liability, sympathy, commiseration, condolence, compassion or a general sense of benevolence	a health care provider or an employee of a health care provider	the patient, a relative of the patient, the patient’s survivors or a health care decision maker for the patient	inadmissible as evidence of an admission of liability or as evidence of an admission against interest.
<b>CAL. EVID. CODE § 1160 (West 2001) Admissibility of expressions of sympathy or benevolence; definitions (repealed)</b>	A portion of 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		made to that person or to the family of that person	Not explicit as to patients or health care;  A statement of fault, however, which is part of, or in addition to, any of the above shall not be inadmissible.
<b>COLO. REV. STAT. ANN. § 13-25-135 (West 2003) Evidence of admissions—civil proceedings—unanticipated outcomes—medical care</b>	any and all statements, affirmations, gestures, or conduct expressing apology, fault, sympathy, commiseration, condolence, compassion, or a general sense of benevolence	health care provider or an employee of a health care provider	the alleged victim, a relative of the alleged victim, or a representative of the alleged victim	inadmissible as evidence of an admission of liability or as evidence of an admission against interest
<b>CONN. GEN. STAT. ANN. § 52-184d (West 2006) Inadmissibility of apology made by health care provider to alleged victim of unanticipated outcome of medical care</b>	any and all statements, affirmations, gestures or conduct expressing apology, fault, sympathy, commiseration, condolence, compassion or a general sense of benevolence	health care provider or an employee of a health care provider	alleged victim, a relative of the alleged victim or a representative of the alleged victim and that	inadmissible as evidence of an admission of liability or as evidence of an admission against interest.
<b>DEL. CODE ANN. tit. 10, § 4318 (2006) Compassionate communications</b>	Any and all statements, writings, gestures, or affirmations made by a health care provider or an employee of a health care provider that express apology	health care provider or an employee of a health care provider	the person, the person’s family, or a friend of the person or of the person’s family	expressions or admissions of liability or fault are admissible

NO ROLE FOR APOLOGY

<p><b>D. C. CODE § 16-2841 (2007)</b>  <b>Inadmissibility of benevolent gestures.</b></p>	<p>an expression of sympathy or regret made in writing, orally, or by conduct</p>	<p>by or on behalf of the healthcare provider</p>	<p>a victim of the alleged medical malpractice, any member of the victim's family, or any individual who claims damages by or through that victim</p>	<p>Nothing herein shall preclude the court from permitting the introduction of an admission of liability into evidence</p>
<p><b>FLA. STAT. ANN. § 90.4026 (West 2001)</b>  <b>Statements expressing sympathy; admissibility; definitions</b></p>	<p>The portion of statements, writings, or benevolent gestures expressing sympathy or a general sense of benevolence</p>		<p>made to that person or to the family of that person</p>	<p>A statement of fault, however, which is part of, or in addition to, any of the above shall be admissible</p>
<p><b>GA. CODE ANN. § 24-3-37.1 (West 2006)</b>  <b>Statements or activities constituting offers of assistance or expressions of regret, mistake, etc.; not admission of liability</b></p>	<p>any and all statements, affirmations, gestures, activities, or conduct expressing benevolence, regret, apology, sympathy, commiseration, condolence, compassion, mistake, error, or a general sense of benevolence</p>	<p>a health care provider or an employee or agent of a health care provider</p>	<p>the patient, a relative of the patient, or a representative of the patient</p>	<p>The General Assembly issued findings regarding this statute.           Statements are inadmissible as evidence and shall not constitute an admission of liability or an admission against interest</p>
<p><b>HAW. REV. STAT. § 626-1 409.5 (2007)</b>  <b>Admissibility of expressions of sympathy and condolence</b></p>	<p>Evidence of statements or gestures that express sympathy, commiseration, or condolence concerning the consequences of an event in which the declarant was a participant</p>			<p>This rule does not require the exclusion of an apology or other statement that acknowledges or implies fault even though contained in, or part of, any statement or gesture excludable under this rule.</p>

<p><b>IDAHO CODE ANN. § 9-207. (2006)</b>  <b>Admissibility of expressions of apology, condolence and sympathy</b></p>	<p>all statements and affirmations, whether in writing or oral, and all gestures or conduct expressing apology, sympathy, commiseration, condolence, compassion, or a general sense of benevolence, including any accompanying explanation</p>	<p>made by a health care professional or an employee of a health care professional</p>	<p>a patient or family member or friend of a patient</p>	<p>inadmissible as evidence for any reason including, but not limited to, as an admission of liability or as evidence of an admission against interest</p>
<p><b>735 ILL. COMP. STAT. ANN. § 5/8-1901 (West 2005)</b>  <b>Admission of liability—Effect. Ruled unconstitutional</b></p>	<p>The providing of, or payment for, medical, surgical, hospital, or rehabilitation services, facilities, or equipment by or on behalf of any person, or the offer to provide, or pay for, . . . shall not be construed as an admission of any liability . . .</p> <p>Testimony, writings, records, reports or information with respect to the foregoing shall not be admissible in evidence as an admission of any liability in any action of any kind in any court or before any commission, administrative agency, or other tribunal in this State, except at the instance of the person or persons so making any such provision, payment or offer.</p>	<p>a “health care provider” (any hospital, nursing home or other facility, or employee or agent thereof, a physician, or other licensed health care professional.)</p>	<p>a patient, the patient’s family, or the patient’s legal representative about an inadequate or unanticipated treatment or care outcome that is provided within 72 hours</p>	<p>This section was found unconstitutional due to inseverability with other sections of the law. It is included as an example of a statute that attempts to do something different than most of the other “Apology” laws.</p> <p>Nothing precludes the discovery or admissibility of any other facts regarding the patient’s treatment or outcome as otherwise permitted by law.</p> <p>The disclosure of any such information, whether proper, or improper, shall not waive or have any effect upon its confidentiality or inadmissibility.</p>

NO ROLE FOR APOLOGY

<p><b>IND. CODE ANN. § 34-43.5-1-3 (West 2006)</b>  <b>“Communication of sympathy” defined; IND. CODE ANN. § 34-43.5-1-4 (West 2006)</b>  <b>Admissions into evidence; § IND. CODE ANN. § 34-43.5-1-5 (West 2006)</b>  <b>Statements of fault</b></p>	<p>a court may not admit into evidence a communication of sympathy (“communication of sympathy” means a statement, a gesture, an act, conduct, or a writing that expresses: (1) sympathy; (2) an apology; or (3) a general sense of benevolence.)</p>			<p>A court may admit a statement of fault into evidence, including a statement of fault that is part of a communication of sympathy, if otherwise admissible under the Indiana Rules of Evidence.</p> <p>that relates to causing or contributing to: (1) a loss; (2) an injury; (3) pain; (4) suffering; (5) a death, or (6) damage to property</p>
<p><b>IOWA CODE ANN. § 622.31 (West 2007) Evidence of regret or sorrow</b></p>	<p>that portion of a statement, affirmation, gesture, or conduct expressing sorrow, sympathy, commiseration, condolence, compassion, or a general sense of benevolence</p>	<p>against a person in a profession regulated by one of the [professional boards] boards or in any other licensed profession recognized in this state, a hospital licensed . . . , or a licensed health care facility</p>	<p>the plaintiff, relative of the plaintiff, or decision maker for the plaintiff</p>	<p>Any response by the plaintiff, relative of the plaintiff, or decision maker for the plaintiff to such statement, affirmation, gesture, or conduct is similarly inadmissible as evidence.</p>

<p><b>LA. REV. STAT. ANN. § 3715.5 (2005)</b>  <b>Confidentiality of communication from health care provider</b></p>	<p>Any communication, including but not limited to an oral or written statement, gesture, or conduct . . . expressing or conveying apology, regret, grief, sympathy, commiseration, condolence, compassion, or a general sense of benevolence</p>	<p>a health care provider</p>	<p>a patient, a relative of the patient, or an agent or representative of the patient</p>	<p>A statement of fault, however, which is part of, or in addition to, any such communication shall not be made inadmissible pursuant to this Section.</p> <p>[s]hall not constitute an admission or a statement against interest, and shall not be admissible in evidence to establish liability or for any other purpose, including impeachment, in a medical review panel proceeding, arbitration proceeding, or civil action</p>
<p><b>ME. REV. STAT. ANN. tit. 24, § 2907 (2009)</b>  <b>Communications of sympathy or benevolence</b></p>	<p>any statement, affirmation, gesture or conduct expressing apology, sympathy, commiseration, condolence, compassion or a general sense of benevolence</p>	<p>a health care practitioner or health care provider or an employee of a health care practitioner or health care provider</p>	<p>the alleged victim, a relative of the alleged victim or a representative of the alleged victim</p>	<p>Nothing in this section prohibits the admissibility of a statement of fault.</p> <p>inadmissible as evidence of an admission of liability or as evidence of an admission against interest.</p>

NO ROLE FOR APOLOGY

<p><b>MD. CODE ANN., CTS. &amp; JUD. PROC. § 10-920 (2005) Health care providers; expression of regret or apology</b></p>	<p>an expression of regret or apology, . . . including an expression of regret or apology made in writing, orally, or by conduct,</p>	<p>made by or on behalf of the health care provider</p>		<p>Inadmissible as evidence of an admission of liability or as evidence of an admission against interest.</p> <p>Inadmissible as evidence of an admission of liability in a civil action.</p> <p>An admission of liability or fault that is part of or in addition to a communication made . . . is admissible as evidence of an admission of liability or as evidence of an admission against interest</p>
<p><b>MASS. GEN. LAWS ch. 233 § 23D (West 2000) Admissibility of benevolent statements, writings or gestures relating to accident victims</b></p>	<p>Statements, writings or benevolent gestures (actions which convey a sense of compassion or commiseration emanating from humane impulses ) expressing sympathy or a general sense of benevolence</p>		<p>person or to the family of such person</p>	
<p><b>MO. ANN. STAT. § 538.229 (West 2010) Certain statements, writings, and benevolent gestures inadmissible, when— definitions</b></p>	<p>The portion of statements, writings, or benevolent gestures (actions which convey a sense of compassion or commiseration emanating from humane impulses) expressing sympathy or a general sense of benevolence</p>		<p>that person or to the family of that person</p>	<p>Inadmissible as evidence of an admission of liability in a civil action.</p> <p>Nothing in this section shall prohibit admission of a statement of fault.</p>

<p><b>MONT. CODE ANN. § 26-1-814 (2010) Statement of apology, sympathy, or benevolence--not admissible as evidence of admission of liability for medical malpractice</b></p>	<p>A statement, affirmation, gesture, or conduct expressing apology, (a statement, writing, or gesture that expresses regret) sympathy, commiseration, condolence, compassion, or a general sense of benevolence</p>		<p>the person, the person's family, or a friend of the person or of the person's family</p>	<p>Not admissible for any purpose in a civil action for medical malpractice.</p>
<p><b>NEB. REV. STAT. § 27-1201 (2010) Unanticipated outcome of medical care; civil action; health care provider or employee; use of certain statements and conduct; limitations.</b></p>	<p>any and all statements, affirmations, gestures, or conduct expressing apology, sympathy, commiseration, condolence, compassion, or a general sense of benevolence</p>	<p>a health care provider or an employee of a health care provider</p>	<p>the alleged victim, a relative of the alleged victim, or a representative of the alleged victim</p>	<p>A statement of fault which is otherwise admissible and is part of or in addition to any such communication shall be admissible.  Inadmissible as evidence of an admission of liability or as evidence of an admission against interest.</p>
<p><b>N. H. REV. STAT. ANN. § 507-E:4 (West 2010) Evidence of Admissions of Liability.</b></p>	<p>A statement, writing, or action that expresses sympathy, compassion, commiseration, or a general sense of benevolence</p>		<p>that individual or to the individual's family</p>	<p>This section does not apply to a statement of fault, negligence, or culpable conduct that is part of or made in addition to a statement, writing, or action  inadmissible as evidence of an admission of liability in a medical injury action</p>
<p><b>N. C. GEN. STAT. ANN. § 8C-1 (West 2004) Rule 413. Medical actions; statements to ameliorate or mitigate adverse outcome</b></p>	<p>Statements . . . apologizing for an adverse outcome in medical treatment, offers to undertake corrective or remedial treatment or actions, and gratuitous acts to assist affected persons</p>	<p>a health care provider</p>		<p>shall not be admissible to prove negligence or culpable conduct by the health care provider in an action brought under Article 1B of Chapter 90 of the General Statutes.</p>

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<p><b>N. D. CENT. CODE § 31-04-12 (2010) Expressions of empathy</b></p>	<p>A statement, affirmation, gesture, or conduct . . . that expresses apology, sympathy, commiseration, condolence, compassion, or benevolence</p>	<p>a health care provider, or health care provider's employee or agent</p>	<p>a patient or to a patient's relative or representative</p>	<p>not admissible as evidence of liability or as an admission against interest in a civil action, arbitration proceeding, or administrative hearing regarding the health care provider</p>
<p><b>OHIO REV. CODE ANN. § 2317.43 (West 2010) Use of defendant's statement in medical liability action prohibited</b></p>	<p>any and all statements, affirmations, gestures, or conduct expressing apology, sympathy, commiseration, condolence, compassion, or a general sense of benevolence</p>	<p>a health care provider or an employee of a health care provider</p>	<p>the alleged victim, a relative of the alleged victim, or a representative of the alleged victim</p>	<p>inadmissible as evidence of an admission of liability or as evidence of an admission against interest</p>
<p><b>OKLA. STAT. ANN. tit. 63 § 1-1708.1H. (West 2010) Statements, conduct, etc. expressing apology, sympathy, etc.—Admissibility—Definitions</b></p>	<p>any and all statements, affirmations, gestures, or conduct expressing apology, sympathy, commiseration, condolence, compassion, or a general sense of benevolence</p>	<p>a health care provider or an employee of a health care provider</p>	<p>the plaintiff, a relative of the plaintiff or a representative of the plaintiff</p>	<p>inadmissible as evidence of an admission of liability or as evidence of an admission against interest.</p>

<p><b>OR. REV. STAT. ANN. § 677.082 (West 2010)</b>  <b>Person licensed by Board of Medical Examiners, expression of regret or apology does not constitute an admission of liability in civil action</b></p>	<p>For the purposes of any civil action against a person licensed by the Oregon Medical Board, any expression of regret or <b>apology</b> made by or on behalf of the person, including an expression of regret or apology that is made in writing, orally or by conduct</p>			<p>does not constitute an admission of liability for any purpose</p> <p>A person who is licensed by the Oregon Medical Board, or any other person who makes an expression of regret or <b>apology</b> on behalf of a person who is licensed by the Oregon Medical Board, may not be examined by deposition or otherwise in any civil or administrative proceeding including any arbitration or mediation proceeding with respect to an expression of regret or apology made by or on behalf of the person, including expressions of regret or apology that are made in writing orally or by conduct.</p>
<p><b>S. C. CODE ANN. § 19-1-190 (2010)</b>  <b>South Carolina Unanticipated Medical Outcome Reconciliation Act; legislative purpose; inadmissibility of certain statements; waiver of inadmissibility; impact of South Carolina Rules of Evidence.</b></p>	<p>any and all statements, affirmations, gestures, activities, or conduct expressing benevolence, regret, apology, sympathy, commiseration, condolence, compassion, mistake, error, or a general sense of benevolence</p>	<p>a health care provider, <b>an</b> employee or agent of a health care provider, or by a health care institution</p>	<p>the patient; a relative of the patient, or a representative of the patient and which are made during a designated meeting to discuss the unanticipated outcome</p>	<p>SC legislature issued findings regarding this statute.</p> <p>shall be inadmissible as evidence and shall not constitute an admission of liability or an admission against interest</p> <p>The defendant in a medical malpractice action may waive the inadmissibility of the statements</p>

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<p><b>TENN. RULES OF EVIDENCE; Article IV. Relevance; Rule 409.1. Expressions Of Sympathy Or Benevolence</b></p>	<p>That portion of statements, writings, or benevolent gestures (actions which convey a sense of compassion or commiseration emanating from humane impulses ) expressing sympathy or a general sense of benevolence</p>			<p>Not specific to health care, patients, or physicians.  A statement of fault that is part of, or in addition to, any of the above shall not be inadmissible.</p>
<p><b>TEX. CIV. PRAC. &amp; REM. CODE ANN. § 18.061 (West 2009) Communications of Sympathy</b></p>	<p>a communication (a statement; a writing; or a gesture that conveys a sense of compassion or commiseration emanating from humane impulses.) that: expresses sympathy or a general sense of benevolence relating to the pain, suffering, or death of an individual involved in an accident;</p>			<p>Not explicit as to health care, patients, or physicians.  a statement or statements concerning negligence or culpable conduct pertaining to an accident or event, is admissible to prove liability of the communicator.</p>
<p><b>UTAH CODE ANN. § 78B-3-422 (West 2010) Evidence of disclosures— Civil proceedings— Unanticipated outcomes— Medical care</b></p>	<p>any unsworn statement, affirmation, gesture, or conduct [that] expresses apology, sympathy, commiseration, condolence, or compassion; or a general sense of benevolence; or describes the sequence of events relating to the unanticipated outcome of medical care; or the significance of events; or both</p>	<p>the defendant (defendant in a malpractice action against a health care provider (includes an agent of a health care provider))</p>	<p>the patient (defined as any person associated with the patient)</p>	<p>Does not alter any other law or rule that applies to the admissibility of evidence in a medical malpractice action</p>

<p><b>VT. STAT. ANN. tit. 12 § 1912 (West 2010)</b>  <b>Expression of regret or apology by health care provider inadmissible</b></p>	<p>An oral expression of regret or apology, including any oral good faith explanation of how a medical error occurred</p>	<p>made by or on behalf of a health care provider or health care facility, that is provided within 30 days of when the provider or facility knew or should have known of the consequences of the error</p>		<p>does not constitute a legal admission of liability for any purpose and shall be inadmissible in any civil or administrative proceeding against the health care provider or health care facility, including any arbitration or mediation proceeding.</p> <p>may not be examined by deposition or otherwise with respect to the expression of regret, apology, or explanation.</p>
<p><b>VA. CODE ANN. § 8.01-52.1 (West 2011)</b>  <b>Admissibility of expressions of sympathy</b></p>	<p>the portion of statements, writings, affirmations, benevolent conduct, or benevolent gestures expressing sympathy, commiseration, condolence, compassion, or a general sense of benevolence, together with apologies</p>	<p>health care provider or an agent of a health care provider</p>	<p>a relative of the patient, or a representative of the patient about the death of the patient</p>	<p>Pertains only to death, shall be inadmissible as evidence of an admission of liability or as evidence of an admission against interest.</p> <p>A statement of fault that is part of or in addition to any of the above shall not be made inadmissible by this section.</p>

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<p><b>WASH. REV. CODE ANN. § 5.64.010 (West 2010) Civil actions against health care providers-- Admissibility of evidence of furnishing or offering to pay medical expenses-- Admissibility of expressions of apology, sympathy, fault, etc.</b></p>	<p>Evidence of furnishing or offering or promising to pay medical, hospital, or similar expenses occasioned by an injury is not admissible.</p> <p>A statement, affirmation, gesture, or conduct (Any statement, affirmation, gesture, or conduct expressing apology, fault, sympathy, commiseration, condolence, compassion, or a general sense of benevolence; or any statement or affirmation regarding remedial actions that may be taken to address the act or omission that is the basis for the allegation of negligence.) . . . is not admissible as evidence if it was conveyed by a health care provider to the injured person, or to [other statutorily defined] person . . . within thirty days of the act or omission that is the basis for the allegation of professional negligence or within thirty days of the time the health care provider discovered the act or omission that is the basis for the allegation of professional negligence</p>			
<p><b>W. VA. CODE ANN. § 55-7-11a (West 2005) Settlement, release or statement within twenty days after personal injury; disavowal; certain expressions of sympathy inadmissible as evidence</b></p>	<p>statement, affirmation, gesture or conduct . . . expressing apology, sympathy, commiseration, condolence, compassion or a general sense of benevolence</p>	<p>a healthcare provider who provided healthcare services to a patient,</p>	<p>to the patient, a relative of the patient or a representative of the patient</p>	<p>shall not be admissible as evidence of an admission of liability or as evidence of admission against interest in any civil action</p>

<p><b>WYO. STAT. ANN. § 1-1-130. (2009)</b>  <b>Actions against health care providers; admissibility of evidence</b></p>	<p>any and all statements, affirmations, gestures or conduct expressing apology, sympathy, commiseration, condolence, compassion or a general sense of benevolence</p>	<p>health care provider or an employee of a health care provider</p>	<p>the alleged victim, or to a relative or representative of the alleged victim</p>	<p>inadmissible as evidence of an admission of liability or as evidence of an admission against interest.</p>
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# **Delayed and Denied: Toward an Effective ERISA Remedy for Improper Processing of Healthcare Claims**

**Katherine T. Vukadin \***

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## INTRODUCTION

ERISA is a comprehensive statute designed to promote the interests of employees and their beneficiaries in employee benefit plans.<sup>1</sup>

[E]very dollar provided in benefits is a dollar spent by . . . the employer; and every dollar saved . . . is a dollar in [the employer's] pocket.<sup>2</sup>

The healthcare reform effort culminating in the Patient Protection and Affordable Care Act (PPACA) has focused, to date, on the plight of the uninsured and on barriers to insurance such as pre-existing condition exclusions. Reform efforts focus less often, however, on threats to healthcare benefits for people who *do* have health insurance. When insured individuals suffer a serious illness, does their insurance live up to its promise? One overlooked threat to the insured concerns administration of employer-sponsored health insurance plans. Specifically, participants' benefits are threatened by the lack of consequences when administrators of such plans improperly process claims for healthcare benefits by delaying the decision, failing to conduct a complete review, or simply denying the claim incorrectly.

For those covered by healthcare plans ("Participants"), a claim for benefits occurs each time the plan Participant seeks to access benefits under the plan. A Participant may seek benefits retrospectively or prospectively.<sup>3</sup> In the case of a retrospective claim, a Participant seeks medical care and then files a claim with the plan, following the plan's prescribed process.<sup>4</sup> The healthcare provider may file the claim on the Participant's behalf if the Participant has assigned benefits to the provider.<sup>5</sup> The Participant then waits for the decision-maker<sup>6</sup> to send the

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1. *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 90 (1983).

2. *Metro. Life Ins. Co. v. Glenn*, 554 U.S. 105, 112 (2008) (quoting *Bruch v. Firestone Tire & Rubber Co.*, 828 F.2d 134, 144 (3d Cir. 1987)).

3. Kanika Kapur, Carole Roan Gresenz & David M. Studdert, *Managing Care: Utilization Review in Action at Two Capitated Medical Groups*, HEALTH AFF. 276 (June 18, 2003), <http://content.healthaffairs.org/content/early/2003/06/18/hlthaff.w3.275.full.pdf>.

4. *How to File a Claim for Your Benefits*, U.S. DEP'T OF LABOR, [http://www.dol.gov/ebsa/publications/how\\_to\\_file\\_claim.html](http://www.dol.gov/ebsa/publications/how_to_file_claim.html) (last visited Feb. 16, 2011).

5. D. Brian Hufford, *Managed Care Litigation: The Role of Providers*, in HEALTH CARE LITIGATION: WHAT YOU NEED TO KNOW AFTER PEGRAM 487, 501 (Practising Law Inst. ed., 2000) ("[P]hysicians frequently obtain assignments from their patients in order to permit them to

required written notice of a decision, and if the claim is denied, the Participant decides whether to appeal.<sup>7</sup> When the Participant seeks benefits prospectively, the Participant requests pre-authorization from the plan for the intended treatment.<sup>8</sup> Prospective denials can also be appealed, although a Participant faced with a denial of pre-authorization must either go forward with the treatment or await a decision on appeal.<sup>9</sup>

Employer-sponsored healthcare plans are governed by the Employee Retirement Security Income Act of 1974 (ERISA).<sup>10</sup> When Congress enacted ERISA, healthcare and claim denials were less problematic. At that time, insurers tended to pay claims after patients received treatment, without requiring pre-approval, and deferred to the diagnoses and treatment decisions of healthcare providers.<sup>11</sup> Rising healthcare costs, however, prompted insurers to control costs through utilization review<sup>12</sup> and pre-certification.<sup>13</sup>

In addition, increasing numbers of ERISA plans are self-funded.<sup>14</sup> Under a self-funded (also known as a self-insured) plan, an employer (or other plan sponsor) pays the cost of claims directly, rather than purchasing insurance on an employee's behalf.<sup>15</sup> Self-funded plans are not considered insurance products and are therefore beyond the reach of many state insurance regulations.<sup>16</sup> As a result, these plans have avoided insurance reform at the state level.<sup>17</sup>

communicate with and be paid directly by insurance companies for providing medical services.”).

6. As discussed in Section I.A *infra*, the entity with decision-making power may be an insurance company, a third-party administrator, or the employer itself.

7. *Id.*

8. Hufford, *supra* note 5, at 492.

9. *See, e.g.*, Grijalva v. Shalala, 946 F. Supp. 747, 757 (D. Ariz. 1996) (explaining that a denial of preauthorization often prevents receipt of treatment due to delay).

10. 29 U.S.C. §§ 1001-1461 (2006).

11. JAMES A. WOOTEN, THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974: A POLITICAL HISTORY 283 (2004).

12. Utilization review is the review of requested care to determine whether it is necessary, particularly with a view to controlling costs. MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY (11th ed. 2008), available at [http://www.merriam-webster.com/dictionary/utilization\\_review](http://www.merriam-webster.com/dictionary/utilization_review).

13. Precertification is “authorization for a specific medical procedure before it is done or for admission to an institution for care.” Elsevier, MOSBY'S MEDICAL DICTIONARY (8th ed. 2009), available at <http://medical-dictionary.thefreedictionary.com/precertification>.

14. In 2010, fifty-nine percent of covered workers were in a self-funded plan, up from forty-four percent in 1999. THE KAISER FAMILY FOUND. & HEALTH RESEARCH & EDUC. TRUST, EMPLOYER HEALTH BENEFITS: 2010 ANNUAL SURVEY 154 (2010), <http://ehbs.kff.org/pdf/2010/8085.pdf>.

15. *Id.*

16. *Id.*

17. WOOTEN, *supra* note 11, at 284 (noting the “backlash” against ERISA’s lack of remedies and the increase in reform initiatives and noting that these reforms do not reach self-funded plans).

ERISA's regulations set out the specifics of claims processing, including guidelines that health insurance companies must follow when they establish internal rules for claims processing. The regulations set time limits for deciding claims and appeals, govern the content of notices to participants of claim denials and rights to appeal, and require consistent decisions on similar types of claims. These are largely procedural matters, but they affect the availability of benefits directly. Most denied claims are never appealed—if a claim is decided incorrectly or appeal rights are not conveyed, the incorrect denial simply stays undisturbed.<sup>18</sup>

The current approach to claims regulation enforcement does not match the importance of these procedures in the lives of plan participants. For example, what is the consequence when a health insurance company does not abide by these claims processing regulations? What if a health insurance company improperly denies certain claims when they are initially filed, then pays those claims if they are appealed, perhaps banking on many Participants becoming discouraged and walking away without an appeal? What is the consequence if a health insurance company improperly denies a significant claim, then pays it only during litigation? As this Article will show, in each of these cases, the health insurance company suffers little or no penalty for violating claims regulations. And yet, the financial incentive to do so, thereby avoiding paying claims, is enormous.<sup>19</sup>

For Participants, the consequences are significant. An incorrect retrospective denial or underpayment results in either the Participant or the healthcare provider absorbing the unpaid costs.<sup>20</sup> And if the Participant is unable to absorb the cost, financial hardship or even medical bankruptcy may result.<sup>21</sup> An incorrect prospective denial may well mean that the participant is unable to access the

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18. Caroline E. Mayer, *The Claim Game*, AARP THE MAGAZINE, Nov.-Dec. 2009, at 32 (quoting Connecticut's health care advocate Kevin Lembo as stating that ninety-six percent of denials are not appealed); *General Information on How To File Insurance Appeals*, ADVOCACY FOR PATIENTS WITH CHRONIC ILLNESS, INC., [http://www.advocacyforpatients.org/hi\\_file.html](http://www.advocacyforpatients.org/hi_file.html) (last visited Mar. 25, 2011) (stating that ninety-four percent of denials are never appealed).

19. See discussion of financial incentives at *infra* Section I.A.

20. AM. MED. ASS'N, *APPEAL THAT CLAIM* (2008), available at <http://www.ama-assn.org/ama1/pub/upload/mm/368/appeal-that-claim.pdf> (providing examples of physician practices that routinely lose money because Payors underpay for treatments already provided); Fawn Johnson, *Big Health Firms Underpay Claims*, WALL ST. J., June 25, 2009, <http://online.wsj.com/article/SB10001424052970204621904574248061750721736.html> (noting that when Payors underpay claims, participants make up the difference; the amounts overpaid by participants are difficult to estimate).

21. *Bankruptcy Reform: Hearing Before the S. Comm. on the Judiciary*, 109th Cong. (2005) (statement of Professor Elizabeth Warren, Harvard Law Professor) (noting that one million people file bankruptcy each year following a serious illness and that three quarters of those people have health insurance).

necessary care. Such a denial may be life-threatening or even fatal.<sup>22</sup>

Physicians and other healthcare providers also suffer when healthcare claims are improperly delayed or denied. Busy physician practices and other healthcare providers must devote additional time and personnel to appeals and follow-up.<sup>23</sup> And if providers do not follow up on improperly processed claims, they risk losing significant amounts of money for services that were legitimately provided.<sup>24</sup>

This Article advocates a new framework for the enforcement of claims-processing regulations. Under the current approach, most non-compliance is excused under the “substantial compliance”<sup>25</sup> doctrine, and even substantial departures from the claims regulations generally result in no substantive remedy.<sup>26</sup> This approach excuses practically all instances of regulatory non-

22. In one such case, a father of four sought inpatient treatment for alcoholism; such treatment was expressly included as a term of his benefit plan. *Andrews-Clarke v. Travelers Ins. Co.*, 984 F. Supp. 49, 52 (D. Mass. 1997). The utilization review provider, however, “repeatedly and arbitrarily denied” the treatment and refused to authorize it. *Id.* Lacking a private placement for treatment, a court that had conducted a commitment hearing ordered him to treatment in a correctional facility, where he received little treatment and was abused by other inmates. *Id.* at 51. The man died after consuming a six-pack of beer three weeks after his release. *Id.* at 52. In the subsequent lawsuit that went “right to the heart of the benefit determination process,” the court dismissed the surviving spouse’s wrongful death, breach of contract, and other claims, noting that ERISA provided no other choice. *Id.* at 53. The court referred to ERISA as a “legal Pac-Man” and noted that ERISA now provides a “shield of near absolute immunity [that] cannot be justified.” *Id.* at 63. The court concluded that there was no legal choice but to “slam the courthouse doors in [the surviving spouse’s] face and leave her without any remedy.” *Id.* at 53. In another case, a plan administrator’s delay in approving a bone marrow transplant procedure was alleged to have proven fatal, where cancer metastasized to the patient’s brain during the delay period, thereby disqualifying her from having the bone marrow transplant. *Bast v. Prudential Ins. Co.*, 150 F.3d 1003 (9th Cir. 1998) (holding that the “unfortunate consequence of the compromise Congress made in drafting ERISA” left plaintiff without a remedy).

23. “[P]hysicians and practice staff should all participate in the audit process. . . . You might also consider hiring a consultant who specializes in billing and collections to assist in specified audit tasks.” AM. MED. ASS’N, *supra* note 20, at 11.

24. *See id.* at 8-9 (citing numerous examples of physician practices whose claims were being underpaid, sometimes by as much as \$100,000 per month).

25. The exact contours of the “substantial compliance” doctrine depend on the court applying it and the particular circumstances of the case. Generally, however, “substantial compliance” is understood to mean technical non-compliance with the claims regulations, such that the regulation’s purpose is nonetheless accomplished. *See, e.g., Larson v. Old Dominion Freight Line, Inc.*, 277 F. App’x 318, 321-22 (4th Cir. 2008) (holding that even if the administrator’s communications did not technically comply with the regulations in that they did not give the basis for the claim denial, they provided a sufficient understanding of the administrator’s position and therefore substantially complied).

