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ONLINE THREATS TO SENIOR SAFETY: THE DIRECT-TO-CONSUMER  
MEDICAL MARKETPLACE AND eELDER ABUSE

*By Kimberly M. Lovett and Timothy K. Mackey*

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I. INTRODUCTION

U.S. Census data shows that the senior population (individuals over 65 years old) is growing rapidly and outpacing younger generations.<sup>1</sup> This trend is likely to continue as

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1 Between 2000 and 2010, the population of persons in the United States 16 years of age and over grew

the Baby Boomer generation — those born between 1946 and 1964 — enters senior ages.<sup>2</sup> Further, as the senior population expands and healthcare costs continue to rise, access to healthcare services and especially Medicare-related funding will continue to decrease as cost shifting occurs during difficult economic times.<sup>3</sup> This reduced access to healthcare resources in addition to other unique vulnerabilities of seniors — including decreased mobility, fixed incomes, and polypharmacy<sup>4</sup> — put this already vulnerable population of patients at increased risk of being exploited by and suffering harm from an unfettered and rapidly expanding online direct-to-consumer (DTC) medical marketplace. Indeed, Baby Boomers and seniors are increasingly accessing the Internet for healthcare information, services, and products.<sup>5</sup>

In addition, the National Prevention Strategy — the nation's first national prevention and health promotion strategy (which is included in the Affordable Care Act) — has encouraged seniors to obtain preventive screening and proactive medical care.<sup>6</sup> These policy initiatives, occurring in the context of exploding Internet presence<sup>7</sup> and consumer healthcare utilization,<sup>8</sup> make it particularly imperative to account for the DTC medical marketplace to ensure consumer protection and patient safety are priority considerations. Several studies have already highlighted precarious risks specifically associated with the

12 percent, whereas the populations of persons ages 45 to 64 and over 64 grew 31.5 percent and 21 percent, respectively. Lindsay M. Howden & Julie A. Meyer, *Age and Sex Composition: 2010, 2010 Census Briefs 2*, <http://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf> (U.S. Census Bureau, May 2011).

- 2 *Id.* “The population aged 45 to 64 grew at a rate of 31.5 percent [between 2000 and 2010]. The large growth in this age group is primarily due to the aging of the Baby Boom population.”
- 3 Christopher J. Truffer et al., *Health Spending Projections Through 2019: The Recession's Impact Continues*, 29 *Health Affairs* 522, 527–528 (2010). See Soc. Sec. Advisory Board, *The Unsustainable Cost of Health Care* 12, [http://www.ssab.gov/documents/TheUnsustainableCostofHealthCare\\_graphics.pdf](http://www.ssab.gov/documents/TheUnsustainableCostofHealthCare_graphics.pdf) (Sept. 2009).
- 4 Polypharmacy is the concomitant use by a single patient of multiple prescription medications that may or may not be clinically necessary; polypharmacy implies increased medication management complexity for patients resulting from high prescription medication burden. Polypharmacy increases the risk for adverse clinical outcomes, including: a) adverse drug reactions, b) drug-drug interactions, and c) increased financial cost to patients. Polypharmacy is a common problem among the elderly. Maryann M. Fulton & Elizabeth R. Allen, *Polypharmacy in the Elderly: A Literature Review*, 17 *J. Am. Acad. Nurse Pract.* 123, 123–132 (2005).
- 5 “Eight in ten [I]nternet users look online for health information, making it the third most popular online pursuit ... following email and using a search engine.” Susannah Fox, *Health Topics: 80% of Internet Users Look for Health Information Online 2*, [http://www.pewinternet.org/~media/Files/Reports/2011/PIP\\_Health\\_Topics.pdf](http://www.pewinternet.org/~media/Files/Reports/2011/PIP_Health_Topics.pdf) (Pew Internet & Am. Life Project, Feb. 1, 2011).
- 6 See *Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act*, 75 *Fed. Reg.* 41726 (July 19, 2010). See also Nat'l Prevention Council, *National Prevention Strategy: America's Plan for Better Health and Wellness* 18, <http://healthcare.gov/prevention/nphpphc/strategy/report.pdf> (June 2011).
- 7 Between 1995 and 2002, the percentage of adults adopting use of the Internet rose from 14 percent to 61 percent. In 2012, 82 percent of all adults in the United States used the Internet. Pew Internet & Am. Life Project, *Trend Data (Adults), Internet Adoption, 1995–2012*, [http://www.pewinternet.org/Trend-Data-\(Adults\)/Internet-Adoption.aspx](http://www.pewinternet.org/Trend-Data-(Adults)/Internet-Adoption.aspx) (2012).
- 8 Since 1965 and the introduction of publicly funded healthcare coverage, out-of-pocket contributions of healthcare consumers have dropped substantially. This reduction in out-of-pocket contributions increases consumer utilization of healthcare services. See Soc. Sec. Advisory Board, *supra* n. 3, at 11–12.

DTC medical marketplace including: fraudulent online drug marketing, counterfeit drug sales, and unproven medical screening tests including genetic, cardiac, and oncologic testing.<sup>9</sup> Given the combination of increasing Internet accessibility and use among seniors, rising health costs, increasing senior population size, and unique senior vulnerabilities, seniors are at particularly high risk of being exploited and harmed by this unfettered DTC medical marketplace, resulting in what we term “eElder abuse.” In this way, advances in technology must provoke adaptations within law and policy to respond to new and rising threats to vulnerable seniors.

Although “elder abuse” is an established yet often variable term used within state laws,<sup>10</sup> it often relies on several factors that are not present in online situations. This piece proposes reform that would broaden existing elder abuse definitions to encompass specific eElder abuse harms. We propose that eElder abuse laws target illicit online drug marketing and sales as well as fraudulent or reckless online advertising and sale of medical screening and pharmaceutical products that specifically result in physical and financial harm to seniors.

Part II provides an overview of aging populations and the prevalence of Internet use. This section reviews online pharmaceutical purchasing patterns as well as increasing use of online health information seeking and consumption among seniors.

Part III discusses the characteristics of the online DTC medical marketplace, reviews the plethora of pharmaceutical and screening products available online, discusses the general risks and pitfalls of the DTC medical marketplace, and highlights unique vulnerabilities of seniors related to the availability of these DTC pharmaceutical and screening test products.

Part IV reviews a subset of current state Elder Abuse laws, definitions, and the weakness of these laws in addressing online harms to seniors resulting from the DTC medical marketplace. Here, we specifically explore key concepts of elder abuse and their

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9 A number of scientific studies have identified the numerous risks associated with health-related products available in the direct-to-consumer (DTC) marketplace, including those marketed via social media. E.g. Bryan A. Liang & Timothy Mackey, *Commentary: Direct-to-Consumer Advertising with Interactive Internet Media: Global Regulation and Public Health Issues*, 305 J. Am. Med. Assn. 824 (2011) [hereinafter *Interactive Internet Media*]. Studies show that use of social media is highly pervasive and largely unregulated by both licit and illicit actors. This in turn is fueling an illicit global drug trade for counterfeit medicines. E.g. Tim K. Mackey & Bryan A. Liang, *Global Health Commentary: The Global Counterfeit Drug Trade: Patient Safety and Public Health Risks*, 100 J. Pharm. Sci. 4571 (2011) [hereinafter *Global Counterfeit Drug Trade*]; Bryan A. Liang & Timothy K. Mackey, *Prevalence and Global Health Implications of Social Media in Direct-to-Consumer Drug Advertising*, 13 J. Med. Internet Research e64 (2011). Indeed, DTC marketing has extended to a number of medical screening tests, including those for cardiovascular disease and cancer. E.g. Kimberly M. Lovett & Bryan A. Liang, *Direct-to-Consumer Cardiac Screening and Suspect Risk Evaluation*, 305 J. Am. Med. Assn. 2567, 2567–2568 (2011) [hereinafter *DTC Cardiac Screening*]; Kimberly M. Lovett et al., *Risks of Online Direct-to-Consumer Tumor Markers for Cancer Screening*, 30 J. Clinical Oncology 1411, 1411–1414 (2012) [hereinafter *DTC Tumor Markers*]; Kimberly M. Lovett & Bryan A. Liang, *Comment: Risks of Online Advertisement of Direct-to-Consumer Thermography for Breast Cancer Screening*, 11 Nat. Rev. Cancer 827 (2011) [hereinafter *DTC Thermography*].

10 Historically, state laws often vary in their definitions of “elder abuse” and hence lack uniformity. See Jeanette M. Daly & Gerald Jogerst, *Statute Definitions of Elder Abuse*, 13 J. Elder Abuse & Neglect 39, 47–54 (2003).

limitations when taking into consideration potential harms online.

Finally, Part V proposes reform to current definitions of elder abuse to encompass the concept of eElder abuse. Specifically, this section highlights and addresses the particular limitations of current elder abuse definitions to address these emerging online threats to seniors. Additionally, we propose legal strategies using existing tools to target online medical testing and pharmaceutical vendors to limit harms accrued by senior consumers. Lastly, we describe how the various stakeholders associated with elder abuse can combine and coordinate efforts for the protection of vulnerable seniors from the threats posed by the emerging online DTC medical marketplace.

