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Marketing Medicine to Millennials: Preparing Institutions and Regulations for Direct-to-Consumer Healthcare

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**MARKETING MEDICINE TO MILLENNIALS:
PREPARING INSTITUTIONS AND REGULATIONS FOR
DIRECT-TO-CONSUMER HEALTHCARE**

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Change is coming to how healthcare is delivered in the United States. Millennials, and the generations that will follow, have entirely novel expectations about how services need to be delivered – namely

that they be efficient, and cost-effective. Unfortunately, the traditional healthcare delivery model is simply incompatible with these needs. This is due in part to the shortfalls of current regulatory structures, and the complexities of the healthcare marketplace generally. Huge tech companies have taken note of new demands resulting from the dissonance between our healthcare system, the market for its current service structure, and the deleterious effects of federal regulations. Targeting to the needs of the emerging, tech-dependent generations, and exploiting regulators' and healthcare institutions' failure to adapt, big tech is on a path to consolidating an essentially unregulated method of healthcare delivery – direct-to-consumer goods and services. This article examines the inevitable shifts in healthcare markets that are to come, and touches on areas that regulators have – as yet – failed to take proactive measures. By examining current and past shortfalls in healthcare regulation, this article illuminates imminent issues that need to be addressed by considered legislation. The healthcare industry has a lot to lose if giant tech companies consolidate healthcare delivery markets before some action is taken – the time for such action is now.

INTRODUCTION

It's Sunday morning and you wake with a pain in the back of your throat. While putting on a pot of tea, you enter your symptoms including fever and elevated white blood cell count, per your smartwatch, into an app. Before the tea kettle steams, you are discussing your sore throat with a provider, and one hour later a treatment pack arrives at your doorstep. Can you imagine a world like this, where you could receive healthcare on demand, at your convenience, without leaving your own home? Amazon and Google can, in fact, six of the largest companies in the world are betting billions that you can.¹

Healthcare is likely to become the next industry revolutionized by the Millennial consumer, just as other traditional purchase models have adapted to meet the growing change in consumer expectations. Big tech's recent involvement in the healthcare industry suggests such a

1. In 2018 alone, Amazon, Apple, Berkshire-Hathaway, JPMorgan Chase, and Google invested billions in major health initiatives. Robert Pearl, *Why Did Google Hire Geisinger CEO Dr. David Feinberg*, FORBES (Nov. 10, 2018, 8:42 AM), <https://www.forbes.com/sites/robertpearl/2018/11/10/google/#2558a2d242c0>.

looming disruption of the current healthcare delivery model; however, the traditional healthcare industry is inapposite to a developing “direct-to-consumer healthcare” approach where companies are born online and sell directly to their customers, effectively eliminating the need for a storefront.² In the case of healthcare, a direct-to-consumer model eliminates much of existing traditional healthcare delivery in hospitals and face-to-face visits.

Considered the first digitally native generation, Millennials³ have unique expectations of technology that differ from any preceding generation.⁴ Unlike Baby Boomers⁵ and GenXers,⁶ Millennials expect technology to be readily available and efficiently meet most of their needs.⁷ Consequently, this dependence on technology has adjusted the Millennial perception of services and Millennials display entirely new patterns of social and purchasing behavior.⁸ Most industries have

2. Adele Chapin, *What is the Direct-to-Consumer Sales Model and Why Should you Care*, RACKED (Aug. 11, 2016, 10:02 AM), <https://www.racked.com/2016/8/11/12412470/direct-to-consumer-sales-explainer> (explaining the recent development of the direct-to-consumer business model).

3. Based on a July 1, 2017 census, there are 30.6 million millennials in the United States, accounting for over 23% of the population. *So How Many Millennials Are There in the US*, MARKETING CHARTS (Apr. 30, 2018), <https://www.marketingcharts.com/featured-30401> [hereinafter *How Many Millennials*].

4. Micah Solomon, *For Small Businesses Week: All About Millennial Consumers and Millennial-Friendly Customer Experiences*, FORBES (May 3, 2018, 9:26 PM), <https://www.forbes.com/sites/micahsolomon/2018/05/03/for-small-business-week-all-about-millennial-consumers-and-millennial-friendly-customer-experiences/#648644292f91>.

5. Baby Boomers are those born between the mid-1940s to the 1960s. Anna Johnston, *Gen When?*, THE SUN (May 25, 2018, 3:00 PM), <https://www.thesun.co.uk/fabulous/5505402/millennials-baby-boomers-generation-groups-z-y-x-explained/>.

6. GenXers are those born between the mid-1960s and the early 1980s. *Id.* This generation is savvy, skeptical, self-reliant, and known for its work ethic. Paul Taylor & George Gao, *Generation X: America's Neglected 'Middle Child'*, PEW RESEARCH CENTER (June 5, 2014), <http://www.pewresearch.org/fact-tank/2014/06/05/generation-x-americas-neglected-middle-child>.

7. Solomon, *supra* note 4.

8. Maxime Rieman, *Insurance Companies Need to Adjust Product and Approach to Address Millennials*, FORBES (Jan. 5, 2018, 8:30 AM), <https://www.forbes.com/sites/forbesbusinessdevelopmentcouncil/2018/01/05/insurance-companies-need-to-adjust-product-and-approach-to-address-millennials/#3fdc01a87a4d>.

embraced these shifts in an effort to capture the disposable income of the population's largest generation.

Traditional service industries have redefined delivery methods and identified marketing strategies to provide constant, continuous, and convenient access to their products, knowing they will profit significantly from Millennials. But the traditional healthcare industry has failed to keep pace, and Millennials are, perhaps consequently, the least likely to seek medical treatment. Possibly due to high cost and general inconvenience, Millennials are driven to a familiar marketplace that meets their healthcare needs on demand: online platforms and direct-to-consumer health products. Contrary to the traditional model, these alternatives provide answers in real time, for next-to-no cost.

This article examines legal shortfalls in the United States as they relate to this shift in healthcare delivery, driven by Millennials, to direct-to-consumer medicine. Part I of this article will review the business of healthcare, focusing on the current delivery model and its recent incorporation of technology. Part II will examine forms of direct-to-consumer medicine, focusing on direct-to-consumer advertising and the direct-to-consumer health products available today. Part III will discuss possible strategies to protect the patient-consumer during this shift in healthcare delivery to direct-to-consumer medicine, assessing first a retroactive response and finally proactive reform. This article will conclude by highlighting the imminent need for institutions and regulators to address these changes before the face of healthcare is changed forever – to the detriment of the healthcare industry.

I. THE BUSINESS OF HEALTHCARE

Healthcare is one of the largest industries in the United States, employing approximately 13,000,000 American workers,⁹ and accounting for nearly 18% of the GDP.¹⁰ Interestingly, healthcare is a

9. *Total Health Care Employment*, HENRY J. KAISER FAM. FOUND., <https://www.kff.org/other/state-indicator/total-health-care-employment> (last visited May 1, 2019).

10. D. Yoni Blumberg, *Here's the Reason Health Care Costs So Much More in the US*, CNBC (Mar. 22, 2018, 11:37 AM), <https://www.cnbc.com/2018/03/22/the-real-reason-medical-care-costs-so-much-more-in-the-us.html> (citing Irene Papanicolaos, Liana Woskie & Ashish Jha, *Health Care Spending in the United States and Other High-Income Countries*, 39 JAMA 1024 (2018)).

social need, yet simultaneously an extremely lucrative business. Like other industries, healthcare is a service. What makes healthcare unlike most industries, however, is that it provides a service that is not only essential to society, but also operates based on individually specified needs. For example, a patient does not know when they will be diagnosed with cancer or hit by a car and require care. Consequently, in an effort to ensure Americans have the ability to obtain healthcare when it is required, legislatures place extensive regulations on the industry at the state and federal level.¹¹ Unfortunately, some of these regulations inhibit the healthcare industry's ability to incorporate changing societal and consumer expectations driven by the emergence of the Millennial consumer cohort.

A. *The Current Healthcare Model*

The United States notoriously over-spends on healthcare, with costs nearly double those of comparable industrialized countries.¹² Despite having the most expensive medical care in the world, the United States' healthcare system is the worst-performing of eleven developed countries – including Canada, France, Germany, and the U.K. – in terms of access, efficiency, and equity.¹³

Healthcare delivery in the U.S. is an anomaly among developed countries in that it operates mostly through private hospitals and physician-negotiated fee structures.¹⁴ Pricing is thus largely unconstrained, resulting in rising costs of medication, medical services, and hospital administration.¹⁵ Treatment compensation levels are also

11. Needless to say, the number of healthcare regulations that effect the market vast; thus, this comment will not address most of the complexities of healthcare regulation.