26. *See* discussion of lack of incentives to comply *infra* Section II.B.

compliance and places the enforcement burden on those least able to shoulder it—the individuals seeking and paying for medical care. Instead, ERISA’s goal of ensuring contracted benefits would be better served if enforcement moved to a presumed-harm approach, akin to the approach used in numerous consumer finance laws. This Article argues that the same concerns driving consumer financial protections have even greater force where healthcare is concerned.

Part I of this Article sets out the problem of improper claims processing and provides background on ERISA and its regulations. Part II examines the claims processing regulations and their current interpretation in the courts. Part III explains the case for a presumed-harm approach to enforcement of the claims processing regulations and suggests two remedies: First, non-compliance with claims processing regulations should be penalized through an expanded view of attorney’s fee awards. Second, the Truth in Lending Act shows how ERISA reform could adopt the presumed-harm approach and thereby lend predictability, efficiency, and equity to the enforcement of ERISA’s claims processing regulations.

## I. THE CLAIMS PROCESSING PROBLEM AND ERISA

ERISA was enacted in 1974 with pension plan reform in mind.<sup>27</sup> At the time, few imagined that ERISA would serve such a significant role with regard to healthcare.<sup>28</sup> Since 1974, increasing numbers of employers have redesigned their employee benefit plans as ERISA plans, in order to take advantage of the limited plaintiff remedies available under ERISA and ERISA’s protection from state regulation.<sup>29</sup> Today, ERISA governs most of America’s non-Medicare healthcare coverage,<sup>30</sup> and ERISA’s regulations set the ground rules for processing

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27. WOOTEN, *supra* note 11, at 281.

28. *Id.*

29. In a notorious example of an insurance executive’s frank assessment of ERISA’s advantages, the executive noted in a memo that

[t]he advantages of ERISA . . . are enormous: state law is preempted by federal law, there are no jury trials, there are no compensatory or punitive damages, relief is usually limited to the amount of benefit in question, and claims administrators may receive a deferential standard of review. . . . [For a set of] 12 claim situations where we settled for \$7.8 million in the aggregate . . . [i]f these 12 cases had been covered by ERISA, our liability would have been between zero and \$0.5 million.

The memorandum goes on to note: “While our objective is to pay all valid claims and deny invalid claims, there are gray areas, and ERISA applicability may influence our course of action.” Memorandum from Jeff McCall to IDC Mgmt. Grp. & Glenn Felton (Oct. 2, 1995), *available at* <http://www.erisa-claims.com/library/Provident%20memo.pdf>.

30. THE KAISER FAMILY FOUND. & HEALTH RESEARCH & EDUC. TRUST, *supra* note 14.

healthcare claims.<sup>31</sup> As set out below, the ERISA statute’s origins in reform and access to benefits have grown into a complex thicket that leaves participating employees and their beneficiaries with fewer remedies than they had before ERISA’s enactment.

*A. The Problem: Why Claims Regulations Matter*

As written, ERISA’s claims processing regulations are intended to help ensure accurate, prompt initial decisions on healthcare claims.<sup>32</sup> The regulations set out time frames for claims processing and procedures for appealing a denial.<sup>33</sup> They require clear communication of Participants’ rights.<sup>34</sup> A violation of claims regulations may result in an improper denial, or it may leave a Participant with insufficient information about a denial or the Participant’s right to appeal. Whether or not the violation ultimately results in an improper denial, the effect is that the Participant is denied information, rights, and, potentially, coverage to which the Participant is entitled.

The regulations also allow the Participant to sue and have a federal judge decide whether the claim should have been paid after a plan administrator repeatedly denies a healthcare claim. But the vast majority of Participants whose claims are denied do not sue.<sup>35</sup> In fact, most do not even appeal the claim internally to a plan administrator.<sup>36</sup> Upon initial submission, healthcare claims are denied at a rate of approximately one in seven, so that two hundred million of the 1.4 billion claims submitted annually are initially denied.<sup>37</sup> According to the American Medical Association’s most recent estimate, about twenty percent of

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31. The regulations derive from 29 U.S.C. § 1133, which requires every employee benefit plan, in accordance with regulations of the Department, to “provide adequate notice in writing to [any] participant or beneficiary whose claim for benefits under the plan has been denied, setting forth the specific reasons for such denial, written in a manner calculated to be understood by the participant,” and to “afford a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review by the appropriate named fiduciary of the decision denying the claim.” 29 U.S.C. § 1133 (2006).

32. The regulations require that plan procedures “contain administrative processes and safeguards designed to ensure and to verify that benefit claim determinations are made in accordance with governing plan documents and that, where appropriate, the plan provisions have been applied consistently with respect to similarly situated claimants.” 29 C.F.R. § 2560.503-1(b)(5) (2009).

33. *Id.* § 2560.503-1(f), (h), (i).

34. *Id.* § 2560.503-1(c)(3)(iv).

35. In order to sue, participants must first exhaust their appeal rights within the plan. *Id.* § 2560.503-1(c)(3)(iii).

36. *See supra* note 18 and accompanying text.

37. *See Mayer supra* note 18.

all healthcare claims are processed incorrectly.<sup>38</sup> More than ninety percent of claim denials, according to most estimates, are never appealed.<sup>39</sup> Of the denials that are appealed, about half are reversed in favor of the Participant.<sup>40</sup>

Even though so many denied claims are never appealed, health insurance companies are not penalized when claims are denied upon initial submission and paid only upon first or second appeal.<sup>41</sup> Even a procedural violation, such as a failure to communicate appeal rights, may be excused if the error is cured at some later point.<sup>42</sup> This regulatory approach provides no remedy for the many Participants that drop out of the appeals process at the first miscommunication.

At the same time, health insurance companies and employers offering self-insured plans (together, “Payors”) profit enormously when claims are denied or otherwise diminished.<sup>43</sup> Empirical research links higher net profits with an increased tendency to discount or deny claims.<sup>44</sup> Therefore, Payors, whether

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38. Press Release, Am. Med. Ass’n., National Health Insurer Report Card (June 14, 2010), available at <http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/heal-claims-process/national-health-insurer-report-card.shtml> (reporting that approximately twenty percent of claims are processed incorrectly and advocating a uniform, national set of standards for processing healthcare claims); see also Press Release, Cal. Nurses Ass’n/Nat’l Nurses Org. Comm., California’s Real Death Panels: Insurers Deny 21% of Claims (Sept. 2, 2009), available at <http://www.calnurses.org/media-center/press-releases/2009/september/california-s-real-death-panels-insurers-deny-21-of-claims.html> (estimating the denial rate at twenty-one percent and quoting the organization’s co-president Deborah Burger, stating “[t]he routine denial of care by private insurers is like the elephant in the room no one in the present national healthcare debate seems to want to talk about”).

39. See, e.g., Mayer, *supra* note 18, at 32.

40. Walecia Konrad, *Fighting Denied Claims Requires Perseverance*, N.Y. TIMES, Feb. 6, 2010, at B6, available at <http://www.nytimes.com/2010/02/06/health/06patient.html>.

41. Occasionally, courts raise the argument that reputational concerns weigh against the significant financial incentives favoring aggressive claim denials. As leading ERISA scholar John Langbein notes, most potential employees accept the health insurance benefits available when they accept a particular job, and potential employees are unlikely to inquire about other employees’ healthcare claims experience before accepting a job. John H. Langbein, *Trust Law as Regulatory Law: The Unum/Provident Scandal and Judicial Review of Benefit Denials Under ERISA*, 101 NW. U. L. REV. 1315, 1328 (2007).

42. *Wade v. Hewlett-Packard Dev. Co. LP Short Term Disability Plan*, 493 F.3d 533, 539-40 (5th Cir. 2007) (holding that a plan’s substantial regulatory compliance in the final level of appeal cured the non-compliance in the first two levels, in that the initial telephone contact in place of the required written notice, and the subsequent inadequate written notice, were cured by a subsequent compliant written notice at the first level of review).

43. Jeffrey D. Greenberg et al., *Reimbursement Denial and Reversal by Health Plans at a University Hospital*, 117 J. AM. MED. 629, 633 (2004) (finding a “strong positive correlation” between net profit margin and the adjusted odds that a plan would discount the cost of a day’s stay in the hospital).

44. *Id.*

administering plans or directing others to do so, have a strong incentive to act against Participants' interests.<sup>45</sup>

Whether plans are fully insured or self-insured, incorrect denials amount to enhanced profit for the would-be Payor. In the case of fully insured plans, the decision-maker and Payor are the same entity, such that money saved on participants' medical care equates to greater amounts of money available for salaries, administrative expenses, and profits.<sup>46</sup> Accordingly, courts recognize the conflict that arises when the same entity both determines benefit eligibility and pays benefits.<sup>47</sup>

In the case of self-funded plans, the financial conflict analysis is different, because claims processing is generally handled by a third-party administrator (TPA), at least with regard to initial claims decisions.<sup>48</sup> There is, however, no prohibition against an employer's administering claims in-house, and some larger employers may choose to do so if they have the necessary personnel and resources to assess claims.<sup>49</sup> Employers may rely on a TPA for utilization review as well. Where a TPA processes claims for the ultimate Payor—the employer—the conflict of interest may be less direct than if the ultimate Payor determines eligibility and then pays claims directly out of its own pocket.

But a Payor's delegation of some day-to-day plan operations to a TPA, which serves at the pleasure of the Payor, does not necessarily neutralize the conflict. While the conflict may be somewhat attenuated when the Payor does not also act as the decision-maker, the Payor may still have a hand in the process in several ways: through the terms of its relationship with the TPA, through

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45. *DiFelice v. Aetna U.S. Healthcare*, 346 F.3d 442, 459 (3d Cir. 2003) (“ERISA’s remedial scheme gives HMOs every incentive to act in their own and not in their beneficiaries’ interest while simultaneously making it incredibly difficult for plan participants to pursue what meager remedies they possess, a confounding result for a statute whose original purpose was to protect employees.”).

46. U.S. DEPT. OF HEALTH & HUMAN SERVS., INSURANCE COMPANIES PROSPER, FAMILIES SUFFER, available at <http://nchc.org/sites/default/files/resources/insuranceprofits.pdf> (last visited Feb. 16, 2011) (noting that three of the top five insurers spent less on participant medical care, while spending more on “salaries, administrative expenses, and profits”).

47. *Metro. Life Ins. Co. v. Glenn*, 554 U.S. 105, 112 (2008) (noting that the payor’s fiduciary interest “may counsel in favor of granting a borderline claim while its immediate financial interest counsels to the contrary”). Thus, the payor has an interest “conflicting with that of the beneficiaries.” *Id.*

48. *Understanding Your Fiduciary Responsibilities Under a Group Health Plan*, U.S. DEP’T OF LABOR (Oct. 2008), <http://www.dol.gov/ebsa/publications/ghpfiduciaryresponsibilities.html> (“Employers often hire outside professionals (sometimes called third-party service providers) . . . to manage some or all of the plan’s day-to-day operations.”).

49. See, e.g., HEALTH CARE ADM’RS ASS’N, <http://www.hcaa.org/selffunding.html> (last visited Mar. 25, 2011) (noting that employers can either retain a third-party administrator or administer claims themselves).

influence over the TPA, or through retention of control over appealed claims.<sup>50</sup> As one court explained, “delegation of claims administration does not negate a structural conflict outright.”<sup>51</sup> Although the Payor delegates claims responsibility to the TPA, the Payor may still influence the TPA’s decision-making process.<sup>52</sup> For example, in one case where the employer had delegated the decision as to whether benefits should be provided, the court found evidence that the employer still retained some oversight of the process and gave financial incentives to the TPA if the plan was administered as the employer wished.<sup>53</sup> Thus, Payors retain control of the claims process, to varying degrees ranging from some control to considerable control, despite delegation to a TPA.<sup>54</sup>

Correct initial processing of claims is particularly important because plan administrators’ decisions are given deference by the courts under ERISA. In 1989, the Court decided that where plan terms give the plan administrator discretion to determine benefit eligibility and interpret plan terms, plan administrators’ decisions should be given deference unless the decisions are arbitrary and capricious.<sup>55</sup> Each circuit court of appeals articulates and applies the arbitrary and capricious standard slightly differently, but a decision is typically considered arbitrary and capricious if there was no reasonable basis for the decision.<sup>56</sup> If the determination is one of medical necessity, for example, a plan administrator must take treating physicians’ opinions into account, but is free to disagree with treating physicians if the plan reviewers find other evidence more compelling.<sup>57</sup> This deferential standard applies even if the plan

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50. *See, e.g.*, *Univ. Hosps. of Cleveland v. Emerson Elec. Co.*, 202 F.3d 839, 844 (6th Cir. 2000) (noting that even where a TPA makes the initial claims decision, a conflict may still exist if appeals are decided by a board appointed by the payor/employer). The court “should be particularly vigilant in situations where, as here, the plan sponsor bears all or most of the risk of paying claims, and also appoints the body designated as the final arbiter of such claims. Under these circumstances, the potential for self-interested decision-making is evident.” *Id.*

51. *Leu v. Cox Long-Term Disability Plan*, No. 2:08-CV-00889-PHX-JAT, 2009 WL 2219288, at \*2 (D. Ariz. July 24, 2009).

52. *Nord v. Black & Decker Disability Plan*, 296 F.3d 823 (9th Cir. 2002) (finding that a TPA merely made recommendations regarding benefit eligibility to the plan administrator while the administrator made final decisions), *rev’d on other grounds*, 538 U.S. 822 (2003).

53. *Mazur v. Pac. Telesis Grp. Comprehensive Disability Benefits Plan*, No. C07-01904 JSW 2008 WL 564796 (N.D. Cal. Feb. 28, 2008).

54. *Williams v. BellSouth Telecomms., Inc.*, 373 F.3d 1132, 1135-37 (11th Cir. 2004) (finding that an employer had delegated claims processing to a TPA but still influenced the claims process).

55. *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 109 (1989).

56. *See, e.g.*, *Gannon v. Metro. Life Ins.*, 360 F.3d 211, 213 (1st Cir. 2005) (noting that evidence is substantial if it “is reasonably sufficient to support a conclusion, and the existence of contrary evidence does not, in itself, make the administrator’s decision arbitrary”).

57. *See, e.g.*, *Love v. Dell, Inc.*, 551 F.3d 333, 337 (5th Cir. 2008) (reviewing plan administrator’s decision for abuse of discretion and upholding plan administrator’s conclusion that

administrator both decides and pays claims, as many do.<sup>58</sup> In such situations, there is a perfect dollar-for-dollar conflict every time a claim is granted: “[E]very dollar provided in benefits is a dollar spent by . . . the employer; and every dollar saved . . . is a dollar in [the employer’s] pocket.”<sup>59</sup> And, as explained above, even if the plan administrator is a separate entity from the Payor, the Payor generally selects and hires the plan administrator and may well retain direct or indirect control over claims processing, such that the conflict remains. If the plan does not grant discretion to the administrator to determine benefit eligibility and interpret plan terms, then the decision must be reviewed *de novo*.<sup>60</sup> In a *de novo* review, the court does not defer to the plan administrator’s decision, but instead interprets the plan and reviews the evidence itself in order to decide the claim for benefits.<sup>61</sup> However, the Court is increasingly narrowing the circumstances under which *de novo* review is available, and the Court recently reaffirmed its approval of the abuse of discretion standard and noted its disapproval of *ad hoc* exceptions to deferential review.<sup>62</sup> Because of this deference and because so few Participants pursue their rights to appeal and sue, the accuracy of the initial claims decision and the communication of the Participants’ rights are critically important in achieving ERISA’s goal of ensuring contracted benefits.<sup>63</sup>

### B. ERISA’s Purpose and Background

The ERISA claims processing regulations derive from the larger ERISA scheme that was enacted in 1974.<sup>64</sup> Congress enacted ERISA to protect Participants’ interests in employer-sponsored benefit plans by setting out regulations and providing access to the federal courts.<sup>65</sup> In enacting ERISA,

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a seventeen-year-old’s intensive inpatient treatment for serious mental illness and substance abuse was not medically necessary, despite treating physicians’ opinion that it was).

58. *See Metro. Life Ins. Co. v. Glenn*, 554 U.S. 105, 120 (2008) (noting that the conflict-of-interest concern applies to the “lion’s share” of ERISA benefit denial cases).

59. *Id.* at 112.

60. *Id.*

61. *Id.* at 112-13.

62. *Id.*

63. HEALTH, EDUC. & HUM. SERVS. DIV., U.S. GEN. ACCOUNTING OFFICE, B-276104, EMPLOYER-BASED MANAGED CARE PLANS: ERISA’S EFFECT ON REMEDIES FOR BENEFIT DENIALS AND MEDICAL MALPRACTICE 25-30 (1998) (noting that the Department of Labor and others favor stronger remedies for non-compliance with the claims process, so that “upstream” compliance is improved).

64. Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406, 88 Stat. 832 (1974) (codified as amended at 29 U.S.C. §§ 1001-1461 (2006)).

65. *Id.* § 1001 (“The Congress finds . . . that the continued well-being and security of millions of employees and their dependents are directly affected by these plans; . . . it is therefore desirable in the interests of employees and their beneficiaries . . . that minimum standards be provided

Congress addressed two main risks to pension plans: the risk of default and the risk of poor administration.<sup>66</sup> ERISA contains rules that are specific to pension plans, as well as rules that apply to both pension plans and welfare benefit plans, such as healthcare plans.<sup>67</sup> While pension plans are vulnerable to default or insolvency risk, welfare benefit plans are exposed to the risk of poor administration in the same way as pension plans.<sup>68</sup> For this reason, Congress brought welfare plans under ERISA's umbrella, so that ERISA's fiduciary rules would apply.<sup>69</sup>

### C. Basis in Trust Law

In developing ERISA, Congress did not create a new legal approach, but instead imported trust law as ERISA's framework.<sup>70</sup> ERISA sets out fiduciary duties applicable to the administration of plans,<sup>71</sup> including the rules of loyalty and prudence and the exclusive benefit rule.<sup>72</sup> Instead of setting out all of the specific powers of trustees and other fiduciaries, Congress imported the common law of trusts to describe the responsibilities of ERISA fiduciaries.<sup>73</sup>

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assuring the equitable character of such plans and their financial soundness. . . . It is hereby declared to be the policy of this chapter to protect interstate commerce and the interests of participants in employee benefit plans and their beneficiaries . . . ."); *Aetna Health, Inc. v. Davila*, 542 U.S. 200, 208 (2004); *Donovan v. Dillingham*, 688 F.2d 1367, 1370 (11th Cir. 1982) ("Congress enacted ERISA to protect working men and women from abuses in the administration and investment of private retirement plans and employee welfare plans.").

66. John H. Langbein, *What ERISA Means by "Equitable": The Supreme Court's Trail of Error in Russell, Mertens, and Great-West*, 103 COLUM. L. REV. 1317, 1322-23 (2003) (explaining that the movement that led to the passage of ERISA "effectively commenced in 1963, when the financially troubled automaker, Studebaker, defaulted on its pension plan, frustrating the support expectations of several thousand workers and retirees").

67. 29 U.S.C. § 1002(1) (stating that the term "employee welfare benefit plan" includes medical, accident, disability, death, unemployment, child care, training, scholarship, prepaid legal, and vacation benefit plans).

68. Langbein, *supra* note 66, at 1323.

69. *Id.*

70. *Firestone Tire & Rubber v. Bruch*, 489 U.S. 101, 110 (1989) ("ERISA abounds with the language and terminology of trust law" and stating that ERISA's legislative history shows that principles of trust law were meant to apply to ERISA fiduciaries); H.R. REP. NO. 93-533, at 11 (1974), *reprinted in* 1974 U.S.C.C.A.N. 4639, 4651 ("The principles of fiduciary conduct are adopted from existing trust law, but with modifications appropriate for employee benefit plans."); Langbein, *supra* note 66, at 1319 ("Congress made a deliberate choice to subject these plans to the pre-existing regime of trust law rather than to invent a new regulatory structure.").

71. *Varity Corp. v. Howe*, 516 U.S. 489, 496 (1996).

72. 29 U.S.C. § 1104(a)(1)(A).

73. *Cent. States, Se. & Sw. Areas Pension Fund v. Cent. Transp., Inc.*, 472 U.S. 559, 570 (1985).

Under ERISA, those who exercise discretion over management of the plan or who are named as fiduciaries in the plan are subject to fiduciary duties, and so is any person exercising material discretion over plan assets or administration.<sup>74</sup> This means that the individuals who make healthcare benefit decisions are acting as fiduciaries and are bound by these duties; ERISA’s legislative history supports the imposition of fiduciary duties upon those who make claims determinations and pay plan benefits.<sup>75</sup>

ERISA fiduciaries must discharge their duties with respect to the plan “solely in the interest of the participants and beneficiaries. . . .”<sup>76</sup> Fiduciaries are also required to carry out their duties “in accordance with the documents and instruments governing the plan[.]”<sup>77</sup>

The traditional trustee “is not permitted to place himself in a position where it would be for his own benefit to violate his duty to the beneficiaries.”<sup>78</sup> Under ERISA, however, a trustee can be in exactly that position, having financial interests directly opposed to plan Participants.<sup>79</sup> An ERISA fiduciary can be in the position of making healthcare claims determinations that, if decided against the beneficiary, would place additional funds in the fiduciary’s employer’s pocket to the beneficiary’s detriment.<sup>80</sup>

ERISA, therefore, imports trust law but ignores one of trust law’s most important principles—the principle that plan fiduciaries should not breach their duties to beneficiaries and, certainly, should not be in a position to benefit financially from breaching those duties. Given these diametrically opposed interests and the profit-earning goals of Payors, additional incentives to comply with claims processing regulations are needed, as set out below.

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74. 29 U.S.C. § 1002(21)(A); Langbein, *supra* note 66, at 1324-25.

75. *See, e.g.*, H.R. REP. NO. 93-1280, at 301 (1974) (Conf. Rep.), *reprinted in* 1974 U.S.C.C.A.N. 5038, 5081 (discussing procedures for delegating fiduciary duties, such as “allocation or delegation of duties with respect to payment of benefits”); 120 CONG. REC. 29,929 (1974) (remarks of Sen. Williams) (stating that ERISA imposes “strict fiduciary obligations upon those who exercise management or control over the assets or administration of an employee pension or welfare plan . . .”).

76. 29 U.S.C. § 1104(a)(1).

77. *Id.* § 1104(a)(1)(D).

78. *Pegram v. Herdich*, 530 U.S. 211, 225 (2000) (quoting IIA WILLIAM F. FRATCHER, SCOTT ON TRUSTS § 170 (4th ed. 1998)).

79. *Id.*

80. *See, e.g.*, *Metro. Life Ins. Co. v. Glenn*, 554 U.S. 105, 120 (2008) (Roberts, J., concurring in part and concurring in the judgment) (noting that the conflict-of-interest concern applies to most ERISA benefit denial cases).

*D. Preemption and Enforcement*

ERISA preempts all state laws that “relate to” ERISA plans, as well as any cause of action that duplicates or supplants a claim under ERISA’s enforcement provisions.<sup>81</sup> ERISA thus takes away most state-law claims and remedies, but courts struggle with what, if anything, ERISA provides in their place. Indeed, the preemption provision often takes away state-law claims but gives no replacement claim at all.<sup>82</sup> ERISA’s preemption provision was always intended to be broad.<sup>83</sup> But, Congress also intended that ERISA would be supplemented by a federal common law, developed in the federal courts and tailored to ERISA and its purposes.<sup>84</sup> As explained below in Subsection II.B.4, no such remedial, tailored federal common law has emerged.

The remedies available under ERISA are notoriously limited, heightening the need for plan administrators to determine initial claims and appeals accurately.<sup>85</sup> ERISA typically provides little relief when administrators violate claims regulations by, for example, failing to give adequate notice about appeals or reviewing a claim improperly, even though these violations often leave legitimate claims unpaid.

ERISA contains an integrated civil enforcement scheme consisting of the six provisions found in section 1132(a) of the statute; these are the exclusive means of enforcing ERISA’s provisions.<sup>86</sup> ERISA’s enforcement provisions have taken on particular importance because ERISA takes away other traditional state law causes of action and remedies.<sup>87</sup> A wronged Participant cannot sue immediately

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81. 29 U.S.C. §§ 1132, 1144.

82. *Corcoran v. United Healthcare, Inc.*, 965 F.2d 1321, 1338 (5th Cir. 1992) (“[T]he result ERISA compels us to reach means that the Corcorans have no remedy, state or federal, for what may have been a serious mistake.”); *see also* WOOTEN, *supra* note 11, at 283-84 (discussing the limited remedies available to plan participants).

83. WOOTEN, *supra* note 11, at 282.

84. Upon presenting the Conference Report to the full Senate, principal sponsor Senator Javits stated, “It is also intended that a body of Federal substantive law will be developed by the courts to deal with issues concerning rights and obligations under private welfare and pension plans.” 120 CONG. REC. 29, 942 (1974) (statement of Sen. Javits); *see also* *Mass. Mut. Life Ins. Co. v. Russell*, 473 U.S. 134, 156 (1985) (Brennan, J., concurring) (discussing Congress’s intention that the courts would develop a federal common law of ERISA).

85. *See, e.g.*, *DiFelice v. Aetna U.S. Healthcare*, 346 F.3d 442, 456 (3d Cir. 2003) (Becker, J., concurring) (“[V]irtually all state law remedies are preempted [by ERISA] but very few federal substitutes are provided.”).

86. *Aetna Health Inc. v. Davila*, 542 U.S. 200, 209 (2004) (citing *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 55 (1986)).

87. *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. at 55 (“The deliberate care with which ERISA’s civil enforcement remedies were drafted and the balancing of policies embodied in its choice of remedies argue strongly for the conclusion that ERISA’s civil enforcement remedies were intended

in federal court but must first exhaust administrative remedies within the plan.<sup>88</sup>

Faced with a claim denial, a Participant must first appeal according to a plan's internal procedures. An internal appeal generally results in appealing a claim once or twice within the health insurance company or third-party administrator's system.<sup>89</sup> After exhausting these administrative remedies, the Participant is then eligible to file an ERISA lawsuit in federal court. Under the basic claim for benefits, a participant brings a cause of action under ERISA section 501(a)(1), for "benefits due." This provision permits recovery of the benefit's value. ERISA contains an attorney's fee provision permitting the award of attorney's fees to either party, within the court's discretion.<sup>90</sup>

ERISA provides that plaintiffs can recover equitable relief under certain circumstances.<sup>91</sup> Despite careful and convincing scholarship to the contrary, the Supreme Court does not include a make-whole remedy within those remedies.<sup>92</sup> Thus, if the Participant wins the lawsuit, the Participant is generally awarded the value of the benefit and nothing more.<sup>93</sup> Under current Supreme Court authority,

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to be exclusive."). This exchange of traditional remedies for ERISA remedies has come to be known as the "ERISA bargain"—the idea that in exchange for security in benefits, employees gave up their traditional state-law remedies. The "ERISA bargain" is recognized by courts and is frequently cited when the intersection between ERISA's broad preemption provision and the lack of any equivalent federal remedy results in harms without remedies:

Plaintiffs and employees similarly situated receive the many protections of ERISA in exchange for certain rights to sue under previous federal and state law. Congress has decided that they are better off for the bargain. Whatever injustices this scheme may tolerate in isolated instances are more than compensated by the general security provided to pension rights under ERISA—plaintiffs themselves are now enjoying the fruits of rights which Caterpillar could not and cannot divest. If workers deserve further protection, it will be up to Congress to provide it.

*Willams v. Caterpillar, Inc.*, 720 F. Supp. 148, 152 (N.D. Cal. 1989).

88. *LaRue v. DeWolff, Boberg, & Assocs.*, 552 U.S. 248, 259 (2008).

89. In some circumstances, Participants can also submit denied claims for independent, external review. Karen Politz et al., *Assessing State External Review Programs and the Effects of Pending Federal Patients' Rights Legislation*, KAISER FAMILY FOUNDATION (Revised May 2002), <http://www.kff.org/insurance/externalreviewpart2rev.pdf>. On average, external reviews overturn forty-five percent of denials submitted to them. *Id.* at v-vi. External reviews are, however, complicated to access and underused; in New York, for example, only 902 consumers filed for external review in the reporting year ending in June 2000, although 8.4 million consumers are covered by the external review law in that state. *Id.*

90. 29 U.S.C. § 1132(g) (2006).

91. *Id.* § 1132(a)(3)(B).

92. WOOTEN, *supra* note 11, at 282.

93. *See, e.g., Mass. Mut. Life Ins. Co. v. Russell*, 473 U.S. 134, 148 (1985) (permitting no extra-contractual damages for delayed processing of claim).

ERISA does not contemplate extra-contractual damages for consequential harms, even when the result is that the Participant is not made whole.<sup>94</sup> The Participant might also receive attorney's fees at the court's discretion.<sup>95</sup>

Thus, if a claim is improperly denied, and the Participant appeals within the plan, pursues a federal lawsuit and wins, the Participant stands to gain only the value of the benefit that was denied. Attorney's fees may be awarded, but are not presumed. The current lack of consequential and punitive damages means that the improper denial is typically not separately and distinctly penalized at all. Because of these features of the ERISA regime, the accuracy and completeness of the initial claims review is doubly important and should be incentivized accordingly.

## II. A REGULATORY FRAMEWORK WITH LITTLE INCENTIVE TO COMPLY

As currently interpreted, the regulations that govern claims processing do not contain incentives to comply with any precision. Unless the regulatory violation results in serious, direct harm, noncompliance is generally excused under the "substantial compliance" doctrine set out below. Even where noncompliance is substantial, ERISA provides no substantive remedy. In most cases, even after a Participant has sued in federal court, the plan administrator is not penalized but is simply instructed to go back and take the action that it should have taken in the first instance.

### A. *The Regulatory Background*

Department of Labor (DOL) regulations set out a framework of minimum standards for processing healthcare benefit claims.<sup>96</sup> ERISA authorizes these regulations and provides that every employee benefit plan shall give adequate notice of a claim denial and afford a reasonable opportunity for a full review of denied claims.<sup>97</sup> Participants must exhaust these internal processes before filing suit in federal court, but the internal claims and appeal processes are deemed exhausted in the absence of strict compliance with the claims regulations.<sup>98</sup>

The PPACA added new requirements for internal claims review and appeal

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94. *See, e.g.,* *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 255 (1993).

95. 29 U.S.C. § 1132(g).

96. Most of the regulations apply to claims for healthcare benefits but also to claims for benefits under other types of ERISA plans. *Aetna Health, Inc. v. Davila*, 542 U.S. 200, 220 (2004) ("These regulations, on their face, apply equally to health benefit plans and other plans, and do not draw distinctions between medical and nonmedical benefits determinations.").

97. 29 U.S.C. § 1133.

98. 29 C.F.R. § 2590.715-2719(b)(2)(ii)(F) (2010) (providing that where a plan fails to establish or follow claims procedures consistent with the regulation's requirement, a claimant shall be deemed to have exhausted the internal procedures and the claim is to be reviewed de novo).

processes, as well as external review.<sup>99</sup> The new regulations apply to employee benefit plans (and other types of group health plans) for plan years beginning September 23, 2010.<sup>100</sup> The regulations do not apply to “grandfathered” plans, that is, plans that were in effect before the enactment of the PPACA that have not been significantly altered in terms of coverage or benefits.<sup>101</sup>

Under the regulations, plan administrators have an obligation to maintain reasonable claims procedures.<sup>102</sup> Claims procedures are defined as unreasonable if they contain any provision unduly inhibiting the processing of claims, such as requiring a person to receive prior authorization when the person is unconscious or requiring that a person pay a fee to appeal a claim denial.<sup>103</sup> Procedures must contain “administrative processes and safeguards” designed to ensure that plan provisions are interpreted and applied consistently, and that decisions are made according to plan documents.<sup>104</sup> Claims for benefits must be processed within thirty days after the plan’s receipt of the claim, unless the plan administrator determines that a fifteen-day extension is necessary and sends written notice of the extension.<sup>105</sup> The statute does not require Payors to pay interest on late-paid claims.