## II. SENIORS, BABY BOOMERS, AND THE INTERNET

### A. Trends of Increasing Internet Use

Searching for online health information is now common<sup>11</sup> and is likely fueling a growing online direct-to-consumer (DTC) medical industry.<sup>12</sup> Seniors continue to close the digital divide with younger generations for Internet use, particularly in healthcare, with surveys showing that almost three of four seniors with Internet access have searched for at least one major health topic online.<sup>13</sup> Indeed, there exist initiatives that are focused on facilitating senior access to the Internet and further closing the digital divide to improve convenience and accessibility to online health services for this vulnerable demographic.<sup>14</sup>

Given that the Baby Boomer generation is tomorrow's senior population, it is also important to understand online use trends of this population segment. Baby Boomers have rapidly adopted e-commerce devices and access.<sup>15</sup> Of note, 81 percent of Baby Boomers research and 70 percent buy products using e-commerce.<sup>16</sup> This "research and purchase" culture is, in fact, a predominant characteristic of online Baby Boomers and their consumer habits.<sup>17</sup>

### B. Internet Use and Access to Healthcare Resources

Searching for and purchasing health information and products online is common and has become much more accessible, with the presence of DTC advertising of medi-

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11 See Fox, *supra* n. 5, at 2.

12 Bryan A. Liang & Tim Mackey, *Searching for Safety: Addressing Search Engine, Website, and Provider Accountability for Illicit Online Drug Sales*, 35 Am. J. L. Med. 125, 143 (2009).

13 This includes, for example, 73 percent of seniors between 66 and 74 years of age searching for health information online. Fox, *supra* n. 5, at 5.

14 M. Kay Cresci & Patricia A. Jarosz, *Bridging the Digital Divide for Urban Seniors: Community Partnership*, 31 Geriatric Nursing 455, 455 (2010).

15 As of 2008, 74 percent of Baby Boomers used the Internet, 62 percent had broadband at home, 43 percent used WiFi connections for Internet access, and 47 percent used cloud-computing software. In addition, more than half of Baby Boomers were online each day and 41 percent went online "just for fun." Lee Rainie, *Baby Boomers and the Internet*, [http://pewinternet.org/Trend-Data-\(Adults\)/Online-Activities-Total.aspx](http://pewinternet.org/Trend-Data-(Adults)/Online-Activities-Total.aspx) (Pew Internet & Am. Life Project, Jan. 10, 2009).

16 *Id.*

17 See Pew Internet & Am. Life Project, *Trend Data (Adults), Total Online Activities*, [http://pewinternet.org/Trend-Data-\(Adults\)/Online-Activities-Total.aspx](http://pewinternet.org/Trend-Data-(Adults)/Online-Activities-Total.aspx) (2012).

cal products and services despite only being legally permitted in the developed countries of the United States, New Zealand, and South Korea.<sup>18</sup> Seniors, being less mobile and limited by fixed incomes, as well as having greater disease burden, are significantly more prone to need the access, convenience, and advertised cost-savings of Internet-based products and services.<sup>19</sup> Moreover, seniors are facing medical inflation, gaps in Medicare Part D coverage, and rising costs, and those with Internet access and digital prowess may turn to the Internet as an alternative.<sup>20</sup>

These financial and mobility factors have led to suspect online purchases.<sup>21</sup> Indeed, seniors have been reported to represent 54 percent of Internet traffic for top-selling Canadian online pharmacies and the most dominant age group visiting these websites.<sup>22</sup> This is despite the fact that importing medications purchased online from foreign-based Internet sellers is generally prohibited by federal and state law.<sup>23</sup> Yet, Baby Boomers and seniors are even more likely than younger generations to access online health information increasing their exposure to these suspect sellers.<sup>24</sup> This trend is likely only to increase as more tech-savvy Baby Boomers transition into the senior age groups and online purchasing of goods and services becomes more commonplace.<sup>25</sup> Consequently, as citizens of the Baby Boomer generation retire, become Medicare participants, develop age-related diseases, evolve toward living on fixed incomes, and develop reduced access to a wide range of healthcare services, it is imperative that the DTC medical industry be evaluated, regulated, and that potential online abuses to seniors be addressed with clear policy initiatives.

### III. THE ONLINE MEDICAL MARKETPLACE

Over the years, seniors have been solicited by entities via both direct mail and telemarketing campaigns.<sup>26</sup> This type of targeted marketing often represents scam operations designed specifically to defraud seniors.<sup>27</sup> These types of dubious campaigns to defraud seniors have entered cyberspace and are engaging these vulnerable citizens through on-

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18 Fox, *supra* n. 5, at 2.

19 See Jason Roberson, *To Cut Costs, Seniors Get Drugs from Online Canadian Pharmacies*, Dallas Morn. News, <http://www.dallasnews.com/health/headlines/20100927-To-cut-costs-seniors-get-8103.ece> (Sept. 28, 2010). See also Mackey & Liang, *Global Counterfeit Drug Trade*, *supra* n. 9, at 4574.

20 See Roberson, *supra* n. 19.

21 *Canadian Pharmacies Online*, Senior Mag. Online, <http://www.seniormag.com/canadianpharmacy/articles/canadian-market.htm> (Sept. 20, 2004).

22 *Id.*

23 Liang & Mackey, *supra* n. 12, at 152–155.

24 See Fox, *supra* n. 5. See also Sydney Jones & Susannah Fox, *Pew Internet Project Data Memo: Generations Online in 2009*, [http://pewinternet.org/~media/Files/Reports/2009/PIP\\_Generations\\_2009.pdf](http://pewinternet.org/~media/Files/Reports/2009/PIP_Generations_2009.pdf) (Pew Internet & Am. Life Project, Jan. 28, 2009).

25 See Pavel Alpeyev & Yoshinori Eki, *The iPad Leads Apple to the Elderly*, Bloomberg Businessweek, [http://www.businessweek.com/magazine/content/10\\_34/b4192039623670.htm](http://www.businessweek.com/magazine/content/10_34/b4192039623670.htm) (Aug. 12, 2010).

26 Protecting Seniors From Fraud Act, Pub. L. No. 106-534, § 2, 114 Stat. 2555 (2000). The Act states, “(7) According to the National Consumers League, telemarketing fraud costs consumers nearly \$40,000,000,000 each year ... (8) Senior citizens are often the target of telemarketing fraud ... (9) Fraudulent telemarketers compile the names of consumers who are potentially vulnerable to telemarketing fraud into the so-called ‘mooch lists’ ... (10) It is estimated that 56 percent of the names on such ‘mooch lists’ are individuals age 50 or older.”

27 *Id.*

line marketing.<sup>28</sup> The online DTC medical marketplace is emerging rapidly with little regulation or oversight.<sup>29</sup> This virtual environment includes expanding access to medical products and medical services peripheral to physician oversight.<sup>30</sup> Often, consumers who enter this unregulated market for medical products and services have little knowledge of the scope or presence of the risk that this online industry poses to their individual health and well-being.<sup>31</sup> In this section, we review characteristics of the online DTC medical marketplace, including identified pharmaceutical and testing products risks, as well as unique vulnerabilities and risks to the senior population.

### A. Pharmaceuticals

#### 1. Risks of Online DTC Pharmaceutical Purchasing

Illicit online pharmacies pose serious threats to public and patient safety.<sup>32</sup> First, without appropriate professional oversight or the need to provide a valid prescription while accessing prescription drugs, there is a higher risk of prescription drug abuse, adverse events, and/or death.<sup>33</sup> Second, non-FDA-approved overseas factories may be manufacturing and selling these medical products, increasing the chances of encountering substandard or counterfeit medications.<sup>34</sup>

Further, counterfeit pharmaceuticals cause harm not only because they fail to treat the medical condition they were purchased to target, but also because they may be composed of harmful chemicals or lack active pharmaceutical ingredients.<sup>35</sup> Consequently, users risk significant harm from ineffective treatment and/or toxicity from materials that are used to produce fake or tainted products, including chalk, floor wax, boric acid (which causes renal failure in humans), and toxic road paint.<sup>36</sup> Illustratively, the recent death of Baby Boomer Marcia Bergeron was reported as directly resulting from counterfeit drugs purchased online.<sup>37</sup> She had purchased a variety of drugs including hypnotics, anti-anxiety, and over-the-counter medications that were found to be counterfeit and containing toxic levels of heavy metals.<sup>38</sup> Further, seniors have been identified as

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28 Studies indicate that DTC online advertising is largely unregulated in the medical services and products industry due to the challenges of a global marketplace and the limitations of regulating the Internet. See Liang & Mackey, *Interactive Internet Media*, *supra* n. 9. This has led to a proliferation of suspect online drug sellers, whose products have led to patient deaths. Liang & Mackey, *supra* n. 12, at 143, 152.

29 Liang & Mackey, *Interactive Internet Media*, *supra* n. 9.

30 *Id.*

31 Liang & Mackey, *supra* n. 12, at 131; Bryan A. Liang, *Fade to Black: Importation and Counterfeit Drugs*, 32 *Am. J. L. Med.* 279, 283–284 (2006).

32 Liang & Mackey, *supra* n. 12, at 126, 129.

33 *Id.*

34 *Id.* at 128, 136.

35 Cyveillance, *Clamping Down on American Companies That Assist Cybercrime*, <http://www.cyveillance-blog.com/legal/clamping-down-on-american-companies-that-assist-cybercrime> (Aug. 13, 2010); Liang, *supra* n. 31; Mackey & Liang, *Global Counterfeit Drug Trade*, *supra* n. 9, at 4572.