12. In 2016, the United States spent 17.8% of its GDP on health care, meanwhile, the average spending of ten other high-income countries (Canada, Germany, Australia, the U.K., Japan, Sweden, France, the Netherlands, Switzerland, and Denmark) was only 11.5%. Blumberg, *supra* note 10.

13. Olga Khazan, *U.S. Healthcare: Most Expensive and Worst Performing*, THE ATLANTIC (June 16, 2014), <https://www.theatlantic.com/health/archive/2014/06/us-healthcare-most-expensive-and-worst-performing/372828>.

14. Arthur Daemmrich, *U.S. Healthcare Reform and the Pharmaceutical Industry* 4 (Working Paper 12-015 Sept. 14, 2011), <https://www.hbs.edu/faculty/Publication%20Files/12-015.pdf>.

15. Blumberg, *supra* note 10.

largely driven by Medicare reimbursement rates, which are set by the government,¹⁶ and consequently hospital systems often push providers to meet standardized performance measures to comply with requirements outlined by the federal government.¹⁷ While this procedure was implemented in an effort to improve quality, instead it placed unnecessary and distracting requirements on the patient visit – frustrating both the patient and the provider. For example, 2019 marks “year three” of Medicare MIPS reimbursement model.¹⁸ Under this program, providers receive an allocated deduction of 7% in Medicare reimbursement costs for failing to satisfy quality reporting measures.¹⁹ While this program in theory promotes quality of care, because these guidelines are generalized, a Medicare patient being seen for a specific issue may be required to answer seemingly irrelevant questions about their general health in an effort for the provider to meet the MIPS measure.²⁰ In essence, these Medicare reimbursement guidelines are complex, confusing, and often force providers to focus on ways to meet

16. Tamera Jackson, *Medicare Reimbursement*, MEDICARE.COM (July 6, 2018), <https://medicare.com/administration/how-do-i-get-reimbursed-by-medicare>.

17. Congress has served as a catalyst for this trend in its efforts to convert Medicare reimbursement rates to a merit-based system. Alas, “CMS is required by law to implement quality payment incentive program[s],” including the Merit-based Incentive Payment System (MIPS) to meet those requests, replacing previous programs like PQRS. Under MIPS, eligible-clinicians (determined by clinician type, volume of charges under the Medicare Physician Fee Schedule, and the number of Medicare Part B patients) are rewarded based on value and patient outcomes. Each clinician’s performance measure is determined on scores in quality, improvement activities, promoting interoperability, and cost. Each category is based on specific measures created by CMS. Performance in these categories are converted into a score, which determines each clinician’s payment adjustment for their Medicare patients. Thus, clinicians are required to meet these measures to “earn” the greatest reimbursement. *MIPS Overview*, DEP’T OF HEALTH & HUMAN SERVICES, <https://qpp.cms.gov/mips/overview> (last visited May 1, 2019).

18. Susan Moschella, *2019 MIPS Requirements*, MEDISOLV: BLOG (Nov. 16, 2018), <https://blog.medisolv.com/2019-mips-requirements>.

19. *Id.* “Each category of MIPS has a different set of requirements that you must follow in order to fully participate and have your best chance at earning incentive money. There are four categories that make up the MIPS program: quality, promoting interoperability (formerly advancing care information), improvement activity, and cost. Each of these categories carries a different weight. Your score in each category will be totaled into one final MIPS score.” *Id.*

20. *2019 MIPS Rules*, MD INTERACTIVE, <https://mdinteractive.com/2019-mips-rules> (last visited May 1, 2019).

a reimbursement measure rather than a patient's chief complaint. Moreover, given its profitability, current and conventional healthcare policy focuses on "cost versus quality."²¹

Americans spend 60% more on insurance than citizens of any other developed country in the world and typically receive health insurance through their employer, the government, or a private payer system.²² Those who are unable to afford private coverage, do not receive benefits from their employer, and are not eligible for Medicare,²³ may be eligible for Medicaid;²⁴ but many have no coverage at all.²⁵ This system functions as an incomplete patchwork of coverage, leaving many Americans unable to afford insurance premium costs.²⁶ Consequently, the healthcare industry covers the costs for those who choose, or are financially obliged not to have health insurance.²⁷

Furthermore, healthcare costs are greatly influenced by the United States pharmaceutical market,²⁸ which totals over \$1 trillion a year.²⁹ The United States has a unique approach to pharmaceuticals as its drug regulations do not extend beyond safety and efficacy. Therefore, once approved under the safety standards set forth by the Food and Drug

21. Nicolas P. Terry, *Will the Internet of Things Transform Healthcare?*, 2 VAND. J. ENT. & TECH. L. 327, 329 (2016).

22. Daemmrch, *supra* note 14, at 2.

23. *See* 42 U.S.C. § 1395c (2019).

24. *See* 42 U.S.C. § 1396a(a)(10) (2018).

25. Guixiang Zhao et al., *Trends of Lack of Health Insurance Among US Adults Aged 18-64 Years: Findings from the Behavioral Risk Factor Surveillance System, 1993-2014*, 146 PUB. HEALTH 108, 109 (2017).

26. Notably, 60% of bankruptcies in 2007 stemmed from medical debts. Daemmrch, *supra* note 14, at 2 (citing David Himmelstein et al., *Medical Bankruptcy in the United States, 2007: Results of a National Survey*, 122 AM. J. MED. 74 (2009)).

27. Maureen Groppe, *Who Pays When Someone Without Insurance Shows Up in the ER?*, USA TODAY (July 13, 2017, 1:14 AM), <https://www.usatoday.com/story/news/politics/2017/07/03/who-pays-when-someone-without-insurance-shows-up-er/445756001>.

28. The United States holds over 45% of the global pharmaceutical market. *U.S. Pharmaceutical Industry – Statistics & Facts*, STATISTA, <https://www.statista.com/pics/1719/pharmaceutical-industry> (last visited May 1, 2019).

29. In 2015, the economic output from the pharmaceutical industry included \$558 billion in revenue for biopharmaceutical businesses and \$659 billion from suppliers and worker spending. *Biopharmaceutical Spotlight: The Biopharmaceutical Industry in the United States*, SELECT USA, <https://www.selectusa.gov/pharmaceutical-and-biotech-industries-united-states> (last visited May 1, 2019).

Administration (FDA), the government does not regulate or negotiate prescription drug prices.³⁰ Many other countries task government agencies with determining prescription pricing.³¹ Instead, the United States allows drug makers to set their own prices for a given prescription.³² As a result, each of the thousands of health insurance plans, including Medicare, negotiates its own prices with drug makers separately.³³

Unfortunately for the American consumer, the fragmented dispersal of health insurance plans has diminished insurers' bargaining power to demand lower prescription costs for their policy holders.³⁴ Consequently, the cost of a given medication differs drastically in the United States compared to the cost of the same medication in any other country in the world.³⁵

B. Technology and Healthcare

In light of growing demand, the healthcare industry has shifted its willingness to incorporate technology into the traditional delivery model. Industry professionals believe incorporating technology will improve quality of care and accessibility of healthcare services. Beyond technological advances in care specifically, hospital systems have been encouraged to embrace technology since the early 2000s. At that time, lawmakers hoped to incentivize hospital systems to transition from paper to electronic charting by including the Privacy Rule in an effort to improve documentation and patient care.³⁶

30. Sarah Kliff, *The True Story of America's Sky-High Prescription Drug Prices*, VOX (May 10, 2018, 9:19 AM), <https://www.vox.com/science-and-health/2016/11/30/12945756/prescription-drug-prices-explained>.