If a claim is denied, a written denial must set out the basis for the denial, reference the specific plan provision upon which the decision was based, and give a description of any additional material or information needed to pursue the claim.<sup>106</sup> If an internal rule, guideline, protocol, or similar criterion was relied upon in the denial, that rule or criterion must be disclosed to the claimant upon request.<sup>107</sup> In addition, the notice must be written “in a manner calculated to be

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99. The PPACA (along with the Health Care and Education Reconciliation Act (HCERA)) created authority for additional internal and external claims and appeals to be issued jointly by the Department of Treasury’s Internal Revenue Service, the Department of Labor’s Employee Benefits Security Administration (EBSA), and the Department of Health and Human Services (HHS). These agencies published their interim final rules with a request for comments on July 23, 2010. The interim final regulations are published at 26 C.F.R. § 54.9815-2719T (2010) (IRS), 29 C.F.R. § 2590.715-2719 (EBSA), and 45 C.F.R. § 147.136 (HHS). Citations herein will be to the EBSA version of the regulations.

100. 29 C.F.R. § 2590.715-1251(d).

101. *Id.* § 2590.715-1251(c); *see also* Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 43,330, 43,332 (July 23, 2010).

102. 29 C.F.R. § 2560.503-1(b).

103. *Id.* § 2560.503-1(b)(3).

104. *Id.* § 2560.503-1(b)(5).

105. *Id.* § 2560.503-1(f)(2)(iii)(B).

106. *Id.* § 2560.503-1(g)(1).

107. *Id.* § 2560.503-1(g)(v)(A), (j)(5)(i); *see also* *FAQs About the Benefit Claims Procedure Regulation*, U.S. DEP’T OF LABOR, [http://www.dol.gov/ebsa/faqs/faq\\_claims\\_proc\\_reg.html](http://www.dol.gov/ebsa/faqs/faq_claims_proc_reg.html) (last visited April 12, 2011). (“The [D]epartment [of Labor] also has taken the position that internal

understood by the claimant.”<sup>108</sup> The notice must also contain appropriate information as to the steps required if the Participant wishes to submit the claim for review.<sup>109</sup> When benefits are denied, the plan must afford the Participant the opportunity for a full and fair review.<sup>110</sup>

The new regulations expand the definition of adverse benefit determination to include a coverage rescission (a cancellation or discontinuance of coverage), such that rescissions of coverage are subject to internal review just as any other adverse benefit determination would be.<sup>111</sup> Notably, the regulations revise the conflict-of-interest rules so that compensation of claims-processing personnel cannot be directly tied to the proportion of claims denied.<sup>112</sup> All of these new regulations amount to progress for the plan Participant—but the lack of compliance still results in no direct, substantive remedy. The new regulations also expand the availability of external review of denied healthcare claims. Plans and issuers not presently subject to a state external review process will be subject to a federal process.<sup>113</sup> The preamble to the regulations explains that ERISA preemption prevents a state external review process from applying to most self-insured plans and that these plans are now subject to the federal external review process.<sup>114</sup> An external review process, however, represents yet another step that Participants must take in order to reverse an improperly denied claim.

To fully protect Participants, many of whom will never follow up on denied claims, Payors must be incentivized to comply with the regulations by accurately processing and properly approving claims in the first place.

### *B. Little Incentive To Comply*

While the regulations set out specific requirements for claims processing,

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rules, guidelines, protocols, or similar criteria would constitute instruments under which a plan is established or operated within the meaning of section 104(b)(4) of ERISA and, as such, must be disclosed to participants and beneficiaries.”)

108. 29 C.F.R. § 2560.503-1(g).

109. Under the regulations applicable to this section, the denial notice must contain: (1) the specific reason or reasons for the denial; (2) specific reference to the pertinent plan provisions on which the denial is based; (3) a description of any additional material or information necessary for claimant to perfect the claim and an explanation of why such information is necessary; and (4) appropriate information as to the steps to be taken if the participant or beneficiary wishes to submit his or her claim for review. *Id.*

110. *Id.* § 2560.503-1(h).

111. *Id.* § 2590.715-2719(a)(2)(i).

112. *Id.* § 2590.715-2719(b)(2)(ii)(D).

113. *Id.* § 2590.715-2719(d).

114. Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 43,330 (July 23, 2010).

Participants have little recourse when plan administrators do not comply. Many violations are excused through the generous “substantial compliance” doctrine; more serious or continuing process violations are often conflated with the claim denial at issue and rarely result in an independent, substantive remedy. Only the most flagrant violations provoke a targeted judicial response, and even then, the remedy is almost always procedural rather than substantive.<sup>115</sup> The claim may be returned to the plan administrator for processing in compliance with the plan terms and ERISA regulations, but the Participant receives no compensation for the delay or for the time and effort devoted to appealing the claim and filing a lawsuit.

The regulations as currently interpreted provide little incentive to reject the following strategic approaches to payment of healthcare claims:

- *Denying a claim incorrectly upon initial filing, then, if the Participant appeals, paying the claim upon first-level internal appeal.* ERISA regulations do not provide for any penalty in this situation; moreover, attorney’s fees are not available during the administrative phase.<sup>116</sup> This approach would reduce the number of claims ultimately paid, because a high percentage of Participants do not appeal.<sup>117</sup>
- *Denying certain types of claims incorrectly upon initial filing, then paying them during litigation.* This approach results in practically no penalty at all to the plan administrator, unless the plaintiff persists in the litigation and is awarded attorney’s fees.<sup>118</sup> Again, this approach would reduce the number of claims paid, because a high percentage of Participants do not appeal.
- *Paying claims outside the regulatory deadlines.* Any single instance of delayed payment is likely to be excused within the “substantial compliance” doctrine.<sup>119</sup>

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115. *See, e.g.,* Wade v. Hewlett-Packard Dev. Co. LP Short Term Disability Plan, 493 F.3d 533, 540 (5th Cir. 2007) (“[F]ailure to fulfill procedural requirements generally does not give rise to a substantive damage remedy.” (quoting Hines v. Mass. Mut. Life Ins. Co., 43 F.3d 207, 211 (5th Cir. 1995))).

116. *See, e.g.,* Parke v. First Reliance Standard Life Ins. Co., 368 F.3d 999, 1011 (8th Cir. 2004) (“We join the Second, Fourth, Sixth, and Ninth Circuits in holding that term ‘any action’ in 29 U.S.C. § 1132(g)(1) does not extend to pre-litigation administrative proceedings.”).

117. As set out in Section I.A, an estimated ninety percent of denied claims are not appealed.

118. *See, e.g.,* Schoedinger v. United Healthcare, No. 4:04-cv-664 SNL, 2006 WL 3803935 (E.D. Mo. Nov. 6, 2006) (awarding fees where Payor paid some claims during litigation).

119. *See infra* Subsection I.B.1. If a Payor does not have reasonable claims procedures consistent with the regulation, the Participant may elect to proceed directly to federal court. 29 C.F.R. § 2560.503-1(1). Given the low percentages of denied claims that are appealed, however, proceeding to file a federal lawsuit appears not to be a preferable solution for many plan participants.

- *Failing to communicate the basis for the claim denial or the Participant's right to appeal.* If such a failure comes to light as part of a claims denial, the omission is likely to be excused under the "substantial compliance" doctrine.<sup>120</sup> If the Participant suffers consequential harm due to lack of disclosure, consequential damages are unavailable under current ERISA law.<sup>121</sup>

As described below, these strategies and other kinds of non-compliance are insufficiently addressed by the current regulations and ERISA's enforcement regime. Indeed, ERISA, as currently interpreted, effectively invites such strategic approaches to claims processing.<sup>122</sup>

### 1. *The "Substantial Compliance" Doctrine Sets the Bar Low*

When Participants progress through the internal appeals process and on to federal court, the court first determines whether the non-compliance was substantial and whether the administrator complied with the regulations' purpose. In the case of non-substantial violations, courts apply the judicially created "substantial compliance" doctrine, which excuses many instances of non-compliance. This doctrine relaxes the technical requirements, excusing non-compliance so long as a "meaningful dialogue" between plan administrator and Participant takes place.<sup>123</sup> Depending on the particular court's analysis, the "substantial compliance" doctrine has the potential to excuse strict compliance or compliance with multiple regulations.<sup>124</sup> A Payor can, for example, delay a decision on the claim beyond the regulatory deadlines and still be within

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120. See *infra* Section I.B.

121. See, e.g., *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 255 (1993).

122. See, e.g., *Langbein*, *supra* note 41, at 1318-33 (detailing the Unum/Provident bad-faith denial scandal and explaining the dangers of plan administrators both deciding and paying claims).

123. See, e.g., *Robinson v. Aetna Life Ins. Co.*, 443 F.3d 389, 392 (5th Cir. 2006) ("Challenges to ERISA procedures are evaluated under the substantial compliance standard."); *Lacy v. Fulbright & Jaworski, L.L.P. Long Term Disability Plan*, 405 F.3d 254, 256-57 (5th Cir. 2005) (holding that where a notice of denial of benefits did not strictly comply with DOL Regulations, it was sufficient to trigger appeal deadlines and only substantial rather than strict compliance with ERISA § 1133 and DOL Regulation § 2560.503-1(f) was required).

124. See, e.g., *Larson v. Old Dominion Freight Line Inc.*, 277 F. App'x 318, 321 (4th Cir. 2008) (holding that even if the Administrator's communications did not technically comply with the regulations in that they did not give the basis for the claim denial, they provided a sufficient understanding of the Administrator's position and therefore substantially complied); *Wade v. Hewlett Packard Dev. Co. LP Short Term Disability Plan*, 493 F.3d 533, 539-40 (5th Cir. 2007) (excusing multiple failures to comply with claims regulations under the substantial compliance doctrine, when the administrator's oral rather than written notice did not comply, a subsequent denial letter did not list the plan criteria or reasons for denial, and it did not specify what information the plaintiff should submit to perfect an appeal).

“substantial compliance” so long as information is still being exchanged with the Participant.<sup>125</sup>

In addition, non-compliance with the regulations at initial levels of appeal may be excused if the plan administrator’s acts during a subsequent level of appeal effectively cure the initial non-compliance.<sup>126</sup> The Fifth Circuit Court of Appeals reasoned that this approach is in keeping with the regulations’ goal of encouraging a meaningful dialogue rather than any particular technical compliance.<sup>127</sup> Significantly, however, this ability to later “cure” any earlier regulatory non-compliance essentially gives companies a second chance to comply, negating the importance of strict initial compliance.

## 2. *Substantial Noncompliance Results in Remand Rather Than a Substantive Remedy*

Even significant regulatory violations rarely trigger a substantive remedy.<sup>128</sup> Remand to the plan administrator for a full and fair review is the most common remedy for substantial regulatory noncompliance.<sup>129</sup> But the regulatory violation itself usually makes little substantive difference to the outcome, because the regulatory violation tends to be conflated with the accompanying improper denial of benefits.<sup>130</sup> Indeed, there is no clear agreement as to whether regulatory non-

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125. *Gilbertson v. Allied Signal Inc.*, 328 F.3d 625, 634-35 (10th Cir. 2003).

126. *Wade*, 493 F.3d at 540 (holding that a plan’s substantial regulatory compliance in the final level of appeal cured the non-compliance in the first two levels; i.e., initial telephone contact in place of a required written notice was cured by a subsequent written notice).

127. *Id.*

128. *See, e.g., Lafleur v. La. Health Serv. & Indem. Co.*, 563 F.3d 148, 157 (5th Cir. 2009) (“[F]ailure to fulfill procedural requirements generally does not give rise to a substantive damage remedy.” (quoting *Wade* 493 F.3d at 540)); *Hines v. Mass. Mut. Life Ins. Co.*, 43 F.3d 207, 211 (5th Cir. 1995) (finding no violation where an employer failed to notify an employee of a change in his health insurance policy); *Duncan v. Assisted Living Concepts, Inc.*, No. Civ. A. 3:03-CV-1931N, 2005 WL 331116, at \*4 (N.D. Tex. Feb. 10, 2005) (“Procedural violations of ERISA do not entitle the plan beneficiary to a substantive remedy unless the beneficiary can prove continuous violations resulting in some prejudice to the beneficiary.”).

129. *See Lafleur*, 563 F.3d at 157 (explaining that remand is typically appropriate and preferable to substantive remedy).

130. Where, for example, an administrator changed the basis for its denial of disability benefits and failed to identify its vocational expert as specifically required by the regulations, the Fifth Circuit found that defendant, Aetna Life Insurance Company, had violated the claims regulations in a manner that constituted “more than mere technical noncompliance.” *Robinson v. Aetna Life Ins. Co.*, 443 F.3d 389, 394 (5th Cir. 2006); *see also Aetna Health Inc. v. Davila*, 542 U.S. 200, 220 (2004) (noting that the regulations “apply equally to health benefit plans and other plans, and do not draw a distinction between medical and nonmedical benefits determinations”). But despite this clear violation, the court imposed no remedy to address this violation as beyond the

compliance can independently result in a remedy at all.<sup>131</sup>

Without any such remedy, administrators perpetuating the vast majority of claims regulations violations tend to suffer no effects other than to be instructed to do what they should have done in the first place. For example, an administrator who fails to provide the full and fair review of a claim as required by ERISA is frequently ordered to go back and conduct the same full and fair review that it should originally have conducted.<sup>132</sup> Likewise, although the claims regulations clearly set out deadlines for making claims decisions, in case after case, administrators suffer no consequence from ignoring the regulations. Instead, the courts most often simply instruct the administrator to approve the initially denied claim, providing the administrator more time in which to do so.<sup>133</sup>

When a claim decision is delayed beyond the regulatory deadlines, there is no penalty except that the claim is “deemed denied” so that the Participant can immediately seek relief in the federal courts.<sup>134</sup> Even where claims on internal

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award of benefits that would have resulted anyway. *See Robinson*, 443 F.3d at 397. The court maintained the abuse of discretion standard of review, slightly modified due to the Payor’s dual role as administrator and insurer. *Id.* at 395. The court entered judgment for the Participant, based on the fact that there was no evidence in the record to support the defendant’s decision. *Id.* at 395. The regulatory violation, therefore, did not alter the outcome that would have occurred without the violation.

131. The Fifth Circuit has discussed, but not directly addressed, whether the court would entertain a remedy for a breach of the regulations or whether there was in fact any legal basis for such a remedy. *Custer v. Murphy Oil USA, Inc.*, 503 F.3d 415, 422 n.5 (5th Cir. 2007) (“[W]e make no holding on the difficult question of what remedy, if any, ERISA provides for a violation of its reporting and disclosure requirements.”).

132. *See, e.g., Smith v. Cont’l Cas. Co.*, 450 F.3d 253, 265 (6th Cir. 2006) (remanding for the entry of an order that the Plan Administrator reconsider the plaintiff’s disability claim where the Plan Administrator had failed to conduct a full and fair review, thus abusing its discretion, in the first instance); *Weaver v. Phx. Home Life Mut. Ins. Co.*, 990 F.2d 154, 159 (4th Cir. 1993) (“Normally, where the plan administrator has failed to comply with ERISA’s procedural guidelines and the plaintiff/participant has preserved his objection to the plan administrator’s noncompliance, the proper course of action for the court is remand to the plan administrator for a ‘full and fair review.’”); *VanderKlok v. Provident Life & Accident Ins. Co.*, 956 F.2d 610, 616-17 (6th Cir. 1992) (holding that the Plan Administrator failed to comply with section 1133, reversing and remanding the benefits decision for a full and fair review); *Duncan*, 2005 WL 331116, at \*4 (ordering the plan administrator to reconsider the plaintiff’s administrative appeal where the plan administrator had failed to conduct a full and fair review, thus abusing its discretion, in the first instance); *Hamilton v. Mecca, Inc.*, 930 F. Supp. 1540, 1552 (S.D. Ga. 1996).

133. *Nave v. Fortis Benefits Ins. Co.*, No. C.A. 98-3960, 1999 WL 238949, at \*5 (E.D. Pa. Mar. 30, 1999) (holding that where insurer had failed to make its decision within the regulatory deadline and had given no notice of any special circumstances requiring an extension the insurer had “neither strictly nor substantially complied” with section 2560.503-1(h) the equitable result was to dismiss plaintiff’s lawsuit and give Payor another fourteen days to make its decision).

134. *Mass. Mut. Life Ins. Co. v. Russell*, 473 U.S. 134, 144 (1985) (holding that a claim is

appeal are deemed denied due to administrator inaction, thereby forcing Participants to go to federal court to even receive a decision on the benefit claim, the deferential standard of review applied to the majority of initial denials is generally left intact.<sup>135</sup> Thus, the Participant, who may have been forced to seek relief in federal court in order to receive a decision on a relatively small dollar amount, can still be denied that relief.

### 3. *The Most Flagrant Violations Do Not Result in a Substantive Remedy*

Even the most serious and continuing violations of ERISA claims regulations rarely result in a substantive remedy.<sup>136</sup> The “paradigmatic example” of this most serious type of violation is the Blau case, in which “the defendants failed to comply with virtually every applicable mandate of ERISA.”<sup>137</sup> In that case, participants were denied benefits under a welfare plan.<sup>138</sup> Upon litigation of the denial, the court found that the claims procedure did not exist in any recognizable form: “[T]here was no summary plan description, no claims procedure, and no provision to inform participants in writing of anything. [The] claims procedure fail[ed] simply because there was none.”<sup>139</sup> The court noted that where procedural violations are so extreme, they “alter the very balance of knowledge and rights between covered employees and their employer.”<sup>140</sup>

For extreme cases such as these, the Fifth Circuit Court of Appeals, for example, contemplates a substantive remedy—in the form of a retroactive

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treated as being denied after the regulatory deadlines pass, enabling the claimant to bring a civil action to have the claim’s merits determined by the court); *see also* 29 C.F.R. § 2560.503-1(h)(4) (2010) (governing regulatory deadlines).

135. *Gilbertson v. Allied Signal Inc.*, 328 F.3d 625 (10th Cir. 2003). *But see* *Jebian v. Hewlett-Packard Co. Employee Benefits Organization Income Protection Plan*, 349 F.3d 1098 (9th Cir. 2002) (applying de novo standard where internal appeal was not decided within applicable deadline).

136. *See, e.g., Lafleur v. La. Health Serv. & Indem. Co.*, 563 F.3d 148, 157 (5th Cir. 2009) (noting that substantive damages for a flagrant regulatory violation could include retroactive reinstatement of benefits but that the court “ha[s] not fully identified the scope of available remedies” for procedural violations); *Abatie v. Alta Health & Life Ins. Co.*, 458 F.3d 955, 971 (9th Cir. 2006) (holding that the most flagrant disregard for claims regulations can result in de novo review of the plan administrator’s decision; citing no possibility of a substantive remedy); *Bard v. Bos. Shipping Ass’n*, 471 F.3d 229, 244 (1st Cir. 2006) (striking evidence and awarding benefits based on remaining evidence where procedural violations were “serious, had a connection to the substantive decision reached, and call[ed] into question the integrity of the benefits-denial decision itself”).

137. *Blau v. Del Monte Corp.*, 748 F.2d 1348, 1353 (9th Cir. 1984).

138. *Id.*

139. *Id.*

140. *Id.*

reinstatement of benefits—but has not yet seen cause to impose it.<sup>141</sup>

A severe procedural violation can result in the denial decision being treated with less deference, lowering the standard of review and leading the courts to conduct a *de novo* review of the administrator's denial of benefits.<sup>142</sup> The reasoning is that by ignoring the claims procedures, the administrator has essentially failed to exercise its contractually accorded discretion, such that there is no exercise of discretion for the court to review.<sup>143</sup> The administrator may also have violated the procedures mandated by ERISA in a way that is “so flagrant as to alter the substantive relationship between the employer and employee, thereby causing the beneficiary substantive harm.”<sup>144</sup> The altered standard of review does not of course necessarily result in any award of benefits or any other remedy: if a *de novo* review does not uncover any error in the denial of benefits, the denial remains intact and no remedy is given.

Even this relatively slight remedy may be in doubt. In a recent opinion, the Supreme Court suggested that an administrator's failure to abide by fiduciary duties should not result in a *de novo* standard of review.<sup>145</sup> The Court examined the effect of the conflict of interest resulting from an insurer acting as the plan administrator, and whether that dual role should imply a lowering of the standard of review from abuse of discretion to *de novo*.<sup>146</sup> The Court held that the abuse of discretion standard should remain intact, but that the administrator's conflict of interest should be a factor in determining whether the administrator abused its discretion in denying the claim.<sup>147</sup> Given this adherence to the abuse of discretion standard in the case of a conflict of interest, the Court could accordingly find that a procedural violation should likewise be a part of the review, rather than a reason to alter the standard.<sup>148</sup>

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141. *Lafleur*, 563 F.3d at 157 (noting that substantive damages for a flagrant regulatory violation could include retroactive reinstatement of benefits, but that the court “[has] not fully identified the scope of available remedies” for procedural violations).

142. *See Abatie v. Alta Health & Life Ins. Co.*, 458 F.3d 955, 971 (9th Cir. 2006) (“When an administrator engages in wholesale and flagrant violations of the procedural requirements of ERISA, and these acts in utter disregard of the underlying purpose of the plan as well, we review *de novo* the administrator's decision to deny benefits.”). *Contra Lafleur*, 563 F.3d at 159 (“[W]e have never definitively rejected the availability of this remedy, [but] we have previously refused to apply it.”).

143. *Abatie*, 458 F.3d at 972.

144. *Duvall v. Reliance Standard Life Ins. Co.*, 646 F. Supp. 2d 1188, 1202 (E.D. Cal. 2009) (quoting *Gatti v. Reliance Standard Life Ins. Co.*, 415 F.3d 978, 985 (9th Cir. 2005)).

145. *Metro. Life Ins. Co. v. Glenn*, 554 U.S. 105, 115-16 (2008).

146. *Id.*

147. *Id.* at 108.

148. *See, e.g., Duvall v. Reliance Standard Life Ins. Co.*, 646 F. Supp. 2d 1188, 1198 (E.D. Cal. 2009) (suggesting that *Glenn*, 554 U.S. at 128, abrogated the proposed lowering of the standard of review for procedural violations set out in *Abatie*, 458 F.3d at 971).

In a small minority of cases, courts have viewed a violation of the claim processing regulations *alone* as an abuse of discretion that could justify an award of benefits. But in these cases, the violation of regulations still did not result in a substantive remedy, because in each case the benefits should have been awarded on the merits anyway. Thus, the defendant again does not suffer any *independent* penalty for failing to follow the claims regulations, because the benefits should have been awarded in the first place.<sup>149</sup>

Where, for example, a defendant disability insurance company failed to obtain the X-rays that it should have obtained to properly assess plaintiff's claim, the court entered judgment for the plaintiff and cited its intention to create a deterrent effect towards other insurers.<sup>150</sup> The court did not use the plan's failure to obtain information as a means of lowering the applicable standard of review. Instead, it applied the abuse of discretion standard and found that the defendant had abused its discretion by failing to provide a full and fair review.<sup>151</sup> The court noted, however, that the plaintiff was in fact disabled, meaning that the effect of the court's decision was simply that the administrator was forced to do what it should have done in the first instance.<sup>152</sup>

#### 4. *Freestanding Claims for Breach of Fiduciary Duty Fail To Address Regulatory Non-compliance*

Section 1132(A)(3)(b) of ERISA is a "catch-all" provision that gives Participants a potential cause of action for breaches of fiduciary duty such as regulatory non-compliance; injunctive and other equitable remedies are

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149. *Salley v. E.I. DuPont de Nemours & Co.*, 966 F.2d 1011, 1015 (5th Cir. 1992) (holding that plan administrator's failure to obtain records from child's second and third hospitalization amounted to abuse of plan administrator's discretion and awarding benefits and attorney's fees to Participant). In this case, the treating physicians agreed that the Participant's hospitalization was medically necessary, while the physicians reviewing the claim for the plan said that the hospitalization was not medically necessary. *Id.* The reviewing physicians had neither examined the Participant nor obtained records regarding two of the three hospitalizations. The court noted that these records would have shown that the hospitalizations were medically necessary. *Id.*

150. *Beauvais v. Citizens Fin. Group Inc.*, 418 F. Supp. 2d 22, 33 (D.R.I. 2006). The court's judgment included an award of past and future disability benefits (because the disability was supported by medical evidence), medical benefits under a plan for which the defendant had been found ineligible due to her lack of disability status, and attorney's fees. The court expressed disapproval of the insurer's actions and awarded attorney's fees and reinstated plaintiff's medical benefits. In awarding attorney's fees, the court noted that such a remedy would serve as a deterrent to other plan administrators inclined to deny benefits based on a failure to produce records they never requested, "a deterrent that will benefit all plan participants." *Id.* at 33.

151. *Id.* at 31.

152. *Id.*

available.<sup>153</sup> But this cause of action is not an easy fit to remedy regulatory non-compliance, and, in addition, this provision's interpretation has proven extremely complex—a “virtual legal labyrinth.”<sup>154</sup>

The “catch-all” provision provides an avenue to remedy breaches of plan terms and regulations. This section gives Participants the right to bring a civil action “(A) to enjoin any act or practice which violates any provision of this title or the terms of the plan, or (B) to obtain other appropriate equitable relief (i) to redress such violations or (ii) to enforce any provisions of this title or the terms of the plan.”<sup>155</sup> This section is described as a “safety net, offering appropriate equitable relief for injuries caused by violations that other recourse available under ERISA does not adequately remedy.”<sup>156</sup> Under this provision, Participants may sue breaching fiduciaries for traditionally available equitable remedies.<sup>157</sup>

Any person exercising “material discretion” over plan assets or administration is subject to fiduciary duties.<sup>158</sup> Thus, individuals who make healthcare benefit decisions such as claims determinations are acting as fiduciaries and are bound by these duties.<sup>159</sup> Each time an administrator fails to comply with the regulations, it breaches its fiduciary duties.<sup>160</sup> Significantly, a breach of fiduciary duty cause of action does not require loss by

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153. 29 U.S.C. § 1132(a)(3) (2006).

154. Colleen E. Medill, *Resolving the Judicial Paradox of Equitable Relief*, 39 J. MAR. L. REV. 827, 829 (2006).

155. 29 U.S.C. § 1132(a)(3).

156. *Varity Corp. v. Howe*, 516 U.S. 489, 512 (1996).

157. *Calhoun v. Trans World Airlines, Inc.*, 400 F.3d 593, 596 (8th Cir. 2005) (“Beneficiaries of ERISA plans may sue for breaches of fiduciary duties under 20 U.S.C. § 1132(a)(3), but the remedies they seek in such an action are limited by the language of the statute to traditionally available equitable remedies.”).

158. Langbein, *supra* note 66, at 1324-25.

159. *See, e.g., Hill v. Blue Cross & Blue Shield of Michigan*, 409 F.3d 710, 717 (6th Cir. 2005) (noting that parties with authority to grant or deny claims are ERISA fiduciaries); *Libbey-Owens-Ford Co. v. Blue Cross & Blue Shield Mut.*, 902 F.2d 1031, 1035 (6th Cir. 1993) (holding that discretionary authority over claims triggered fiduciary status); H.R. REP. NO. 93-1280, at 301 (1974) (Conf. Rep.), *reprinted in* 1974 U.S.C.C.A.N. 5038, 5081 (discussing procedures for delegating fiduciary duties, such as “allocation or delegation of duties with respect to payment of benefits”); 120 CONG. REC. 29,929 (1974) (remarks of Sen. Williams) (stating that ERISA imposes “strict fiduciary obligations upon those who exercise management or control over the assets or administration of an employee pension or welfare plan”).

160. *See, e.g., John Blair Comm., Inc. Profit Sharing Plan v. Telemundo Group, Inc. Profit Sharing Plan*, 26 F.3d 360 (2d Cir. 1994) (finding the failure to comply with certain governing ERISA sections and the applicable Treasury regulations thereunder amounted to a breach of fiduciary duty); *Larsen v. NMU Pension Plan Trust*, 767 F. Supp. 554, 557 (S.D.N.Y. 1991) (“[V]iolation of the regulations is sufficient to establish a breach of fiduciary duty under § 404 of ERISA . . .”).

the plaintiff; gain by the defendant is sufficient.<sup>161</sup> That is, if a defendant “has made a profit through the violation of a duty to the plaintiff to whom he is in a fiduciary relation, he can be compelled to surrender the profit to the plaintiff although the profit was not made at the expense of the plaintiff.”<sup>162</sup> The U.S. Securities and Exchange Commission (SEC), for example, has obtained relief in the form of equitable accounting for profits against defendants violating the securities laws.<sup>163</sup>

The fiduciary duty cause of action and equitable relief, however, have proven inadequate to address ERISA regulatory non-compliance effectively. Claims for equitable accounting for profits<sup>164</sup> have met with some success under limited circumstances—for example, a fiduciary that improperly withholds

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161. *Kardon v. Nat'l Gypsum*, 73 F. Supp. 798, 802 (E.D. Pa. 1947) (“The plaintiff’s case was established when the defendants’ duty and its breach were proved. This was done by showing that the defendants were officers and directors of Western and that they disposed of the bulk of the corporate assets to an outsider, for their own benefit . . . . The remedy follows, which, in this case, is an accounting to ascertain and restore . . . the profits, if any.”). Whether or not trust law includes a make-whole remedy for ERISA plaintiffs is the subject of considerable scholarly debate and judicial comment. For complete analysis of this issue, see Langbein, *supra* note 66, at 1333. However, the disgorgement remedy sidesteps this debate, because disgorgement is not intended to benefit the wronged beneficiary, but to prevent the unjust enrichment of the fiduciary. See *Parke v. First Reliance Standard Life Ins. Co.*, 368 F.3d 999, 1008-09 (8th Cir. 2004) (explaining that the equitable accounting and unjust enrichment disgorgement remedies fit within those traditionally available in equity).

162. RESTATEMENT OF RESTITUTION § 160(d), at 646 (1937); see also Langbein, *supra* note 66, at 1333 (“An aggrieved trust beneficiary . . . may recover (1) for loss incurred, (2) for any profits that the trustee made in breach of trust, and (3) for any gains that would have accrued but for the breach.”).

163. Where, for example, a defendant was found to have aided and abetted in primary violations of books and records, net capital, and reporting violations of the federal securities laws, the defendant was ordered to disgorge the profits earned by those wrongs, including commissions paid to the defendant and markups on securities. *SEC v. Solow*, 554 F. Supp. 2d 1356, 1363 (S.D. Fla. 2008). In such cases, the calculation need not be done with complete certainty. *SEC v. Patel*, 61 F.3d 137, 139-40 (2d Cir. 1995) (noting that plaintiff need only establish “a reasonable approximation of profits causally connected to the violation” to establish the amount owed); *Solow*, 554 F. Supp. 2d at 1363. Indeed, in analogous situations under the securities laws, once a reasonable approximation of the amount of unjust enrichment is established, the burden then shifts to the defendant to show that the approximation is unreasonable. *Solow*, 554 F. Supp. 2d at 1363. The risk of uncertainty in calculating the remedy falls on the defendant, whose illegal actions created the uncertainty. *Id.*

164. Accounting for profits is “a restitutionary remedy based upon avoiding unjust enrichment. In this sense, it reaches monies owed by a fiduciary or other wrongdoer, including profits produced by property which in equity and good conscience belonged to the plaintiff.” BLACK’S LAW DICTIONARY (9th ed. 2009) (quoting DAN B. DOBBS, LAW OF REMEDIES § 4,3(5), at 408 (2d ed. 1993)).

benefits can be held liable for interest on the withheld money on an unjust enrichment theory.<sup>165</sup> But while the “catch-all” provision cause of action is an avenue against a plan administrator or ultimate payor’s unjust enrichment through improper claims processing, this cause of action is difficult to prove and often unfruitful.<sup>166</sup> Any individual instance of non-compliance (such as a failure to communicate appeal rights or the basis for a denial) does not result in significant unjust enrichment to the defendant beyond the amount of the denied claim. In addition, this cause of action does not capture the most significant unjust enrichment of defendants resulting from regulatory non-compliance: The cost savings where claims are improperly denied and not appealed. The unjust enrichment of Payors is more difficult to quantify in an ERISA breach of fiduciary duty claim than in other areas of the law, such as securities law, in which the wrongdoing more often results in a greater single, traceable profit.

Empirical research has found a correlation between higher Payor denial rates and profits.<sup>167</sup> And under trust law, the benefits gained in breach of a trust are subject to equitable disgorgement. When the denials conflict with the terms of ERISA plans and the Payors’ or plan administrators’ fiduciary duties to Participants, the unpaid monies should be recoverable, not as compensation to Participants, but as equitable disgorgement due to unjust enrichment.