36 Liang, *supra* n. 31.

37 Sam Solomon, *BC Woman Killed by Fake Drugs Bought Online*, 4 *Nat'l Rev. Med.*, [http://www.nationalreviewofmedicine.com/issue/2007/07\\_30/4\\_policy\\_politics\\_13.html](http://www.nationalreviewofmedicine.com/issue/2007/07_30/4_policy_politics_13.html) (July 30, 2007).

38 *Id.*

the largest group of consumers purchasing from online drug vendors.<sup>39</sup>

Many online medical drug vendors have been found to not only sell counterfeit and/or poor quality drugs, such as RxNorth.com, but they have also been implicated as supporting organized crime, including Russian cybercriminals who operated CanadianPharmacy.net.<sup>40</sup> Making matters worse, perpetuated misinformation encourages consumers to trust suspect online drug vendors.<sup>41</sup>

Lack of consumer awareness further compounds these already potentially fatal risks. For example, one survey found that 15 percent of U.S. respondents had purchased drugs online;<sup>42</sup> yet, an incredible 93 percent of these respondents who had purchased pharmaceuticals via the Internet never considered that the products might be tainted or counterfeit.<sup>43</sup> Furthermore, despite the fact that more than half (53 percent) of these online consumers noted that there is no way to tell if a pharmaceutical is real or counterfeit, they still purchased it over the Internet.<sup>44</sup> In fact, more than a quarter (27 percent) of respondents believed that if the online vendor guaranteed that the medication was genuine, that was enough information for them to make a purchase.<sup>45</sup> This unchallenged and misplaced trust among consumers toward online pharmaceutical vendors is likely the result of consumer confusion regarding the unregulated nature of online pharmacies compared to relatively controlled traditional brick-and-mortar pharmacies in the U.S.

The National Association of Boards of Pharmacy (NABP), a professional organization made up of state boards of pharmacy, has compiled a “Not Recommended Site” list for online drug sellers, which specifically names “those sites that appear to be out of compliance with state and federal laws or NABP patient safety and pharmacy practice standards.”<sup>46</sup> NABP also provides verification and accreditation services for Internet pharmacies known as its Verified Internet Pharmacy Practice Sites (VIPPS) program.<sup>47</sup> Yet, at the time of this writing, there were only approximately 30 VIPPS verified sites compared to the thousands of online pharmacies not verified. NABP services potentially mitigate some of the risk associated with online pharmacy e-commerce but if consum-

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39 Liang & Mackey, *supra* n. 12, at 132.

40 *Id.* at 130, 133, 136–137.

41 Consumers may rely on specific online pharmacy “validation” services. However, such services have been shown to be weak in assessing the safety and validity of their member sites. Sharon O’Brien, *How to Find the Best Online Pharmacy: Get Canada Pharmacy and U.S. Pharmacy Ratings, Costs, and Delivery Fees*, About.com, <http://seniorliving.about.com/od/manageyourmoney/a/onlinepharmacy.htm> (accessed July 14, 2012). See also Liang & Mackey, *supra* n. 12, at 135.

42 Liang & Mackey, *supra* n. 12, at 131

43 *Id.*

44 *Id.*

45 *Id.*

46 The National Association of Boards of Pharmacy is a professional organization supported by membership of the individual state boards of pharmacy with the aim of ensuring public health and patient safety through pharmacist licensing activities, training and accreditation programs, and verification programs of certain online medical service providers. Nat’l Assn. of Boards of Pharm., *Not Recommended Sites*, <http://www.nabp.net/programs/consumer-protection/buying-medicine-online/not-recommended-sites> (accessed July 14, 2012).

47 Nat’l Assn. of Boards of Pharm., *VIPPS Criteria*, <http://www.nabp.net/programs/accreditation/vipps/vipps-criteria> (accessed July 16, 2012); Liang & Mackey, *supra* n. 12, at 135



ers are unaware that the information or controls exist, they are unlikely to implement the information in their decision-making process.<sup>48</sup>

## 2. DTC Pharmaceuticals and Unique Senior Risks

Even when pharmaceuticals are not counterfeit, offering medications without a physician prescription and without fully detailing the potential hazards and contra-indications of therapy poses serious threats to patients.<sup>49</sup> Seniors are especially at risk of contra-indications and medication interactions because of the high incidence of polypharmacy in this patient population.<sup>50</sup> Indeed, seniors represent the greatest consumer market for online pharmacies.<sup>51</sup> Several suspect pharmacies, for example, offer customers free sildenafil (better known as Viagra<sup>®</sup>) with the purchase of atorvastatin.<sup>52</sup> However, statins are generally advised in patients with known coronary artery disease;<sup>53</sup> and this same senior patient population is also often prescribed nitrates for chest pain.<sup>54</sup> Yet, seniors having high incidence of erectile dysfunction<sup>55</sup> are at clear risk of falling prey to such advertising strategies offering free sildenafil. Unfortunately, concomitant use of nitrates and sildenafil together is expressly contraindicated because of potentially lethal reductions in blood pressure.<sup>56</sup> However, whereas it is the job of physicians and pharmacists to prevent concomitant use of these medication types, online pharmacies generally do not detail any of these risks or contraindications on their website advertising to warn consumers of serious potential harms.<sup>57</sup>

Seniors are also at particular risk of harms related to online purchasing of pharmaceuticals peripheral to physician oversight because of unique senior sensitivities to commonly sought-after medications. A list of several medications potentially dangerous for

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48 Heuristics (aids to learning, discovery, or problem solving) have been shown to influence patients' clinical decision making as well as their perception of clinical risk. One such heuristic that tends to influence patient risk perception is the "availability heuristic" whereby something that is easily brought to mind is deemed more likely and something that is less easily brought to mind is deemed less likely. Thus, information not available to patients is likely to have little influence on their clinical decision making. A.J. Lloyd, *The Extent of Patients' Understanding of the Risk of Treatments*, 10 (Supp. I) *Quality Health Care* i14, i14 (2001).

49 Liang & Mackey, *supra* n. 12, at 129.

50 Liang, *supra* n. 31, at 280.

51 Liang & Mackey, *supra* n. 12, at 132.

52 Bethan Williams & David Brown, *Direct to Consumer Internet Advertising of Statins: An Assessment of Safety*, 21 *Pharmacoepidemiology & Drug Safety*, 352, 361 (2012).

53 See Antonio M. Gotto & Jennifer E. Moon, *Management of Cardiovascular Risk: The Importance of Meeting Lipid Targets*, 110(1)(Suppl.) *Am. J. Cardiology* 3A, 3A (2012).

54 Chest pain related to cardiovascular disease is known as angina pectoris. See Udho Thadani, *Role of Nitrates in Angina Pectoris*, 70(8) *Am. J. Cardiology* 43B, 43B (1992).

55 See Maria Kubin et al., *Epidemiology of Erectile Dysfunction*, 15 *Int'l J. Impotence Research* 63, 63 (2003).

56 Williams & Brown, *supra* n. 52, at 361; MedicineNet.com, *Viagra and Nitrates Don't Mix*, <http://www.medicinenet.com/script/main/art.asp?articlekey=8229> (accessed July 14, 2012). In addition, other studies have shown that online sellers have sold Viagra to consumers even in cases in which Viagra use is expressly contraindicated for the particular consumer. Gunther Eysenbach, *Online Prescribing of Sildenafil (Viagra) on the World Wide Web*, 1 *J. Med. Internet Research* e10 (1999).

57 Williams & Brown, *supra* n. 52, at 361-362.

seniors has been published, which includes skeletal muscle relaxants, sleep medications, anti-anxiety medications, arthritis pain medications, antihistamines, depression medications, blood pressure medications, and more.<sup>58</sup> The risks posed by the potentially dangerous use of these medications in seniors arise from polypharmacy, memory problems, and increased fall risks.<sup>59</sup>

However, the online DTC medical marketplace circumvents a very important safeguard for seniors whereby physicians, pharmacists, Medicare, and insurance companies have checks and balances and may communicate to prevent seniors from being prescribed these potentially dangerous medications.<sup>60</sup> Vulnerable seniors may not be aware of the risks these medications pose when purchasing online, especially given that online sellers generally do not provide the proper risk information, contraindications, or necessary patient consultation when dispensing a pharmaceutical.<sup>61</sup> Further, vulnerable seniors with common conditions such as arthritis, depression, insomnia, and hypertension, may seek these potentially risky medications online without a prescription due to inadequate health coverage or for measures of convenience.<sup>62</sup> Consequently, these seniors are at very high risk of suffering harms resulting from bypassing current traditional healthcare system safeguards aimed at avoiding the use of these medications in the elderly.

Though the risks associated with online purchasing of pharmaceuticals are significant, seniors have particularly increased need for improved access to pharmaceuticals from the comfort of their homes and at a reduced cost. Barriers for seniors to access the traditional healthcare system arise from a combination of factors including: greater average numbers of prescription medications resulting in high monthly pharmaceutical costs;<sup>63</sup> fixed incomes pressuring seniors to seek lower cost products;<sup>64</sup> Medicare Part D coverage gaps pushing seniors to seek lower cost products;<sup>65</sup> and reduced mobility making it difficult for seniors to commute to and from office appointments and pharmacies.<sup>66</sup> Each of these unique characteristics make seniors much more vulnerable to relenting to

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58 Donna M. Fick et al., *Updating the Beers Criteria for Potentially Inappropriate Medication Use in Older Adults: Results of a US Consensus Panel of Experts*, 163 *Archives Internal Med.* 2716, 2719 (2003).