31. *Id.*

32. *Id.*

33. Nearly every drug approved by the FDA is covered by Medicare because Federal law expressly prohibits negotiating drug prices or making decisions about which drugs it covers. *Id.*

34. *Id.*

35. For example, in 2015, the prescription medication "Humira" (used to treat arthritis and psoriasis) cost approximately \$1,362 in the United Kingdom, \$822 in Switzerland, and \$2,669 in the United States. *Id.*

36. Recognizing a need to "maintain strict privacy protection for health information," Congress authorized the Privacy Rule which "creates national standards to keep individuals' medical records and other personal health information

More recently, technology is making its way into the physician-patient encounter. First introduced by NASA in the 1960s to provide treatment to astronauts,³⁷ today telemedicine – utilizing audio and video equipment to establish “two-way, real time interactive communication between the patient, and the physician or practitioner at a distant site”³⁸ – provides a cost-effective alternative to the traditional face-to-face healthcare delivery model by servicing remote or underserved communities.³⁹ While telemedicine is not new, federal and state legislatures have failed to recognize its benefits on expanding access, decreasing cost, and improving quality of care until recently.⁴⁰ For example, not until 2018 did Congress pass a law to authorize reimbursement for care provided via telemedicine to rural populations.⁴¹

However, nearly a decade earlier Congress began allowing online pharmacies to exist and operate freely.⁴² Unlike the tight regulations restricting traditional healthcare delivery, online pharmacies are merely required to satisfy state regulations.⁴³ Given the majority of online pharmacies are based outside of the United States, these companies have circumvented regulation.⁴⁴ Consequently, the illegal prescription

confidential” by restricting health care providers from releasing patient medical records and guaranteeing patient access to their medical records. 45 C.F.R. §§ 160, 164.524(b)(2) (2013).

37. Vera Gruessner, *The History of Remote Monitoring, Telemedicine Technology*, MHEALTH INTELLIGENCE (Nov. 9, 2015), <https://mhealthintelligence.com/news/the-history-of-remote-monitoring-telemedicine-technology>.

38. *Telemedicine*, MEDICAID.GOV, <https://www.medicaid.gov/medicaid/benefits/telemed/index.html> (last visited May 1, 2019).

39. Ioana Ciopraga, *The FDA Guidance Document of Medical Mobile Apps and its Impact on Innovation: Bringing the Promise of a New Way to Look at Medicine Closer, or Pushing it Further*, 6 J.L. TECH. & INTERNET 43, 45-46 (2015).

40. *Telemedicine Benefits*, AM. TELEMEDICINE ASS’N., <http://www.americantelemed.org/main/about/about-telemedicine/telemedicine-benefits> (last visited May 1, 2019).

41. 38 U.S.C. § 1730C (2018); *see also id.*

42. 21 U.S.C. § 831 (2009).

43. Ross D. Silverman, *Regulating Medical Practice in the Cyber Age: Issues and Challenges for State Medical Boards*, 26 AM. J. L. & MED. 255, 267 (2000).

44. A random sample of 10,000 online pharmacies by the FDA found that 97% of them were either illegal or out of compliance with regulations. *Illegal Online Pharmacies: How Endemic Are They?*, PHARMACEUTICAL TECH. (July 20, 2018),

drug market has blossomed over the last decade, and there are approximately 40,000 illegal online pharmacies today.⁴⁵

The online pharmaceutical market also incentivizes patients to avoid the traditional healthcare model, as patients seek faster treatment by skipping the face-to-face provider visit and locating a desired medication online.⁴⁶ In effect, online prescribing represents another way in which the internet offers “unparalleled opportunities for individuals to get exactly what they want.”⁴⁷ It is no surprise that one in four American consumers purchases their prescription medications online.⁴⁸ Thus, the healthcare industry has made attempts to incorporate technology into its traditional delivery model, but is limited by the limited pace of legislation and political priorities. The difference in Congress’ treatment of telemedicine and online pharmacies shows that inconsistencies in regulation that leave the markets for healthcare delivery open to abuse lead to direct, negative impacts on consumers.

C. *The Shift in Healthcare Delivery*

Without question—tech companies are betting on healthcare.⁴⁹ Within the last five years, the top ten tech companies in the United States have spent over \$4.5 billion to finance healthcare projects.⁵⁰ Since the introduction of eCommerce, companies like Amazon have run out competitors in numerous markets by offering direct-to-consumer products at minimal cost, time, or risk to the consumer.⁵¹ Healthcare

<https://www.pharmaceutical-technology.com/comment/illegal-online-pharmacies-endemic> [hereinafter *Illegal Online Pharmacies*].

45. *Id.*

46. Silverman, *supra* note 43, at 266.

47. *Id.*

48. *Illegal Online Pharmacies*, *supra* note 44.

49. *See Where Big Tech is Placing Bets in Healthcare*, CB INSIGHTS (Sept. 13, 2018), <https://www.cbinsights.com/research/top-tech-companies-healthcare-investments-acquisitions> [hereinafter *Tech Bets*]; *see generally* Pearl, *supra* note 1.

50. *Id.*

51. Experts believe Amazon is currently threatening healthcare, electronic retailers, consumable manufacturers, department stores, high-end department stores, food delivery, bookstores, grocery stores, package delivery and logistics. Kate Taylor, Mary Hanbury, & Dennis Green, *Amazon’s Growth Could Threaten These 10 Industries*, BUS. INSIDER (June 28, 2018, 12:11 PM), <https://www.businessinsider.com/amazon-is-killing-these-7-companies-2017-7#pharmacy-9>.

has become Amazon's most recent target, and in a recent acquisition the company purchased an eCommerce prescription medication platform called PillPack for close to \$1 billion.⁵²

This buy-in is indicative of a pattern of market shifts we have seen in other sectors. In the 1980s, mega retailers like K-Mart, Sears, and Target were the typical outlet for average consumers to shop for household items; today, all but one has filed for bankruptcy.⁵³ This is largely due to eCommerce's ability to consolidate markets because of its superior convenience and cost-effectiveness. Amazon's investment in pharmaceutical eCommerce is a strong sign that swaths of the healthcare industry may fall in the same way. Thus, a change in healthcare delivery is undoubtedly inevitable. As such, without legislative reform allowing direct-to-consumer products in the industry, the traditional healthcare delivery model may meet a similar fate as that of Blockbuster⁵⁴ and Borders Books.⁵⁵

With the recent generation shift, Millennials have become the largest segment of the American consumer market.⁵⁶ However,

52. Ingrid Lunden, *Amazon Buys PillPack, an Online Pharmacy, for Just Under \$1B*, TECH CRUNCH (June 2018), <https://techcrunch.com/2018/06/28/amazon-buys-pillpack-an-online-pharmacy-that-was-rumored-to-be-talking-to-walmart>.

53. See Chris Isidore, *Sears' Extraordinary History: A Timeline*, CNN (Oct. 15, 2018), <https://www.cnn.com/interactive/2018/10/business/sears-timeline/index.html>; Jeanette L. Nolen, *Target Corporation: American Corporation*, ENCYCLOPEDIA BRITANNICA (Mar. 14, 2019), <https://www.britannica.com/topic/Target-Corporation>; *A Timeline of the Kmart Corporation*, N.Y. TIMES (Jan. 22, 2002), <https://www.nytimes.com/2002/01/22/business/a-timeline-of-the-kmart-corporation.html>.

54. Blockbuster went bankrupt in 2000 after refusing to accept a partnership offer from Netflix, an online media streaming company which is now the world's most highly valued media and entertainment company. Greg Satell, *A Look at Why Blockbuster Really Failed and Why it Didn't Have to*, FORBES (Sept. 5, 2014), <https://www.forbes.com/sites/gregsatell/2014/09/05/a-look-back-at-why-blockbuster-really-failed-and-why-it-didnt-have-to/#21934d011d64>.

55. Borders Books went bankrupt in 2011 after outsourcing its online book sales to Amazon instead of developing a competitive e-reader device or offering sales online. Josh Sanburn, *5 Reasons Borders Went Out of Business (and What Will Take its Place)*, TIME (July 19, 2011), <http://business.time.com/2011/07/19/5-reasons-borders-went-out-of-business-and-what-will-take-its-place>. Amazon is now the world's largest eCommerce supplier, valued at \$1 trillion. Joel Anderson, *How Much is Amazon Worth?*, GO BANKING RATES (July 26, 2018), <https://www.gobankingrates.com/making-money/business/how-much-is-amazon-worth>.

56. According to a census taken on July 1, 2017, Millennials account for over 23% of the United States population. *How Many Millennials*, *supra* note 3.