Here again, trust law proves inadequate to address the particular needs of ERISA plans, because its application has led only to confusing and uncertain results. ERISA’s legislative history makes clear that the courts are expected to develop the federal common law of ERISA to develop the “appropriate equitable relief” set out in § 1132(a)(3)(B) and other areas of ERISA that were not explicitly drawn.<sup>168</sup> But this section has not led to any clear remedies, and uncertainty still exists as to exactly what relief this provision can provide.

Where a single cause of action is too minimal to bring alone, but the wrong being addressed appears to occur pervasively, the class action mechanism may

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165. *Parke v. First Reliance Standard Life Ins. Co.*, 368 F.3d 999, 1005-09, (8th Cir. 2004) (“[A]n award of interest on wrongfully delayed benefits remains permissible . . . as a remedy for a breach of fiduciary duty to a beneficiary.”); *Dunnigan v. Metro. Life Ins. Co.*, 214 F.R.D. 125, 134-35 (S.D.N.Y. 2003) (noting that interest on wrongfully withheld benefits is available under ERISA because it fits within the relief “typically available in equity”).

166. *See, e.g., Knieriem v. Group Health Plan, Inc.*, 434 F.3d 1058, 1064 (8th Cir. 2006) (dismissing action under 29 U.S.C. § 1132(a)(3)(B) for accounting for profits for alleged wrongful benefits denial).

167. *Greenberg et al., supra* note 43, at 633 (finding a “strong positive correlation” between net profit margin and the adjusted odds that the plan would discount the cost of a day’s stay in the hospital).

168. Senator Jacob Javits, for example, is often cited as noting that the federal courts were to develop “a body of Federal substantive law . . . to deal with issues involving rights and obligations under private welfare and pension plans.” 120 CONG. REC. 29,942 (1974).

provide an avenue for recovery. But class actions have not been a panacea for ERISA non-compliance. Participant classes frequently founder on requirements such as commonality of legal and factual issues, and the causal link between the alleged wrongdoing and resulting damages can be too remote.

For example, where proposed Participant classes have brought lawsuits for interest on denied or delayed claims, courts have found that individualized analysis is required and class action treatment is unsuitable.<sup>169</sup> That is, unless the class meets the requirements under the Federal Rules of Procedure to be brought as a class action, all the parties must be joined and the lawsuit cannot go forward as a class action.<sup>170</sup> Some narrowly drawn classes seeking injunctive relief for specific, plan-wide improper treatment of claims are permitted to go forward.<sup>171</sup> But in order for the class of Participants to have a significant chance of certification, the class must be carefully drawn, the remedy sought must be distinct from the claim for benefits, and the equitable remedy must be traceable to the alleged harm.<sup>172</sup> The class action vehicle is therefore an uncertain and ungainly tool against most instances of regulatory non-compliance.

Thus, regulatory non-compliance in the processing of healthcare claims for the most part results in no remedy at all. The most flagrant examples may result in a procedural action such as remand for further review, but regulatory non-compliance for the most part leads to no substantive remedy. Given the deferential standard of review applied to plan administrators' decisions and the

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169. *See, e.g.,* *Miner v. Empire Blue Cross/Blue Shield*, 2001 WL 96524 (S.D.N.Y. Feb. 5, 2001) (holding that claims for interest on delayed benefit payments may not be brought as a class action); *Dunnigan v. Metro. Life Ins. Co.*, 99 F. Supp. 2d 307, 325-26 (S.D.N.Y. 2000); *Holmes v. Pension Plan of Bethlehem Steel Corp.*, No. Civ. A 98-CV-1241, 1999 WL 554591, at \*7 (E.D. Pa. June 30, 1999), *aff'd*, 213 F.3d 124 (3d Cir. 2000) (“[C]ourts are still required to make individual assessments of each claim, examine the individual facts behind each claim, balance the equities, and determine that a benefit payment was improperly delayed.”).

170. FED. R. CIV. P. 23(a) (“One or more members of a class may sue or be sued as representative parties on behalf of all class members only if: (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.”).

171. *See, e.g.,* *Hill v. Blue Cross & Blue Shield of Michigan*, 409 F.3d 710, 718 (6th Cir. 2005) (reversing dismissal of fiduciary-duty claims). The court wrote, “Only injunctive relief of the type available under § 1132(a)(3) will provide the complete relief sought by Plaintiffs by requiring BCBSM to alter the manner in which it administers all the Programs’ claims for emergency-medical-treatment expenses.” *Id.*

172. *See, e.g., id.*; *Parke v. First Reliance Standard Life Ins. Co.*, 368 F.3d 999, 1004 (8th Cir. 2004) (affirming denial of certification of putative Participant class seeking injunctive relief against insurer’s denial or suspension of disability benefits without evidence that disability no longer existed; disability determination was too individual for class action).

financial conflicts inherent in the process, the available remedies for regulatory non-compliance are simply inadequate to protect Participants' access to their promised benefits.

### III. THE PRESUMED HARM APPROACH TO ENFORCEMENT OF CLAIMS PROCESSING REGULATIONS

If compliance with claims regulations is to be attractive, non-compliance must be financially unattractive.<sup>173</sup> Currently, financial incentives weigh heavily in favor of non-compliance, because non-compliance generally results in no substantive remedy. Two possible approaches to enforcement of claims regulations would disincentivize non-compliance with claims processing regulations. The discretionary attorney's fee remedy could be used more aggressively to penalize regulatory non-compliance, as a minority of courts is already doing. In the longer term, ERISA's enforcement provision and regulations could explicitly adopt the presumed-harm approach of consumer finance statutes.

#### *A. Recognizing the Harm: Attorney's Fees as Deterrent to Regulatory Non-compliance*

Where a defendant fails to comply with claims regulations, some courts award attorney's fees, even if the defendant cures the non-compliance during litigation or the claim is remanded to the plan administrator for further review.<sup>174</sup>

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173. In *Schoedinger v. United Healthcare*, No. 4:04-cv-664 SNL, 2006 WL 3803935, at \*8 (E.D. Mo. Nov. 6, 2006), the court awarded attorney's fees to a healthcare provider who had faced repeated delays and denials of his claims. The court noted:

Whether it be purposeful or negligent, insurance companies regularly reduce and deny claims without cause, thereby increasing the cost of healthcare to providers and patients alike. If it became cost prohibitive for insurance companies to engage in that behavior, it would incentivize more accurate claims administration and processing in the future.

*Id.*

174. See, e.g., *Mizzell v. Provident Life & Accident Ins. Co.*, 32 Fed. App'x 352, 355 (9th Cir. 2002) (affirming award of attorney's fees where court remanded to plan administrator for full and fair review of denial); *Finks v. Life Ins. Co. of N. Am.*, No 08-1272 (ESH)(AK), 2009 WL 2230899, at \*6 (D.D.C. July 24, 2009) (awarding attorney's fees where Payor paid claims during litigation); *Colby v. Assurant Emp. Benefits*, 635 F. Supp. 2d 88 (D. Mass. 2009) (awarding fees upon remand to plan administrator for review); *Moskalski v. Bayer Corp.*, No. 2:06-cv-568, 2008 WL 2096892, at \*1-2 (W.D. Pa. May 16, 2008) (awarding attorney's fees on remand to plan administrator, where administrator's decision "lacked sufficient foundation" and court sought to provide a financial incentive for Payors "to properly support [their] conclusions at the administrative level"); *Schoedinger*, 2006 WL 3803935, at \*7 (awarding attorney's fees where defendant paid some claims during litigation and agreed on other amounts due).

An award of attorney’s fees acts as some deterrent to plan administrators who would delay or deny claims improperly, and this approach can be more widely adopted in order to encourage compliance with claims processing regulations.

In ERISA cases, courts have discretion to award attorney’s fees to either party.<sup>175</sup> A court may award attorney’s fees to either party if the party receives “some degree of success on [the] merits.”<sup>176</sup> An award of ERISA attorney’s fees generally begins with analysis of the following factors:

- (1) the degree of opposing parties’ culpability or bad faith; (2) ability of opposing parties to satisfy an award of attorneys’ fees; (3) whether an award of attorneys’ fees against the opposing parties would deter other persons acting under similar circumstances; (4) whether the parties requesting attorneys’ fees sought to benefit all participants and beneficiaries of an ERISA plan or to resolve a significant legal question regarding ERISA itself; and (5) the relative merits of the parties’ positions.<sup>177</sup>

The factors are not statutory, but are flexible guidelines that courts have used to guide this discretionary analysis.<sup>178</sup>

When a court finds that a plan administrator has not complied with claims regulations and the court remands the claim to the plan administrator, a plaintiff may well receive no attorney’s fee award.<sup>179</sup> As courts address each of the five attorney’s fee factors, non-compliance with claims processing regulations often does not amount to the “culpability or bad faith” addressed in the first attorney’s fee factor.<sup>180</sup> And, where claims processing is concerned, a deterrent effect on

175. 29 U.S.C. § 1132(g)(1) (2006) (providing that in any ERISA action “by a participant, beneficiary, or fiduciary, the court in its discretion may allow a reasonable attorney’s fee and costs of action to either party”).

176. *Hardt v. Reliance Standard Life Ins. Co.*, 130 S. Ct. 2149 (2010) (citing *Ruckelshaus v. Sierra Club*, 463 U.S. 680, 694 (1983)).

177. *Id.* (quoting *Quesinberry v. Life Ins. Co. of N. Am.*, 987 F.2d 1017, 1029 (4th Cir. 1993)).

178. *Foltice v. Guardsman Prods., Inc.*, 98 F.3d 933, 937 (6th Cir. 1996).

179. *See, e.g., Graham v. Hartford Life & Accident Ins. Co.*, 501 F.3d 1153, 1162 (10th Cir. 2007) (holding that attorney’s fee issue was not ripe until after plan administrator’s review on remand); *Quinn v. Blue Cross & Blue Shield Ass’n*, 161 F.3d 472, 479 (7th Cir. 1998) (affirming lower court’s holding that defendant did not complete a proper vocational review and that denial of disability benefits was arbitrary and capricious but reversing fee award because defendant’s decision was not “totally lacking in justification”); *St. Joseph’s Hosp. v. Carl Klemm, Inc.*, 459 F. Supp. 2d 824, 834 (W.D. Wis. 2006) (denying motion for attorney’s fees, based on the absence of evidence that defendant was “simply out to harass” plan participant).

180. *See, e.g., Kansas v. Titus*, 452 F. Supp. 2d 1136, 1153 (D. Kan. 2006) (holding that notification did not comply with claims regulations, but declining to find defendant “culpable” and awarding no fees); *Towner v. CIGNA Life Ins.*, 419 F. Supp. 2d 172, 186 (D. Conn. 2006) (finding that defendant’s claims processing did not comply with regulations, but finding no culpability and

other defendants is not necessarily cited in weighing the attorney's fee factors.<sup>181</sup> Moreover, in addressing the fourth factor, value to other plan participants, most courts understand an ERISA claim dispute as an individual matter, such that the lawsuit has no value to other participants.<sup>182</sup>

A few courts, however, are leading the way in a broader, more consumer-oriented approach. These courts are using an award of attorney's fees to serve as a disincentive to improperly process claims or deny or delay claims until a lawsuit is filed.<sup>183</sup> Broadening the usual constricted view of ERISA remedies, these courts note the present disincentives to adhere to claims processing procedures, and they award fees against plan administrators who refuse to follow the claims processing regulations.<sup>184</sup> These courts look to the incentives created

awarding no fees). *But see* Perrin v. Hartford Life Ins. Co., No. 06-182-JBC, 2008 WL 2705451, at \*3 (E.D. Ky. July 7, 2008) (“[D]efendant was highly culpable” based on “disregard for objective medical evidence”); Elliott v. Metro. Life Ins. Co., No. 04-174-DLB, 2007 WL 1558519, at \*3 (E.D. Ky. May 29, 2007) (finding that defendant was culpable for purposes of fee award, based on disregard of treating physicians and other factors in disability case); Plummer v. Hartford Life Ins. Co., No. C-3-06-094, 2007 WL 838926 (S.D. Ohio Mar. 15, 2007) (finding defendant “at best, highly culpable” due to its reliance on at least three flawed medical opinions and misstatements of law and fact in litigation); Crider v. Highmark Life Ins. Co., No. 1:05-cv-660, 2006 WL 6157958, at \*2 (W.D. Mich. Nov. 21, 2006) (finding defendant “highly culpable” without addressing subjective state of mind, but based on “gross error” in terminating benefits).

181. *St. Joseph's Hosp.*, 459 F. Supp. 2d at 834 (holding that plaintiff “was not provided an opportunity for full and fair review” and awarding no attorney's fees); *Towner*, 419 F. Supp. 2d at 186 (D. Conn. 2006) (finding that defendant's claims processing did not comply with regulations but finding no behavior that warranted deterrence and awarding no fees).

182. *See, e.g., Foltice*, 98 F.3d at 937 (finding that where the lawsuit created no common fund, the fourth factor weighed in favor of defendant); *McDonald v. Western-Southern Life Ins. Co.*, No. C2-98-414, 2002 WL 484623, at \*4 (S.D. Ohio Feb. 20, 2002) (holding that plaintiff sought his own benefits and therefore did not confer any value on other participants).

183. One court explained succinctly the need for an attorney's fee deterrent against mishandling of claims, particularly where the Payor both decides and funds claims:

[T]here is evidence in the record to support a conclusion that the insurance company engaged in a campaign of evaluation and re-evaluation of plaintiff's claim, in a single-minded effort to document reasons for denial. From a purely economic point of view, this is rational behavior. From a fiduciary point of view, it is not. If the only consequence of an arbitrary denial of benefits is the chance of being sued and a possibility of reinstatement of benefits at some future date, insurance companies with this strong conflict of interest will have little incentive to adhere to their fiduciary obligations.

*Crider v. Highmark Life Ins. Co.*, 1:05-cv-660, 2006 WL 6157958, at \*2 (W.D. Mich. Nov. 21, 2006) (awarding attorney's fees against defendant that arbitrarily terminated benefits).

184. *Crider*, 2006 WL 6157958, at \*3; *see also* *Beauvais v. Citizens Fin. Group Inc.*, 418 F. Supp. 2d 22, 33 (D.R.I. 2006) (awarding attorney's fees where defendant discontinued benefits based on plaintiff's failure to produce records that the defendant had never even requested); *Black*

by the lack of ERISA remedies and the comparatively small number of benefit regulation violations that are actually brought to court. As one such court observed:

[A]n award of attorney's fees . . . is an important deterrent measure: first, because of the limited remedy available to ERISA plaintiffs . . . insurers should be dissuaded from prematurely suspending benefits with the hope that some claimants will not sue; and second, because an award of attorney's fees ensures that attorneys continue to take on ERISA cases in which the potential monetary award may be limited.<sup>185</sup>

These courts analyze the ERISA attorney's fee factors differently and with ERISA's overall context in mind. Confronted directly with plan administrators' recalcitrance, or even a cavalier attitude toward ERISA regulations, the consumer-oriented courts are finding fee awards appropriate under a broader view of the five factors.<sup>186</sup>

In one such case, a plan administrator denied a long-term disability claim until the Participant filed suit.<sup>187</sup> During the course of the litigation, the administrator paid the claim.<sup>188</sup> The Participant pressed the lawsuit, and the court awarded interest on the disability benefits and then analyzed the factors

v. Unum Life Ins. Co., 324 F. Supp. 2d 206, 219 (D. Me. 2004) (citing defendant's "low level of care to avoid improper denial of claims, at great human expense").

185. *Giroux v. Fortis Benefits Ins. Co.*, 353 F. Supp. 2d 45, 54 (D. Me. 2005) (quoting *Black v. Unum Life Ins. Co.*, 324 F. Supp. 2d 206, 219 (D. Me. 2004)); *see also* *Curtin v. Unum Life Ins. Co.*, 298 F. Supp. 2d 149, 159 (D. Me. 2004) (awarding attorney's fees where defendant took insufficient care to avoid improper claim denials and noting the "limited remedies available under ERISA for plaintiffs such as [plaintiff] Ms. Curtin").

186. *See, e.g.*, *Perrin v. Hartford Life Ins. Co.*, No. 06-182-JBC, 2008 WL 2705451, at \*4 (E.D. Ky. July 7, 2008) (awarding fees in order to deter other defendants from mishandling claims); *Becker v. Weinberg Grp., Inc.*, 554 F. Supp. 2d 9, 18 (D.D.C. 2008) ("If [defendants] understood that clearly erroneous actions taken by them . . . would be subject to attorneys' fees, that might well deter them from engaging in such conduct."); *Elliott v. Metro. Life Ins. Co.*, No. 04-174-DLB, 2007 WL 1558519, at \*3 (E.D. Ky. May 29, 2007) ("[T]here is also something to be said for the heightened deterrent effect resulting from a fee award. Companies would likely take a much closer look at denial decisions, and the presentation of that decision, if forced to take into account the possibility that fees will be awarded upon remand."); *Risteen v. Youth for Understanding, Inc.*, No. Civ.A. 02-0709(JDB), 2003 WL 22011766, at \*4 (D.D.C. Aug. 19, 2003) ("Awarding attorney's fees to [Plaintiff] will provide future employers added incentive to comply with ERISA . . . regulations, and encourage employers to resolve such disputes sooner rather than later, before attorney's fees mount.").

187. *Finks v. Life Ins. Co. of N. Am.*, No. 08-1272 (ESH)(AK), 2009 WL 2230899, at \*6-8 (D.D.C. July 24, 2009) (awarding attorney's fees where Payor paid claims during litigation).

188. *Id.* at \*1.

governing attorney's fee awards under a broad, remedial lens.<sup>189</sup> In considering the deterrent effect of a fee award, the court noted case law explaining that an attorney's fee award should deter violations of ERISA as well as unnecessary prolongation or unjust resolution of claims.<sup>190</sup> The court also noted the plan administrator's "cavalier attitude" toward ERISA's regulatory deadlines.<sup>191</sup>

While many courts still interpret ERISA's damage provisions narrowly, the broader view of ERISA attorney's fees for regulatory violations appears to be gaining ground in the face of the scant remedies otherwise available.<sup>192</sup> The attorney's fee solution is, however, far from a panacea. Attorney's fees are not available for administrative action without litigation, so the availability of attorney's fees is no detriment at all to administrators who would refuse to pay claims initially and then pay on appeal or settle the claim as soon as litigation is initiated.<sup>193</sup> Furthermore, while more consistent fee awards may act as some deterrent to non-compliance with claims regulations, the attorney's fee provision remains discretionary and therefore uncertain. The attorney's fee provision of ERISA amounts to some financial disincentive against ignoring claims processing regulations. But given the minute percentage of denied claims that proceed through the internal appeal and litigation processes to final judgment, the

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189. *Finks*, 2009 WL 2230899.

190. *Id.* at \*2 (citing *Eddy v. Colonial Life Ins. Co. of Am.*, 59 F.3d 201, 206 (D.C. Cir. 1995)).

191. *Id.* at \*4 (noting with disapproval Payor's insistence that it had not backdated documents so as to appear to be in compliance with regulatory deadlines, because it had no incentive to do so—violation of the regulatory deadline would likely have no effect on Payor anyway). In addition, the court considered the benefit that this lawsuit would confer on others. The court found that the plaintiff's ability to enforce the terms of an insurance contract and perhaps dissuade insurance companies from denying benefits until a lawsuit is filed was a benefit to other plan participants and therefore a factor in the analysis. Instead of weighing in favor of the defendant as in the usual case, this factor, the court found, weighed equally in favor of the plaintiff and defendant. *Id.* at \*5.

192. *See, e.g., Gatlin v. Nat'l Healthcare Corp.*, 16 F. App'x 283, 290 (6th Cir. 2001) ("[A] stiffer penalty encourages plan administrators to alter their behavior with respect to employee appeals. . . ."); *Perrin v. Hartford Life Ins. Co.*, No. 06-182-JBC, 2008 WL 2705451, at \*4 (E.D. Ky. July 7, 2008) ("[T]he defendant will take a closer look at the administrative record and its denial decisions if it is faced with more than the prospect of merely reinstating benefits."); *Elliott v. Metro. Life Ins. Co.*, No. 04-174-DLB, 2007 WL 1558519, at \*3 (E.D. Ky. May 29, 2007) ("Companies would likely take a much closer look at denial decisions, and the presentation of that decision, if forced to take into account the possibility that fees will be awarded."); *Powell v. Premier Mfg. Support Servs., Inc.*, No. Civ.A. 01-05-0012, 2006 WL 1529470, at \*10 (M.D. Tenn. June 1, 2006) ("A fee award serves as a deterrent to conclusory statements that are devoid of specific and fact-supported reasons for denial of benefits.").

193. *Parke v. First Reliance Standard Life Ins. Co.*, 368 F.3d 999, 1011 (8th Cir. 2004) (joining "the Second, Fourth, Sixth, and Ninth Circuits in holding that the term 'any action' in 29 U.S.C. § 1132(g)(1) does not extend to pre-litigation administrative proceedings").

chance of an attorney's fee award being assessed against a plan administrator remains slim.

*B. Presuming the Harm: A Regulatory Solution to Claims Processing Non-compliance*

Consistent enforcement of ERISA's regulations calls for an approach akin to that of consumer financial protections such as the Truth in Lending Act (TILA).<sup>194</sup> TILA's Regulation Z,<sup>195</sup> for example, sets out requirements for disclosure of consumer finance terms and provides penalties for non-compliance regardless of actual harm. Similar enforcement of claims regulations under ERISA would lend consistency to the enforcement process by providing a clear incentive for administrators to comply with claims processing regulations.

A regulatory solution to the problem of claims processing begins by recognizing that trust law requires supplementation in order to fulfill ERISA's purpose: the provision of contracted benefits. At present, the struggle to find essentially regulatory solutions within trust law is undermining the availability of benefits. Lawsuits for non-compliance with claims processing regulations are increasing in complexity as courts vainly sift through arcane trust law in a quest for sensible solutions.<sup>196</sup> Instead, a consumer-oriented regulatory solution would provide the clarity and predictability that those seeking healthcare should have.

*1. Claims Processing Compliance Through a Presumed-Harm Approach Akin to that of the Truth in Lending Laws*

The DOL has issued additional language strengthening claims procedure regulation.<sup>197</sup> In order to be effective, though, the regulations must carry significant, clear consequences for non-compliance. The enforcement provisions of TILA and its Regulation Z exemplify the kind of provisions that could, if adopted as part of ERISA's enforcement provisions and regulations, increase compliance with claims processing regulations.

TILA concerns consumer credit, requiring certain disclosures from those who extend credit.<sup>198</sup> The law was written to address the concern that Americans were uninformed in taking on debt and needed transparency regarding credit terms.<sup>199</sup> TILA's goal was to require disclosures of finance charges and related

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194. 15 U.S.C. § 1601 (2006).

195. 12 C.F.R. § 226 (2010).

196. *See, e.g., Mertens v. Hewitt Assocs.*, 508 U.S. 248, 262 (1993) (noting that ERISA is "an enormously complex and detailed statute" and examining trust law at the time of the divided bench to determine appropriate remedies in ERISA cases).

197. *See* discussion *supra* Section II.A.

198. 15 U.S.C. § 1601(a); *Mourning v. Family Publ'ns Serv., Inc.*, 411 U.S. 356, 363 (1973).

199. *Clement v. Am. Honda Fin. Corp.*, 145 F. Supp. 2d 206, 210 (D. Conn. 2001) (noting that

information so that consumers could find the best terms available to them; TILA also aimed to protect consumers against inaccurate credit billing.<sup>200</sup>

Although ERISA and TILA concern different subjects, these two laws have much in common. Like ERISA, TILA was enacted to address a problem that affected the finances of individuals. ERISA and TILA both regulate an area of law that affects millions of consumer transactions.<sup>201</sup> Both statutes sought to bring uniformity to their respective areas.<sup>202</sup> Moreover, the legislative histories of both ERISA and TILA show an overriding concern for communication and clarity.<sup>203</sup>

In the case of ERISA, as explained above, the initial concern was solvency of pension plans; only later did it come to play a significant role in the regulation of healthcare coverage.<sup>204</sup> As a result, ERISA affects not just the finances but also the health of millions of individuals. While both TILA and ERISA concern matters that affect families' lives, TILA holds defendants to exacting standards and enforcement requires no showing of individual harm—features that are absent from the enforcement of ERISA's claims processing regulations.

Where enforcement is concerned, the two statutes and their regulations are quite different.<sup>205</sup> TILA contains specific statutory remedies for specific

disclosures required by TILA “are intended to provide, especially to the inexperienced and uninformed consumer, a way to avoid ‘the possibility of deception, misinformation, or at least an obliviousness to the trust costs’ of a credit transaction”) (citing *Griggs v. Provident Consumer Discount Co.*, 503 F. Supp. 246, 250 (E.D. Pa. 1980)).

200. *Cf. Mourning*, 411 U.S. at 363 (explaining that TILA was prompted by a finding that consumers were “remarkably ignorant of the nature of their credit obligations”).

201. Matthew A. Edwards, *Empirical and Behavioral Critiques of Mandatory Disclosure: Socio-Economics and the Quest for Truth in Lending*, 14 CORNELL J.L. & PUB. POL'Y 199, 203 (2005) (noting that TILA applies to virtually every consumer credit transaction, including mortgages, car loans, and credit card purchases).

202. Ian S. McCrea, *Truth in Lending, A Discussion of Koons Buick Pontiac GMC, Inc. v. Bradley Nigh*, 32 S.U. L. REV. 269, 269 (2005) (explaining that TILA sought to “provide economic stabilization among credit lending institutions” and “create uniform regulations among the states”).

203. Congress's purpose in enacting the ERISA disclosure provisions was partly to ensure that “the individual participant knows exactly where he stands with respect to the plan . . . .” H. R. REP. NO. 93-533, at 11 (1973); *see also* 15 U.S.C. §1601(a) (2006) (“The informed use of credit results from an awareness of the cost thereof by consumers. It is the purpose of this subchapter to assure a meaningful disclosure of credit terms so that the consumer will be able to compare more readily the various credit terms available to him and avoid the uninformed use of credit . . . .”).

204. WOOTEN, *supra* note 11, at 5, 281.

205. Edwards, *supra* note 201, at 212 (“Although Congress delegated rulemaking responsibility for implementing TILA to the Board of Governors of the Federal Reserve System, enforcement authority for the Act was divided among nine Federal agencies, led by the Federal Trade Commission”). With regard to ERISA, on the other hand, the Secretary of Labor has general regulatory authority, 29 U.S.C. § 1135, and can initiate legal proceedings to enforce ERISA. 29

violations.<sup>206</sup> First, a TILA plaintiff has a cause of action to recover any actual damage sustained by the plaintiff.<sup>207</sup> Second, the plaintiff can recover statutory damages of twice the amount of the finance charge in connection with the transaction, except that the award cannot be less than \$100 or greater than \$1,000.<sup>208</sup> Third, a court has discretion to award statutory damages in the amount of the lesser of \$500,000 or one percent of the defendant's net worth in a class action.<sup>209</sup> The statute also provides for criminal penalties for willful and knowing violations.<sup>210</sup>

Significantly, the award of statutory damages results from the violation of the statute, rather than any particular effect upon the plaintiff. The plaintiff need not show any specific harm flowing from the non-compliance; lenders are generally held strictly liable for inaccuracies, even if there is no showing that the inaccuracies are misleading.<sup>211</sup> In one case, for example, the plaintiffs did not speak or read English and so could not have read the disclosures had they been given. But statutory damages were awarded based on an objective evaluation of the disclosures' compliance with the statute.<sup>212</sup>

While TILA imposes strict liability on lenders, it also contains a "bona fide error" defense for technical mistakes or mistakes made despite "the maintenance of procedures reasonably adapted to avoid any such error."<sup>213</sup> A defendant can avoid liability by showing an error of calculation or omission occurred, and that the defendant employed procedures, such as accuracy reviews, to ensure that mistakes were not made.<sup>214</sup>

By most accounts, TILA is effective in encouraging regulatory compliance and straightforward enforcement. Indeed, it has been called "a tremendous success."<sup>215</sup> The "modest automatic statutory penalty" described above is

U.S.C. § 1132(a)(5). The Department of Treasury regulates ERISA plans claiming tax-exempt status. *Id.* § 1202 (b).

206. 15 U.S.C. § 1640(a) (2006).

207. § 1640(a)(1).

208. § 1640(a)(2)(A).

209. § 1640(a)(2)(B).

210. § 1611.

211. *Smith v. Cash Store Mgmt., Inc.*, 195 F.3d 325, 328 (7th Cir. 1999).

212. *Zamarippa v. Cy's Car Sales*, 674 F.2d 877, 879 (11th Cir. 1982) (holding that where a title transfer fee was included within the cash price of a vehicle rather than within the cost of credit as required by TILA, statutory damages were appropriate "regardless of the district court's belief that no actual damages resulted or that the violation is de minimus"); *see also Sosa v. Fite*, 498 F.2d 114, 116 (5th Cir. 1974).

213. 15 U.S.C. § 1640(c).

214. *Abel v. Knickerbocker Realty Co.*, 846 F. Supp. 445, 449 (D. Md. 1994) (declining to apply bona fide error defense where lender's failure to include origination fee in finance charge was accidental but no procedures were in place to ensure accuracy).

215. *Russell v. Fidelity Consumer Discount Co. (In re Russell)*, 72 B.R. 855, 862 (Bankr. E.D.

particularly effective, one court notes, where “actual damages were perhaps non-existent and [are], in any event, almost impossible to prove.”<sup>216</sup> As previously described, the harm that results when administrators fail to comply with ERISA’s claims processing regulations is similarly difficult to prove, hard to quantify, and in some individual cases non-existent.

Like TILA, ERISA contains statutory penalty provisions related to healthcare claims. ERISA provides for a \$110 per day penalty for each day following the expiration of thirty days following a Participant’s request for a Summary Plan Description<sup>217</sup>; ERISA also provides statutory penalties for failure to provide appropriate COBRA notices.<sup>218</sup> But with regard to disclosure of other required information, such as the basis for a claim denial or the Participant’s right to appeal, the regulations do not provide any specific remedy. Given the likelihood of Participant attrition during the appeal and litigation process, then, the incentive is to skimp on communications that would focus Participants on particular reasons for claim denials or that would provide Participants with information about how advance their appeals.<sup>219</sup>

If reforms were enacted such that certain violations of claims processing regulations led to specific monetary penalties, all parties would have greater certainty as to their expectations with regard to the claims processing procedures and outcomes. The important concerns of uniformity and predictability—for Participants, Payors, and their administrators—would equally be served by strict liability for departures from the claims processing regulations. Participants should be able to expect that the regulations applicable to healthcare claims are followed—that, for example, a review intended to be “full and fair” and completed within a certain period of time actually will be so.<sup>220</sup>

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Pa. 1987); *Regulatory Restructuring: Enhancing Consumer Financial Products Regulation: Hearing Before the H. Comm. on Financial Services*, 111th Cong. 142 (2009) (statement of Travis Plunkett, Legislative Director, Consumers Union) (“Private enforcement is the norm and has worked well as a complement to public enforcement in the vast majority of the consumer statutes that will be consolidated under the CFPA, including TILA . . . . Conversely, the statutes that lack private enforcement mechanisms are notable for the lack of compliance.”).

216. 72 B.R. at 862.

217. 29 U.S.C. §1132(c)(1)(A) (2006).

218. *Id.*

219. *See, e.g.*, U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-11-268, PRIVATE HEALTH INSURANCE: DATA ON APPLICATION AND COVERAGE DENIALS (2011), available at <http://www.gao.gov/new.items/d11268.pdf> (“[D]enials are often coded for the most general reason even though the denial may be for a more specific reason.”).