59 *Id.*

60 Ongoing systems-based communications aimed at increasing communications between healthcare practitioners and pharmacists to reduce adverse drug events in the elderly have been gaining widespread implementation. Kathrin M. Cresswell et al., *Adverse Drug Events in the Elderly*, 83 *British Med. Bull.* 259, 267 (2007). Furthermore, the Agency for Healthcare Research and Quality has published studies of computer-based decision support systems to help pharmacists and physicians catch and prevent potential adverse drug events. Philip A. Routledge et al., *Adverse Drug Reactions in Elderly Patients*, 57 *British J. Clinical Pharmacology* 121, 123–124 (2004). These mechanisms are circumvented in the online DTC medical forum.

61 See Williams & Brown, *supra* n. 52, at 361–362.

62 See Roberson, *supra* n. 19.

63 Fulton & Allen, *supra* n. 4.

64 Roberson, *supra* n. 19.

65 Studies show that falling into the Medicare Part D coverage gap is linked to a reduction in filling medically necessary prescription medications among the elderly. Pengxiang Li et al., *Effect of the Medicare Part D Coverage Gap on Medication Use among Patients with Hypertension and Hyperlipidemia*, 156 *Annals Internal Med.* 776, 776 (2012); Roberson, *supra* n. 19.

66 Roberson, *supra* n. 19.

an online forum, despite the host of risks, in search of cheaper and more easily accessible medical products.

### B. Online DTC Medical Screening Tests

#### 1. Risks of Online DTC Medical Screening Test Purchasing

Safety concerns regarding the DTC online medical marketplace are not limited to online pharmacies but also extend to the DTC availability of medical screening tests. Recent studies evaluating the plethora of offered DTC screening tests demonstrate a conspicuous absence of evidence-based recommendations to support their use in disease screening.<sup>67</sup>

In fact, many of the well-accepted guidelines addressing these medical screening tests that are offered via DTC actually advise against the use of these tests in screening the general population for which they may be targeted.<sup>68</sup> Online DTC advertisements with fraudulent or incomplete information therefore stand a good chance of misleading health-oriented consumers and guiding them to purchase unproven services that subsequently promote unnecessary, potentially risky, and costly interventions.<sup>69</sup> Inappropriate and/or unnecessary DTC screening tests, even where physical harms do not accrue, are financially damaging because consumers must pay for the testing out of pocket even though such screening may be unnecessary or not scientifically supported.<sup>70</sup> Available DTC screening includes testing for a number of serious chronic conditions highly prevalent in the senior population, such as heart disease, cancer, and genetic susceptibility tests for Alzheimer's disease.<sup>71</sup>

Furthermore, every medical test carries some potential for injury even when implemented with the oversight of medical professionals.<sup>72</sup> Patients can easily overlook these

67 Studies indicate that a vast array of medical screening products are available online, many of which are not supported by relevant clinical guidelines or evidence-based medicine. This places patients at both medical and financial risk due to misdiagnosis and the lack of test result interpretation and treatment recommendations by medical professionals. Lovett et al., *DTC Tumor Markers*, *supra* n. 9, at 1412. Lovett & Liang, *DTC Cardiac Screening*, *supra* n. 9, at 2567; Lovett & Liang, *DTC Thermography*, *supra* n. 9, at 827. This also has been observed in sleep apnea screening tests and finger-stick testing. Timothy K. Mackey et al., *Editorial: Waking Up to the Risks of Online Direct-to-Consumer Advertising of Sleep Apnea Screening Tests*, 8 *J. Clinical Sleep Med.* 5, 5 (2012); Kimberly M. Lovett & Bryan A. Liang, *Direct-to-Consumer Disease Screening with Finger-Stick Testing: Online Patient Safety Risks*, 58 *Clinical Chemistry* 1091, 1092 (2012) [hereinafter *DTC Finger-Stick*].

68 *Id.* Justin P. Annes et al., *Risks of Presymptomatic Direct-to-Consumer Genetic Testing*, 363 *New Eng. J. Med.* 1100, 1100 (2010).

69 See Roberson, *supra* n. 19. See also Williams & Brown, *supra* n. 52, at 361.

70 Lovett et al., *DTC Tumor Markers*, *supra* n. 9, at 1412.

71 The website [www.testcountry.com](http://www.testcountry.com) offers a host of DTC medical screening tests. See *Genetic Health Risks Premium Home DNA Test*, TestCountry.com, <http://www.testcountry.com/products.html?product=1965> (accessed July 14, 2012); Kimberly M. Lovett, Bryan A. Liang & Timothy K. Mackey, *Evaluating the Evidence: Direct-to-Consumer Screening Tests Advertised Online*, *J. of Med. Screening* 2012 19(3):141-153 [hereinafter *DTC Screening Tests*].

72 J.M.G. Wilson & G. Jungner, *Principles and Practice of Screening for Disease*, [http://whqlibdoc.who.int/php/WHO\\_PHP\\_34.pdf](http://whqlibdoc.who.int/php/WHO_PHP_34.pdf) (World Health Org., 1968) (accessed July 13, 2012). See also K.G. Marshall, *Prevention: How Much Harm? How Much Benefit?* 4. *The Ethics of Informed Consent for Preventive*

potential harms, as they are unlikely to understand the unique risks posed by various and often complex medical screening tests.<sup>73</sup>

Risks of DTC medical testing include physical risks from invasive testing<sup>74</sup> or radiation exposure,<sup>75</sup> risks of inaccurate disease labeling with false positives resulting in subsequent medical insurance coverage difficulties,<sup>76</sup> risks of over treatment,<sup>77</sup> risks of unnecessary treatment with false positive results,<sup>78</sup> risks of false reassurance and delayed or missed diagnosis with false negative results.<sup>79</sup> Even well-established screening modalities offered with physician oversight carry risks of injury<sup>80</sup> that should be discussed with patients via informed consent discussions, particularly accounting for individual patient circumstances.<sup>81</sup> Several studies confirm the need for educated and contextual assessment of the appropriateness of screening for specific patients.<sup>82</sup>

Another major risk of purchasing online DTC medical screening tests involves the use of this testing for symptom diagnosis purposes.<sup>83</sup> By definition, a screening test is a test used to screen for disease in asymptomatic patients.<sup>84</sup> To date, medical tests available online have only identified online DTC medical screening tests; no studies have yet identified DTC medical testing aimed at symptom diagnosis. This is an important distinction because even though the testing modality may be exactly the same, results interpretation is significantly influenced by the presence or absence of symptoms.<sup>85</sup> Consequently,

*Screening Programs*, 155 *Canadian Med. Assn. J.* 377, 379 (1996).

73 *See id.*

74 Lucy Boyd, *Venipuncture Complications*, *Livestrong.com*, <http://www.livestrong.com/article/101159-venipuncture-complications> (Mar. 18, 2011).

75 Cumulative radiation exposure is linked to increased risk of cancer in emergency room patients. *ScienceDaily*, *Cumulative Radiation Exposure Shows Increased Cancer Risk for Emergency Department Patients*, <http://www.sciencedaily.com/releases/2008/05/080521093034.htm> (May 30, 2008) (accessed July 14, 2012).

76 Many patients have difficulty obtaining health insurance once they have been diagnosed with a disease. In the U.S., when such patients apply for health insurance, they are considered to have a pre-existing condition. Prior to passage of the Patient Protection and Affordable Care Act (ACA) and even with provisions set forth in the ACA, patients still have difficulty obtaining insurance when they have a pre-existing condition. Jean Hall & Janice Moore, *Realizing Health Reform's Potential: Pre-Existing Condition Insurance Plans Created by the Affordable Care Act of 2010*, 100 *Cmmw. Fund I*, [http://www.commonwealthfund.org/~media/Files/Publications/Issue%20Brief/2010/Oct/1445\\_Hall\\_PCIPs\\_and\\_the\\_ACA\\_ib\\_FINAL.pdf](http://www.commonwealthfund.org/~media/Files/Publications/Issue%20Brief/2010/Oct/1445_Hall_PCIPs_and_the_ACA_ib_FINAL.pdf) (2010).

77 Lovett et al., *DTC Tumor Markers*, *supra* n. 9, at 1413; Lovett & Liang, *DTC Cardiac Screening*, *supra* n. 9, at 2567.

78 *Id.*

79 Lovett & Liang, *DTC Finger-Stick*, *supra* n. 67, at 1092.

80 Marshall, *supra* n. 72, at 379.

81 *See the authorities cited in n. 67 supra; see also Marshall, supra* n. 72, at 380.

82 E.g. Vence L. Bonham et al., *Perspective: Screening Student Athletes for Sickle Cell Trait — A Social and Clinical Experiment*, 363 *New Eng. J. Med.* 997, 998 (2010); Steven Woloshin & Lisa M. Schwartz, *Commentary: The Benefits and Harms of Mammography Screening: Understanding the Trade-offs*, 303 *J. Am. Med. Assn.* 164, 164 (2010); N.J. Wald, *Editorial: Screening: A Step Too Far. A Matter of Concern*, 14 *J. Med. Screening* 163, 163 (2007); Marshall, *supra* n. 72, at 380.