Millennials are the least likely to utilize the traditional healthcare delivery model. Survey data indicates that many Millennials do not see a doctor regularly.⁵⁷ Millennials seem to share the opinion that the time-honored model of regular office-based primary care is fading, and models that offer greater convenience, fast service, connectivity, and price transparency are preferable.⁵⁸

Millennials serve a pivotal role in the success of the healthcare industry. Without Millennials buying in to the pillared insurance scheme while healthy, there is less money to cover the costs of older generations.⁵⁹ That cost spreading is required to balance the high costs of delivering healthcare to aging and illness-prone populations.⁶⁰ Furthermore, without Millennials utilizing preventative medicinal strategies, their risk of disease increases; it is uncertain whether the industry will be able to support them when they do eventually require focused care.⁶¹ Simply put, the traditional model no longer fits the desires of the average consumer, and the projected needs of the healthcare market.

Given the huge financial incentive for online retailers to continue consolidating an unfettered direct-to-consumer market, and the

57. A 2015 survey indicated that 9 out of 10 millennials do not see a doctor regularly, and 51% of millennials see a doctor less than once a year. Amy Juaristi, *New Study: Why Americans are Dropping Out of Healthcare*, ZOCDOC (June 23, 2015), <https://www.zocdoc.com/about/news/new-study-why-americans-are-dropping-out-of-healthcare>.

58. One millennial compared the convenience of urgent care to that of “speed dating” where the “services are rendered in a quick manner.” Sandra G. Boodman, *For Millennials, a Regular Visit to the Doctor’s Office is not a Primary Concern*, WASH. POST (Oct. 6, 2018), https://www.washingtonpost.com/national/health-science/for-millennials-a-regular-visit-to-the-doctors-office-is-not-a-primary-concern/2018/10/05/6b17c71a-aef3-11e8-9a6a-565d92a3585d_story.html?utm_term=.fbffa34fab71.

59. Notably, before the ACA, young adults had the highest uninsured rate of any age group. Carmen Heredia Rodriguez, *This is Why Millennials are Struggling to Get Health Insurance*, TIME (Dec. 6, 2017), <http://time.com/5052313/health-insurance-obamacare-challenges>.

60. COMM. ON THE CONSEQUENCES OF UNINSURANCE, INST. OF MED., HIDDEN COSTS, VALUES LOST: UNINSURANCE IN AMERICA 38, 56 (US) (2003). Multi-generational cost spreading also aids in absorbing the cost of health care services received by uninsured individuals which otherwise is covered by practitioners, institutions, and the federal government. *Id.* at 60–61.

61. Boodman, *supra* note 58.

generational shift towards demand for such a model, the writing is on the wall for traditional modes of healthcare delivery. While advertising and marketing trends within other industries have adjusted in an effort to capitalize on comparable shifts, the traditional healthcare model has not. The concern being that an eCommerce or direct-to-consumer healthcare delivery model is one which the traditional healthcare industry will be unable to incorporate without adjustments to the government's current tight regulatory control. As discussed below, emerging direct-to-consumer health products are unaddressed by current legislation. These products have the potential to expand care, decrease costs, and capture the Millennial market. If the traditional healthcare delivery model fails to incorporate direct-to-consumer alternatives, the existence of the healthcare industry may be jeopardized as the market shifts away from the traditional delivery model.

II. DIRECT-TO-CONSUMER MEDICINE

The healthcare industry has long opposed direct-to-consumer advertising strategies, arguing they misinform patients, cripple providers' abilities to provide adequate care, lead to inappropriate prescribing, and escalate drug costs.⁶² Astonishingly, nearly 800,000 pharmaceutical advertisements air on television in a given year.⁶³ Considering the average American watches sixteen hours of pharmaceutical television advertisements a year, the traditional healthcare industry's concerns are warranted.⁶⁴

While these ads have become common place, they were highly controversial when first introduced in the 1980s.⁶⁵ At that time, pharmaceutical companies mimicked the model used in other industries

62. Natasha Parekh & William H. Shrank, *Dangers and Opportunities of Direct-to-Consumer Advertising*, 33 J. GEN. INTERNAL MED. 586, 586 (2018) (citing C. Lee Ventola, *Direct-to-Consumer Pharmaceutical Advertising Therapeutic or Toxic?*, 36 PHARMACY & THERAPEUTICS 669, 669-74 (2011), and Kurt C. Stange, *Time to Ban Direct-to-Consumer Prescription Drug Marketing*, 5 ANNALS FAM. MED. 101, 101-04 (2007)).

63. Joanne Kaufman, *Think You're Seeing More Drug Ads on TV? You Are, and Here's Why*, N.Y. TIMES (Dec. 24, 2017), <https://www.nytimes.com/2017/12/24/business/media/prescription-drugs-advertising-tv.html>.

64. Parekh & Shrank, *supra* note 62, at 586.

65. The first direct-to-consumer pharmaceutical advertisement was for the Pneumovax vaccine in 1981. *Id.*

by marketing medications directly to the American consumer. This marketing strategy encouraged patients to request specific drug treatment from their providers, thus abrogating providers' discretion to recommend appropriate medications. The strategy was overwhelmingly successful.⁶⁶

A. Direct-to-Consumer Advertising in Healthcare

The United States is one of only two countries in the world that permits direct-to-consumer marketing within the healthcare industry.⁶⁷ Despite growing outrage among medical providers, the FDA has been very slow to respond to concerns raised about direct-to-consumer marketing schemes. In the 1960s, Congress granted the FDA prescription drug labeling and advertising regulation authority in an effort to ensure ads were not misleading consumers.⁶⁸ However, after direct-to-consumer advertising exploded in the 1990s, the FDA eased previously enforced "risk" requirements.⁶⁹ Instead, the FDA merely required direct-to-consumer pharmaceutical advertisements to include the "major risks" associated with each medication.⁷⁰ Consequently, the number of direct-to-consumer pharmaceutical advertisements skyrocketed.⁷¹

In response to continuous and systematic misrepresentation of pharmaceutical drugs in the market, the FDA implemented new

66. "The average television viewer in the United States . . . watches as many as nine drug advertisements per day and about 16 hours per year, far exceeding the time an average individual spends with his/her primary physician." *Id.*

67. New Zealand is the other country that permits direct-to-consumer drug advertising; Canada also allows ads that mention the product or the indication of a drug, but the ad cannot include both. Ventola, *supra* note 62, at 669.

68. This authority included ensuring that ads presented a "fair balance" of both drug risks and benefits, included facts that are "material" to a drug's advertised uses, and included a "brief summary" that notes every risk described in the drug's labeling. Parekh & Shrank, *supra* note 62, at 586.

69. *Id.*

70. *Id.*

71. Today, pharmaceutical companies spend \$5 billion on drug commercials a year. *Id.*

guidelines in 2012.⁷² The main effect of these guidelines is that advertisers now simply add a laundry-list of side effects to the tail-end of advertisements. Many researchers suggest these guidelines continue to fail the American consumer, as the “benefit vs risk” requirement⁷³ remains inadequate.⁷⁴ Thus, consumers continue to be misled. Furthermore, these warnings have become so common place they are often overlooked by the average consumer.

Recently, the FDA has been receiving more applications for direct-to-consumer advertisements as medical device companies are employing similar strategies.⁷⁵ Unfortunately, the FDA struggles to update regulations, and direct-to-consumer advertising strategies undermine regulatory restrictions by encouraging more medical products to be used at home.

B. Direct-to-Consumer Health Products

The demands of Millennial consumers have forced a reconceptualization of how goods are marketed and sold. Unlike preceding generations, Millennials quickly adopted purchasing habits that eliminate the need of an in-person retailer. As Millennial consumers shifted their spending to e-Commerce, other services developed direct-to-consumer options to capitalize on the change. Specifically, tech companies have captured the Millennial consumer with direct-to-consumer health products, a mode of delivery the traditional healthcare industry has not been able to adopt.

72. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY DIRECT-TO-CONSUMER TELEVISION ADVERTISEMENTS – FDA DTC TELEVISION AD PRE-DISSEMINATION REVIEW PROGRAM (Draft Guidance 2012).

73. “Benefit versus risk” is the minimum requirement a product must satisfy to obtain FDA approval; the standard is that the product’s benefits must outweigh its risks. Parekh & Shrank, *supra* note 62, at 587.

74. *Id.* at 586–87.