220. Some aspects of the claims process are more susceptible to strict application of penalties than others. For example, the presence or absence of required language in a notice to participants would be more straightforward to assess than whether a plan administrator conducted the required “full and fair” review. However, any lack of clarity in the standard for compliance suggests not that enforcement should be lessened, but that the standard lacks the necessary specificity. At present,

Uniformity and predictability are important to plan administrators and Payors too, as liabilities are difficult to manage if plans are subject to a variety of interpretations.<sup>221</sup> The Court’s solution to the problem of uniformity is for the plan administrator’s decision on claims to be given maximum deference, so that Payors and their administrators can plan their affairs and not be subject to varying interpretations of the plan by different federal courts.<sup>222</sup> But given this adherence to deferential review—even where the plan administrator’s initial interpretation of a plan is completely mistaken—accurate claims processing is even more important. With penalties that would ensure a firm commitment to claims processing regulations, administrators would be more likely to have uniform claims processing procedures in place, and therefore to avoid inaccurate claim denials. Similarly, on appeal, administrators would be more likely to conduct the required full and fair review of denied claims, so that any improperly denied claims could be granted administratively, instead of in litigation, in keeping with ERISA’s goals.<sup>223</sup> Thus, clear monetary penalties for claims procedure non-compliance would increase uniformity and predictability.

Set out below are the same examples of problematic health insurer practices that are described in Section II.B above. Currently, these practices go all but unremedied under ERISA. A reformed TILA-like regime would provide a specific, monetary remedy for the following breaches of claims regulations, with the same kind of bona fide error defense that TILA provides:

- *Denying a claim incorrectly upon initial filing, then, if the Participant appeals, paying the claim upon first-level internal appeal.* Under a more effective enforcement regime, the administrator could be subject to a modest penalty, geared to the dollar amount of the claim; as with TILA, administrators could avoid the penalty completely through a “bona fide error” defense which demonstrates that procedures are in place to avoid errors.
- *Denying certain types of claims incorrectly upon initial filing, then paying them during litigation.* Similar to the example above, the administrator could be subject to a modest penalty, but increased by a multiplier to reflect the Participant’s additional time and trouble, so that it is larger than the penalty for paying the claim

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any risk of confusion or lack of clarity in the regulations falls on Participants, because Payors can maneuver at will within any areas of uncertainty.

221. HEALTH, EDUC. & HUM. SERVS. DIV., *supra* note 63, at 25 (noting that the Department of Labor and others favor stronger remedies for non-compliance with the claims process, so that “upstream” compliance is improved).

222. *Conkright v. Frommert*, 130 S. Ct. 1640, 1650 (2010) (noting that the creation of ad hoc exceptions to deferential review would cause uniformity problems in plan interpretation).

223. *Id.* at 1649 (noting that ERISA encourages claims to be handled at the administrative level rather than through litigation).

during internal appeal.

- *Paying claims outside the regulatory deadlines.* Prompt pay laws enacted by fourteen state governments require interest plus penalties to be paid on late claims.<sup>224</sup> Federal laws should also provide that administrators pay interest on improperly delayed claims.
- *Failing to communicate the basis for the claim denial or the Participant's right to appeal.* Without a clear understanding for the basis of a denial or the manner in which to appeal, the Participant lacks the tools to pursue contracted benefits. Here too, the penalty could be geared to the dollar amount of the claim at issue, with a bona fide error defense available.

A regulatory regime such as this would support ERISA's original goal of ensuring contracted benefits. Congress intended ERISA to provide broad remedies to redress violations and to remove procedural and jurisdictional obstacles to enforcement.<sup>225</sup> While ERISA was based on trust law, Congress also saw fit to add statutory penalties where necessary to advance specific, important goals.<sup>226</sup> Congress imported trust law in order to provide an enforcement framework and impose fiduciary duties on plan decision-makers, but Congress predicted that the federal courts would develop a particular federal common law that would suit ERISA's goals and purposes.<sup>227</sup> Instead of a specialized federal common law, however, current ERISA law has developed into an "unjust and increasingly tangled . . . regime" that often amounts to a "regulatory vacuum."<sup>228</sup>

For this reason, many courts have called for ERISA reform; some urge the Court to revisit its interpretation of equitable remedies available under ERISA.<sup>229</sup> But increasingly, courts and commentators argue that trust law—based on the principles of fiduciary duty<sup>230</sup> that are simply a fiction under ERISA—does not

224. Monica E. Nussbaum, *Prompt Pay Statutes Should Be Interpreted To Grant Providers a Private Right of Action To Seek Enforcement Against Payors*, 15 HEALTH MATRIX 205, 230 (2005) (setting out and comparing fines and penalties contained in states' prompt pay laws).

225. S. REP. NO. 93-127, (1974), reprinted in 1974 U.S.C.C.A.N. 4639, 4871.

226. 29 U.S.C. § 1132(c) (2006) (setting out penalties for failing to meet certain disclosure and notice requirements regarding COBRA, annual reports, summary plan descriptions, and other notice provisions).

227. WOOTEN, *supra* note 11, at 282 (discussing Senator Jacob Javits's concern over the expansion of preemption and the absence of any replacement ERISA action).

228. See, e.g., *Aetna Health v. Davila*, 542 U.S. 200, 222-23 (2004) (Ginsburg, J., concurring) (quoting *DiFelice v. Aetna U.S. Healthcare*, 346 F.3d 442, 453, 457 (3d Cir. 2003) (Becker, J., concurring)).

229. See *id.* at 223 (urging Congress or the Court to revisit the issue of the availability of consequential damages against breaching fiduciaries).

230. Under the exclusive benefit rule, ERISA fiduciaries must discharge their duties with

fit the goals of Congress when it enacted ERISA. The time for firm and precise claims processing and enforcement reform has come.

Of course, no one would relish increased complexity in regulatory compliance or enforcement. But if the compliance and enforcement experience of the TILA is any indication, specific, direct penalties for non-compliance with claims processing regulations should lead to increased compliance rather than increased complexity.<sup>231</sup> Greater compliance favors Participants, but in many ways advances the interests of Payors and their administrators as well.

2. *A Separate Peace: Piecemeal and Inconsistent Private Reform Through Provider Class Actions*

In the absence of effective claims processing regulations, healthcare providers are accomplishing a measure of private reform through class actions.<sup>232</sup> These efforts only underscore the need for regulatory reform, however, because the settlements vary from insurer to insurer, expire after a certain term, and are geared to the parties that brought them, typically providers.

Healthcare providers have long battled health insurance companies over improperly delayed and denied claims. Recently, however, providers have acted through organizations such as the American Medical Association, suing health insurance companies over their claims processing procedures. The complaints have included claims of improper activities to reduce provider reimbursement, including downcoding<sup>233</sup> and bundling,<sup>234</sup> as well as delays and improper

respect to the plan:

[S]olely in the interest of the participants and beneficiaries . . . with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent man acting in like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims.

29 U.S.C. §1104(a)(1).

231. *See supra* note 215.

232. The AMA's website sets out eleven different class action settlements and their terms. *Health Insurer Settlements*, AM. MED. ASS'N, <http://www.ama-assn.org/ama/pub/advocacy/current-topics-advocacy/private-sector-advocacy/health-insurer-settlements.page> (last visited Mar. 27, 2011).

233. AM. MED. ASS'N, *supra* note 20, at 23 ("Downcoding occurs when a health insurer unilaterally reduces the level of complexity of a[] . . . service or procedure. . . . Health insurers often base their payment on a lower valued (and lower complexity) . . . code instead of the higher valued (and higher complexity) . . . code originally reported for payment.").

234. *Id.* at 19 ("Bundling occurs when a practice submits a claim for two or more separate, distinct . . . procedures and services performed on a patient during a single visit. The health insurer considers the two or more separate, distinct procedures and services as one and reimburses the practice for only one procedure or service performed—often the one with the lowest reimbursement—or reduces payment for the two or more procedures or services.").

denials.<sup>235</sup> These lawsuits, notably those consolidated as a Multi-District Litigation lawsuit in Florida, have achieved settlement agreements that include specific, measurable improvements to claims processing procedures.<sup>236</sup> Settlements have included terms that increase transparency and predictability in claims processing, such as the inclusion of specific, detailed definitions of certain plan terms,<sup>237</sup> interest payments for claims paid beyond deadlines, prohibitions against specific actions with regard to billing codes, and other terms.<sup>238</sup>

Reform through class action, however, is a poor substitute for broader reform.<sup>239</sup> First, Participants are not typically parties to these agreements. Plaintiff classes of healthcare providers are certified more readily than classes of Participants, due to the perceived individual facts and lack of uniform defendant actions surrounding the claims.<sup>240</sup> The settlement agreements therefore carve out special rules that do not include all ERISA stakeholders. When Participants are not class members, the resulting agreements, while beneficial to Participants, are geared to the providers' concerns.<sup>241</sup> Second, only providers can enforce the agreements' terms; Participants are left out.<sup>242</sup> Third, the agreements vary from

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235. See, e.g., *Love v. Blue Cross & Blue Shield Ass'n*, No. 03-21296-CIV/MORENO/SIMONTON (S.D. Fla. 2007) (notice of proposed settlement of class action), <http://www.bcbsm.com/pdf/lovenotice.pdf> ("The Complaint in this Action alleges that . . . the Blue Parties, among others, engaged in a conspiracy to improperly deny, delay, and/or reduce payments to physicians.").

236. The Aetna settlement with all U.S. physicians, for example, included a settlement fund of \$100 million to be paid to physicians, a clear definition of "medical necessity," stricter deadlines for paying claims and the payment of interest on late-paid claims, an independent appeal process for physician disputes, and other terms. Christopher Guadagnino, *MDs Weigh HMO Settlements*, PHYSICIAN'S NEWS DIG. (Sept. 23, 2003), <http://www.physiciansnews.com/2003/09/23/mds-weigh-hmo-settlements>.

237. *Id.*

238. *Id.* (noting that the provider class actions have brought about changes in reimbursement practices that provider groups had previously sought—unsuccessfully—through legislative channels and direct negotiation).

239. *Id.* (quoting American Medical Association President Donald J. Palmisano as stating that reform through class action is a "last resort" and advocating more fundamental reform).

240. *Compare Klay v. Humana, Inc.*, 382 F.3d 1241 (11th Cir. 2004) (affirming certification of provider class alleging systematic underpayment of claims), with *In re Managed Care Litig.*, 209 F.R.D. 678, 686 (S.D. Fla. 2002) (denying putative Participant class's motion for certification due to lack of a uniform scheme directed at plaintiffs).

241. See, e.g., *Blue Cross Blue Shield Settlement Information*, AM. MED. ASS'N, <http://www.ama-assn.org/ama/pub/advocacy/current-topics-advocacy/private-sector-advocacy/health-insurer-settlements/blue-cross-blue-shield.page> (last visited June 23, 2010) (detailing business practices such as automatic "downcoding" of certain billing codes that would no longer occur under the settlement agreement's terms).

242. See, e.g., *Highmark Settlement*, HMO SETTLEMENTS.COM, <http://www.hmosettlements>.

lawsuit to lawsuit, so that no generally accepted standards emerge. Fourth, the agreements do not result in enduring change because they expire after a certain term of years.<sup>243</sup>

The class action settlement agreements do, however, show that a reform movement is underway, but also that the results at present are uneven. Consistent, inclusive, and effective reform must come from changes to ERISA and its regulations, so that the rules are applicable to all.

### CONCLUSION

When Participants and their advocates press for ERISA reform, employers and health insurance companies often respond that employee benefits are purely voluntary initiatives, and that if the provision of benefits is too onerous, employers may simply decline to provide them.<sup>244</sup> Even so, employee benefits should not be confused with charity. Employees generally accept benefits in lieu of additional compensation. In turn, employers are able to attract employees by providing benefit packages and are able to receive favorable tax treatment in order to do so.<sup>245</sup> And employees generally contribute to premium costs as well.<sup>246</sup> More importantly, however, the voluntary nature of the system does not excuse the provision of illusory or unfair benefits. In any employer calculation of the cost of benefits, employers should take into account that all regulations and rules will be followed carefully.

The need for new remedies for improper processing of healthcare claims is more pressing than ever. More than 177 million Americans receive health care through their employers,<sup>247</sup> and ERISA plans are now the vehicle for providing the majority of healthcare coverage for those not eligible for Medicare. In addition, increasing numbers of ERISA plans are self-insured,<sup>248</sup> therefore

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com/pages/highmark.html (last visited April 24, 2011) (describing procedures to dispute compliance with settlement terms).

243. *Health Insurer Settlements*, *supra* note 232.

244. *Conkright v. Frommert*, 130 S. Ct., 1640, 1648 (2010) (noting that the provision of employee benefits is purely voluntary); 29 C.F.R. § 2560 (noting the “purely voluntary nature of the system”); HEALTH, EDUC. & HUM. SERVS. DIV., *supra* note 63, at 16.

245. Mark W. Stanton, *Employer-Sponsored Health Insurance: Trends in Cost and Access*, U.S. DEP’T. OF HEALTH AND HUM. SERVS., 2 (Sept. 2004), <http://www.ahrq.gov/research/emspria/emspria.pdf>.

246. *Id.*

247. Carmen DeNavas-Walt et al., *Income, Poverty, and Health Insurance Coverage in the United States: 2007*, U.S. CENSUS BUREAU, 19 (Aug. 2008) <http://www.census.gov/prod/2008pubs/p60-235.pdf>.

248. Self-insured plans are not considered insurance products and are therefore beyond the reach of many state insurance regulations. *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 746-47 (1985).

avoiding reform at the state level.<sup>249</sup> Moreover, benefit denials are now almost always reviewed under the generous abuse-of-discretion standard, and the Supreme Court sees fewer and fewer circumstances in which this standard should be lowered to de novo review.<sup>250</sup>

Whether increased penalties for regulatory violations could be developed by the DOL or by Congress depends on the scope of reform. ERISA gives the DOL authority to “prescribe such regulations as . . . necessary or appropriate to carry out” the statutory provisions securing employee benefit rights.<sup>251</sup> Thus, targeted, additional regulations to strengthen claims processing could be viewed as securing existing ERISA terms and mandates. If regulatory reform were to broaden significantly the penalties for improper processing so as to change fundamentally the remedies available under ERISA, the regulations might be considered beyond the scope of the DOL’s authority such that congressional action would be needed to amend the underlying statute.<sup>252</sup>

The DOL regulations continue to evolve as a result of the PPACA.<sup>253</sup> As the regulations continue to be refined and strengthened, meaningful enforcement of claims processing procedures should be a priority. The incentives to underpay or deny claims still outweigh any consequence, even with the regulatory reforms resulting from the PPACA. Correct, prompt claims processing should not be left to chance or benevolence—direct, specific penalties should counterbalance the financial pressures on health insurance companies and ensure the provision of benefits as Congress intended.

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249. WOOTEN, *supra* note 11, at 284 (noting the “backlash” against ERISA’s lack of remedies and the increase in reform initiatives and noting that these reforms do not reach self-funded plans).

250. *Conkright*, 130 S. Ct. at 1650 (noting that the creation of ad hoc exceptions to deferential review would cause uniformity problems in plan interpretation).

251. 29 U.S.C. § 1135 (2006); *see also* § 1133 (plans shall process claims “[i]n accordance with regulations of the Secretary”).

252. *See Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843-44 (1984) (“If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute.”).

253. Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 43,330, 43,332 (July 23, 2010).

**Transgender Health at the Crossroads: Legal Norms,  
Insurance Markets, and the Threat of Healthcare Reform**

**Liza Khan**\*

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## INTRODUCTION

Few groups confront as many barriers to healthcare as transgender patients.<sup>1</sup> Transgender individuals are frequently denied access to health services because of their gender identity or expression, and many report experiencing verbal and even physical harassment in medical offices and hospitals.<sup>2</sup> Those who are able to locate care often find that they cannot actually access services, due to a lack of insurance or financial resources.<sup>3</sup> Even transgender patients with health insurance have difficulty obtaining care. This is particularly true if the care sought is for transition related purposes, since most policies exclude coverage for gender-confirming interventions and surgeries.<sup>4</sup> The transgender population's lack of access to care is all the more striking when considered alongside the group's elevated risk for a number of serious health problems. One study reports, for example, that forty-one percent of transgender individuals have attempted suicide at some point in their lives.<sup>5</sup>

This Note examines the current landscape of transgender healthcare and

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1. I use the terms "transgender," "gender variant," and "gender nonconforming" interchangeably to reference a wide range of people whose self-identity does not conform to the identity or norms usually associated with the sex they were assigned at birth. Some of these individuals may seek medical care to transition to a different sex while others do not. See A. Evan Eyler, *Primary Medical Care of the Gender-Variant Patient*, in PRINCIPLES OF TRANSGENDER MEDICINE AND SURGERY 15, 19-21 (Randi Ettner et al. eds., 2007) (discussing a range of health treatments sought by transgender patients). I use the term "transsexual" to refer to individuals who seek genital sex reassignment surgery only when the phrase is used in the literature being cited. Like Katharine Franke, I believe the term "transsexual" focuses too much on the alteration of genitalia and ignores the diversity of transgender individuals and their health needs. See Katherine M. Franke, *The Central Mistake of Sex Discrimination Law: The Disaggregation of Sex from Gender*, 144 U. PA. L. REV. 1, 32 n.130 (1995). Finally, I refer to the various procedures that alter a transgender patient's physical appearance to reflect the individual's gender identity as "transition-related," "transitional," or "gender-confirming" care.

2. JAIME M. GRANT ET AL., INJUSTICE AT EVERY TURN: A REPORT OF THE NATIONAL TRANSGENDER DISCRIMINATION SURVEY 73-74 (2011), available at <http://transequality.org/PDFs/>

NTDS\_Report.pdf (reporting that 19% of a national sample of transgender individuals had been refused care by a medical provider due to their transgender or gender non-conforming status; 28% of respondents experienced verbal harassment in a medical setting; 2% were physically attacked in a doctor's office).

3. Transgender individuals are "less likely than the general population to have health insurance, more likely to be covered by public programs such as Medicare or Medicaid, and less likely to be insured by an employer." *Id.* at 76.

4. *Id.* at 77.

5. *Id.* at 82. Transgender populations also experience extraordinarily high rates of physical violence, sexual assault, and HIV, as well as above average rates of drug and alcohol abuse. *Id.* at 80-81.

coverage and evaluates how the Patient Protection and Affordable Care Act (PPACA), the Obama Administration's landmark health insurance legislation, may change the state of transgender care.<sup>6</sup> Called "the most expansive social legislation enacted in decades,"<sup>7</sup> the PPACA extends health insurance to millions of previously uninsured Americans,<sup>8</sup> extensively modifies public insurance plans, and imposes new requirements on private insurance companies.<sup>9</sup> By eliminating pre-existing condition exclusions and mandating certain essential insurance benefits, the PPACA promises to expand access to care. But for transgender populations, the care promised may not be the care sought. Depending on how it is interpreted and applied, the legislation may secure new medical benefits for transgender individuals, or it may worsen the state of transgender healthcare altogether.

The PPACA's impact on transgender patients will hinge on administrative and legal interpretations of the legislation. Medicine and insurance play a part in determining sexual identities for transgender persons, but importantly, so does law. Legal institutions have traditionally understood sex as immutable, unambiguous, and fixed at birth.<sup>10</sup> The law assumes that sex is binary: an individual can be a man or a woman, but not both or neither.<sup>11</sup> Nevertheless, current medical discourse, along with a growing body of legal scholarship, suggests that for gender-variant populations, sex is not solely defined by biological factors, but is actually "a human-made process, often involving a legal process."<sup>12</sup> The state's role in determining and defining sex compels us to consider how benefits, particularly health benefits, are allocated to or withheld from transgender individuals.

This Note proceeds in three Parts. Part I explores the complicated relationship between transgender medicine and transgender law, which has

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6. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) [hereinafter PPACA].

7. Sheryl Gay Stolberg & Robert Pear, *A Stroke of a Pen, Make That 20, and It's Official*, N.Y. TIMES, Mar. 24, 2010, at A19.

8. See Letter from Douglas W. Elmendorf, Dir., Cong. Budget Office, to Nancy Pelosi, Speaker, U.S. House of Representatives tbl. 4 (Mar. 20, 2010), available at <http://www.cbo.gov/ftpdocs/113xx/doc11379/AmendReconProp.pdf>.

9. See, e.g., PPACA § 1001, 124 Stat. 130 (instituting individual and group market reforms); PPACA § 2001, 124 Stat. 271 (delineating Medicaid coverage for the lowest income populations).

10. An individual's legal sex is usually determined by the appearance of external genitalia at birth. Julie A. Greenberg, *The Roads Less Traveled: The Problem with Binary Sex Categories*, in TRANSGENDER RIGHTS 51, 52 (Paisley Currah et al. eds., 2006).

11. *Id.* at 63. Not everyone can be characterized accurately by self-identification or physical features. Intersex individuals, for instance, sometimes exhibit physical attributes of both sexes and could therefore be classified as neither male nor female or both male and female. See *id.* at 57-63.

12. Noa Ben-Asher, *The Necessity of Sex Change: A Struggle for Intersex and Transsex Liberties*, 29 HARV. J.L. & GENDER 51, 53 (2006).

produced the patchwork of inconsistent and disjointed policies that currently regulate sex and gender identity. Courts and legislatures have long relied on medical discourse to justify legal decisions affecting the lives of transgender people.<sup>13</sup> In using medical evidence to dictate the bounds of transgender rights, however, the law fails to adequately consider other aspects of sex that have little to do with anatomy. Developments in transgender law also tend to lag far behind developments in transgender health, suggesting that the gap between medicine and law may be just as concerning as the overlap.

Part II assesses how insurance providers have been able to capitalize on the confusion that results from medical and legal discourses about transgender people, and considers how they have contributed to that confusion themselves. Though courts have sometimes intervened to mandate coverage,<sup>14</sup> insurance coverage for gender-confirming treatments and procedures remains patchy at best. Advocates and legal scholars have produced an extensive body of literature calling for expanded coverage of trans-specific healthcare, but have failed to seriously examine the insurance implications of providing trans-inclusive healthcare.<sup>15</sup> From an insurer's perspective, transgender patients are a politically powerless group with certain medical costs rather than insurable risks. As a result, insurers view curbing coverage for transition-related care through exclusions for pre-existing conditions, experimental or cosmetic interventions, or medically unnecessary procedures as financially sensible and politically harmless. Such exclusions, however, rest on troubling assumptions about the transgender condition and trans-specific care that have gone largely unchallenged to date.<sup>16</sup>

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13. See, e.g., *M.T. v. J.T.*, 355 A.2d 204 (N.J. Super. Ct. App. Div. 1976) (reviewing medical history to determine whether a transgender woman was legally female and so validly married to a male); *Richards v. U.S. Tennis Ass'n*, 400 N.Y.S.2d 267 (1977) (assessing the medical procedures undertaken by tennis player Renee Richards to determine her legal gender).

14. See, e.g., *Pinneke v. Preisser*, 623 F.2d 546, 549 (8th Cir. 1980).

15. See, e.g., Ben-Asher, *supra* note 12; Kari E. Hong, *Categorical Exclusions: Exploring Legal Responses to Health Care Discrimination Against Transsexuals*, 11 COLUM. J. GENDER & L. 88 (2002); Susan Etta Keller, *Crisis of Authority: Medical Rhetoric and Transsexual Identity*, 11 YALE J.L. & FEMINISM 51 (1999); Jerry L. Dasti, Note, *Advocating a Broader Understanding of the Necessity of Sex Reassignment Surgery Under Medicaid*, 77 N.Y.U. L. REV. 1738 (2002).

16. For instance, actuaries have assumed that most individuals who identify as transgender would opt to receive sexual reassignment surgery if it were covered. See J. Denise Diskin, *Taking it to the Bank: Actualizing Health Care Equality for San Francisco's Transgender City and County Employees*, 5 HASTINGS RACE & POVERTY L.J. 129, 154 (2008). In actuality, many transgender patients avoid such surgery because of its risks, the long and painful recovery period, or simply because they do not view surgical interventions as necessary to transition to a different gender. Harper Jean Tobin, *Against the Surgical Requirement for Change of Legal Sex*, 3 CASE W. RES. J. INT'L L. 393, 399-401 (2007).

Part III analyzes how the new federal healthcare legislation could impact the future of transgender healthcare. Though the PPACA is designed to expand healthcare coverage, the reforms implemented through the legislation may actually constrict access to care for transgender patients. The PPACA's new restrictions against pre-existing condition exclusions, lifetime limits on coverage, and mandates requiring greater patient coverage will force insurers to rely on other techniques to control costs. One option that will remain available even after the PPACA's provisions go into full effect is medical-necessity review. This Note predicts that, as insurers are required to cover a growing number of patients without regard to their health status, insurers will likely designate an increasing number of procedures medically unnecessary. A blanket exclusion of transition-related care may emerge as insurers search for health interventions they can refuse to cover without incurring political backlash.

Still, interpreting the PPACA gives judges and policymakers a rare opportunity to redirect the current distribution of transgender health benefits. This Note concludes by suggesting that courts, legislators, and administrative actors should regulate medical-necessity review to include assessment of the legal and social implications of trans-specific medical interventions along with clinical need. Doing so may assure that the PPACA protects access to meaningful healthcare for transgender citizens as strongly as it secures healthcare for other Americans.

## I. MEDICALIZED IDENTITY

Transgender individuals can be described as having “gender identities, expressions, or behaviors” that are inconsistent with social norms associated with their natal sex.<sup>17</sup> Some individuals who identify as transgender demonstrate a desire to adopt a gender different from the one they were assigned at birth, while others rebel against binary gender classifications altogether by adopting features of both genders or completely rejecting gender identity.<sup>18</sup> Transgender people may seek medical treatment to transition to another gender, alter their outward appearance to conform to their chosen gender but refrain from medical procedures, or make no physical changes at all.<sup>19</sup>

Despite the fact that many transgender individuals do not desire transition-related care, legal recognition of transgender individuals remains, for the most part, contingent on evidence of medical transition. This Part examines the

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17. Carey V. Johnson et al., *Health Care Issues Among Lesbian, Gay, Bisexual, Transgender, and Intersex (LGBTI) Populations in the United States: Introduction*, 54 J. HOMOSEXUALITY 213, 216 (2008).

18. JASON CROMWELL, *TRANSMEN AND FTMS* 22-23 (1999); see also Guy Trebay, *Giving Voice to the Once-Silent*, N.Y. TIMES, Aug. 12, 2010, at E6.

19. Eyler, *supra* note 1, at 19-21.

relationship between medicine and law in transgender healthcare and assesses the benefits and problems of relying on a medical model for legal rights.

### *A. Transgender Healthcare*

Given the diversity of the transgender population, it is not surprising that healthcare needs and desires vary dramatically among transgender individuals. For some, sex reassignment surgery, hormonal therapy, and other medical and psychological interventions are necessary to fully actualize a chosen, or non-biological, gender identity.<sup>20</sup> Others elect to receive certain transition-related treatments, but forego others for different reasons: full transition may not be desired<sup>21</sup> or medically feasible,<sup>22</sup> financial and health insurance constraints may limit access to services,<sup>23</sup> or physicians willing to perform certain procedures may be difficult to locate.<sup>24</sup> Some transgender patients do not want transition-related services at all, but prefer to receive medical care from physicians who have worked with other gender-variant individuals and understand how to approach non-normative gender expression or behavior.<sup>25</sup> Doctors who have treated transgender patients may be more sensitive to special anxieties about physical exams or aware of environmental features, like unisex restrooms, that can make transgender individuals more comfortable regardless of the treatment they seek.<sup>26</sup>

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20. Medical and psychological discourses frequently refer to this subset of the transgender population as transsexuals, even though the most recent edition of the *Diagnostic and Statistical Manual of Mental Disorders (DSM-IV)* has replaced “transsexualism” as a clinical diagnosis with “gender identity disorder.” Despite the title change, the definition remains the same. Ben-Asher, *supra* note 12, at 51 n.1. As Jerry Dasti notes, “the term ‘transgender’ can (and does) encompass transsexuals; the term ‘transsexual’ does not necessarily encompass all transgender people.” Dasti, *supra* note 15, at 1739 n.2.

21. CROMWELL, *supra* note 18, at 22 (describing “transgenderists” as people who “neither want nor desire sex reassignment surgery” even though “they live the majority of their lives in a gender that opposes their biological sex”).

22. Medical technology, for instance, has advanced enough to allow surgeons to create fully functioning vaginas, but not penises. See Taylor Flynn, *The Ties That (Don't) Bind: Transgender Family Law and the Unmaking of Families*, in *TRANSGENDER RIGHTS* 32, 39 (Paisley Currah et al. eds., 2006).

23. Dasti, *supra* note 15, at 1767-68 (“The cost of sex-reassignment surgery is prohibitively high, placing it out of the reach of many transsexuals . . .”).

24. DEBORAH RUDACILLE, *THE RIDDLE OF GENDER* 220 (2005) (discussing barriers to adequate healthcare for LGBT patients, including poor physician access, lack of awareness in the medical community about the health concerns of LGBT patients, and the failure of curricula in most medical schools to address LGBT health issues).

25. Eyler, *supra* note 1, at 20.

26. HARVEY J. MAKADON ET AL., *THE FENWAY GUIDE TO LESBIAN, GAY, BISEXUAL AND*

Physicians with experience in trans-specific care, however, can be difficult to locate and transgender patients often encounter discrimination from doctors rather than understanding. Testimony from transgender individuals indicates that many healthcare professionals routinely refuse to treat even non-transition-related health issues.<sup>27</sup> Robert Eads, for example, a female-to-male transperson with ovarian cancer, visited more than twenty physicians who all refused to treat him because they feared that taking on a transgender patient would harm their practices.<sup>28</sup> Those who are able to access care may find that their insurance plan will not cover treatment for certain illnesses, even if they do not stem from transition. A female-to-male transperson interviewed in 2001, for instance, reported being denied coverage for uterine cancer by his insurance company because the insurer did not “treat uterus in men.”<sup>29</sup> Common health problems that receive routine treatment in other contexts may not receive adequate attention when the patient is transgendered.<sup>30</sup>

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TRANSGENDER HEALTH 354 (2007) (“Many transgender patients are extremely sensitive about having their bodies looked at, touched, and prodded. It is common for transgender men to refuse breast and pelvic exams, and for transgender women to refuse testicular and prostate exams. . . . [T]aking the time to establish a solid alliance with the patient over a series of visits is often required before a patient will permit these exams.”).

27. Grant, *supra* note 2, at 76. The National Center for Transgender Equality reports that nineteen percent of transgender individuals have been refused care due to their transgender or gender-nonconforming status. *Id.* at 72.

28. SOUTHERN COMFORT (Kate Davis, director and producer, 2001). Eads finally received treatment at the Medical College of Georgia in the last year of his life. But by this point he was diagnosed with stage III or IV cancer, which rendered his surgery and radiation treatments unlikely to be a curative. See Caitlin Rockett, “Southern Comfort” *More Than Art, More Than Culture*, TENN. JOURNALIST (Nov. 29, 2007), <http://tnjn.com/2007/nov/29/southern-comfort-more-than-art>. Though the earlier physicians Eads visited clearly denied him care because he was transgender, refusing to treat a transgender patient for ovarian cancer is not necessarily always motivated by prejudice. Ovarian cancer in its later stages usually has a very poor prognosis, and some doctors may reasonably view treatment at this point as futile or beyond the scope of their knowledge. CAROL L. KOSARY, NAT’L CANCER INST., SEER PROGRAM, SEER SURVIVAL MONOGRAPH: CANCER SURVIVAL AMONG ADULTS: U.S. SEER PROGRAM, 1988-2001, PATIENT AND TUMOR CHARACTERISTICS 137 (L.A.G. Ries et al. eds., 2007), available at [http://seer.cancer.gov/publications/survival/surv\\_ovary.pdf](http://seer.cancer.gov/publications/survival/surv_ovary.pdf); see also Tom Tomlinson et al., *Futile Care in Oncology*, 2 LANCET ONCOLOGY 759, 763 (2001); Antoni Viganó et al., *Clinical Survival Predictions in Patients with Advanced Cancer*, 160 ARCHIVES INTERNAL MED. 861, 861-62 (2000).

29. Jody Marksamer & Dylan Vade, *Recommendations for Transgender Health Care*, TRANSGENDER LAW CENTER, <http://www.transgenderlaw.org/resources/tlchealth.htm> (last visited Apr. 13, 2011).