83 Lovett et al., *supra* n. 9, at 1413

84 Wilson & Jungner, *supra* n. 72, at 11.

85 For example, a negative mammogram in an asymptomatic woman will not result in further testing.

even assuming that consumers have correctly identified and purchased the correct testing product, consumers may be falsely reassured by negative testing results in the presence of concerning symptoms that actually warrant further evaluation despite normal screening test results.

The types of testing modalities used by the online DTC medical testing industry also put consumers at high risk. One study notes that a major testing modality implemented by the DTC medical marketplace involves the use of finger-stick testing.<sup>86</sup> However, as highlighted by this study, finger-stick testing carries significant risks of inaccuracy resulting from user error, temperature variations during sample transportation, higher false negative rates as compared to standard venous blood testing, and others.<sup>87</sup> Another study highlighted the very low sensitivity of thermography, an imaging modality being advertised online to screen for breast cancer.<sup>88</sup> Yet, as both studies note, the risks associated with these forms of testing have not been outlined in DTC website advertisements to appropriately disclose and warn the consumer.<sup>89</sup>

Finally, the fact that the online DTC medical marketplace does not generally provide follow-up care and/or results interpretation puts consumers at even greater risk once a purchase of a screening product has been made online.<sup>90</sup> A very important aspect of medical screening testing involves health care professionals helping patients understand what the testing results mean and what they do not mean. Further, as mentioned above, it is very important to understand whether or not the testing was indeed used as a screening test or pursued by consumers as a test for symptom evaluation.<sup>91</sup> By failing to provide this crucial follow-up and/or results interpretation, consumers are left abandoned to either precariously self-interpret the results or seek care with a medical professional who is likely to repeat testing that would likely not have been warranted in the first place.<sup>92</sup>

## 2. DTC Medical Screening Tests and Unique Senior Risks

With greater disease burden and potential for polypharmacy, seniors are at much greater risk of having concerning signs and symptoms of illness that may result in consumer demand for medical testing.<sup>93</sup> Furthermore, as outlined above, mobility and financial issues may force seniors to relent to the online DTC medical marketplace for low-

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whereas a negative mammogram in the presence of a breast mass still warrants further testing, including ultrasound and/or breast biopsy. John H. Leversee, *Evaluating Palpable Breast Lumps with Negative Mammography*, 150 W. J. Med. 196, 196 (1989). Under current guidelines, clinically apparent breast lumps require a “Triple Test,” which includes mammogram, ultrasound, and biopsy. Susan Klein, *Evaluation of Palpable Breast Masses*, 71 Am. Fam. Phys. 1731, 1735 (2005).

86 Finger-stick testing is a method of performing a blood test via administration of a finger prick and subsequent analysis of the produced blood droplet. Finger-stick testing modalities use a small amount of blood and usually incorporate more basic and less reliable machines for analysis of the finger-stick blood sample. Lovett & Liang, *DTC Finger-Stick*, *supra* n. 67, at 1092.

87 *Id.*

88 Lovett & Liang, *Risks of Online Advertisement*, *supra* n. 9, at 827.

89 *Id.*; Lovett & Liang, *DTC Finger-Stick*, *supra* n. 67, at 1092.

90 Lovett, et al., *DTC Screen Tests*, *supra* n. 71 at 105.

91 *Id.*

92 *Id.*

93 *Supra* n. 4; Liang, *supra* n. 31, at 280.

cost and convenient sources of evaluating symptoms of disease.<sup>94</sup> Similarly, simply by virtue of the advanced age of their friends, spouses, and parents, seniors are more likely to have lost loved ones to heart disease and cancer as age-related illnesses. Seniors are therefore likely more vulnerable than younger generations to emotional marketing pleas (such as those highlighted by one study on DTC cancer screening<sup>95</sup>) advising consumers to “be cancer concerned”<sup>96</sup> or detect diseases identified as “silent killers.”<sup>97</sup>

Despite the complexities and potential harms of medical screening and medical treatment, online companies offering these DTC medical services generally do not provide information on their websites aimed at guiding seniors toward appropriate use of online-advertised DTC medical screening tests. Within the online DTC medical marketplace, results of DTC medical screening tests can lead to faulty self-diagnosis, pursuit of unnecessary care, foregoing needed care due to potential misunderstandings of test applicability and/or results, or even dangerous self-treatment with pharmaceuticals purchased from illicit online pharmacies.<sup>98</sup> Further, many of these online DTC medical products vendors fail to participate in informed consent discussions, provide opportunities for consumers to ask questions or address concerns, provide necessary follow-up of results with qualified medical professionals, and accept accountability for fraudulent claims made on their websites.<sup>99</sup> Yet, there has been a conspicuous lack of legal action against online vendors engaged in negligent and/or fraudulent activity within the largely unregulated DTC medical marketplace.<sup>100</sup>

#### IV. LEGAL CONSIDERATIONS

##### A. Definitions in State Elder Abuse Laws

###### 1. Overview

Elder abuse can generally be described as actions inflicting unnecessary suffering, injury, pain, loss, or violation of human rights upon a senior.<sup>101</sup> These actions can include physical abuse, including violent conduct such as grabbing, striking, slapping, and other physical battering of seniors.<sup>102</sup> Elder abuse also encompasses financial exploitation resulting in use of senior funds, property, or resources.<sup>103</sup> Financial exploitation of seniors

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94 Roberson, *supra* n. 19; Liang, *supra* n. 31, at 316.

95 Lovett et al., *supra* n. 9, at 1412.

96 *Id.*

97 Lovett & Liang, *DTC Cardiac Screening*, *supra* n. 9, at 2567.

98 Lovett, et. al, *DTC Screen Tests*, *supra* n. 71 at 150.

99 *Id.*

100 Liang & Mackey, *supra* n. 12, at 151–155.

101 Cal. Welfare and Instns. Code § 15656 (2011); Cal. Penal Code § 368 (2011); Donna Schuyler & Bryan A. Liang, *Reconceptualizing Elder Abuse: Treating the Disease of Senior Community Exclusion*, 15 *Annals Health L.* 275, 278 (2006); Arthur Meirson, *Prosecuting Elder Abuse: Setting the Gold Standard in the Golden State*, 60 *Hastings L.J.* 431, 438 (2008).

102 *Id.*

103 Cal. Welfare and Instns. Code § 15656 (2011); Cal. Penal Code §368 (2011); *supra* n. 10, at 41.

can be quite lucrative for perpetrators.<sup>104</sup> Because of the vulnerable status of many seniors, certain elder abuse laws provide for expedited trials, enhanced penalties for perpetrators, enhanced financial incentives for attorneys to take on civil elder abuse cases, and protective orders and prohibitions against abuser profiting (e.g., by inheritance) from their abuse of a senior.<sup>105</sup>

Although there are federal laws governing elder rights, elder abuse prosecutions are generally state-based.<sup>106</sup> California has taken an active and leading role because, as a state, it has the greatest number of senior residents.<sup>107</sup> Indeed, California has been recognized globally as a leader in elder and dependent adult protection.<sup>108</sup> In 1991, California passed a comprehensive elder abuse statute to address what was deemed as “the nation’s shame.”<sup>109</sup> The law provides for prosecution against elder physical abuses including: assault, battery (including sexual assault); assault with a deadly weapon or force likely to produce great bodily injury; unreasonable physical constraint; prolonged or continual deprivation of food or water; and use of physical or chemical restraint or psychotropic medication for punishment, caregiver convenience, or for any period beyond instruction or purpose not authorized by a physician.<sup>110</sup>

Under the California law, financial exploitation is also subject to elder abuse prosecution.<sup>111</sup> Financial exploitation describes situations in which any person who is in the care or custody of, or who stands in a position of trust to a senior, takes or appropriates his/her money or property, for any use or purposes not in the due and lawful execution of his or her trust.<sup>112</sup>

## 2. Further Definitions for Elder Abuse

Given the unique vulnerabilities of seniors and the tremendous harms posed by various forms of elder abuse, controversies and differences exist regarding the elements

104 For example, the average bank robbery nets \$7,500 per heist. Jason Koebler, *What You Should Know Before Robbing a Bank*, U.S. News & World Report, <http://www.usnews.com/news/articles/2012/06/11/what-you-should-know-before-robbing-a-bank> (June 11, 2012). Defrauding a senior, however, nets on average \$60,000. Schuyler & Liang, *supra* n. 101, at 279.

105 Cal. Welfare and Instns. Code § 15656 (2011); Cal. Penal Code § 368 (2011); Schuyler & Liang, *supra* n. 101, at 286–290.

106 Sarah B. Berson, *Prosecuting Elder Abuse Cases*, in Philip Bulman, *Elder Abuse Emerges from the Shadows of Public Consciousness*, 265 Nat’l Inst. Just. J. 4, <http://www.nij.gov/journals/265/elder-abuse-prosecuting.htm> (2010).

107 Howden & Meyer, *supra* n. 1.

108 Laura Watts & Lisa Sandhu, *Essay: The 51st State – The “State of Denial”: A Comparative Exploration of Penal Statutory Responses to “Criminal” Elder Abuse in Canada and the United States*, originally published in 14 Elder L.J., [http://www.bcli.org/sites/default/files/The\\_51st\\_State\\_-\\_A\\_State\\_of\\_Denial.pdf](http://www.bcli.org/sites/default/files/The_51st_State_-_A_State_of_Denial.pdf) (2006). Meirson, *supra* n. 101, at 451–452.

109 Schuyler & Liang, *supra* n. 101, at 286–290; Cal. Penal Code § 368 (2011); Cal. Welfare and Instns. Code §§ 15630–15632 (2011).