75. “As the regulating body of DTC advertising, the FDA is responsible for ensuring that advertising ‘is truthful, balanced, and accurately communicated’ through regulation, surveillance, and education.” *Id.* (quoting *The Impact of Direct-to-Consumer Advertising*, U.S. FOOD & DRUG ADMIN. (2015), <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143562.htm>).

1. Medical Devices

Within the last ten years, biotechnology companies have capitalized on the trend toward direct-to-consumer advertising by focusing on medical devices for use at home. The FDA defines medical devices as instruments “intended for use in the diagnosis of disease or other conditions, . . . the cure, mitigation, treatment, or prevention of disease, or . . . to affect the structure of any function of the body of man or other animals.”⁷⁶ Unfortunately, the FDA’s conception of a medical device fails to encompass all products available on the market for purchase, and fails to link the medical device to the healthcare provider. Effectively, these direct-to-consumer medical devices can create larger gaps in care as providers are unaware of any decisions the patient may have made based off direct-to-consumer products.⁷⁷

The rise of wearable fitness trackers is a notable example of this phenomenon. What started as a tool to support healthy lifestyles, evolved into a device that not only encourages but also drives care. When introducing the newest Apple Watch model in 2018, Apple COO Jeff Williams announced the watch’s sensor technology promises to “become an intelligent guardian for your health.”⁷⁸ Effectively, Apple has promised its consumers they now have the ability to monitor their own health by means such as tracking their heart rhythm so abnormalities can be detected by simply wearing the watch.⁷⁹ Features like these may allow consumers to make better decisions about their health, but they are also indicative of big tech’s leverage on the market

76. Jamie Lynn Flaherty, *Digital Diagnosis: Privacy and the Regulation of Mobile Phone Health Applications*, 40 AM. J. L. & MED. 416, 422 (2015).

77. Providers make medical recommendations based on a review of the detailed patient record, evaluation of current symptoms, and a physical examination. Critical data captured in a direct-to-consumer product is undoubtedly missing from the patient’s medical record.

78. On September 12, 2018, while introducing the newest model of Apple Watch Series 4, Apple COO Jeff Williams announced the Watch’s “health sensor.” Sara Salinas & Eugene Kim, *Apple Adds Heart Monitoring to Apple Watch*, CNBC (Sept. 12, 2018, 1:13 PM), <https://www.cnbc.com/2018/09/12/apple-watch-series-4.html>.

79. *Id.*

for novel healthcare solutions.⁸⁰ As economists note: “Apple just gave every Android user a life-saving reason to switch to the iPhone.”⁸¹

Similar to the health monitoring services emerging from big tech, other novel health services are becoming widespread and influential. Nearly a decade ago, a biochemist in Silicon Valley developed the first at home genetic testing kit that could provide health reports based on DNA samples collected from customers’ saliva.⁸² After launching in 2009, 23andMe prospered until the FDA ordered the company cease all sales in 2013 for providing medical information directly to its consumers from an unregulated medical device.⁸³ Unlike its competitors, who focused efforts on ancestry, 23andMe advertised its ability to provide health information while never undergoing FDA certification.⁸⁴ Today, despite its marketing insisting information about genetic health risks, wellness, and carrier status,⁸⁵ 23andMe is only approved to notify consumers of the risks of developing ten medical conditions based on their DNA.⁸⁶

At home genetic testing and wearables present new problems to the FDA; both products effectively market themselves as medical devices, yet are shielded from regulation by the loose language of the FDA’s definition. Furthermore, with big tech’s continued investments in the

80. It was predicted that Apple would ship 18 million units in 2018. Mikey Campbell, *Kuo: High PreOrder Demand for Apple Watch Series 4, Low Expectations for 5.8 Inch iPhone XS*, APPLE INSIDER (Sept. 16, 2018, 8:53 PM), <https://appleinsider.com/articles/18/09/16/kuo-high-preorder-demand-for-apple-watch-series-4-low-expectations-for-58-inch-iphone-xs>.

81. Salinas & Kim, *supra* note 78.

82. In 2006, Anne Wojcicki sought to disrupt the healthcare industry and put “sophisticated DNA analyses into the hands of . . . consumers, giving them information about health, disease, and ancestry.” Erika C. Hayden, *The Rise and Rise Again of 23andMe*, NATURE (Oct. 11, 2017), <https://www.nature.com/news/the-rise-and-fall-and-rise-again-of-23andme-1.22801>.

83. *Id.*

84. See David Dobbs, *The F.D.A. vs. Personal Genetic Testing*, THE NEW YORKER (Nov. 27, 2013), <https://www.newyorker.com/tech/annals-of-technology/the-f-d-a-vs-personal-genetic-testing> (observing that 23andMe operated without FDA approval).

85. *Our Health + Ancestry DNA Service*, 23ANDME, <https://www.23andme.com/dna-health-ancestry> (last visited May 1, 2019).

86. In 2017, the FDA approved notifying consumers of the risks of developing ten specific medical conditions based on their DNA, including Parkinson’s disease and late-onset Alzheimer’s. Hayden, *supra* note 82.

industry, it is likely additional products are already in development that are essentially medical devices, but will reach consumers without being regulated by the FDA.

2. *The mHealth Boom*

Over the last five years, the prevalence of mobile health applications (“mHealth apps”) have exploded. From 2015 to 2017, the number of mHealth apps available for download doubled,⁸⁷ and the market for these apps is estimated to be \$26 billion.⁸⁸ The FDA estimates that over 500 million smartphone users have downloaded at least one mHealth app.⁸⁹ Experts anticipate this boom will continue as the mobile app economy⁹⁰ is expected to increase in size from \$1.3 trillion to \$6.3 trillion by 2022.⁹¹

Unlike other direct-to-consumer products, mHealth apps allow for unlimited access to care without significant effort by the consumer. However, unbeknownst to the public, these mHealth apps are widely unregulated because even apps that are considered “medical devices” escape regulation if they are not classified as a “high risk.”⁹² Regulation of mHealth apps is especially complex because it involves four separate governmental agencies, each focusing on distinct aspects within the application, and fails to assess the application in its entirety.⁹³

87. Terry, *supra* note 21, at 333.

88. Michelle M. Ovansian, *Healthcare Begins a Mobile Revolution*, 1 GEO. L. TECH. REV. 170, 170 (2016).

89. *Id.* at 173.

90. App Economy includes buying and downloading applications, making purchases within the applications, and targeted advertising within those applications. Gene Marks, *The App Economy is About to Explode*, WASH. POST (June 28, 2017), https://www.washingtonpost.com/news/on-small-business/wp/2017/06/28/the-app-economy-is-about-to-explode/?noredirect=on&utm_term=.c48770d0a8eb.

91. *Id.* Economists suspect mobile shopping could be the reason behind this expected increase, as “the mobile commerce market now accounts for approximately 90 percent of mobile app usage[.]” *Id.*

92. Under current law, the FDA regulates only those apps that qualify as “medical devices and/or pose significant risks to patients” and most mHealth apps fall outside of that category. Flaherty, *supra* note 76, at 418–22.

93. Current regulators of mHealth include The Health and Human Services Office of Civil Rights, the Federal Trade Commission, the Federal Consumer Commission, and the Food and Drug Administration. Recently, all four government

As an example, the healthcare data collected by mHealth apps creates an unanticipated wrinkle for the FTC, tasked with protecting sensitive health information that is owned by individual telecommunication carriers. Most mobile applications regulated by the FTC are not required to comply with HIPAA's zone of protection,⁹⁴ thus the FTC's regulation of data is not extensive enough to protect patient information stored in mobile data.^{95,96} Moreover, mHealth apps face unique cyber security concerns, as the FTC has not completely reigned in the use of consumer data, and not all suppliers even require privacy disclosures.⁹⁷

The complexities of this emerging health technology as it relates to FTC regulation alone illuminate the shortfalls already present in regulation. This is so even without considering the difficulties created by mHealth apps for the FCC, FDA, and Health and Human Services Office of Civil Rights, and the oncoming wave of such technologies that the current market shift promises.

3. Pharmaceuticals

The pharmaceutical industry is moving into the direct-to-consumer realm as well, and major online retailers are tackling the traditional pharmaceutical market head on.⁹⁸ In June 2018, Amazon acquired a

organizations "jointly developed an interactive tool in an attempt to guide application, or app developers through the regulatory confusion." Terry, *supra* note 21, at 339.