30. While discrimination from healthcare providers is a major barrier to meeting the health needs of gender-variant populations, inadequate training and research about gender-variant healthcare is also an issue. In medicine, research is critical to setting guidelines and standards of care. But as one commentator remarks, “research on LGBT issues typically begins and ends with

*B. Transgender Law and Medicine: Intersection or Disconnect?*

For transgender populations, legal recognition is usually closely tied to medical treatment. Medical and surgical practices often drive the legal construction—and reconstruction—of sex. In most states, the sex designation on documents like birth certificates, driver's licenses, and social security cards cannot be changed without at least some evidence of gender-related medical treatment.<sup>31</sup> Medical evidence is also discussed, often at length, in legal cases involving transgender persons. For instance, in assessing the validity of a marriage between a male-to-female transsexual and her husband, a New Jersey trial court reviewed the facts of the wife's sex reassignment surgery in great detail.<sup>32</sup> The court's opinion upholding the legality of the union included testimony from the woman's doctor who stated that her vagina had a "good cosmetic appearance" and was "the same as a normal female vagina after a hysterectomy."<sup>33</sup> Similarly, in *Kantaras v. Kantaras*, a custody battle between a transman and his ex-wife turned on medical evidence describing Mr. Kantaras' genitalia and testimony about the couple's sex life.<sup>34</sup> Mrs. Kantaras asked the Florida Circuit Court to invalidate her marriage to Mr. Kantaras, and thus terminate his custody rights, on the grounds that Mr. Kantaras was legally female, making their marriage legally untenable under Florida law. To determine Michael Kantaras' legal gender during the union, the court heard extensive testimony describing the transition-related interventions Mr. Kantaras had undergone and his capacity to "consummate" the marriage given his decision not to undergo phalloplasty.<sup>35</sup> As these cases demonstrate, routine legal rights for

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AIDS research." RUDACILLE, *supra* note 24, at 220.

31. Policies permitting gender reclassification on identity documents vary widely, depending on the jurisdiction and type of document in question. In California, for instance, changing the sex listed on a birth certificate requires a letter from a physician confirming that an individual has had at least one of a number of specified gender-related surgeries. Meanwhile, to amend a driver license to reflect a sex change, the New York Department of Motor Vehicles requires a statement from a physician, psychologist or psychiatrist stating that one gender predominates over the other and that the licensee in question is either a male or female. A few states will not alter birth-assigned gender on certain government issued documents under any circumstances. Idaho, Ohio, and Tennessee, for example, will not amend the gender markers on a birth certificate even if an individual has undergone genital surgery. Dean Spade, *Documenting Gender*, 59 HASTINGS L.J. 731, 733, 735-36 (2008).

32. *M.T. v. J.T.*, 355 A.2d 204 (N.J. Super. Ct. App. Div. 1976).

33. *Id.* at 206.

34. *Kantaras v. Kantaras*, 884 So. 2d 155 (Fla. Dist. Ct. App. 2004).

35. RUDACILLE, *supra* note 24, at 218 (discussing testimony in *Kantaras* case). Despite the lengthy medical evidence presented, the court denied the validity of the Kantaras' marriage by reading the Florida marriage statutes to permit marriage only between individuals of opposite birth

others can “hinge upon surgical status or medical evidence” when a person is transgender.<sup>36</sup>

Many transgender advocates condemn the fact that legal protections for transpeople usually require medical confirmation of transition. When legal rights are tied to medical procedures, transgender individuals who have no desire to alter their biological sex often remain invisible under the law.<sup>37</sup> Such invisibility can, and often does, have dire consequences. For instance, a transperson who is unable to amend the sex listed on basic identification documents because evidence of genital surgery is required risks “being ‘outed’ in the job application process.”<sup>38</sup> Since few jurisdictions prohibit employment discrimination based on gender identity, possessing identification that reflects current gender status can be critical to economic security.<sup>39</sup>

Even those who do medically transition may find that their bodies still do not meet the standards necessary to adopt a different legal sex. The gender marker on a birth certificate, for instance, can usually only be changed with evidence of specific surgical interventions. New York City’s Department of Vital Records will amend the sex listed on a birth certificate only if an individual can demonstrate that he or she has received vaginoplasty or phalloplasty.<sup>40</sup> This policy not only excludes transpeople who have undergone other, more common transitional procedures,<sup>41</sup> but also fails to consider the limits of current medical technology. Doctors often discourage individuals who are transitioning from female to male from pursuing phalloplasty because the surgery “presents significant risks, including permanent loss of orgasmic capability, severe scarring, and irreversible damage to the urethra.”<sup>42</sup> Since fully functional vaginas

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sex. The *Kantaras* court recognized that medical science has a central role in determining the marriage rights of “postoperative transsexuals,” but found that the appropriate place to weigh such medical evidence was in the legislature, not the courtroom. *Kantaras*, 884 So. 2d at 161.

36. Dean Spade, *Resisting Medicine, Remodeling Gender*, 18 BERKELEY WOMEN’S L.J. 15, 30 (2003).

37. There are many reasons why transpeople may reject medical interventions that change their bodies. Some are comfortable with their anatomy and have no desire to surgically alter their sexual features. Others believe that surgical transition stems from social norms regarding gender binaries that ought to be resisted. Finally, some do not believe that the current state of medical technology can create the physical characteristics they desire. CROMWELL, *supra* note 18, at 21-30.

38. Spade, *supra* note 31, at 752.

39. *Id.*

40. 24 RCNY § 207.05(a)(5) (2006).

41. Three out of four transgender individuals surveyed in San Francisco reported using hormone therapy to facilitate their transition, but only fifteen percent indicated that they had undergone any sort of sex reassignment surgery. SHANNON MINTER & CHRISTOPHER DALEY, *TRANS REALITIES: A LEGAL NEEDS ASSESSMENT OF SAN FRANCISCO’S TRANSGENDER COMMUNITIES* app. B (2003).

42. Flynn, *supra* note 22, at 39.

can be constructed without similar problems, gender reclassification policies that turn on the presence of the “right” genitalia “result[] in far more trans women receiving legal recognition of their identified sex than trans men.”<sup>43</sup>

Medicine clearly shapes the legal rights available to transgender individuals, but legal assumptions about sex can influence medical protocol for transgender patients too. The law’s understanding of sex is almost always strictly binary: legally, one must be either male or female.<sup>44</sup> Until fairly recently, most medical providers who treated gender-variant individuals also subscribed to this binary conception of sex, despite a significant body of biological evidence suggesting that sex appears in more than just two forms.<sup>45</sup> Medical literature, for instance, has long documented the presence of intersex infants who are born with ambiguous or noncongruent sex characteristics.<sup>46</sup> Surgical intervention to “correct” the genitalia of these children continues to be routine in many places.<sup>47</sup> These surgeries are driven by a desire to “enhance health and well-being [of intersex children] to the greatest extent possible.”<sup>48</sup> Since legal identity recognizes only two sexes, not pursuing a normalizing genital surgery early in an intersex child’s life is often viewed as medically irresponsible.<sup>49</sup> It is only after this “normalizing” procedure is performed that “the sex that matches the surgically created genitalia is . . . assigned on the birth record.”<sup>50</sup>

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43. *Id.*

44. Julie A. Greenberg, *Defining Male and Female: Intersexuality and the Collision Between Law and Biology*, 41 ARIZ. L. REV. 265, 266-67 (1999). Though an individual’s designation as male or female can have important consequences on marriage rights, legal identification, and ability to claim protection under employment discrimination statutes, legal definitions of sex are extremely rare. *Id.* at 269-70. New York City used to have an odd exception to the standard binary classification of legal sex. Until 2006, local law in New York City allowed transgender individuals who had undergone sexual conversion surgery to obtain new birth certificates, but the new certificates had no gender marker. 24 RCNY § 207.05(a)(5) (2005).

45. See, e.g., Melanie Blackless et. al., *How Sexually Dimorphic Are We?*, 12 AM. J. HUM. BIOLOGY 151, 161 (2000) (reporting that roughly 1.7% of all infants have intersex characteristics that are chromosomal, anatomical, or hormonal in nature).

46. See, e.g., Keith M. Schneider et al., *Surgical Management of Intersexuality in Infancy and Childhood*, 2 ANNALS SURGERY 255, 255 (1968).

47. Ben-Asher, *supra* note 12, at 60-62.

48. RUDACILLE, *supra* note 24, at 109.

49. Dasti, *supra* note 16, at 1746.

50. Greenberg, *supra* note 10, at 53. Greenberg convincingly argues that socially derived norms may drive the characterization of sex just as much as biology. She writes:

If the genitalia [of an infant] appear[s] ambiguous, sex is assigned, in part, based on sex-role stereotypes. The presence of an “adequate” penis in an XY infant leads to the label *male*, while the absence of an “adequate” penis leads to the label *female*. A genetic (XY) male with an “inadequate” penis (one that

Conditions that must be met in order to legally transition to another gender may impact treatment choices. If a state requires evidence of a specific surgical intervention before permitting a transperson to change the gender marker listed on a birth certificate, it is possible that the individual will elect to undergo the procedure even if it is not otherwise desired or needed.<sup>51</sup> Legal reasons for pursuing treatment may also influence a physician's protocol when treating transgender patients.<sup>52</sup> The *Diagnostic and Statistical Manual of Mental Disorders IV* requires individuals to demonstrate "strong and persistent cross-gender identification" before they can be diagnosed with gender identity disorder.<sup>53</sup> Legal norms may have informed this requirement; since the law only offers two gender choices, male or female, it might be considered medically irresponsible to support transition-related care that leaves an individual sexually ambiguous.

Legal issues can also directly affect the type of treatment physicians provide to transgender individuals. Mayhem statutes that forbid "the amputation of any body part . . . that might prevent a male-bodied individual from being able to serve as a soldier," for example, have been active in almost every jurisdiction in the United States for centuries.<sup>54</sup> While it is unclear how castration would impact military service, few doctors were willing to test the limits of the laws to perform transition related surgeries until the 1960s. In fact, during the 1950s and early 1960s, the "mayhem statut[e] w[as] the single greatest obstacle faced by every transsexual person in America unable to travel overseas for [gender reassignment] surgery or locate one of the few surgeons willing to flout the law

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physicians believe will be incapable of penetrating a female's vagina when the child reaches adulthood) is "turned into" a female even it means destroying his reproductive capacity. A genetic (XX) female who may be capable of reproducing, however, is generally assigned the female sex to preserve her reproductive capability, regardless of the appearance of her external genitalia. If her phallus is considered to be too large to meet the guidelines for a typical clitoris, it is surgically reduced, even if it means that her capacity for satisfactory sex may be reduced or destroyed. In other words, men are defined based on their ability to penetrate females, and females are defined based on their ability to procreate.

*Id.* at 52.

51. Admittedly, there are no existing data that support this claim. Surveys on transgender healthcare usually do not ask about the legal motivations behind decisions to pursue transition related care. Many surveys, articles, and books do, however, discuss the importance of legal identification reflecting an adopted gender to a transgender individual's economic and physical welfare. *See, e.g.,* Spade, *supra* note 31.

52. RUDACILLE, *supra* note 24, at 116.

53. AM. PSYCHIATRIC ASS'N, *DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS* (4th ed. 1994) [hereinafter *DSM-IV*].

54. RUDACILLE, *supra* note 24, at 116.

by performing [the] surgery.”<sup>55</sup>

While medicine appears sensitive to legal issues that affect transgender individuals, evidence suggests that the law lags behind medical developments in transgender health. Many medical professionals now recognize that sex determination does not rest on the appearance of genitalia alone and binary sex categories do not encompass the full variety of sexual identities. A host of factors inform an individual’s sex, including genetic or chromosomal characteristics, gonadal appearance, internal reproductive morphology, external morphologic sex, genital appearance, hormonal levels, phenotypic characteristics or secondary sex features, assigned sex or gender of rearing, and self-identified sex.<sup>56</sup> Incongruence or ambiguity among these factors occasionally occurs, and a growing body of medical literature suggests that this variation should not necessarily be corrected or ignored.<sup>57</sup> Healthcare providers who work with gender-variant populations are also increasingly likely to consider self-identity when making treatment suggestions.<sup>58</sup> Medical communities are slowly moving beyond a strictly physical and binary understanding of sex, yet the law remains committed to the idea that sexual categories are exclusive, fixed, and based on genitalia alone.

### *C. Negotiating the Medical Construction of Gender: A Transgender Debate*

Despite the medical community’s growing understanding of the diversity in gender-variant populations, transgender individuals intensely debate whether medical conclusions about sex and gender should be accepted at all. Many transgender advocates resist the medicalization of gender variance, arguing that the description of transgender people in medical terms leads to an understanding of non-normative gender identity as diseased or disordered.<sup>59</sup> Medical definitions of transgender identity found in manuals like the *Diagnostic and Statistical Manual of Mental Disorders* imply that transgender identity is a mental disorder

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55. *Id.*

56. Greenberg, *supra* note 10, at 54.

57. See, e.g., Bruce E. Wilson & William G. Reiner, *Management of Intersex: A Shifting Paradigm*, 9 J. CLINICAL ETHICS 360, 364 (1998) (“[T]he right of the individual to determine what happens to his or her body has been increasingly asserted.”); Joel Frader et al., *Health Care Professionals and Intersex Conditions*, 158 ARCHIVES PEDIATRICS & ADOLESCENT MED. 426, 427 (2004) (“Children have the right to know about their bodies. Professionals and parents should tell children . . . how and why they have anatomical differences from others. The differences should provide opportunities to explore the value of individuality and diversity, not occasions for humiliation and shaming.”).

58. Greenberg, *supra* note 10, at 68.

59. See, e.g., Ben-Asher, *supra* note 12, at 58 n.23; Dasti, *supra* note 15, at 1738.

requiring medical treatment.<sup>60</sup> Gender-variant individuals may be unable to secure health benefits unless they are willing to present themselves as diseased or disordered within the narrow confines of this diagnosis.<sup>61</sup>

Others within the transgender community frequently argue that, at least for instrumental purposes, a medical definition of the transgender “condition” is necessary. Without a diagnosis of gender identity disorder, individuals seeking surgical interventions or hormonal treatments to transition would probably be unable to access insurance benefits to pay for the procedures. As one scholar notes, “in the United States . . . it won’t be an option to have the state or insurance companies pay for the procedures without first establishing that there are serious and enduring medical and psychiatric reasons for doing so.”<sup>62</sup> Furthermore, since legal status for transgender people usually depends on medical evidence,<sup>63</sup> depathologizing gender variance risks eliminating legal rights.

The next Section of this Note analyzes what happens when insurers enter this medicalized identity debate. Insurance providers have largely replaced physicians as the key gatekeepers to transition-related interventions, particularly for low- and moderate-income transgender people who cannot pay for gender-confirming care out of pocket. Coverage practices regarding transitional procedures may therefore have a meaningful impact on the movement to depathologize gender variance.

## II. GENDER CONFUSION IN INSURANCE MARKETS

Despite the complex health needs of gender-variant individuals,<sup>64</sup> many lack health insurance or other resources to pay for those needs.<sup>65</sup> Even individuals who have insurance find that most providers refuse to cover transition-related

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60. DSM-IV, *supra* note 53, at 532-38.

61. Benedict Carey, *Psychiatry’s Struggle To Revise the Book of Human Troubles*, N.Y. TIMES, Dec. 18, 2008, at A1.

62. Judith Butler, *Undiagnosing Gender*, in TRANSGENDER RIGHTS 274, 287 (Paisley Currah et al. eds., 2006).

63. See *supra* notes 31-39 and accompanying text.

64. RUDACILLE, *supra* note 24, at 219 (“[Transgender people] have the highest suicide rate for any demographic group, a very high incidence of depression and other mental health problems, and a very high incidence of substance abuse. They have unique medical needs associated with hormonal therapy (breast cancer in genetic males, for example), sexual reassignment surgery and misdiagnosis for ailments (like ovarian cancer in female to male transsexuals).”).

65. A recent national survey of transgender and gender non-conforming individuals found that 19% of the 6450 survey participants lacked any type of health insurance. Grant, *supra* note 2, at 2, 76. An additional 19% of the sample was enrolled in public insurance plans, *id.* at 77, which often do not provide coverage for transition-related care. See *infra* note 146.

care.<sup>66</sup> Some insurers also deny coverage to transgender patients for medical issues unrelated to transition.<sup>67</sup>

This Part evaluates why transgender individuals are regularly denied coverage for the care they seek and assesses the insurance risks that transgender patients may pose to insurers and insurance pools alike. From an insurer's perspective, transgender individuals do not have an insurable interest; rather, they are seeking coverage for a condition they already have that is commonly understood as expensive to treat. Gender variance, moreover, does not provoke the popular sympathy and support that more common health conditions incite. As a result, insurers can classify transition-related care as "medically unnecessary" without much fear of public or political backlash.

Yet transition-related care is not only medically appropriate for many individuals diagnosed with gender dysphoria, it is also, in certain cases, absolutely critical.<sup>68</sup> Gender plays a significant, though often overlooked, role in our daily lives, and an inability to fully assume a certain gender can have dire consequences for an individual's mental health, personal safety, and employment opportunities. Misperceptions of gender variance and transition-related interventions also lead to inaccurate conclusions about the kinds of treatments sought by transgender patients and, as a consequence, the costs associated with treating transgender patients. Transgender patients are not a monolithic group of individuals who are all seeking sex reassignment surgery; many desire, and are effectively treated with, far less invasive and expensive interventions. In many ways, transgender individuals are not quite the insurance risks that many insurers make them out to be.

#### *A. Is Gender Variance an Insurable Interest?*

Insurance providers have traditionally protected consumers only from the

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66. See, e.g., *Removing Barriers to Care for Transgender Patients: AMA Resolution Supporting Health Insurance Coverage for Treatment of GID*, GAY & LESBIAN ADVOCATES & DEFENDERS, 2 (2008), <http://www.glad.org/uploads/docs/publications/ama-resolution-fact-sheet.pdf> (reporting that almost all insurance plans categorically exclude coverage for GID-related medical treatment, through either specific exclusions or by finding GID-related treatments to be cosmetic).

67. Some insurers use transgender status, or even the possibility of transgender status, to avoid covering health problems that are unrelated to gender transition. For example, a lesbian in San Francisco who had breast cancer in one breast decided, in consultation with her physician, to remove both of her breasts in order to lessen the chances of a recurrence. Her insurance company covered the first mastectomy, but "worried that the second breast was 'elective surgery' and that, if they paid for that, it would be setting a precedent for covering elective transsexual surgery." Butler, *supra* note 62, at 283; see also *supra* text accompanying note 29-30.

68. Hong, *supra* note 15, at 92 ("[F]or many who do [desire surgical alignment], denial of medical surgery can lead to depression and even trigger suicidal tendencies.").

risk of uncertain loss.<sup>69</sup> Health insurance, in the strict sense, funds medical care only in the event of an unpredictable illness;<sup>70</sup> an already existing condition is not an insurable risk, but a health problem that must be treated with accumulated savings.<sup>71</sup> Under this framework of health insurance, gender variance will almost never be considered an insurable risk. Gender variance is not an illness that strikes suddenly, but rather a condition that patients are often aware of long before they enroll in an insurance plan.<sup>72</sup> Insurance plans that offer coverage for transition-related care are thus expected to attract transgender patients who enroll just to take advantage of such care, rather than individuals who would like to protect against the occurrence of gender variance. The moral hazard problem predicts that including coverage for transitional interventions in health benefit packages will also encourage gender-variant insureds to consume more of these interventions than they would if insurance providers were not paying for the procedures.

It is not difficult to see why health insurers operating in an unregulated, competitive market would be inclined to exclude transition-related care from their list of covered benefits. Health insurance providers, however, no longer operate in an unregulated climate. It is not an overstatement to classify health insurance today as “a separate species of insurance – distinct in function, and therefore content, from conventional indemnity insurance models.”<sup>73</sup> Federal and state insurance regulations limit, and sometimes even prohibit, health insurers from using many of the risk classification tools routinely employed in other insurance markets.<sup>74</sup> Also, unlike other types of insurers, few health insurance

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69. George L. Priest, *Insurance Crisis and Modern Tort Law*, 96 YALE L.J. 1521, 1539 (1987).

70. Kenneth T. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 963 (1963) (“Among people who already have chronic illness . . . insurance in the strict sense is probably pointless.”).

71. Priest, *supra* note 69, at 1539.

72. Many transgender individuals are reportedly conscious of their gender variance from a young age. In recent years, as popular awareness of gender variance has increased, there has been a tremendous growth in the number of transgender children treated by clinics specializing in gender-identity disorders for youth. See Hanna Rosin, *A Boy’s Life*, ATLANTIC, Nov. 2008, at 56, 58. “Children like Brandon are being used to paint a more conventional picture; before they have much time to be shaped by experience, before they know their sexual orientation, even in defiance of their bodies, children can know their gender.” *Id.* at 62. This is, however, not true for everyone and many individuals only become aware of their transgender status later in life. Some trans-activists, like Dean Spade, argue that the childhood narrative of gender variance forces acceptance of “some theory of innate sexuality and forecloses the possibility that anyone, gender troubled childhood or not, could transgress sexual and gender norms at any time.” Spade, *supra* note 36, at 20.

73. Wendy K. Mariner, *Health Reform: What’s Insurance Got To Do with It? Recognizing Health Insurance as a Separate Species of Insurance*, 36 AM. J.L. & MED. 436, 438 (2010).

74. Some state laws, for instance, “prohibit or limit risk rating on the basis of gender, at least in group [health] policies.” *Id.* at 441-42. Gender rating is permitted and common, however, in

providers focus exclusively on underwriting risks. In addition to providing coverage for unanticipated health problems, health insurers regularly offer preventative and routine health services to all enrolled members. The inclusion of health services in these insurance policies is a “striking departure from insurance jurisprudence, which has prized the risk spreading function of insurance above all other possible purposes.”<sup>75</sup>

Health insurance plans, whether public or private, have evolved from functioning primarily as risk spreading devices to operating mainly as cost spreading vehicles. The principal purpose of health insurance is no longer to underwrite health risks, but to finance healthcare.<sup>76</sup> Under this model, the insurability of a health condition depends not just on whether the condition is the result of an unpredictable illness, but also on whether treating the condition serves a socially beneficial purpose important enough to mandate insurance coverage of the treatment.<sup>77</sup> Gender variance may nonetheless be eligible for coverage under plans that condition coverage on whether a treatment is beneficial, rather than on whether there is a risk for illness.

Even under a social welfare conception of health insurance, healthcare programs still “determine what kind of care should be available to all: what to pay for; how to price it; what sources of revenue to use; what limits to put on which services; and how to encourage the most appropriate care.”<sup>78</sup> The next two sections explore how insurers have made such decisions with respect to gender-confirming care.

### *B. Approaches to Excluding Gender-Confirming Care*

This section examines the reasons insurers most frequently give for denying coverage of transitional procedures. Insurers, disciplined by competition and

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other types of insurance, including auto insurance and life insurance. George Lauer, *Gender Rating in Health Insurance Under Review in California*, CAL. HEALTHLINE (Feb. 23, 2009), <http://www.californiahealthline.org/features/2009/gender-rating-in-health-insurance-under-review-in-california.aspx>.

75. Mariner, *supra* note 73, at 444.

76. *Id.* at 441.

77. A growing number of federal and state laws require insurers to pay for care that was routinely excluded by insurers in the past. Even interventions that are perhaps more cosmetic than medical in nature, like the removal of port-wine stains, are sometimes mandated, in recognition of the fact that such treatment can be socially, if not medically, necessary. See Victoria Craig Bunce & J.P. Wieske, *Health Insurance Mandates in the States 2010*, COUNCIL FOR AFFORDABLE HEALTH INS., 12 (2010), [www.cahi.org/cahi\\_contents/resources/pdf/MandatesintheStates2010.pdf](http://www.cahi.org/cahi_contents/resources/pdf/MandatesintheStates2010.pdf) (reporting insurance mandates for port-wine stain elimination in a number of states, including Arkansas, Arizona, California, Colorado, and Connecticut).

78. Mariner, *supra* note 73, at 449.

driven by self-preservation, have long tried to curb costs by barring coverage of pre-existing conditions, cosmetic, or experimental procedures, as well as medically unnecessary interventions.<sup>79</sup> Insurance organizations have restricted coverage of transition-related treatments on all three of these grounds at one point or another.

### *1. Denials for Pre-existing Conditions*

Insurers have sometimes excluded gender-confirming care from healthcare plans by classifying gender variance as a pre-existing condition. A pre-existing condition is generally defined as a health-related problem that exists prior to enrolling in a health insurance plan.<sup>80</sup> A pre-existing condition is no longer a health risk to be insured against, but a definite occurrence that may or may not require treatment. Insurance firms have historically dealt with pre-existing conditions through a number of different strategies. Some companies limit coverage of the pre-existing condition for a specific period of time; insurance benefits will usually cover treatments for new illnesses that appear during this period, but not any care or services related to the pre-existing condition.<sup>81</sup> Other insurance providers increase an individual's premiums to reflect the medical interventions that the individual will likely access to treat the pre-existing condition once insured.<sup>82</sup> Finally, some insurers have used certain pre-existing conditions as grounds for exclusion, either from any kind of health insurance coverage or from coverage of the specific condition for the lifetime of the policy.<sup>83</sup>

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79. See David M. Cutler, *A Guide to Health Care Reform*, 8 J. ECON. PERSPECTIVES 13, 18 (1994) (noting “many insurers exclude preexisting conditions from coverage” due to fear of adverse selection or moral hazard); Mark A. Hall & Gerard F. Anderson, *Health Insurers’ Assessment of Medical Necessity*, 140 U. PA. L. REV. 1637, 1640-41 (1991-1992) (discussing the “long series of ordinary contract disputes over the interpretation of terms such as ‘medical necessity’ or ‘experimental’ which determine the coverage of health insurance policies”); James P. Jacobson, *To Pay or Not To Pay, That is the Question: Coverage Disputes Between Health Plans and Members*, 29 HAMLINE J. PUB. L. & POL’Y 445, 448-49 (2007) (discussing exclusions for cosmetic and experimental treatments).

80. Christina M. Finello, *Issues in the Third Circuit: One Word Can Make All the Difference: An Examination of the Third Circuit’s Handling of Health Care Insurance Policy Exclusion Clauses for Pre-Existing Conditions*, 48 VILL. L. REV. 1355, 1356-57 (2003).

81. Paul Cotton, *Preexisting Conditions ‘Hold Americans Hostage’ to Employers and Insurance*, 265 JAMA 2451 (1991) (finding that it is not unusual for an insurer to impose “waiting periods for coverage of preexisting conditions”).

82. Robert Pear, *Insurers Offer to Soften a Key Rate-Setting Policy*, N.Y. TIMES, Mar. 25, 2009, at B1 (“Insurance policies [are priced], in part, on the basis of a person’s medical condition or history.”).

83. Theresa Williams, “Going Bare”: *Insurance and the Pre-Existing Condition Problem*, 15

Insurers have often relied on pre-existing condition exclusions to deter consumption of transition-related services.<sup>84</sup> From an insurer's perspective, providing coverage for transition-related interventions invites adverse selection of certain risks. A policy that offers transitional care does not further the interests of insurance firms if only those individuals who are certain to take advantage of transition-related treatments enroll. While it may be tempting to conclude that pre-existing condition exclusions for transgender individuals are warranted in this context, the argument is problematic. Providing coverage for transition-related treatments does not mean that only individuals who are certain to take advantage of those interventions will enroll. The transgender community is quite diverse and the type of medical care sought varies from person to person.<sup>85</sup> A trans-person may be more apt to enroll in an insurance policy that provides coverage for gender-confirming care, but it does not follow that the individual will necessarily elect to have a procedure like sexual reassignment surgery. Transgender identity is unlike many other health conditions in that a diagnosis of gender variance does not automatically require a specific medical intervention.

Pre-existing condition exclusions that target transgender individuals also ignore the critical role that physicians play as gatekeepers to medical services sought by transgender patients. A transgender individual cannot access hormone therapy or sex reassignment surgery just because a health insurance policy covers these interventions; a doctor or surgeon has to approve the desired medical service. The "professional relationship between [the] physician and patient limits the normal hazard in various forms of medical insurance. By certifying to the necessity of [a] given treatment or the lack thereof, the physician acts as a controlling agent on behalf of the insurance companies."<sup>86</sup> If incentivized, physicians may exercise sufficient third-party control over gender-confirming care to alleviate concerns about overconsumption of transition-related interventions.

Pre-existing condition exclusions impede the ability of transgender insureds to access gender-confirming care, but more disturbingly, such exclusions appear to license insurance firms to deny coverage to transgender individuals for other types of care as well. Though exclusions for trans-specific care should not preclude access to insurance coverage for other healthcare services, "some insurance companies maintain a broad definition of 'transition-related' [issues]

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J.L. & COM. 375, 375 (1995).

84. Diskin, *supra* note 16, at 136-37. Interestingly, such "exclusions . . . do not forbid coverage of procedures used in medical transition when they are being performed on non-transgender people." *Id.* at 137.

85. *See supra* Section I.A.

86. Arrow, *supra* note 70, at 961.

and create false connections between illness and transition.”<sup>87</sup> One insurance company stopped paying for a transgender patient’s therapy sessions after discovering through her therapist’s case notes that she had undergone sex reassignment surgery.<sup>88</sup> Another insurer denied a transsexual patient coverage for blood tests, physical exams, sinus medication, an emergency room visit for a cut on the hand, and treatment for kidney cysts because of her transgender “condition.”<sup>89</sup> Gender status thus may not only bar transgender people from accessing health insurance for transition-related care, it can sometimes keep them from accessing health insurance for any kind of care at all.

## 2. Exclusions for Cosmetic and Experimental Procedures

When not excluded as part of a pre-existing condition, insurers traditionally have framed gender-confirming care as either cosmetic or experimental, and hence, not insurable.<sup>90</sup> From the insurance industry’s perspective, a line must be drawn limiting the number of unessential procedures covered to control healthcare costs. Cosmetic procedures, generally considered optional or elective in nature,<sup>91</sup> and experimental interventions, usually believed to have questionable medical value,<sup>92</sup> typically fall outside this line. Some insurers explicitly restrict coverage for transition-related treatments on the grounds that they are cosmetic or experimental.<sup>93</sup> Others simply rely on contract interpretation to reject claims for gender-confirming care under these categories.<sup>94</sup>

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87. Diskin, *supra* note 16, at 137.

88. The insurer refused to pay for the patient’s therapy even though she was receiving treatment for depression and the company had been paying for her psychological care for ten years. Hong, *supra* note 15, at 97 n.42.

89. *Id.* at 97-98.

90. See, e.g., Ben-Asher, *supra* note 12, at 58 (describing attempts by state Medicaid administrations to deny coverage for sex reassignment surgeries by classifying them as “cosmetic” or “experimental”).

91. See Cristine Nardi, Comment, *When Health Insurers Deny Coverage for Breast Reconstructive Surgery: Gender Meets Disability*, 1997 WIS. L. REV. 777, 784 (defining cosmetic procedure as a procedure intended to enhance a normal structure).

92. Hall & Anderson, *supra* note 79, at 1638 (“The ‘experimental’ exclusion common in health insurance policies responds to a growing concern that most current medical procedures were adopted without ever having been tested rigorously and that at least some of the procedures commonly used today have limited or no medical value.”).

93. See HUMAN RIGHTS CAMPAIGN, Health Insurance Discrimination for Transgender People (2011), available at <http://www.hrc.org/issues/transgender/9568.htm>, for examples of transgender insurance exclusions.