110 Schuyler & Liang, *supra* n. 101, at 286–290; Cal. Penal Code § 368 (2011); Cal. Welfare and Instns. Code §§ 15630–15632 (2011).

111 Cal. Welfare and Instns. Code § 15656 (2011); Cal. Penal Code § 368 (2011); Daly & Jogerst, *supra* n. 10, at 44.

112 Cal. Welfare and Instns. Code § 15656 (2011); Cal. Penal Code § 368 (2011); Daly & Jogerst, *supra* n. 10, at 57.

required for a perpetrator to meet a standard of elder abuse.<sup>113</sup> These differences generally include: a) whether a disability requirement is necessary for elderly victims; b) whether a “special relationship” between the elder and the perpetrator is necessary; c) whether the abuse and neglect are defined as and reflect patterns of conduct (not single acts); and d) whether the abuse requires intent.<sup>114</sup> Specifically, the disability requirement points to the unique status of the elderly who are often in a state of vulnerability or dependence that necessitate special protections, but also requires that this standard be met in order to qualify as elder abuse.<sup>115</sup> However, comprehensive assessment of whether a senior qualifies as vulnerable or dependent, or whether a senior makes the transition into such a state can be difficult to determine, leading to limitations in interpretation.<sup>116</sup>

Other definitions associated with elder abuse require a “special relationship” in which the abuser is in a “position of trust, confidence, or dependency” with the senior victim.<sup>117</sup> Under this requirement, those who are generally viewed as “strangers” and who perpetuated a crime against an elder may not fall under the strict definition of elder abuse.<sup>118</sup> However, there have been recent challenges to this strict definition of “special relationship” given that unfamiliar perpetrators may seek out relationships of trust with their elderly victims specifically for the purposes of abuse and fraud.<sup>119</sup> Meeting this “special relationship” requirement is also especially challenging in the digital health marketplace, where misleading marketing, fraudulent claims, and other forms of virtual Internet-based messaging may blur the lines between traditional notions of relationships of trust and confidence.

## B. State Elder Abuse Laws and the DTC Medical Marketplace

### 1. Overview

Examining the scope of practices and resultant harms accruing via the online medical marketplace, it is clear that many forms of elder abuse, including physical abuse, financial or material exploitation, and self-neglect can easily occur.<sup>120</sup> Further, controversial definitions and requirements of elder abuse may directly apply to eElder abuse. Special relationships may be formed in which online providers seek to establish relationships of trust with their elderly customers through marketing ploys or direct communica-

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113 Meirson, *supra* n. 101, at 437.

114 Lisa Nerenberg, *Elder Abuse Prevention: Emerging Trends and Promising Strategies* 21–24 (Springer Publ. Co. 2008).

115 *Id.* at 21.

116 *See id.*

117 This generally includes family members, friends, caregivers, individuals who live with the victim, service providers, intimate partners, and generally anyone who has a legal or financial responsibility to the victim. Nerenberg, *supra* n. 114, at 22.

118 *Id.*

119 *Id.*

120 Self-neglect includes elderly persons making conscious and voluntary decisions to engage in acts that threaten their health and safety. Martin J. Gorbien & Amy R. Eisenstein, *Elder Abuse and Neglect: An Overview*, 21 *Clinics Geriatric Med.* 279, 282 (2005). Self-neglect also can occur when an elderly person engages in unsafe health behavior, including taking drugs obtained without a prescription.



tion. Intent is also clear when online providers are aware and are deliberate about their fraudulent and/or illegal online activities.<sup>121</sup> Finally, low health literacy, lack of Internet savvy, or low risk awareness regarding the potential for online fraud and abuse may result in seniors who are clearly “disabled” when it comes to accessing online health services. We outline some of these risks below and further discuss how they meet elder abuse definitions.

## 2. Medically Related Guidance, Seniors, and Special Relationships

The DTC medical marketplace provides medical information, advertisements for medical products, medical screening tests, and pharmaceuticals to consumers peripheral to patient-specific physician guidance and prescriptions.<sup>122</sup> A major role of physicians is to account for patient-specific complexities and needs when advising the use of various medical tests and pharmaceuticals.<sup>123</sup> Indeed, because patients depend on the education and expertise of physicians to make medically related decisions, physicians and other healthcare providers are held accountable for the prescriptions they write and the medical advice they give.<sup>124</sup> The primary criteria for judging the medical professional decisions of physicians include whether the advised intervention falls within the standard of care and whether that advised intervention led to patient harm.<sup>125</sup> The DTC medical marketplace, however, advises consumers to make medically related decisions without the parallel accountability to which physicians are held. Consequently, it is difficult to hold anyone responsible for advertisements guiding patients into medical decisions related to marketed DTC products that fall outside of the standard of care and lead to harm.

Despite this lack of accountability, patients may trust DTC advertisements warning them that they “must be cancer concerned”<sup>126</sup> and should be screening for “silent killers”<sup>127</sup> such as cardiac and carotid artery diseases to protect themselves. As mentioned previously, most surveyed consumers trust an online medication source as genuine, so long as the advertisement assures them of legitimacy.<sup>128</sup>

Indeed, many DTC advertisements for both screening tests and pharmaceuticals assure patients of the safety and the utility for the advertised medical interventions despite interventions falling outside the scope of care standards.<sup>129</sup> In fact, much of the information included in many DTC advertisements for medical interventions is fraudu-

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121 Nerenberg, *supra* n. 114, at 22–23.

122 Lovett, et al., *DTC Screening Tests*, *supra* n. 71 at 149-150.

123 Wilson & Jungner, *supra* n. 72.

124 William J. Curran, *A Symposium on Professional Negligence—Professional Negligence: Some General Comments*, 12 *Vanderbilt L. Rev.* 535, 535–540 (1959).

125 John W. Ely et al., *Determining the Standard of Care in Medical Malpractice: The Physician’s Perspective*, 37 *Wake Forest L. Rev.* 861, 861–863 (2002).

126 Given that patients trust DTC advertising for pharmaceuticals as already established, it is not difficult to postulate that patients would believe online advertisements regarding various medical screening tests. See Liang & Mackey, *supra* n. 12, at 131. See also Lovett et al., *supra* n. 9, at 1411.

127 Lovett & Liang, *DTC Cardiac Screening*, *supra* n. 9, at 2567.

128 Liang & Mackey, *supra* n. 12, at 131.

129 See the authorities cited in n. 67 *supra*. See generally Lovett, et al, *DTC Screening Tests*, *supra* n. 71 (detailing the wide range of screening tests available directly to consumers as well as the advertisements detailing testing utility).

lent, misleading, or incomplete.<sup>130</sup> However, because of the reliance that consumers have regarding the accuracy of health-related advice found throughout online DTC medical marketplace advertisements, the special vulnerabilities of senior consumers regarding their medical care, the high complexity involved in medical decision making, and the DTC medical marketplace bypassing traditional medical care, online DTC medical marketplace advertisers and providers should be deemed as engaging consumers in special relationships (as are physicians).

Accordingly, specific to elder abuse laws, these online DTC medical marketplace providers should also be deemed as establishing special relationships with seniors and held to the same standards of accountability as physicians, caregivers, and other health-care providers for elder abuse purposes. As a consequence of the unique vulnerabilities of seniors and the trust that must accompany the giving and acceptance of medical advice, it is clear that online DTC medical marketplace advertisers and sellers should be held to a higher standard than regular advertisers of non-medically related products and services. Just as a physician might be held accountable for elder abuse if he or she defrauds a senior of financial resources for his or her own financial gain, so too should online DTC medical marketplace vendors be held accountable for suspect product and medical service sales and guidance.

### 3. Harms to Seniors

The online purchase of suspect medical testing and/or illicit pharmaceuticals may certainly result in physical harm to seniors.<sup>131</sup> Seniors may be duped through fraudulent, misleading, or false online claims about screening and disease status and therefore be subject to unwarranted physical abuse. Indeed, they are intruded upon by the physical act of blood testing even when potential adverse effects of testing do not accrue. Furthermore, invasive testing can result in potential harms, including thrombophlebitis or infection after venipuncture<sup>132</sup> or increased cancer risk from radiation exposures.<sup>133</sup> Finally, seniors purchasing pharmaceutical products online run the obvious aforementioned risks resulting from medication interactions, counterfeit medications, or inappropriate treatment.<sup>134</sup>

Yet under the California elder abuse law, harms resulting from the online purchase of suspect medical screening tests or illicit pharmaceuticals do not appear to be within the confines of the statute. Drugs and medications are mentioned only as relating to chemical restraints and inappropriate use by caregivers under physical abuse standards.<sup>135</sup> Suspect medical screening is difficult to fit at all within the physical elder abuse provisions since it does not easily fall within assault, battery, unreasonable restraints, deprivation, and/or abuse of drugs against the elder by a caregiver.<sup>136</sup> It should be noted that any medical

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130 Williams & Brown, *supra* n. 52, at 361–362.

131 See Solomon, *supra* n. 37.

132 Boyd, *supra* n. 74.

133 ScienceDaily, *supra* n. 75.

134 Liang & Mackey, *supra* n. 12, at 130–131.

135 Cal. Welfare and Instns. Code § 15610.63(f) (1996); Schuyler & Liang, *supra* n. 101, at 287; Daly & Jogerst, *supra* n. 10, at 56.