94. HIPAA, a statutory protection of privacy in health information, contains a "zone of protection" which requires healthcare institutions to protect the disclosure of patient health information. Mobile apps are not within this zone because HIPAA attaches to the individual housing the data and not the data itself. Thus, since mHealth apps are not developed or operated by a healthcare institution as defined by the law, they are not held to guidelines required by HIPAA. *Id.*

95. The FDA has divided the types of mobile apps subject to oversight into three distinct categories: (1) those that are extensions of medical devices; (2) those that transform a mobile platform into a medical device; and (3) those that become a regulated medical device. Ciopraga, *supra* note 39, at 49.

96. Flaherty, *supra* note 76, at 422.

97. This article will not discuss the litany of cyber security issues associated with mHealth apps.

98. See Angelica LaVito, *Amazon has Quietly Launched an Exclusive Line of Over-the-Counter Health Products*, CNBC (Feb. 20, 2018, 3:14 PM), <https://www.cnbc.com/2018/02/20/amazon-has-quietly-launched-an-exclusive-line-of-over-the-counter-health-products.html>.

supplier of customized medication packs called PillPack for just under \$1 billion according to sources close to the deal.⁹⁹ PillPack offers delivery of all prescription medications, vitamins, and any over-the-counter medications in individual daily packs for the consumer.¹⁰⁰ This service makes accessing, dividing, and taking medications from multiple medical providers easier.¹⁰¹ To facilitate this process, PillPack developed software that accounts for multiple prescriptions taken at once.¹⁰² This approach to prescription delivery removes the complexity and frustration of managing multiple medications while establishing a radical shift in chronic care management.¹⁰³

Amazon's willingness to pay ten figures for a service like PillPack is indicative of its potential to reshape the traditional pharmaceutical model.¹⁰⁴ However, the traditional pharmacy model would never be able to sustain such an effective service as it stands today because traditional pharmacies do not have the infrastructure to achieve this end. The loose regulation of online pharmacies discussed above, coupled with big technology companies' economic clout, thus threaten to force ill-equipped and overregulated traditional models to fall by the wayside.

C. Current Regulations

In the last two decades, the United States government has focused intently on issues related to healthcare because of their effect on so many people. In the late 1990s, Congress addressed protections for patients in the clinical setting with the passage of the Health Insurance

99. Lunden, *supra* note 52.

100. *How it Works*, PILLPACK, <https://www.pillpack.com/how-it-works> (last visited May 1, 2019).

101. *Id.*

102. PhamarcyOS constantly monitor's your prescriptions, making required changes when necessary, takes a comprehensive view of client's medications, synchronizes medications, and tracking any anticipated changes in medications. *The Pharmacy System that Goes Beyond the Pharmacy*, PILLPACK: PHARMACYOS, <https://www.pharmacyos.com> (last visited May 1, 2019).

103. *Id.*

104. Prior to Amazon's announcement, the "global online pharmacy market was worth about \$29 billion," and predicted to reach \$128 billion by 2023. Jim Butschili, *Amazon's PillPack Acquisition Could Transform Online Pharmacy Market*, LOGISTICS FOR THE LIFE SCI. (July 16, 2018), <https://www.logisticsforthelifesciences.com/amazons-pillpack-acquisition-could-transform-online-pharmacy-market>.

Portability and Accountability Act of 1996 (HIPAA).¹⁰⁵ HIPAA was intended to improve the continuity of health insurance coverage, decrease fraud, improve access to long-term care, address privacy concerns, and simplify the administration of health insurance.¹⁰⁶ More recently, Congress passed broad legislation to address the financial impact of healthcare on patients with the Patient Protection and Affordable Care Act.¹⁰⁷ While such legislation is put in place to protect patients, it has greatly limited the ability of traditional institutions in the industry to enter the direct-to-consumer market.

When passing HIPAA, Congress specifically targeted Medicare fraud in an effort to protect the patient.¹⁰⁸ However, when it comes to other healthcare legislation, it appears Congress was willing to overlook possible industry-wide abuse – including Medicare fraud and substance abuse – by allowing online pharmacies to exist with limited restriction.¹⁰⁹ Perhaps persuaded by the economic impact of the pharmaceutical industry, recent legislation suggests public policy supports less restrictions on the sale of specific medicinal commodities compared to the service of providing care.

105. See generally Health Insurance Portability and Accountability Act, Pub. L. No. 104–191, 100 Stat. 2548 (1996) [hereinafter HIPAA].

106. “HIPAA represents a large and very significant legislative reform of the health insurance industry, and is codified primarily in Titles 18, 29, and 42 of the United States Code.” Deborah F. Buckman, *Validity, Construction, and Application of Health Insurance Portability and Accountability Act of 1996 (HIPAA) and Regulations Promulgated Thereunder*, 194 AM. L. REP. FED. 133 (2004). See also Clay J. Countryman, *HIPAA and the Practice of Law*, 52 LA. B.J. 103, 103 (2004).

107. See generally Patient Protection and Affordable Care Act, 111 Pub. L. 148, 124 Stat. 119 (2010).

108. See Buckman, *supra* note 106.

109. A specific example of lack of oversight is the opioid epidemic. In 2017, Health and Human Services declared the United States opioid epidemic a public health emergency after over 47,000 Americans died from opioid overdoses in a single year. *What is the U.S. Opioid Epidemic?*, U.S. DEPT. HEALTH & HUM. SERVICES, <https://www.hhs.gov/opioids/about-the-epidemic/index.html> (last visited May 1, 2019). Significantly, “[t]he Centers for Disease Control and Prevention estimates that the total ‘economic burden’ of prescription opioid misuse alone in the United States is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.” *Opioid Overdoes Crisis*, NAT’L INST. DRUG ABUSE, <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis> (last visited May 1, 2019).

Unlike the direct-to-consumer model, there are several realities that make the traditional model uncompetitive including complicated cost structures, time inefficiencies, and geographic challenges. The economics of healthcare are complicated as, unlike other industries, healthcare delivery relies primarily on insurance reimbursement to drive cost. Under this model, healthcare providers rely on guidelines set out by insurance companies to navigate appropriate treatment options, which limits innovation and consumer choice. Furthermore, the traditional model has been around for a century, and its entrenched structure makes acquiring healthcare services a significant time commitment for patients.¹¹⁰ The current model involves patient time spent receiving, reviewing, and reconsidering treatment plans, and receiving proper care often takes multiple visits with multiple providers. Finally, the traditional healthcare delivery model requires face-to-face interactions between patients and providers. The provider must actually see and speak to the patient in order to deliver the service. Thus, despite telemedicine, which still requires “face-to-face” contact, the traditional healthcare delivery model faces vast institutional barriers to meeting modern consumer needs.

These challenges highlight the overarching problem with the traditional model: patients must spend a lot of time and money to get treatment. Millennials are not buying into the traditional healthcare delivery model because it directly contradicts the qualities of service they value—namely efficiency and access. While proponents of the traditional model may not see that demand in the market is shifting away for precisely this reason, direct-to-consumer advertisers and tech companies have taken note.

III. CONCEPTUALIZING POSSIBLE SOLUTIONS TO PROTECT THE PATIENT-CONSUMER

Despite the direct-to-consumer health market being highly saturated and profitable,¹¹¹ the traditional healthcare industry is failing to capitalize on it. As a result, a major patient-consumer demographic, Millennials, has drifted from the traditional model and fully embraced new technology that can resolve their medical concerns. Most other

110. See generally Boodman, *supra* note 58.

111. “In 2012, there were 828 companies in the high tech medical device industry, generating over an estimated \$60 billion[.]” Ciopraga, *supra* note 39, at 46.

industries have incorporated a direct-to-consumer strategy to increase profits and capitalize on this shift, but the traditional healthcare model may be unable to adapt.¹¹² Unfortunately, in many ways current policy makes changing to a direct-to-consumer model impracticable.

A. Retroactive Responses

The amount of money funneled into the healthcare industry should convince lawmakers to get out ahead of these inevitable changes in the market, as, in reality, major changes have already taken place. Instead, the government's actions have handicapped the traditional healthcare industry's ability to embrace these shifts. To address this problem, legislators should reflect on these market changes, and adopt appropriate legislation. Specifically, they should take an honest look at the hurdles the industry currently faces in its attempts to deliver adequate care under the traditional model—the most significant of which is cost.