94. See, e.g., Davidson v. Aetna Life & Cas. Ins. Co., 420 N.Y.S.2d 450, 451 (Sup. Ct. 1979). The insurance company in this case did not have an express clause in its policy prohibiting coverage for transition-related interventions but it did have a section denying coverage for cosmetic procedures. When a transgender insured tried to obtain coverage for sexual reassignment surgery

The small body of case law dealing with coverage disputes over gender-confirming care indicates that transgender litigants have had varied success in persuading courts that transitional interventions should not be dismissed as cosmetic or experimental. Private insurance claims for hormone therapy and sex reassignment surgery are generally upheld only when there are no explicit exclusions in the insurance contract denying coverage for transition-related treatments.<sup>95</sup> In *Davidson v. Aetna Life & Casualty Insurance Co.*, a transgender plaintiff filed suit against her insurance company for refusing to bear the medical expenses of the sex reassignment surgery recommended by her physician. The insurer argued that because “there is nothing physically wrong with a transsexual’s body,”<sup>96</sup> the plaintiff’s sexual reassignment surgery was “cosmetic in nature” and thus “not necessary and unreasonable.”<sup>97</sup> The court found that sexual reassignment surgery could not be considered strictly cosmetic given its purpose and outcomes: “It is performed to correct a psychological defect, and not to improve muscle tone or physical appearance . . . . While many seem appalled at such surgery, it nevertheless has demonstrated proven benefits for its recipients . . . .”<sup>98</sup>

After *Davidson*, many insurers revised their contracts to insert clauses explicitly rejecting coverage of transition-related procedures in order to sidestep judicial disagreement with their classification of such interventions as cosmetic or experimental.<sup>99</sup> Courts generally view these clauses as “bargained-for contractual term[s] [that] preclude[] further . . . actions against an insurer.”<sup>100</sup> However, given that the insurance firm generally holds all of the bargaining power in its relationship with the insured and most transgender patients have little choice as to the provider selected by their employers, “the notion that [these] healthcare policies contain bargained-for terms is a legal fiction.”<sup>101</sup>

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under the policy, the insurer refused to pay for the surgery on the grounds that it was a cosmetic procedure ineligible for coverage. *See also* G.B. v. Lackner, 145 Cal. Rptr. 555 (Ct. App. 1978) (describing how the Director of the California Board of Health tried to deny Medicaid coverage to a transgender individual who had undergone sex reassignment surgery based on an assessment that the surgery was cosmetic).

95. Hazel Glenn Beh, *Sex, Sexual Pleasure, and Reproduction: Health Insurers Don’t Want You To Do Those Nasty Things*, 13 WIS. WOMEN’S L.J. 119, 153 (1998). Beh argues “courts are likely to find [transition-related] treatment medically necessary and not experimental” under those “contracts that do not expressly exclude sex reassignment surgery and/or hormonal treatment.” *Id.*

96. *Davidson*, 420 N.Y.S.2d at 452.

97. *Id.* at 451.

98. *Id.* at 453.

99. Hong, *supra* note 15, at 100.

100. *Id.*

101. *Id.* Insurance contracts are, of course, not invalid just because they are contracts of adhesion. Courts will enforce contract agreements even when one party holds all of the bargaining

The insurance industry's general conclusion—that transitional interventions are cosmetic or experimental—presents several issues that courts and government agencies should consider in regulating health insurance policies. First, a significant body of medical evidence and behavioral science research documenting the efficacy of transition-related interventions casts doubt on some insurers' classification of gender-confirming care as experimental.<sup>102</sup> Medical professionals have been providing transitional treatments to transgender patients for over thirty years and medical advancements in this area demonstrate that interventions like hormonal therapy and sex reassignment surgery are “established treatment[s] . . . in th[e] ‘refining’ stage, much like coronary bypass surgery.”<sup>103</sup> Even state Medicaid agencies have found that such interventions “can be appropriate and medically necessary for some people and . . . [should not be] considered experimental.”<sup>104</sup>

Second, transition-related procedures are arguably more akin to reconstructive surgery “performed on abnormal structures of the body, caused by congenital defects, developmental abnormalities, trauma, infection, tumors or disease” than to cosmetic surgery “performed to reshape normal structures of the body in order to improve the patient’s appearance and self-esteem.”<sup>105</sup> A number

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power as long as the terms of the contract are not unconscionable. *See, e.g., Trend Homes, Inc. v. Superior Court*, 32 Cal. Rptr. 3d 411, 416-17 (Ct. App. 2008).

102. For discussion about the general acceptance of hormonal therapy and surgical reassignment surgery as appropriate treatments for gender dysphoria, see P.T. Cohen-Kettenis & L.J.G. Gooren, *Transsexualism: A Review of Etiology, Diagnosis and Treatment*, 46 J. PSYCHOSOMATIC RES. 315, 326 (1999); David A. Gilbert et al., *Transsexual Surgery in the Genetic Female*, 15 CLINICS PLASTIC SURGERY 471, 486 (1988); and Donald R. Laub et al., *Vaginoplasty for Gender Confirmation*, 15 CLINICS PLASTIC SURGERY 463, 470 (1988). Acceptance of these treatments does not mean that there are no risks associated with the administration of cross-sex hormones or that every potential side effect of sex reassignment surgery in transgender patients has been detected. *See* Louis J. Gooren & Henriette A. Delemarre-van de Waal, *Hormone Treatment of Adult and Juvenile Transsexual Patients*, in PRINCIPLES OF TRANSGENDER MEDICINE AND SURGERY 73, 80-84 (Randi Ettner et al. eds., 2007) (reviewing side effects of hormonal sex reassignment and noting that hormone-dependent tumors are “of particular concern”). Also, appropriate management of transition-related care may be particularly challenging since there is usually no training provided for the treatment of transgender patients in medical school or residency and relatively few resources regarding such care exist. *See* Kathleen A. Oriel, *Medical Care of Transsexual Patients*, 4 J. GAY & LESBIAN MED. ASS’N 185, 193 (2000). Given these caveats, it is fair to say that while transition-related procedures are becoming increasingly well-established in common medical practice, there are circumstances where certain treatments may be controversial and perhaps even experimental. However, insurers can monitor transition-related care to identify these risks, without restricting this care altogether.

103. Eric B. Gordon, *Transsexual Healing: Medicaid Funding of Sex Reassignment Surgery*, 20 ARCHIVES SEXUAL BEHAV. 61, 72 (1991).

104. *Smith v. Rasmussen*, 249 F.3d 755, 760 (8th Cir. 2001).

105. Nardi, *supra* note 91, at 783-84 (emphasis removed).

of studies indicate neurobiological causes for gender variance, suggesting gender identity is “much less a matter of choice and much more a matter of biology.”<sup>106</sup> Though psychosocial and environmental factors can influence gender identity, genetic, hormonal, and physiological factors appear to play a significant role as well, thereby distinguishing gender variance from strictly cosmetic conditions.<sup>107</sup> The decision to pursue gender-confirming care, moreover, is not exclusively at the discretion of the patient; doctors impose stringent requirements on transgender patients that have no real parallel in most other treatment contexts.<sup>108</sup> Finally, once one considers the physical and social consequences of transition-related treatment, it is difficult to see it as cosmetic in nature. Hormone therapy and sex reassignment surgery do not simply enhance ordinary biological features: they radically change the anatomy and biological function of patients’ bodies. Transitioning to a different gender, moreover, can put family relationships, friendships, and employment at risk.<sup>109</sup> Few undergo this “long and arduous” procedure just to improve their appearance or self-esteem.<sup>110</sup>

Insurance providers sometimes also argue that transition-related interventions are purely cosmetic because they alter “normal” features that are

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106. Frederick L. Coolidge et al., *The Heritability of Gender Identity Disorder in a Child and Adolescent Sample*, 32 BEHAV. GENETICS 251, 251-57 (2002); see also Gender Identity Research and Education Society, *Atypical Gender Development – A Review*, 9 INT’L J. TRANSGENDERISM 29, 38 (2006) (describing how scientific evidence supports the paradigm that transsexualism is strongly associated with the neurodevelopment of the brain). It is clear that the condition cannot necessarily be overcome by “consistent psychological socialisation as male to female from very early childhood, and it is not responsive to psychological or psychiatric treatments alone.” *Id.* (internal quotations removed).

107. See Gender Identity Research and Education Society, *supra* note 106, at 42 (citing Pamela Connolly, Psychologist, Lecture at the Annual Conference of the Harry Benjamin Int’l Gender Dysphoria Ass’n, Ghent, Belgium: Transgendered Peoples of Samoa, Tonga and India: Diversity of Psychosocial Challenges, Coping, and Styles of Gender Reassignment (Sept. 2003)).

108. To qualify for sex reassignment surgery, a patient must show “(1) [a] recommendation in writing by two behavioral scientists, one of whom has known the patient in a therapeutic relationship for 6 months; (2) a successful cross-living test over a 1-year period; and (3) legal, social, psychological, sexual and (exogenous) endocrine success during cross-living.” Beh, *supra* note 95, at 152.

109. Gender Identity Research and Education Society, *supra* note 106, at 31.

110. Beh, *supra* note 95, at 154 (discussing *Davidson v. Aetna Life & Cas. Ins. Co.*, 420 N.Y.S.2d 450 (Sup. Ct. 1979)) (“The court also explained that the arduous and radical procedure was rarely sought and even more infrequently done, implying that it was never done for cosmetic purposes . . . .”); see also *G.B. v. Lackner*, 145 Cal. Rptr. 555, 558 (Ct. App. 1978) (“Surely, castration and penectomy cannot be considered surgical procedures to alter the texture and configuration of the skin and the skin’s relationship with contiguous structures of the body. Male genitals have to be considered more than just skin, one would think.” (citing definition of cosmetic surgery adopted by California Department of Health)).

fully functional.<sup>111</sup> This claim might have some merit if insurers covered only function-restoring medical interventions treating physical deformities. Insurance policies, however, regularly cover procedures that reconstruct physical appearance but do not result in any new functional capacity, like surgeries implanting prosthetic eyes and breast reconstruction following a mastectomy.<sup>112</sup> Biologically, these procedures have no functional outcome, but they are generally viewed as improving quality of life in a way that distinguishes them from strictly cosmetic interventions. Gender-confirming care has a similar, and oftentimes even more dramatic, impact on personal satisfaction and life outcomes.<sup>113</sup>

It is perhaps best, then, to think of transition-related procedures as medically necessary despite having certain cosmetic features. One problem with this conception of transitional interventions, however, is that non-transgender patients regularly seek these same interventions for what insurance providers consider aesthetic purposes.<sup>114</sup> To insurers, a treatment is presumptively cosmetic, and hence uninsurable, when it is *ordinarily* “directed at improving the patient’s appearance.”<sup>115</sup>

However, interventions that are regarded as cosmetic in certain contexts should not necessarily be considered cosmetic in all contexts. Transgender patients do not pursue treatments that alter their physical features to simply improve their looks, but rather to “cure or mitigate the distress and maladaptation caused by [gender identity disorder].”<sup>116</sup> Such procedures may be required to “‘pass’ convincingly in public”<sup>117</sup> as a member of the opposite sex, acquire legal

111. *Pinneke v. Preisser*, 623 F.2d 546, 549 (8th Cir. 1980) (“The Iowa Department of Social Services established an irrebuttable presumption that the procedure of sex reassignment surgery can never be medically necessary when the surgery is a treatment for transsexualism and removes healthy, undamaged organs and tissue.”).

112. Nardi, *supra* note 91, at 783.

113. Anne A. Lawrence, *Factors Associated with Satisfaction or Regret Following Male-to-Female Sex Reassignment Surgery*, 32 ARCHIVES SEXUAL BEHAV. 299, 299 (“232 male-to-female transsexuals operated on between 1994 and 2000 . . . reported overwhelmingly that they were happy with their SRS [sexual reassignment surgery] results and that SRS had greatly improved the quality of their lives.”); see also Jamil Rehman et al., *The Reported Sex and Surgery Satisfaction of 28 Postoperative Male-to-Female Transsexual Patients*, 28 ARCHIVES SEXUAL BEHAV. 71 (1999) (reporting greater satisfaction in quality of life and more psychological stability among most of the post-operative transsexual patients surveyed).

114. Transgender as well as non-transgender individuals regularly seek rhinoplasty, for example.

115. I.R.C. § 213(d)(9)(B) (2006) (defining cosmetic surgery, which does not qualify as deductible medical care under the U.S. tax code). How the federal government views a procedure in the tax code can influence how insurers, particularly public insurers, treat the procedure for coverage purposes.

116. *O'Donnabhain v. Comm'r*, 134 T.C. 34, 92 (2010).

117. *Id.* at 43.

recognition of one's "true" gender, and alleviate the internal discord that may arise when one's gender identity does not align with one's anatomical features.<sup>118</sup> Certain interventions may therefore be medically necessary for transgender populations even though the same treatments are perhaps more appropriately classified as cosmetic for other patient groups.

Still, for transgender patients, instances may arise where it is difficult to distinguish between medically necessary transitional procedures with cosmetic aspects and elective cosmetic procedures with transitional aspects. Public as well as private insurers do not fund cosmetic surgery in part because the aim of cosmetic surgery is usually to produce an aesthetic ideal, not to treat a medical condition. Though transgender patients may pursue surgical interventions primarily to transition to a new gender, they are not immune to the same desires for physical perfection that can motivate other individuals to obtain cosmetic surgery.<sup>119</sup>

While sometimes it may be difficult to police the line between transition and perfection, it is not impossible to do so. A recent ruling by the United States Tax Court provides an example of how medically necessary transition-related interventions can be distinguished from largely cosmetic procedures. In *O'Donnabhain v. Commissioner*, the Tax Court held that a transgender woman's medical expenses for hormone therapy and sex reassignment were tax-deductible because the interventions treated "the distress and suffering occasioned by GID" and "accordingly are not 'cosmetic surgery'" under the tax code.<sup>120</sup> The Court, however, ruled that the petitioner could not deduct expenses for her breast augmentation surgery because hormone treatment before the surgery had already produced breasts "within a normal range of appearance."<sup>121</sup> Her breast augmentation surgery "merely improved her appearance" and thus fell squarely within the definition of cosmetic surgery "excluded from deductible 'medical care.'"<sup>122</sup> As this case demonstrates, accepting the proposition that transition-

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118. See AM. MED. ASS'N HOUSE OF DELEGATES, RESOLUTION 114, REMOVING BARRIERS TO CARE FOR TRANSGENDER PATIENTS (June 16, 2008), available at [www.ama-assn.org/ama1/pub/upload/mm/471/114.doc](http://www.ama-assn.org/ama1/pub/upload/mm/471/114.doc).

119. Transgender individuals who see many transition related procedures as medically necessary still acknowledge that the "line between 'medically necessary' and 'elective'" can become blurry. One transwoman contemplating rhinoplasty remarked, "I don't want it to be the case where I'm always looking for the next procedure to feel more complete—to be the person I should be. I want to get to the point where I'm happy with myself." Amanda Hess, *When Gender Transition Requires a Long, Strange Trip*, SEXIST (July 30, 2009, 10:17 am), <http://www.washingtoncitypaper.com/blogs/sexist/2009/07/30/when-gender-transition-requires-a-long-strange-trip>.

120. 134 T.C. at 70.

121. *Id.* at 73.

122. *Id.*

related procedures are generally medically necessary does not preclude insurers from rejecting certain interventions as cosmetic, and ineligible for coverage.

### 3. *Medical-Necessity Review*

Both public and private insurers attempt to control healthcare costs by refusing coverage for procedures they believe are not “medically necessary.”<sup>123</sup> Medically unnecessary interventions include, but are not limited to, procedures insurers conclude are cosmetic or experimental. The medical-necessity requirement is at once the broadest and least defined exclusion clause in most insurance plans.

Medical-necessity review has played a major role in determining whether transgender Medicaid recipients receive access to transitional care. Medicaid is a state-run program funded with federal and state dollars that provides medical insurance to low-income individuals.<sup>124</sup> States have significant discretion in determining which services they will provide under the Medicaid Act, which requires only that the standards adopted for determining the extent of medical assistance be “reasonable” and “consistent with the objectives” of the Act.<sup>125</sup> As long as states follow a “formal” rulemaking process, they are free to exclude certain interventions as medically unnecessary.<sup>126</sup> Because rulemaking procedures are not necessarily consistent across states, different decisions may result about which procedures are eligible for Medicaid coverage and which are not.

Most states have restricted Medicaid coverage for at least some transition-related interventions on medical-necessity grounds. A survey conducted by the Iowa Department of Human Services found that forty states do not fund sex reassignment surgery through Medicaid.<sup>127</sup> In *Smith v. Rasmussen*, the Eighth Circuit upheld Iowa’s refusal to fund sex reassignment surgery, acknowledging that while the surgery “may be medically necessary in some cases,” the “availability of other treatment options” for gender identity disorder and “lack of consensus in the medical community” about the efficacy of the surgery permits states to refuse coverage for the intervention under Medicaid.<sup>128</sup> The appellate court also cited fiscal concerns as a valid reason to reject coverage of surgical

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123. “Medical necessity” does not mean life-or-death necessity; it refers to medically appropriate or medically beneficial treatment. The intent of the standard is to exclude coverage for care that is harmful, of no benefit, or nonstandard. *See generally* *Dallis v. Aetna Life Ins. Co.*, 574 F. Supp. 547 (N.D. Ga. 1983) (discussing the meaning of the term “necessary”), *aff’d*, 768 F.2d 1303 (11th Cir. 1985).

124. 42 U.S.C. § 1396 (2006).

125. *Beal v. Doe*, 432 U.S. 438, 441 (1977) (quoting 42 U.S.C. § 1396a(a)(17) (1970)).

126. *Smith v. Rasmussen*, 249 F.3d 755, 760 (8th Cir. 2001).

127. *Id.* at 761 n.5.

128. *Id.* at 760.

interventions that facilitate transition.<sup>129</sup>

Some courts have been less willing to accept broad restrictions against transition-related interventions in Medicaid programs. Courts rejecting statutory or regulatory bans on sex reassignment surgery contend that such bans violate federal Medicaid regulations by arbitrarily imposing restrictions on “the amount, duration, or scope of a required service . . . solely because of diagnosis, type of illness or condition.”<sup>130</sup> In *Doe v. Minnesota Department of Public Welfare*, for example, the Minnesota Supreme Court found, “the total exclusion of transsexual surgery from eligibility for [medical assistance] benefits [was] void” because the ban was “directly related to the type of treatment involved” rather than to an evaluation determining whether the intervention was medically necessary.<sup>131</sup> What is most interesting about the *Doe* decision, and many other decisions invalidating state Medicaid bans on sex reassignment surgery, is the court’s finding that sex reassignment surgery is the “only medical procedure known to be successful in treating the problem of transsexualism.”<sup>132</sup> Cases overturning Medicaid restrictions against sex reassignment surgery, as well as cases upholding them, understand the medical necessity of the intervention as turning on whether or not there are other treatments for gender disorder.

Whether this is actually the right approach to assessing the medical necessity of transition-related interventions is, at best, questionable. A medical-necessity standard that mandates coverage of an intervention only if it is “the only successful treatment known to medical science”<sup>133</sup> is inconsistent with the way medical necessity is generally defined and interpreted. Insurers and courts alike usually deem a medical intervention to be “necessary” when an attending physician finds it to be medically appropriate and the physician’s judgment is in line with the medical community’s recommended treatments for the condition.<sup>134</sup> Doctors widely recognize mental health services, hormonal therapy, and many sex reassignment surgeries as effective in treating gender variance. The American Medical Association, arguably the leading authority on the appropriateness of medical interventions, formally announced its support for gender-confirming care in 2008, citing that “medical literature has established the effectiveness and *medical necessity* of mental healthcare, hormone therapy, and sex reassignment surgery in the treatment of patients diagnosed with [gender

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129. *Id.* at 760-61.

130. *Rush v. Parham*, 625 F.2d 1150, 1157 n.12 (5th Cir. 1980) (citing 42 C.F.R. §440.-230(c)(1)).

131. *Doe v. Minn. Dep’t of Public Welfare*, 257 N.W.2d 816, 820 (Minn. 1977).

132. *Id.* at 819.

133. *Id.*

134. *Hall & Anderson*, *supra* note 79, at 1647 n.32, 1649-50.

identity disorder].”<sup>135</sup>

Despite widespread endorsement of transition-related interventions in the medical community, insurers as well as courts remain skeptical of their medical necessity for several reasons. First, the cost of providing gender-confirming care can seem prohibitively expensive; “costs as high as \$75,000 per person have been cited as justification for exclusion” of transition-related health benefits.<sup>136</sup> In this era of escalating healthcare costs, attempts to control costs through medical-necessity determination are understandable and should be encouraged. Insurers and occasionally courts play an important gate-keeping function to medical services by checking physicians’ incentives to find every procedure “medically necessary,” and in so doing make insurance more affordable for everyone.<sup>137</sup>

The experience of insurers who have covered transition-related care suggests, however, that the expense of providing transitional treatments is lower than insurers might imagine.<sup>138</sup> San Francisco, for instance, found that the cost of providing coverage for transition-related interventions was much lower than had been anticipated when it began providing health benefits that covered the costs of hormone treatment, psychotherapy and surgical procedures in 2001.<sup>139</sup> Actuaries had estimated that thirty-five of the city’s thirty-seven thousand employees would use the new benefits in the first year they were available to access gender reassignment surgery at a cost of \$1.75 million to the city.<sup>140</sup> Actual claim data released in 2005 showed that only eleven claims for transition-related surgery

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135. AM. MED. ASS’N, *supra* note 118 (emphasis added). But note that less than a third of all practicing physicians belong to the AMA. Joseph Shapiro, *Poll Finds Most Doctors Support Public Option*, NPR (Sept. 14, 2009), <http://www.npr.org/templates/story/story.php?storyId=112818960>.

136. Mary Ann Horton, *The Cost of Transgender Health Benefits* (2008) (unpublished report) (on file with author), *available at* <http://www.tgender.net/taw/thbcost.html>.

137. Hall & Anderson, *supra* note 79, at 1663, 1674.

138. In 1997, the San Francisco Human Rights Commission estimated the costs of a variety of transition related medical treatments. The San Francisco Human Rights Commission found that hormone treatments for male-to-female patients (usually Premarin™) cost between \$200 and \$500 per year, while different kinds of vaginoplasty ranged in price from \$1,350 to \$30,000. Hormone treatments for female-to-male patients were estimated to cost between \$70 and \$540 per year. Some female-to-male individuals also spend \$4,000-\$7,000 on a bilateral mastectomy, \$4000-\$18,000 on a hysterectomy and oophorectomy, and anywhere from \$5,500 to \$38,000 for either a phalloplasty or metoidoplasty. Diskin, *supra* note 16, at 141 (citing S.F. HUMAN RIGHTS COMM’N, INSURANCE COVERAGE FOR TRANSEXUAL EMPLOYEES OF THE CITY AND COUNTY OF SAN FRANCISCO (1997)); *see also* Benefit Update, City and County of San Francisco, San Francisco City and County Transgender Health Benefit 2 (Mar. 31, 2006), *available at* <http://www.tgender.net/taw/SanFranciscoTGBenefitUpdateMar3106.pdf> (reporting that City’s actuaries estimated thirty five eligible members of the member population would spend \$50,000 on transition related care annually).

139. Rachel Gordon, *S.F. to Finance Staff Sex-Changes*, S.F. CHRON., May 1, 2001, at A1.

140. Diskin, *supra* note 16, at 154.

were filed between July 1, 2001, when benefits first went into effect, and July 30, 2004.<sup>141</sup> Financing gender reassignment surgery for transgender employees cost the city only \$182,374 *over four years*, far less than officials had projected for a single year in 2001.<sup>142</sup>

Another reason that many insurers and courts question the medical necessity of gender-confirming care may have to do with the fact that not all transgender individuals seek transition-related interventions. It is difficult to justify health expenditures for a “condition” that is not always treated with medicine, particularly as transgender individuals themselves sometimes resist the notion that medical interventions are necessary to “correct” non-normative gender identities.<sup>143</sup>

In truth, there is no one-size-fits-all treatment for gender variance. This does not mean, however, that transition-related procedures are not medically appropriate interventions for some transgender individuals. Few patient groups have uniform health needs and transgender individuals are no exception. Though some transgender people do not access transition-related care, others find medically facilitated transition vital to their mental health and quality of life. Physical features play an enormous, complex, and often understated role in one’s own understanding of gender identity as well as society’s perception of gender. Incongruence between physical appearance and gender identity can cause severe psychological distress and limit some transgender individuals’ “ability to function and survive in society, given current biases and beliefs.”<sup>144</sup>

The issue of health insurance coverage for transition-related care will not be resolved by a medical-necessity standard that bases access to a transitional intervention on evidence that it is the “only medical procedure known to be successful in treating the problem of transsexualism.”<sup>145</sup> Instead, insurance companies, the courts, and government agencies must articulate a consistent policy recognizing the diversity of health needs among transgender individuals, which renders transition-related treatments medically necessary for some gender-variant patients.

### *C. Categories of Coverage for Transition-Related Care*

Just as there is no single treatment protocol that meets the needs of all transgender patients, there is no one uniform insurer response to claims related to gender transition. While many insurers explicitly deny coverage for transition-

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141. *Id.* at 159.

142. *Id.*

143. Dasti, *supra* note 15, at 1743; *see also supra* Section I.C.

144. Keller, *supra* note 15, at 72.

145. *Doe v. Minn. Dep't of Public Welfare*, 257 N.W.2d 816, 822 (Minn. 1977).

related services,<sup>146</sup> a small number of insurance firms have begun to provide some transitional benefits.<sup>147</sup> The insurers that do cover transitional care, however, rarely support all medical interventions related to sex reassignment.<sup>148</sup> Health insurance providers that fund gender-confirming care are more apt to do so when a particular intervention seems relatively low-cost and is routinely accessed by other patients to treat medical problems unrelated to transition.

The transitional treatments most frequently covered by insurance providers are mental health services and hormone replacement therapy. Compared to other types of gender-confirming care, mental health counseling and hormone treatments appear to be fairly inexpensive: one year of hormone replacement therapy for a female-to-male (FTM) patient can cost as little as \$229 while the average price of primary, or “top,” surgery for the same patient is approximately \$8500.<sup>149</sup> Figures like these, however, hide the fact that mental health therapy and hormonal interventions are rarely single-dose treatments and may, over a patient’s lifetime, be more expensive than a one-time surgical procedure. Transgender patients are also more likely to seek mental health and hormone treatments than other transitional interventions, so it may be more costly overall to finance these treatments than pricier, but less utilized, procedures like surgery. Cost seems to be a factor, but not the driving factor, explaining why certain kinds of transition-related treatments are covered and others are not.

One factor that does seem critical for obtaining coverage for gender-confirming care is the availability of an intervention for non-transitional purposes. Though insurers do not explicitly condition transition-related benefits

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146. Many states do not permit individuals to use Medicaid benefits to fund transition related care. *See, e.g.*, Regs. Conn. State Agencies § 17b-262-612(k) (2006) (“The department [of health] shall not pay for the following: . . . transsexual surgery or for a procedure which is performed as part of the process of preparing an individual for transsexual surgery, such as hormone therapy and electrolysis.”). The federal Medicare statute explicitly excludes coverage for “transsexual surgery” or “sex reassignment surgery . . . [b]ecause of the lack of well controlled, long-term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism.” 54 Fed. Reg. 34,572 (Aug. 21, 1989). The American Civil Liberties Union reports that most private insurance companies “either expressly exclude many forms of transition-related services or are unclear about whether such services are covered.” *Know Your Rights-Transgender People and Law*, ACLU (Nov. 19, 2009), [http://www.aclu.org/hiv-aids\\_lgbt-rights/know-your-rights-transgender-people-and-law](http://www.aclu.org/hiv-aids_lgbt-rights/know-your-rights-transgender-people-and-law).

147. *See, e.g.*, *Clinical Policy Bulletin: Gender Reassignment Surgery*, AETNA, [http://www.aetna.com/cpb/medical/data/600\\_699/0615.html](http://www.aetna.com/cpb/medical/data/600_699/0615.html) (last modified Mar. 25, 2011).

148. Electrolysis, for instance, is generally excluded as cosmetic in nature, even though it may be medically necessary for some transgender patients. *See, e.g.*, *Clinical Policy Bulletin: Cosmetic Surgery*, AETNA, [http://www.aetna.com/cpb/medical/data/1\\_99/0031.html](http://www.aetna.com/cpb/medical/data/1_99/0031.html) (last modified March 22, 2011).

149. Horton, *supra* note 136, at 3, 7, 11. Horton defines primary top surgeries for FTM patients to include bilateral mastectomy and chest reconstruction.

on whether a treatment is used by other patients for other purposes, almost all covered transitional therapies are regularly prescribed in other contexts. One reason for this may be that insurers are more familiar with, and therefore more accepting of, transition-related treatments frequently used for purposes other than transition. Insurers might more readily approve claims for hormone treatments that facilitate transition, for instance, because such treatments are also regularly used to alleviate more common conditions that stem from menopause, prostate cancer, and growth hormone deficiencies.<sup>150</sup> It can also be easier to obtain coverage for transition-related care when such care serves multiple functions for a patient, at least one of which is treating an approved condition. If an insurance policy routinely covers mental health services for depression, for example, a transgender patient suffering from depression may be able to bill his insurance company for counseling services treating both conditions even if trans-specific care is not covered under the policy.<sup>151</sup> Finally, patients may be able to avoid coverage restrictions against trans-specific care by masking the fact that a treatment with multiple purposes is being used for transition. Most insurance plans reportedly cover around eighty percent of hormone prescriptions for a patient in the maintenance, as opposed to the transition, period of hormone therapy because, as one paper notes, “the patient is documented as their new gender.”<sup>152</sup> A male gender marker may help a female-to-male transgender patient access testosterone with little question from a new insurer who knows nothing about the patient’s gender history and believes the hormone is being used for approved purposes.

The availability of an intervention for non-transitional purposes may be necessary to obtain coverage for gender-confirming care, but it is hardly sufficient to receive such care under most health insurance policies. Surgical interventions facilitating transition are much less likely to be covered, even if the same surgery is covered for other conditions. Hysterectomies—the most commonly performed gynecological surgery—are routinely covered to treat even

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150. See *Health Guide: Growth Hormone Deficiency*, N.Y. TIMES (Sept. 13, 2009), <http://health.nytimes.com/health/guides/disease/growth-hormone-deficiency/overview.html>; Mayo Clinic Staff, *Hormone Therapy: Is it Right for You?*, MAYO CLINIC (Feb. 19, 2010), <http://www.mayoclinic.com/health/hormone-therapy/WO00046> (discussing hormone replacement therapy to treat menopause); *Prostate Cancer Treatment*, NATIONAL CANCER INSTITUTE, <http://www.cancer.gov/cancertopics/pdq/treatment/prostate/Patient/page4> (last modified Nov. 5, 2010).

151. Some insurance policies, however, explicitly exclude psychiatric treatment for gender dysphoria from coverage. Testimony from a number of transgender patients indicates that any mention of gender variance in a case file can make obtaining coverage for mental health counseling, even for a condition unrelated to gender variance, nearly impossible under these policies. See Hong, *supra* note 15, at 97.

152. Horton, *supra* note 136, at 8.

relatively benign gynecological conditions.<sup>153</sup> Transgender patients who seek the surgery for transitional purposes, however, often find the intervention foreclosed by policy exclusions for sex reassignment surgery or dismissed by the insurer under restrictions banning cosmetic, experimental, or medically unnecessary treatment.<sup>154</sup>

Treatments with no application other than facilitating transition are almost never covered by insurance. Even insurers with trans-inclusive policies that fund “medically necessary” surgical procedures deny coverage for these trans-specific interventions. A transgender patient with a trans-friendly policy will generally have a better chance of obtaining coverage for breast reconstructive surgery, which is regularly performed on women with breast cancer,<sup>155</sup> than for facial feminization surgery, which is virtually never conducted on anyone other than transgender individuals.<sup>156</sup> Transgender patients themselves, however, sometimes view interventions like facial feminization surgery as more essential to transition than procedures aimed at altering primary or secondary sex characteristics.<sup>157</sup>

Finally, procedures explicitly barred for non-transgender policyholders are usually excluded from coverage for transgender policyholders as well. Insurance companies generally view electrolysis, used to remove unwanted facial and body hair, as a strictly cosmetic procedure, and therefore ineligible for coverage under any circumstance.<sup>158</sup> While most patients probably do seek electrolysis for cosmetic reasons, transgender individuals may rely on the procedure to transition to a new gender. Some male-to-female patients view permanent removal of androgen-driven hair, particularly facial hair, as vital to reducing the dissonance between their true gender and the gender assigned to them at birth.<sup>159</sup> Facial hair

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153. See, e.g., *Cigna Medical Coverage Policy: Hysterectomy*, CIGNA, 4-8 (effective April 15, 2010), [http://www.cigna.com/customer\\_care/healthcare\\_professional/coverage\\_positions/medical/mm\\_0128\\_coveragepositioncriteria\\_hysterectomy.pdf](http://www.cigna.com/customer_care/healthcare_professional/coverage_positions/medical/mm_0128_coveragepositioncriteria_hysterectomy.pdf) (listing indications/conditions for which hysterectomy is covered).