136 Though it could be battery, or at least negligence, except for the specification that it must be the caregiver who produces the harm.

intervention resulting in harm without appropriate informed consent prior to the intervention is properly deemed as battery.<sup>137</sup> Because DTC medical screening is generally offered without informed consent, resultant harms of physical contact testing should also appropriately be identified as battery.

Furthermore, marketing and sale of unproven screening tests while claiming preventive and diagnostic benefit should be considered fraudulent along with the sale of counterfeit and substandard medicines that can result in both physical and financial harm. When fraudulent advertising encourages seniors to spend already limited fixed financial resources, this should be considered elder abuse through misappropriation of elder assets.

Yet again, like physical abuse, it appears that even under California's extensive elder abuse laws, these forms of eElder abuse do not fit into the strict definitions of financial abuse. Financial exploitation rests on a relationship with a caregiver or other persons of trust, such as healthcare providers.<sup>138</sup> Suspect screening test purveyors and illegal online drug sellers are not explicitly considered as engaging in these special relationships with seniors, though these virtual relationships may clearly fall within these categories. However, the absence of explicit inclusion of this form of financial abuse may preclude its use or application in the law's elder abuse definitions.

Similarly, many states are subject to the same limitations of their elder abuse definitions when statutory efforts for elder abuse accountability and consumer protection may not encompass this evolving form of elder abuse: eElder abuse. Indeed, the top five states by Baby Boomer and senior populations — California, Texas, New York, Florida, and Pennsylvania<sup>139</sup> — have similar weaknesses within their laws.<sup>140</sup> Further, according to Adult Protective Services laws, many states and U.S. territories link potential abuse liability to direct physical injury or a status such as a caregiver or others with a fiduciary responsibility to a senior.<sup>141</sup> Consequently, there is a need to assess and adapt elder abuse

137 The key element of battery is that the touching be without consent, not that there is intent to harm. Thus, forcing even beneficial care on an unwilling patient could be deemed as battery. Justice Corodozo articulates this premise in his opinion in *Schoendorff v. Socy. of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914).

138 Cal. Welfare and Instns. Code § 15656(c) (2011); Cal. Penal Code § 368(i) (2011).

139 Watts & Sandhu, *supra* n. 108.

140 Cal. Penal Code § 368 (2011); Cal. Welfare and Instns. Code §§ 15630–15632 (2011); Tex. Hum. Res. Code Ann. § 48.002 (2011); Fla. Stat. Ann. § 415.102 (2010); N.Y. Soc. Servs. L. § 473 (2010); Pa. Stat. Ann. tit. 35, § 10225.103 (2011).

141 The following state and territory statutes and regulations address elder abuse but do not specifically address forms of eElder abuse as identified in this paper: Ala. Code § 38-9-2 (2007); Alaska Stat. § 47.24.900 (2008); Ariz. Rev. Stat. § 46-451 (2008); Ark. Code Ann. § 12-12-1703 (2007); Colo. Rev. Stat. § 26-3.1-101 (2008); Conn. Gen. Stat. § 17b-450 (2007); Del. Code Ann. tit. 31, § 3902 (2007); D.C. Code Ann. § 7-1901 (2008); Guam Code Ann. § 2951 (2006); Haw. Rev. Stat. § 346-222 (2007); Idaho Code § 39-5302 (2007); Iowa Code § 235B.2 (2007); Kan. Stat. Ann. § 39-1430 (2006); Ky. Rev. Stat. Ann. § 209.020 (2007); La. Rev. Stat. Ann. § 14:403.2 (2007); Minn. Stat. § 626.5572 (2008); Miss. Code Ann. § 43-47-5 (2007); Mont. Code Ann. § 52-3-803 (2007); Neb. Rev. Stat. § 28-351 (2008); Nev. Rev. Stat. § 200.5092 (2007); N.H. Rev. Stat. Ann. § 161-F:43 (2007); N.J. Stat. Ann. § 52:27D-407 (2007); N.M. Stat. Ann. § 27-7-16 (2007); N.C. Gen. Stat. § 108A-101 (2007); N.D. Cent. Code § 50-25.2-01 (2007); Ohio Rev. Code Ann. § 5101.60 (2007); Okla. Stat. tit. 43A, § 10-103 (2007); Or. Rev. Stat. § 124.050 (2007); R.I. Gen. Laws § 42-66-4.1 (2007); S.C. Code Ann. § 43-35-10 (2007); Tenn. Code Ann. § 71-6-102 (2008); Utah Code Ann. § 62A-3-301 (2008); Vt. Stat. Ann. tit. 33, § 6902 (2007); Wash. Rev. Code § 74.34.020 (2007); Wisc. Stat. Ann. § 46.90 (2008); Wyo. Stat. Ann. § 35-20-102 (2007).

laws to ensure that accountability will extend to online purveyors of fraudulent medical products and services directed at the senior population.

## V. REFORM

### A. Limited Attention

The harms resulting from unfettered suspect online marketing and sale of pharmaceuticals and screening tests are potentially severe for already vulnerable seniors, including delayed treatment, reduced quality of life, increased morbidity and mortality, and loss of financial means/resources.<sup>142</sup> Unfortunately, current legal mechanisms are limited in dealing specifically with this emerging online exploitation as forms of elder abuse.

Generally, Internet drug sales have had limited regulation and prosecution, usually focusing on sales of illicit controlled substances.<sup>143</sup> Even here, the effectiveness of efforts to cease online illicit drug sales has been disappointingly limited.<sup>144</sup> Additionally, there have recently been few focused legal efforts to stem the sale of non-evidence-based screening tests.<sup>145</sup> Unfortunately, however, specific prosecutions targeting the harms to seniors resulting from deceptive practices by vendors within the online medical marketplace have not been initiated. Indeed, prosecuting online fraud has not been a priority for state Attorneys General, and continued calls for reform and attention to specifically address online and Internet-based activities have been called for.<sup>146</sup>

Because of the significant emerging risks of the online DTC medical marketplace, ongoing trend of seniors and Baby Boomers engaging in Internet research and commerce, the special vulnerabilities of seniors in relying on the Internet as a source of health services, the unique healthcare risks of seniors, and the absence of effective regulatory oversight in this eHealth marketplace, policymakers should take immediate action. Changes in law and policy may avert potential harms by proactively responding to the emergence of the eHealth marketplace and high-technology avenues of targeting seniors. Three areas of reform may produce desired results: new laws; use of existing legal tools; and stakeholder support for reform.

### B. Statutory Reform

First, on the federal level, policymakers could move to introduce and pass legislation to address illicit online pharmaceutical vendors. All sales of pharmaceuticals should be presumptively illegal, unless the online vendors have secured accreditation by the

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142 See the authorities cited in n. 67 *supra*.

143 Liang & Mackey, *supra* n. 12, at 151–155.

144 See *id.*

145 For example, Illinois Attorney General Lisa Madigan brought suit against a DTC screening company for inappropriate sales tactics. Marshall Allen, *Illinois Sues Heart Check America Over Body Scan Sales*, Chi. Trib., [http://articles.chicagotribune.com/2011-06-23/health/chi-lawsuit-accuses-heart-check-america-of-deceptive-practices-20110623\\_1\\_multiple-scans-electron-beam-tomography-heart-disease](http://articles.chicagotribune.com/2011-06-23/health/chi-lawsuit-accuses-heart-check-america-of-deceptive-practices-20110623_1_multiple-scans-electron-beam-tomography-heart-disease) (June 23, 2011).

146 Reece Rushing et al., *Online Consumers at Risk and the Role of State Attorneys General* 9, [http://cdt.org/privacy/20080812\\_ag\\_consumer\\_risk.pdf](http://cdt.org/privacy/20080812_ag_consumer_risk.pdf) (Ctr. for Am. Progress and Ctr. for Democracy & Tech., 2008).

NABP Verified Internet Pharmacy Practice Site (VIPPS) program.<sup>147</sup> VIPPS mandates on-line pharmaceutical vendors to fulfill a wide array of quality and safety mandates, including documentation, an on-site survey, and agreement to consumer protection policies.<sup>148</sup> VIPPS also requires licensure information, specific internal pharmacy policies, disclosure of website information, adherence to patient privacy rights, authentication activities, prescription order security, quality assurance, and provisions for meaningful pharmacist consultation.<sup>149</sup> Further, accreditation is not static; re-surveys of pharmacies can occur anytime in the event of a complaint.<sup>150</sup>

Such a bright-line prohibition of online pharmaceutical sales would send a clear statutory message to would-be illicit Internet drug sellers of the clear illegality of their actions.<sup>151</sup> Indeed, reifying such notions, Internet search engines should be mandated to include a prominent FDA banner above pharmaceutical key-word searches, indicating only VIPPS-accredited pharmacies are permitted to sell pharmaceuticals.<sup>152</sup> A link to a list of VIPPS pharmacies at NABP and FDA websites should be included. This would have the advantage of protecting all patient populations including seniors, Baby Boomers, and others.

Within this federal statutory reform, all vendors of DTC medical screening tests should be required to provide informed consent, pre- and post-test counseling, and follow-up guidance with a qualified medical professional, as is typical with traditional screening and preventive health efforts.<sup>153</sup> Further, when these DTC medical screening tests are made available for sale online, the risks, benefits, and evidence-base of the aforementioned services should be expressly delineated in online advertisements. Finally, when DTC medical screening tests are available for purchase online for at-home use, a mechanism for telephone consultation with a qualified healthcare provider for informed consent discussions and follow-up should be required.