Many Americans consider the cost of healthcare to be one of the most important public policy concerns.¹¹³ While the ACA attempted to address consumer costs, unfortunately it did not go far enough. This is likely because the healthcare industry is complex, entangled with many other institutions and markets.

1. Medical Education

The problems with healthcare costs start at the beginning, as specialty healthcare education is highly expensive and takes a long time to complete. Additionally, a newly minted medical school graduate is paid very little when completing residency programs required to

112. “With millennials representing the largest living generation, having now surpassed baby boomers in total population, new patterns of purchasing and social behavior are emerging that seem likely to change insurers that try to hold to tried-and-true marketing practices.” Rieman, *supra* note 8.

113. Exit polling following the 2018 midterm elections indicated the majority of voters felt health care was “very important” in making their voting decisions and a quarter indicated it was their “most important issue.” Ashley Kirzinger et. al., *2018 Midterms*, KFF (Oct. 18, 2018), <https://www.kff.org/health-reform/poll-finding/kff-election-tracking-poll-health-care-in-the-2018-midterms>.

specialize in a desired field.¹¹⁴ Depending on the specialty, residency can range from two to seven years.¹¹⁵ During that time, the majority of physicians are unable to pay back their federal loans, as their income does not meet the cost of required living expenses.¹¹⁶ Medical school students and residents are told that they will *eventually* be compensated for their time, and it is well known that doctors are generously compensated once they actually complete the training process.¹¹⁷

As the traditional healthcare model depends heavily on the services provided by doctors, reducing these early costs would go far to reduce the impact on the consumer. One possible solution would be for medical schools to consider making adjustments to expedite the learning process. This would in turn expedite “onboarding” of physicians into the medical profession. There are other fields that train medical professionals without being fundamentally economically inefficient. For example, physician assistant programs appropriately train people without hobbling them with decades of unavoidable debt.¹¹⁸ Training programs for healthcare professionals should

114. Based on a 2018 report, despite most residents working over 60 hours per week, the average salary for their first-year was \$55,200. See Sandra Levy, *Medscape Residents Salary & Debt Report 2018*, MEDSCAPE (July 18, 2018), <https://www.medscape.com/slideshow/2018-residents-salary-debt-report-6010044#8>.

115. The residency follows an internship year. Jennifer Whitlock, *Doctors, Residents, Interns, and Attendings: What's the Difference*, VERY WELL HEALTH (Oct. 31, 2018), <https://www.verywellhealth.com/types-of-doctors-residents-interns-and-fellows-3157293>.

116. Nearly half of all medical students graduate with medical school debt exceeding \$200,000; 23% have debt exceeding \$300,000. Levy, *supra* note 114.

117. In 2018, the median household income in the United States was \$62,175. *June 2018 Median Household Income*, SEEKING ALPHA, <https://seekingalpha.com/article/4193310-june-2018-median-household-income> (last visited May 1, 2019). The average salary for a single American physician in 2018 was \$299,000. *The Highest-Paid Doctors (and the Lowest)*, According to Medscape, ADVISORY BOARD (Sept. 5, 2018), <https://www.advisory.com/daily-briefing/2018/04/11/physician-compensation> [hereinafter *According to Medscape*].

118. Physician Assistants (“PA”) earn a Master’s Degree after two to three years of coursework. Most schools suggest the PA curriculum is extremely similar to the “in class” curriculum taken by medical doctors. To earn a Doctorate in Medicine a medical student is required to complete eight-week clinical rotations in each specialty in their final two years of medical school before choosing a residency program. However, PA’s are eligible to begin work as soon as they meet their state qualifications. Similar to residency, PA’s gain their specialized experience on the job. Sophie Cresswell, *What is the Difference Between a Doctor and a Physician*

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reconsider their pedagogical models and examine ways to cut costs or reduce the time it takes to complete a degree in an effort to reduce overall healthcare costs.

2. Service Costs

Service costs are extraordinarily inflated in the United States. This is largely a reflection of administrative overhead and healthcare professionals' salaries. Unlike most industries that compensate based on promotional structure, healthcare compensates based on level of specialty and billed services.¹¹⁹ This "fee for service" model drives up cost of pay for the average patient, but most doctors fail to accept responsibility for the cost of healthcare in the United States.¹²⁰

Furthermore, the market for healthcare services does not reflect consumer demand. Unlike most industries where costs are driven down by competition, health service and pharmaceutical costs in the United States are driven up as insurers negotiate pricing with for-profit hospital systems and pharmaceutical companies directly.¹²¹ These costs eventually fall back on the patient; as a result, every aspect of the provider visit costs more in the United States than anywhere else in the world.¹²² It is no surprise that patients – especially Millennial patients who are the least likely to invest in healthcare – are willing to consider other available options in an effort to circumvent this system.

Assistant?, GAPMEDICS: BLOG (Oct. 16, 2013), <https://www.gapmedics.com/blog/2013/10/16/what-is-the-difference-between-a-doctor-and-a-physicians-assistant>.

119. Within the last year, physicians saw an average compensation increase ranging from 9-16%. Based on a 2018 Medscape survey, the average salary for non-specialty preventive care physicians (pediatricians, family medicine, and internal medicine) is \$220,000. The highest salary for a specialty physician (Plastic Surgery) is \$501,000. The lowest average salary for a specialty physician (Endocrinology) is \$212,000. *According to Medscape, supra* note 117; *see also* Jacquelyn Smith, *The Best and Worst – Paying Jobs for Doctors*, FORBES (July 20, 2012, 4:45 PM), <https://www.forbes.com/sites/jacquelynsmith/2012/07/20/the-best-and-worst-paying-jobs-for-doctors-2/#1c28b1eba2a3>.

120. Robert Pearl, *Healthcare's Dangerous Fee-for-Service Addiction*, FORBES (Sept. 25, 2017, 12:55 PM), <https://www.forbes.com/sites/robertpearl/2017/09/25/fee-for-service-addiction/#1e89a742c8ad>.

121. *See* Kliff, *supra* note 30.

122. Blumberg, *supra* note 10.

As the market forces affecting healthcare costs cut against the consumer, and the cost of healthcare is driving consumers to options not yet embraced by the traditional healthcare model, decision makers should pay attention. Specifically, hospital administrators should consider implementing available direct-to-consumer tools that fit within the current model – such as telemedicine, mHealth, and online pharmacies – in an effort to decrease service costs.

3. *Pharmaceutical Drug Costs*

Insurance companies and Congress should reconsider their reimbursement model and realistically reform the costs of patient care and pharmaceuticals. While lawmakers have examined numerous methods to successfully combat the rising cost of prescription drugs in the United States, the most impactful solution that has been proposed would expand the price negotiation power of Medicare.¹²³ Some experts believe that allowing Medicare to negotiate drug prices with pharmaceutical companies would save the government \$15 billion a year.¹²⁴ This would also drive down costs of drugs taken by non-government insurance policy holders, as insurance companies often look to Medicare for benchmark pricing when negotiating costs.

Nevertheless, this solution has met its fair share of criticism. Patient advocacy groups fear that providing the government extended oversight into the pharmaceutical industry will decrease patient access to new drugs and disincentivize innovation.¹²⁵ Furthermore, pharmaceutical companies directed significant financial resources toward lobbying Congress in an effort to exclude this policy from the ACA.¹²⁶ As a result, lawmakers are instead focusing on incrementally addressing the public's concerns through less impactful policies, including pressuring companies to set lower prices.¹²⁷

The current administration has proposed the most comprehensive effort yet to address prescription costs with a plan entitled “American

123. See Rena M. Conti & Meredith B. Rosenthal, *Pharmaceutical Policy Reform – Balancing Affordability With Incentives for Innovation*, 374 NEW ENGLAND J. MED. 703, 704 (2016).

124. *Id.*

125. *Id.*

126. *Id.* (citing Daemmrich, *supra* note 14).

127. *Id.* at 704–05.