154. See AM. MED. ASS’N HOUSE OF DELEGATES, RESOLUTION 122 (A-08): REMOVING FINANCIAL BARRIERS TO CARE FOR TRANSGENDER PATIENTS 2 (2008), available at [http://www.tgender.net/taw/ama\\_resolutions.pdf](http://www.tgender.net/taw/ama_resolutions.pdf).

155. Women’s Health and Cancer Rights Act of 1998, 29 U.S.C. § 1185b (2006) (requiring health insurance companies and self-insured group health plans that cover mastectomies to provide benefits for breast reconstruction surgery).

156. See FACIAL FEMINIZATION SURGERY, <http://www.facialfeminizationsurgery.info> (last visited Dec. 6, 2010).

157. See, e.g., *Facial Feminization Procedures 2010 Update*, TRANSSEXUAL ROAD MAP (Jan. 4, 2011), <http://www.tsroadmap.com/physical/face/facesurgidx.html> (transgender individual who has had facial feminization surgery stating, “If being accepted as female is your goal, one of the most important things to consider is facial feminization surgery . . . . I feel the key to being accepted as female is from the neck up.”).

158. See, e.g., Clinical Policy Bulletin: Cosmetic Surgery, *supra* note 148.

159. *Hair Removal*, TRANSSEXUAL ROAD MAP (Apr. 29, 2011), <http://www.tsroadmap.com/>

can be a “constant reminder of . . . masculinity.” As one trans-woman writes, “facial hair is so masculine a trait that I feel uncomfortable about having a relationship and waking up in company with a five o'clock in the morning shadow.”<sup>160</sup>

As this remark indicates, for most individuals gender is not merely about self-identification; how others perceive gender often has an enormous impact on how you understand your own gender. “Passing” as well as one can in a chosen gender is therefore very important to some transgender people.<sup>161</sup> For transgender women seeking to “pass” while out in public, electrolysis is often “the most important thing they do to become passable.”<sup>162</sup> Since the visibility of facial hair makes it “one of the strongest male gender cues,” failing to remove it puts transgender women at risk of being “outed,” or being perceived by others as male. Without procedures like electrolysis, public acceptance of an adopted gender is often extremely difficult.

Covering these procedures for transgender patients, however, can lead to difficult issues for insurers. Interventions like electrolysis are popular among non-transgender individuals, and it might be difficult for insurers to justify covering them for only gender-variant populations, particularly when a non-transgender patient’s motivation for pursuing a particular procedure is not that different from a transgender patient’s reason. Would funding electrolysis for

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physical/hair. For some transgender patients, permanent hair removal is more vital to transition than other procedures that are more likely to be covered by insurers, like genital reconfiguration. *When in My Transition Should I Start Hair Removal?*, TRANSSEXUAL ROAD MAP (Jan. 4, 2011), <http://www.tsroadmap.com/physical/hair/zappriority.html> (“If I had to choose between having a beard and having a penis, I would rather have the penis. It was much easier to get rid of than the facial hair.”).

160. *When in My Transition Should I Start Hair Removal?*, *supra* note 159.

161. There are also practical reasons that can drive the desire to pass in public. As one trans-person comments:

Discrimination frequently forces talented and qualified individuals out of their pre-transition careers, and makes it difficult for them to find new jobs. The individual whose facial hair or other characteristic makes it difficult to “pass” frequently faces even more discrimination than those who do “pass.” Finding themselves unable to get any job whatsoever and unable to afford electrolysis, even talented and well-educated individuals sometimes find themselves in a downward-financial spiral which leaves only sex work as an alternative to homelessness.

*Id.*

162. *Electrolysis*, TRANSSEXUAL ROAD MAP (Jan. 4, 2011), <http://www.tsroadmap.com/physical/hair/zapidx.html> (“Passing as well as you can in your chosen gender will generally make your life much easier, since there are few things more disturbing to most people than a contradictory gender presentation.”).

transgender patients mean, for instance, that insurers would also have to approve a biological female's request for electrolysis to permanently remove her beard and mustache growth? On what grounds could insurers deny this request, but still approve electrolysis claims from transgender patients? Until such questions are resolved, coverage of transition-related claims will remain limited and somewhat disconnected from the actual aims and purposes of transition.

#### *D. Conforming to the Discourse of Disease*

Despite the barriers that frequently impede access to adequate health insurance for transgender individuals, some policies cover certain transition-related services. A growing number of private employers explicitly provide health insurance coverage for transition-related procedures to their employees.<sup>163</sup> Transition-related benefits are typically self-insured by the employer who “puts money directly into a plan which then pays for the covered benefits when the claims are incurred rather than paying premiums to insurance companies.”<sup>164</sup> Evidence that these employers are able to fund trans-specific healthcare at a relatively low cost has been instrumental to convincing other employers to include transition-related benefits in their health plans as well.<sup>165</sup>

Yet even when trans-specific health benefits are available, transgender individuals will likely find that eligibility depends on their ability to describe their gender identity within a specific discourse of disease. As Judith Butler points out, “most medical, insurance, and legal practitioners are committed to supporting access to sex change technologies only if we are talking about a disorder.”<sup>166</sup> Butler describes the sequence of events that insurers generally expect to occur before they will provide access to gender-confirming treatment:

A [gender] conflict has to be established; there has to be enormous suffering; there has to be persistent ideation of oneself in the other gender; there has to be trial period of cross-dressing throughout the day to see if adaptation can be predicted; there have to be therapy sessions, and letters attesting to the balanced state of one's mind. In other words, one must be subjected to a regulatory apparatus . . . .<sup>167</sup>

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163. “A survey conducted by the Human Rights Campaign indicates that about 120 employers provide coverage for transition-related medical services or treatments.” *Corporate Equality Index 2011: Rating American Workplaces on LGBT Equality* 27, HUMAN RIGHTS CAMPAIGN (2011), <http://www.hrc.org/documents/HRC-CEI-2011-Final.pdf>.

164. Diskin, *supra* note 16, at 139 (citing HUMAN RIGHTS CAMPAIGN, TRANSGENDER ISSUES IN THE WORKPLACE, n.36). While this kind of “self insurance is a cost-effective option for many large employers, it remains out of reach for most small employers.” *Id.*

165. Diskin, *supra* note 16, at 152.

166. Butler, *supra* note 62, at 288.

167. *Id.* at 287.

Medical discourse also plays a critical role in litigation attempting to secure insurance coverage for trans-specific healthcare. Courts that have ordered states or insurance companies to fund transition-related procedures emphasize the importance of medical evidence in reaching these decisions.<sup>168</sup> Medical opinion is often instrumental to favorable outcomes for transgender plaintiffs seeking insurance coverage. Cases involving insurance privileges for transition-related services all recount an almost identical and medically focused narrative. First, medical evidence is presented to confirm that the plaintiff has been diagnosed as a “true transsexual.”<sup>169</sup> Courts define a true transsexual as someone whose biological sex conflicts with his or her gender identity in a very specific way; the court is confronted with either “an anatomical male with a female gender identity”<sup>170</sup> or an anatomical female with a male gender identity. Once it is established that the plaintiff “suffers” from transsexualism, the court will usually evaluate medical evidence to determine whether the treatment for which the plaintiff seeks insurance coverage “is the only procedure available for treatment,”<sup>171</sup> only considering the plaintiff’s request if it is.

Obtaining coverage for transition-related care can also require rigid allegiance to conventional gender norms. Though non-transgender people who defy “assumptions and preconceptions about how men and women are supposed to behave, dress, and appear” are protected under federal sex discrimination laws,<sup>172</sup> transgender individuals attempting to secure insurance coverage to alter their bodies are usually expected to adhere to traditional notions of masculine and feminine identity. They must “completely . . . assume the [stereotypical] role of the opposite sex” through their appearance, demeanor, and sometimes even their sexual preferences.<sup>173</sup> One insurance company, for instance, will find sexual reassignment surgery medically necessary only when a member has “live[d] in society as a member of the other sex for at least 2 years” and “does not gain sexual arousal from cross-dressing.”<sup>174</sup>

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168. See Dasti, *supra* note 15, at 1758 (“The explanation of transgender identities in medical and diagnostic terms is common throughout the case law, even in cases that do not deal specifically with sex reassignment surgery or sex designation.”); Richard F. Storrow, *Naming the Grotesque Body in the “Nascent Jurisprudence of Transsexualism,”* 4 MICH. J. GENDER & L. 275, 279 (1997) (underscoring the pervasiveness of medical evidence in judicial decisions involving transgender people).

169. See, e.g., *Rush v. Parham*, 625 F.2d 1150, 1153 (5th Cir. 1980); *Doe v. Minn. Dep’t of Public Welfare*, 257 N.W.2d 816, 819 (Minn. 1977).

170. *Rush*, 625 F.2d at 1153.

171. *Pinneke v. Preisser*, 623 F.2d 546, 548 (8th Cir. 1980).

172. Kylar W. Broadus, *Employment Discrimination Protections, in* TRANSGENDER RIGHTS 93, 95 (Paisley Currah et al. eds., 2006); see also *Price Waterhouse v. Hopkins*, 490 U.S. 228 (1989).

173. Butler, *supra* note 62, at 279.

174. Clinical Policy Bulletin: Gender Reassignment Surgery, *supra* note 147.

Building a successful insurance claim for transition-related procedures has traditionally depended on one's ability and willingness to "perform" gender in a way that indicates "true transsexualism."<sup>175</sup> Conforming to this narrow conception of gender variance may help some acquire health insurance for gender-confirming care, but it comes with costs. Many advocates and scholars argue that the narrative recounted by those seeking transition-related services invariably frames transgender identity as a disorder that can only be corrected through medical intervention. This, they maintain, continues the historic pathologization of transgender identity.<sup>176</sup> Even if one can use the gender dysphoria "diagnosis as a pure instrument, a vehicle for achieving one's goals,"<sup>177</sup> others will be left with the impression that gender variance is a disease that must be treated. This is disturbing to those who view transgender identity as a natural, and even normal, variation of human sexuality. It is also offensive to those who reject the idea that insurance support should depend on one's ability and willingness to conform to a narrow definition of transsexualism and adhere to gender stereotypes. When only individuals who feel "trapped in the body of a person of the opposite sex" qualify for insurance coverage, insurers ignore the diversity of gender-variant populations and reinforce binary gender and sex paradigms.

By making gender-confirming treatment available only to individuals who demonstrate a prescribed set of characteristics, insurers also give transgender individuals incentive to frame their "symptoms" in a manner that will grant them access to desired interventions. Dean Spade describes "great, sad conversations with [other transgender] people who know all about what it means to lie and cheat their way through the medical establishment."<sup>178</sup> Procuring gender-confirming care requires "proving, through talk, that they have always felt, as far back as they can remember, like the gender other than the one they were assigned," even if their actual experience of gender variance was more complex or did not fit traditional gender stereotypes.<sup>179</sup> Ironically, there is no room for ambivalent or nonconformist ideas about gender norms when trying to access insurance coverage for transitional services.

Some transgender individuals have been savvy about circumventing narrow

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175. JUDITH BUTLER, *GENDER TROUBLE* 25 (1990) (describing gender as "performative—that is, constituting the identity it is purported to be").

176. *See, e.g.*, Butler, *supra* note 62, at 275; Spade, *supra* note 36, at 36.

177. Butler, *supra* note 62, at 280. Butler argues that even when an individual strategically uses diagnosis to access transition-related benefits, it may still lead to "a certain subjection to the diagnosis such that one does end up internalizing some aspect of the diagnosis, conceiving of oneself as mentally ill or 'failing' in normality." *Id.*

178. Spade, *supra* note 36, at 23.

179. Keller, *supra* note 15, at 54 n.17 (citing SUZANNE J. KESSLER & WENDY MCKENNA, *GENDER: AN ETHNOMETHODOLOGICAL APPROACH* 117 (1978)).

eligibility criteria and exclusions for trans-specific services. There is anecdotal evidence of transgender patients strategically employing treatment for an “acceptable” condition to obtain gender-confirming care. One trans advocate who documents such maneuverings writes, “many women get [hormone replacement therapy] covered through insurance as a ‘hormonal imbalance.’”<sup>180</sup> This usually slips under the insurance radar even on policies that specifically exclude transsexual surgery and related services. Even complicated, expensive, and universally rejected procedures can be covered if one is particularly shrewd: “Some have been able to get face work tacked on as part of other corrective procedures. One woman writes she had her nose fixed during a correction to her jaw following a car accident. Another got her chin feminized as part of oral surgery to correct her overbite.”<sup>181</sup> It is difficult for insurers to police this kind of behavior, particularly when healthcare professionals participate in efforts to “cover” transitional treatments with procedures that receive little scrutiny from insurance companies.

As this discussion suggests, the terms that currently define the limits of coverage for transition related care impose significant costs on insurers as well as policyholders. Coverage policies ignore the diversity of transgender health needs and encourage manipulation to obtain uncovered care. In consequence, the present insurance landscape reflects an inefficient allocation of transition related services. The next Part addresses how new national healthcare regulations may reshape this landscape.

### III. THE PATIENT PROTECTION AND AFFORDABLE CARE ACT: IMPLICATIONS FOR TRANSGENDER CARE

The PPACA is the most sweeping piece of healthcare legislation passed in decades.<sup>182</sup> The PPACA and its companion bill, the Health Care and Education Reconciliation Act of 2010,<sup>183</sup> impose an ambitious set of reforms on the healthcare industry aimed at expanding insurance coverage while controlling medical spending. The media has repeatedly referred to the legislation as an “overhaul” of the American healthcare system,<sup>184</sup> and in certain ways, it is. For the first time in American history, insurance companies will have to comply with

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180. *Transition and Insurance*, TRANSSEXUAL ROAD MAP (Jan. 4, 2011), <http://www.tsroadmap.com/reality/insurance.html>.

181. *Id.* The site also comments that therapy for gender variance “is quite easy to get through [insurance] by listing it as ‘depression.’” *Id.*

182. PPACA, Pub. L. No. 111-148, 124 Stat. 119 (2010).

183. Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010).

184. See, e.g., Stolberg, *supra* note 7, at A19; Janet Adamy, *Ten Questions on the Health-Care Overhaul*, WALL ST. J., JULY 21, 2009, at A16.

new regulations that prohibit denying coverage to those with pre-existing conditions.<sup>185</sup> Insurers will no longer be able to exclude individuals with particular health problems or vary their rates according to one's health status.<sup>186</sup> Up to 129 million Americans with medical issues that insurers may classify as pre-existing conditions stand to benefit from this new coverage mandate.<sup>187</sup>

Eliminating pre-existing condition exclusions, however, will not necessarily end discriminatory practices by health insurance organizations. Though insurers will not be permitted to deny coverage to particular populations outright, they will, in most circumstances, retain the right to refuse coverage for "medically unnecessary" procedures.<sup>188</sup> The necessity of medical interventions will likely be scrutinized more closely than ever before, since it is one of the few areas where insurers can still control costs and manage risk. When insurance coverage turns on medical necessity, however, transgender individuals almost always lose. Insurers have traditionally dismissed transition-related procedures as unnecessary and thus undeserving of coverage.<sup>189</sup> Absent further regulation of the insurance industry, transgender populations may gain expanded access to health insurance through the PPACA, but confront restricted access to care.

Part III of this Note argues that securing health benefits for transgender populations under the PPACA requires recasting the definition of medical necessity imposed by health insurers. Whether a given intervention is medically necessary is usually viewed as an objective question that turns on clinical need. Yet medical necessity can be more complicated than this definition suggests, particularly for transgender individuals. Certain medical interventions may be necessary for reasons beyond immediate health outcomes. Transgender individuals frequently seek transition-related treatment to access legal rights, secure economic opportunities, and abide by social norms. When medical interventions are the only way to achieve these goals, they are no less necessary because the outcomes sought are not strictly confined to health results. Medical treatments may, in fact, be even *more* necessary in this context.

#### *A. Expanded Access to Health Insurance, Constricted Access to Care*

As discussed in Part II, insurers have traditionally employed the presence of

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185. PPACA § 1201, 124 Stat. at 156.

186. *Id.*

187. Amy Goldstein, *Study: 129 Million Have Preexisting Conditions*, WASH. POST, Jan. 18, 2011, at A1.

188. Under the PPACA, insurers must provide only "minimum essential coverage" to policyholders. PPACA § 1201, 124 Stat. at 161; *Id.* § 1302(a), 124 Stat. at 163. The PPACA does not actually define "minimum essential coverage"; the Department of Health and Human Services (HHS) has this responsibility. *Id.* § 1302(b), 124 Stat. at 163.

189. *See supra* Section II.B.

pre-existing conditions to deny or delay coverage or charge higher premiums.<sup>190</sup> The PPACA requires insurers to extend coverage on a guaranteed issue basis, regardless of an individual's health status: "[E]ach health insurance issuer that offers health insurance coverage in the individual or group market must accept every employer and individual in the State that applies for such coverage."<sup>191</sup> Rate discrimination based on health status is also prohibited under the PPACA to prevent insurers from simply increasing premiums to cover additional costs incurred by covering higher risk insureds. Under the PPACA, premiums may vary only by family status, geography, age, and tobacco use.<sup>192</sup>

Like other Americans, many transgender individuals will experience increased access to health insurance as a result of these reforms. Once the PPACA takes effect, insurers will be unable to discriminate on the basis of "any health status-related factors," defined broadly to include health status, medical condition (including both physical and mental illnesses), claims experience, receipt of healthcare, medical history, genetic information, evidence of insurability (including conditions arising out of acts of domestic violence), disability, and any other status-related factor deemed appropriate by the Secretary of Health and Human Services.<sup>193</sup> For transgender individuals, this means that they will not be denied insurance coverage or confront insurance rescission because of transgender status or prior receipt of transition-related services. Transgender individuals will also no longer have to pay higher premiums to access insurance coverage since the PPACA does not permit rate discrimination based on transgender identity. The PPACA appears to be, in many ways, "a huge leap forward for the transgender community."<sup>194</sup>

It is, however, unlikely that the PPACA will end discrimination against transgender individuals in healthcare. The new legislation restricts medical organizations and providers from practicing many forms of discrimination,

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190. The Health Insurance Portability and Accountability Act (HIPAA) of 1996 has already limited the ability of insurers to include pre-existing condition clauses in employment-related group insurance policies. 29 U.S.C. § 1181 (2006); 42 U.S.C. § 300(g)(g). HIPAA "imposes a reasonably narrow definition of pre-existing condition (excluding, for example, genetic predisposition or domestic violence); it limits the look-back period for determining whether a pre-existing condition exists to six months; and in most instances, it only permits the pre[-]existing conditions clause to operate for a maximum period of twelve months." TIMOTHY STOLTZFUS JOST, *THE REGULATION OF PRIVATE INSURANCE* 28 (2009), [http://www.nasi.org/sites/default/files/research/The\\_Regulation\\_of\\_Private\\_Health\\_Insurance.pdf](http://www.nasi.org/sites/default/files/research/The_Regulation_of_Private_Health_Insurance.pdf).

191. PPACA § 1201, 124 Stat. at 156.

192. *Id.*

193. *Id.*

194. Press Release, National Center for Transgender Equality, Health Care Reform Signed into Law: How Will it Affect Transgender People? (Mar. 23, 2010), *available at* [www.transequality.org/news10.html](http://www.transequality.org/news10.html).

including that which is based on race, ethnicity, sex, age, and disability.<sup>195</sup> But the PPACA does not explicitly prohibit discrimination against transgender populations, even though these groups experience exceedingly high rates of discrimination in healthcare.<sup>196</sup> While this legislation may promise more healthcare rights to transgender individuals, it will not necessarily help them realize or guard these rights.

Furthermore, the new healthcare legislation does not protect access to transition-related health benefits. As discussed in Part II, insurers frequently deny coverage for transition-related care on the grounds that such care is not “medically necessary.” The PPACA will likely continue this trend, unless the Department of Health and Human Services (HHS) issues regulations that designate transition-related care as an essential health benefit that every healthcare plan must provide. This is unlikely to happen, given the fact that none of the LGBT-related provisions from earlier versions of the healthcare reform bill are included in the final PPACA.<sup>197</sup>

Finally, there is a strong possibility that the new provisions enacted by the PPACA may worsen transgender access to healthcare. Eliminating pre-existing condition exclusions may lead to coverage of more people, but may also spur coverage of fewer services, at least for certain populations. Since pre-existing condition exclusions can no longer be used to deny coverage or charge higher rates to those with medical problems, insurers will undoubtedly turn to other measures to exclude high-risk clients and curb costs. To do so, insurers may increase medical-necessity review, particularly for treatments that could be considered cosmetic or lifestyle related. Once the PPACA takes effect, insurers may less readily accept a provider’s conclusions about the medical necessity of a given procedure and more proactively impose their own narrow conceptions of medical necessity to avoid paying for certain treatments. Though politically sympathetic groups, like cancer patients or young children, might avoid increased scrutiny of the medical services they consume, the transgender population may not be as fortunate. Any coverage of transition-related care provided in the past may disappear altogether under the PPACA as insurers employ more demanding standards of medical necessity.

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195. PPACA § 1201, 124 Stat. at 156.

196. A survey by Lambda Legal found that seventy percent of transgender and gender-nonconforming respondents had experienced some form of discrimination by medical providers. LAMBDA LEGAL, *WHEN HEALTH CARE ISN'T CARING: LAMBDA LEGAL'S SURVEY ON DISCRIMINATION AGAINST LGBT PEOPLE AND PEOPLE LIVING WITH HIV* (2010), available at [http://data.lambdalegal.org/publications/downloads/whcic-report\\_when-health-care-isnt-caring.pdf](http://data.lambdalegal.org/publications/downloads/whcic-report_when-health-care-isnt-caring.pdf).

197. Chris Johnson, *LGBT Provisions Cut From Health Care Reform Bill*, DC AGENDA, Mar. 26, 2010, at 20.

*B. Recasting Medical Necessity*

Insurers have long used medical-necessity arguments to restrict transgender patients' access to healthcare, and the influence of these arguments on transgender medicine may grow under the new federal healthcare legislation. This Section suggests that what is troubling is not medical-necessity review itself, but rather the *way* insurers define and apply medical necessity in making coverage decisions that affect transgender populations.

Insurers, along with most of the judicial and state actors that regulate them, have traditionally relied on medical criteria alone to determine whether a particular medical intervention is necessary and warrants coverage. As discussed in Part II, insurance plans regularly dismiss transition-related care as cosmetic or experimental, and thus unnecessary. Under the PPACA, insurers will have more incentive than ever before to narrow the kinds of services considered medically necessary, especially for politically powerless groups like transgender individuals. Also, as factions within the transgender community increasingly call for rejecting the pathologization of gender variance, it may become even easier for insurers to avoid funding transitional services on necessity grounds. Unless policymakers and courts intervene, transition-related care could disappear under the PPACA.

But why should these actors intervene? If even transgender individuals do not necessarily view transitional care as medically necessary, why should regulatory actors require insurers to include such care in their policies? The answer to this question depends on how one defines medical necessity. If medical necessity is a standard that turns strictly on how essential a particular treatment is to one's bodily or mental well-being, then transition-related care is arguably not medically necessary, since many individuals who identify as transgender can survive, and perhaps even thrive, without it.

Such a view of medical necessity is, however, somewhat myopic. Just because some transgender individuals do not need transitional procedures does not mean they are inappropriate for all transgender individuals. Patients with the same condition often have diverse medical needs, and interventions that are medically necessary for one patient may not be medically necessary for another. All individuals suffering from Lyme disease, for example, do not necessarily receive the same medical protocol, but we do not dismiss certain Lyme disease treatments as medically unnecessary just because every patient with Lyme disease does not utilize them.

Furthermore, a strict conception of medical necessity for transition-related procedures is inconsistent with the use of the standard in other contexts. As noted in Part II, a given treatment is usually considered necessary when a patient's physician finds that the intervention is medically appropriate for a patient's

condition.<sup>198</sup> Insurers and courts typically defer to the physician’s judgment, provided it aligns with the medical community’s recommended treatments for the condition. When insurers review claims for gender-confirming care, however, they are often less willing to accept a physician’s conclusions about medical necessity.<sup>199</sup>

Finally, current medical-necessity review for trans-specific interventions rarely considers the significant impact social norms can have on the medical benefits these individuals seek. One scholar argues that transition-related treatment is important to “an individual’s ability to function and survive in society, given current biases and beliefs.”<sup>200</sup> Transgender individuals suffer high rates of discrimination in the workplace, and the current law offers little relief. In thirty-seven states, it remains legal for employers to discriminate on the basis of gender identity, and federal anti-discrimination laws do not cover gender-variant populations.<sup>201</sup> Anatomical features that deviate from what society considers “normal” can lead to severe harassment at work—that is, if one can even manage to hold on to a job despite transgender status.<sup>202</sup>

When the violence frequently encountered by transgender individuals is considered, it is difficult to dismiss transitional care as medically unnecessary. Reports of assault, rape, and murder of transgender people are fairly common and often brutal.<sup>203</sup> Victims frequently describe receiving little compassion from police officers and emergency medical personnel when reporting these crimes.<sup>204</sup> When even those responsible for protecting transgender groups from violence and redressing their harm react transphobically, concealing transgender identity with gender-confirming care may be, for some, the only way to avoid danger and discrimination.<sup>205</sup>

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198. *See supra* text accompanying note 134.

199. *See supra* text accompanying notes 136-137.

200. Susan Etta Keller, *supra* note 15, at 72.

201. *Fact Sheet: The Employment Non-Discrimination Act (ENDA)*, NATIONAL CENTER FOR TRANSGENDER EQUALITY (Aug. 2009), available at [transequality.org/Resources/NCTE\\_ENDA09.pdf](http://transequality.org/Resources/NCTE_ENDA09.pdf).

202. *Id.*

203. *See, e.g.,* Rebecca Cathcart, *Boy’s Killing, Labeled a Hate Crime, Stuns a Town*, N.Y. TIMES, Feb. 23, 2008, at A11; Carolyn Marshall, *Two Guilty of Murder in Death of a Transgender Teenager*, N.Y. TIMES, Sept. 13, 2005, at A20.

204. Twenty-two percent of 6450 respondents in a national survey assessing discrimination against transgender and gender-nonconforming people reported being “harassed, physically assaulted, or sexually assaulted” by police officers because they were transgender or gender-nonconforming. Grant, *supra* note 2, at 158, 172 n.1.

205. Avoiding violence appears to be a significant factor in decisions to obtain transition related interventions. One woman writes, “As a pre-op trans woman who generally always blends and is read as cis, concerns about attackers turning murderous and emergency and medical personnel reacting transphobically are always mingled with any concerns about sexual assault.

Many will no doubt argue that social norms outside the doctor's office should play no part in determining what happens within it. After all, healthcare is designed to address medical issues, not social problems. Yet a system in practice often deviates from design and medicine is no exception. Whether we like it or not, social norms *do* impact our assessment of medically necessary procedures. Breast cancer patients who receive mastectomies for breast cancer, for instance, do not always require reconstructive surgery for clinical reasons. Yet federal law mandates coverage of breast reconstruction in connection with mastectomies.<sup>206</sup> For better or worse, breasts play a significant part in both personal and social understanding of female identity, so the desire to restore them after breast cancer is universally understood. Transgender individuals seek transitional care for some of the same reasons breast cancer survivors seek reconstructive surgery: to shape their bodies to match their personal identities and to simply fit in.

Along with considering the social necessity of treatment, medical-necessity review should take into account the legal implications of transition-related care. As Part I of this Note argues, the legal rights available to transgender individuals frequently depend on medical evidence demonstrating transition to a new sex. The ability to change gender markers on identification documents, to maintain the validity of a marriage, and to win custodial rights after divorce can turn on medical or surgical alteration of sex characteristics. Often, the medical interventions required to win legal recognition of an adopted gender are quite drastic; there are no states, for instance, that permit changes to the sex listed on a birth certificate without evidence of gender reassignment surgery.<sup>207</sup> As long as legal rights remain contingent on medical confirmation of sex change, medical-necessity review must take legal implications into account.

The obvious objection to this argument, perhaps from transgender advocates and opponents alike, is that incorporating legal analysis into medical-necessity review will strengthen the role of medicine in determining the legal understanding of gender. While we should not abandon efforts to make legal recognition of sex turn on factors other than medical evidence, the current law is not even close to divorcing itself from medicine in the area of transgender rights. In recent years, transgender advocates have focused on lessening, rather than

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Haven't really come up with any solutions for myself to handle the possibility other than get [sexual reassignment surgery] and don't be assaulted." Nicole, Comment to *We are the Dead: Sex, Assault, and Trans Women*, FEMINISTE (Apr. 12, 2010, 1:16 PM), <http://www.feministe.us/blog/archives/2010/04/12/we-are-the-dead-sex-assault-and-trans-women>; see also Donna, Comment to *We are the Dead: Sex, Assault, and Trans Women*, *supra* ("I have to admit that having had [sexual reassignment surgery] last year makes me a \*little\* less afraid of things like [assault and harassment] happening to me.").

206. Women's Health and Cancer Rights Act of 1998, 29 U.S.C. § 1185b (2006).

207. Spade, *supra* note 31, at 768.

eradicating, the influence of medical interventions on legal opportunities. One recent victory for the transgender community involves the State Department's decision to eliminate gender reassignment surgery as a prerequisite to alteration of gender markers listed on passports.<sup>208</sup> Though reassignment surgery may no longer be required to obtain a passport with a new gender, transgender citizens will still need a letter from their physician stating that they have received "appropriate clinical treatment" for gender transition.<sup>209</sup> This is clearly a victory for the transgender population, but it is a victory that remains contingent on medical evidence. Until legal rights are separated from medical authority, it is irresponsible to ignore the legal implications of care when reviewing the medical necessity of transition-related interventions.

### CONCLUSION

The PPACA has revived social legislation in America and launched a new era in healthcare. Designed to guarantee healthcare access to all Americans, the new legislation eliminates the ability of insurers to discriminate against patients on the basis of race, sex, and even health status. It is not an overstatement to call the PPACA, as the President has, a "patient's bill of rights on steroids."<sup>210</sup>

It is important to realize, though, that the PPACA will not completely strip insurers of their authority to determine which individuals do and do not deserve care. New requirements will increase pressure on insurers to find other ways to avoid costly patients without prompting political backlash and additional regulation. An increased reliance on medical-necessity arguments to exclude certain procedures from coverage is likely, particularly if the value of these interventions is not widely recognized by the public or powerful special interest groups.<sup>211</sup> Transgender patients may find themselves subject to greater scrutiny for the health services they consume and may receive less coverage for transition-related interventions, which insurers are apt to find increasingly

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208. 7 U.S. DEP'T OF STATE, FOREIGN AFFAIRS MANUAL 1300 app. m (2011), *available at* <http://www.state.gov/documents/organization/143160.pdf>; *see also* Press Release, U.S. Dep't of State, New Policy on Gender Change in Passports Announced (June 9, 2010), *available at* <http://www.state.gov/r/pa/prs/ps/2010/06/142922.htm>.

209. Press Release, U.S. Dep't of State, *supra* note 208.

210. President Barack Obama, Remarks by the President to the House Democratic Congress, (Mar. 20, 2010), *available at* <http://www.whitehouse.gov/the-press-office/remarks-president-house-democratic-congress>.

211. *See* Jessica Mantel, *Health Care Reform: Setting National Coverage Standards for Health Plans*, 57 UCLA L. REV 221, 227 (2010) (arguing that though adverse selection will push most plans to offer only a minimum essential benefits package, politics will intervene to force coverage for some conditions). "Political considerations would lead politicians to push for an essential health benefits package that includes those conditions and treatments demanded by the public or influential special interest groups, regardless of the merits . . ." *Id.*

unnecessary under the PPACA.

Heavier reliance on medical-necessity review, however, does not *have* to terminate transitional care for transgender patients. The PPACA grants HHS the opportunity to reassess and update the traditional interpretation of medical necessity by defining what constitutes essential health services under the new legislation. For transgender individuals, medical interventions are often critical to more than just health, so medical-necessity review should look beyond the clinical implications of care. Securing meaningful access to healthcare for transgender patients under the PPACA requires expanding medical-necessity review to account for the social and legal consequences of transition-related interventions. This is a pivotal moment for change in the definition and application of medical-necessity review for transition-related claims.