Each of these provisions is important to allow for patient comprehension of the risks and benefits of offered screening tests as well as the opportunity to ask questions and discuss concerns. This process would also ensure appropriate patient selection as well as accountability for advising use of various screening tests; the aim would be to create rigorous accountability for website representations and claims about healthcare services, which understandably represents an area of special consumer vulnerability.<sup>154</sup> Indeed, the special complexities of medical decision making, medical testing, and pharmaceutical choice creates a necessity for consumers to trust the online sources of information directing them toward specific medical testing and treatment.

Even beyond providing appropriate disclosure to patients, mandated healthcare

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147 See Nat'l Assn. of Boards of Pharm., *supra* n. 46. See also Nat'l Assn. of Boards of Pharm., *Find a VIPPS Online Pharmacy*, <http://www.nabp.net/programs/accreditation/vipps/find-a-vipps-online-pharmacy> (accessed July 14, 2012).

148 Nat'l Assn. of Boards of Pharm., *supra* n. 47.

149 *Id.*

150 *Id.*

151 See Liang & Mackey, *supra* n. 12, at 155–173.

152 *Id.*

153 Marshall, *supra* n. 72, at 379–380. See also Wilson & Jungner, *supra* n. 72, at 11.

154 See Liang & Mackey, *supra* n. 12, at 131.

provider counseling and informed consent discussions would help determine whether a consumer is seeking screening for asymptomatic disease or if a consumer has symptoms requiring diagnostic testing and follow-up. Filtering these symptomatic patients will significantly mitigate the impact of false negative testing and henceforth reduce missed or delayed diagnosis of disease.<sup>155</sup>

### C. Use of Existing Legal Tools and Enforcement

Beyond new legislation, the FDA also may employ its extant powers<sup>156</sup> to protect seniors against suspect online DTC medical marketplace activities. Since online advertisements for pharmaceuticals and screening tests are potentially false, misleading, and misbranded, while also being marketed across state lines, FDA is empowered<sup>157</sup> to work with the Department of Justice (DOJ) to file for temporary restraining orders (TRO) in an *ex parte* hearing<sup>158</sup> to have websites stop their potential violations of the Food, Drug, and Cosmetic Act (FDCA).<sup>159</sup> In the short run, under a TRO, patient protections against these suspect sites may be put into place until full hearings can occur. At these latter hearings, FDA and DOJ can seek permanent injunctions against offending websites. If these websites and their owners are offshore and unreachable, FDA can work with DOJ and others to cease and terminate these websites with relevant service providers as they have in the past.<sup>160</sup>

FDA and DOJ also should consider employing the “Park Doctrine” established by the U.S. Supreme Court, whereby corporate owners and other responsible officials can be held liable for misdemeanors without any proof that these persons acted with criminal intent, negligence, or even knowledge.<sup>161</sup> In this case, misdemeanor prosecutions for FDCA violations, if successful against these entities, automatically create felonies for any subsequent FDCA violation.<sup>162</sup> These felony prosecutions also do not require proof that the corporate official acted with intent to defraud or mislead.<sup>163</sup>

Using the Park Doctrine is particularly apropos for enforcement against suspect online medical marketplace circumstances when the FDA considers whether the violation in question involves actual or potential public harm, is obvious, reflects a pattern of illegal

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155 Accurately and efficiently diagnosing symptomatic disease is key to mitigating morbidity and mortality resulting from diseases most relevant to senior Baby Boomers and seniors in other age groups, such as cardiovascular disease and cancer. See Wilson & Jungner, *supra* n. 72, at 11; Marshall, *supra* n. 72, at 378.

156 Liang & Mackey, *supra* n. 12, at 144–147.

157 Daniel Schultz, *FDA Oversight of Direct-to-Consumer Advertising of Medical Devices*, <http://www.fda.gov/NewsEvents/Testimony/ucm096272.htm> (U.S. Food and Drug Administration, Sept. 17, 2008).

158 Liang & Mackey, *supra* n. 12, at 172; Timothy K. Mackey & Bryan A. Liang, *Promoting Online Drug Safety: Using Public-Private Partnerships to Deter Illicit Online Drug Sales*, 17 J. Com. Biotechnology 266, 269–270 (2011).

159 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331–332 (2007); see also Liang & Mackey, *supra* n. 12, at 144–145.

160 Liang & Mackey, *supra* n. 12, at 147, 152

161 *United States v. Park*, 421 U.S. 658 (1975).

162 *Id.*

163 *Id.*

behavior, is widespread, is serious, and has adequate legal and factual support.<sup>164</sup> Each of these factors would appear to be present within the circumstances posed by questionable online advertisement and availability of DTC medical products. Additionally, these prosecutions could be coordinated with other federal and state consumer protection laws, providing additional deterrence against suspect advertisement and/or sale of DTC medical tests and/or pharmaceuticals.

Although federal law and regulation is more appropriate to address Internet marketing behavior being perpetrated by suspect vendors across state lines due to its ability to regulate interstate commerce, state level elder abuse laws should also be reassessed and adapted to protect and vindicate the rights of each senior when misled and/or harmed by online DTC medical marketplace activities without adequate informed consent. This review and updating of state laws for digital age practices is critical, since the key prosecution powers against elder abuse for protection of seniors reside in state laws, whereas terminating online operations would be the focus of federal and state regulatory efforts.<sup>165</sup>

State reforms should clearly include eElder abuse physical harms resulting from illicit DTC medical products and services within definitions of physical elder abuse. The silent harms resulting from substandard or fake drugs as well as unsupported medical screening tests cannot be underestimated from a personal or social policy perspective.

Further, state elder abuse laws must take into account the financial losses to seniors resulting from fraudulent sales of suspect pharmaceuticals and medical screening tests that lack evidence-based support. As a consequence of circumventing the learned intermediary of traditional healthcare — the primary care provider — online advertisers and sellers of these medical products and services should be identified as establishing a trust relationship with seniors,<sup>166</sup> and hence subject to statutory provisions allowing them to be prosecuted for financial exploitation under eElder abuse provisions. By updating these laws, elder abuse prosecutions can evolve to address online activities that clearly harm seniors both physically as well as financially.

#### D. Stakeholder Efforts

Beyond legal and regulatory efforts, a coalition could be formed comprised of key public and private stakeholders, including the Administration on Aging, the American Association of Retired Persons, the American Geriatrics Society, the U.S. Department of Justice, the U.S. Food and Drug Administration, the Gerontological Society of America, the National Center on Elder Abuse, and the National Committee for the Prevention of Elder Abuse. This coalition should make a concerted effort to publicize the emerging threat of eElder abuse through public awareness and educational campaigns, and should

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<sup>164</sup> *Id.*

<sup>165</sup> State laws generally govern the prosecution of elder abuse; Rushing et al., *supra* n. 146, at 10. Cal. Penal Code § 368 (2011); Cal. Welfare and Instns. Code §§ 15630–15632 (2011). Yet commentators have suggested that regulation of online pharmacies might be best pursued by a combination of state and federal efforts. Jaykant Patel, *The Regulation of Online Pharmacies: The Need for a Combined Federal and State Effort*, [http://www.law.columbia.edu/center\\_program/ag/Library?exclusive=filemgr.download&file\\_id=96238&rtcontentdisposition=filename%3DPatel,+J+--+Regulation+of+Online+Pharmacies+NE+Law+School.pdf](http://www.law.columbia.edu/center_program/ag/Library?exclusive=filemgr.download&file_id=96238&rtcontentdisposition=filename%3DPatel,+J+--+Regulation+of+Online+Pharmacies+NE+Law+School.pdf) (2005) (accessed July 14, 2012).

<sup>166</sup> Cal. Penal Code § 368 (2011); Cal. Welfare and Instns. Code §§ 15630–15632 (2011).

be supported by federal funding available through the recently passed Elder Justice Act within healthcare reform.<sup>167</sup>

The proposed coalition should engage in two primary activities that focus on new aspects of this emerging form of elder abuse: 1) education of seniors and Baby Boomers regarding safe online research and purchasing of medical products and services, and 2) advocacy for complementary federal and state legislation aimed at regulating suspect online vendors while also providing prosecution tools for eElder abuse. This coalition should prioritize efforts to include policy reform in conjunction with exploring initiatives to increase senior access to preventive care and treatment.

## VI. CONCLUSION

Seniors and Baby Boomers are increasingly actively integrated into online activities, searching for and purchasing healthcare goods and services. Yet the Internet offers a safe haven for unfettered and suspect advertising and sale of medical services and pharmaceuticals that both federal and state laws have failed to adequately address. A modernization of laws, regulations, education, and outreach recognizing the inherent risks of eElder abuse confronted by seniors is urgently needed. This requires broader recognition and advocacy of this unique public health problem from all relevant stakeholders. We suggest a possible way forward, through a combination of policy-based reform, increased use of existing tools of prevention and enforcement, and greater stakeholder engagement. Through these efforts we can promote consumer protection for seniors and ensure accountability for online criminals who are seeking to exploit this vulnerable group of patients.

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<sup>167</sup> See Elder Justice Act, Pub. L. No. 111-148, (2010); see also Times News, *Federal Elder Justice Act Summary*, <http://www.tnonline.com/2010/jul/03/federal-elder-justice-act-summary> (July 3, 2010).