Patients First.”¹²⁸ Under this plan, the Department of Health and Human Services (HHS) has identified challenges in the American drug market and isolated goals for reform including improving competition and enabling cost negotiation.¹²⁹

Under this plan, by lifting previously imposed barriers and shifting coverage of medications between sectors, Medicare will be able to negotiate the cost of physician-administered medications.¹³⁰ These subtle changes may achieve the outcome American’s are hoping for, but only if Congress is willing to revisit the laws that are responsible for driving up prescription drug costs in the first place.¹³¹ While this proposition is a step in the right direction, it fails to address any solution to make medications more affordable by focusing primarily on increasing competition.¹³² While the plan discusses the influence of increased competition on the prices of the medications,¹³³ it fails to address how the plan will actually attack the price of the medication itself. Experts believe failing to focus on decreasing the net price of prescription medications undermines the potential positive effects of the proposed legislation.

Though policy makers seem to be interested in addressing the significant weaknesses in our current healthcare system, as of yet few

128. DEP’T OF HEALTH & HUMAN SERVICES, AMERICAN PATIENTS FIRST: THE TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS 9 (2018).

129. “HHS has identified four challenges in the American drug market: high list prices for drugs; seniors and government programs overpaying for drugs due to lack of the latest negotiation tools; high and rising out-of-pocket costs for consumers; [and] foreign governments free-riding off of American investment in innovation.” *Id.*

130. On August 7, 2018, U.S. Health and Human Services Secretary Alex Azar announced President Trump’s plan to reduce high prescription drug prices by establishing a number of solutions to enhance competition among retail and hospital administered drugs in an effort to bring drug prices down. Avik Roy, *Trump’s New Medicare Rule to Reduce Prescription Drug Prices Through Competition*, FORBES: THE APOTHECARY (Aug. 7, 2018 9:44 PM), <https://www.forbes.com/sites/the-apothecary/2018/08/07/trumps-new-medicare-rule-to-reduce-prescription-drug-prices-through-competition/#29d4746f7e88>.

131. These include the Orphan Drug Act of 1983 which allows companies with no intellectual property to charge high prices for drugs used to treat rare diseases, and the Biologics Price, Competition, and Innovation Act of 2009 which has not done enough to encourage competition for off-patent biotech drugs.

132. See Roy, *supra* note 130.

133. *Id.*

truly effective solutions have been put in place. Moreover, the traditional healthcare industry has not taken steps to adapt to the imminent changes in the marketplace and prevent these historical shortfalls from being inevitably exacerbated. Policy makers should take an honest, comprehensive look back at the things that have not been working in the healthcare industry and change course now before it is too late.

B. Proactive Reform

Alternatively – and perhaps more realistically – we should look to trends in other industries as a model for legislative reform in an effort to protect and propel the healthcare industry as it braces for change. Despite the value in reflecting on past successes or failures, perhaps it would also be valuable to consider the hurdles the industry *will* face as the industry embraces direct-to-consumer health methods.

As discussed above, if history repeats itself, big tech companies will change the way we receive healthcare. Many other industries have been disrupted by direct-to-consumer strategies in this way, and healthcare is likely next.¹³⁴ Thus, for the traditional healthcare delivery model to survive, the industry should adopt strategies that have proved effective in other sectors. In essence, the patient should be viewed as a consumer and the service should be redefined as a product.

1. The FTC and HIPAA

Traditionally, legislatures are less restrictive in terms of oversight over the sale of goods versus the implementation of services. This distinction is illustrated in the healthcare industry by Congress's willingness to embrace the sale of drugs online, and simultaneous refusal to reimburse medical visits performed online; Congress allowed for online pharmacies nearly a decade before addressing telemedicine.¹³⁵ While HIPAA currently protects patient information in a traditional setting, it has not been adjusted to protect patient

134. *Tech Bets*, *supra* note 49.

135. *Compare* 21 U.S.C. § 831 (2009), *with* 38 U.S.C. § 1730C (2018).

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information in a non-traditional, direct-to-consumer context.¹³⁶ To reconcile this contradiction, healthcare oversight should be adjusted, namely how FTC in HIPAA regulations operate, to allow the traditional healthcare industry to incorporate alternative delivery options.

2. *mHealth Regulation*

Though the capabilities of mHealth apps continue to evolve, government regulation has not kept up. Consequently, users are left exposed to privacy risks and being misled by overpromising, unregulated applications.¹³⁷ To bring mHealth under the ambit of current consumer protections, healthcare reform should allow hospitals to implement direct-to-consumer options like mHealth.

Experts predict hospitals could save over \$300 billion in administrative costs a year by implementing mHealth apps on a large scale by “reducing travel time and improving communication of medical decisions.”¹³⁸ The use of mHealth apps will also “reduce emergency room visits and hospital readmissions [by providing] timely, efficient, and effective care management” as an alternative to relying solely on the traditional treatment scheme.¹³⁹ Capitalizing on this delivery system could help keep healthcare dollars contained within the traditional delivery model.

As mHealth and other emerging technologies are already revolutionizing the healthcare industry, the strategies put in place now to cope with these inevitable changes are critically important. The gaps and overlaps in regulatory measures that place a yoke on traditional healthcare institutions’ abilities to modernize by utilizing these technologies are thus ripe for reconsideration.

136. “The dichotomy between the highly regulated HIPAA zone and the lightly regulated external zone is a function of the sectoral approach to data protection in the United States.” Terry, *supra* note 21, at 339.

137. Ovansian, *supra* note 88, at 174.

138. Flaherty, *supra* note 76, at 420.

139. Barry Liss, *HIPAA and Mobile Health: Where’s the App for That*, 34 *COMPUTER & INTERNET LAW*. 9, 9 (2017).

3. Monopoly Oversight

Finally, the legislature should take a hard look at the potential monopolization of healthcare by big tech companies that are already consolidating emerging, unregulated markets, and which will likely develop their own healthcare systems. Companies like Amazon and Google are shifting their focus to health in an effort to resolve all the problems the American consumer faces when it comes to care.¹⁴⁰

In 2018, Google launched a health initiative to monetize “its profitable search and business proficiencies within the world of healthcare[.]”¹⁴¹ Moreover, Google’s newest member of its executive team Dr. David Feinberg is an advocate for bringing care out of the medical facility and into the home.¹⁴² Previously referring to hospitals as “Blockbuster,” Dr. Feinberg predicts 50% of today’s inpatient medical services “will soon be rendered in people’s homes, and without the many risks associated with a hospital stay.”¹⁴³ The traditional healthcare model is no match for the energy and resources of big tech.

Without embracing this shift in care, the American consumer will watch these tech companies swallow up the largest hospital systems in the country.¹⁴⁴ Thus, for the traditional healthcare delivery model to survive the current and future disruptions within the industry, and avoid companies like Amazon and Google overtaking them, serious regulatory reform is needed.

CONCLUSION

While Congress continues its partisan battles over healthcare reform, it is failing to see the forest through the trees and missing the clear shift within the industry. Tragically, those in need of healthcare are the ones that will continue to suffer. As nearly all products and services available to the American consumer today have, the healthcare industry will likely shift substantially into different delivery models. Millennials’ expectation of direct-to-consumer purchasing, in

140. *Tech Bets*, *supra* note 49.

141. Pearl, *supra* note 1.

142. *Id.*

143. *Id.*

144. *C.f.* Taylor, Hanbury, & Green, *supra* note 51.

combination with the \$3.5 trillion incentive,¹⁴⁵ makes this shift practically inevitable. Over the next decade, the patient will become the consumer, and today the patient-consumer has no place in traditional healthcare delivery.

The writing is on the wall, our healthcare system is fundamentally unprepared for the change that is coming. The patchwork of inconsistent regulation and selectivity of legislative priorities have left the American consumer of healthcare out in the cold. The maneuvering of big tech companies, the proliferation of online pharmacies, and the emergence of opportunistically unregulated medical devices all point to one thing – action is needed now. As with many of the partial solutions currently in place, the critical issues our healthcare system will face in the coming years will only pass on more costs to consumers if something is not done to resolve them.

Legislators need to reconcile the gaps in regulation that are currently being exploited and plan ahead for market shifts that will inevitably affect the rights and pocketbooks of patients. Decision makers within the healthcare industry should take both internal action to deal realistically with costs, taking into account their need to modernize, and lobby for external actions to modulate the imminent disruption of their industry. The purpose of having a healthcare system in the first place is to ensure that patients can get the care they need. Of course, this need must be balanced with economic interests of institutions engaged in the business of providing care. However, without thoughtful and comprehensive action to head off the dynamics emerging in our current system, the American consumer of healthcare will continue to bare ever increasing costs. Change is coming—and change is needed.

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145. See Pearl, *supra* note 1.

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