Volume 27 | Issue 2
SPRING 2018

LOYOLA UNIVERSITY CHICAGO
SCHOOL *of* LAW

BEAZLEY INSTITUTE FOR HEALTH LAW AND POLICY

Annals OF Health Law

ADVANCE DIRECTIVE

The Student Health Policy and Law Review of
LOYOLA UNIVERSITY CHICAGO SCHOOL *of* LAW

ANNALS OF HEALTH LAW
Advance Directive

THE *STUDENT* HEALTH POLICY AND LAW REVIEW OF
LOYOLA UNIVERSITY CHICAGO SCHOOL OF LAW

BRINGING YOU THE LATEST DEVELOPMENTS IN HEALTH LAW

Beazley Institute for Health Law and Policy

VOLUME 27, STUDENT ISSUE 2 SPRING 2018

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ANNALS OF HEALTH LAW
Advance Directive

Editor's Note

The *Annals of Health Law* is proud to present the Twentieth Issue of our online, student-written publication, *Advance Directive*. The Spring 2018 Issue will focus on the crossroads of health law, exploring the unique interdisciplinary legal issues that impact the broad and complex field commonly referred to as "health law."

Indeed, there are numerous legal issues unique to health care, including telehealth and telemedicine, Medicare and Medicaid, fraud and abuse, informed consent, and health care privacy laws, such as the Health Insurance Portability and Accountability Act. However, many traditional areas of the law profoundly impact health care, including tax law, business law, administrative law, and constitutional law, among many others. A healthcare attorney in the field often must understand the various intersectional issues that are present to deliver effective counsel. With health law poised at the crossroads of a vast array of subdisciplines, our authors examine a variety of these issues, including how they arise and effect the delivery of health care and the healthcare field as a whole.

The Issue begins by exploring the health privacy risks associated with mandated mental health screenings in public elementary and secondary schools, and evaluates, in light of the societal stigma surrounding mental illness, whether the existing law sufficiently safeguards students' privacy in the school setting. Next, we examine health multi-level marketing and how these enterprises, which often become unstable pyramid schemes, are insufficiently regulated and pose a danger to consumers—both from financial and health perspectives.

Our authors then investigate the future outlook of the healthcare field as a result of the enactment of the Tax Cuts and Jobs Act of 2017, specifically, how repeal of the individual mandate will increase premiums and put additional stress not only on public health programs, but also on states and American small businesses. The Issue then offers a narrower analysis of the healthcare sector by addressing the impact of mergers and acquisitions on smaller pharmacy market participants and consumers, which has dramatically affected access to care in underserved communities.

The Issue then delves into the complex field of administrative law, where we evaluate Federal agencies' role in creating harmful inefficiencies associated with the current health insurance appeals processes. The article ultimately advocates for a more uniform set of procedures that enable policyholders to appeal in a timelier manner. Next, our authors examine how insufficient regulation of authorized generics has caused significant issues within the intellectual property and antitrust arenas, with larger pharmaceutical companies avoiding patent litigation suits while simultaneously monopolizing the generic market.

Transitioning to the subdiscipline of constitutional law, we focus on the delivery of health care in the prison context—asking whether charging incarcerated individuals co-pays constitutes a violation of the Eighth Amendment to be free from cruel and unusual punishment. This author posits that *not* charging inmates co-pays would positively impact anti-recidivism efforts, as well as boost the health of the communities to which released prisoners return. The Issue then goes on addresses the pros and cons underlying the "patient hotel" concept, which has been implemented

in some European nations and is now being taken seriously by American hospital systems to combat ever-increasing regulatory pressure associated with meeting quality of care requirements.

Returning to the field of antitrust law, we analyze the mechanisms—as well as the relevant obstacles—by which a high-profile online retailer could successfully enter the health care market. The final article in this Issue advocates for regulation mandating that the National Collegiate Athletic Association ("NCAA") require all NCAA member colleges and universities to cover medical expenses associated with athletic injuries, as some student-athletes are exposed to potentially devastating financial consequences in the event that they are injured in competition.

We would like to thank Jordan Donnelly, our Technical Production Editor, because without his knowledge and commitment this Issue would not have been possible. We would like to give special thanks to our *Annals* Editor-in-Chief, Adrienne Testa, for her leadership and support. The Annals Executive Board Members, Christine Bulgozdi and Lauren Batterham, and the Annals Senior Editors, Alex Thompson, Kevin Pasciak, and Lauren Park provided additional invaluable editorial assistance with this Issue. The *Annals* members deserve special recognition for their thoughtful and topical articles and for editing the work of their peers. Lastly, we must thank the Beazley Institute for Health Law and Policy and our faculty advisors, Professor Lawrence Singer, Megan Bess, and Kristin Finn for their guidance and support.

We hope you enjoy our twentieth issue of *Advance Directive*.

Sincerely,

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Exploring the Privacy Risks of Mandated Mental Health Screenings in Public Elementary and Secondary Schools

Emily A. Boyd

I. INTRODUCTION

Schools in numerous states are legally mandated to screen students' vision and hearing and for scoliosis or other potential physical health problems.[1] Physical health screenings have demonstrated their ability to decrease the negative academic effects of health issues through early identification and referrals for appropriate treatment.[2] As society becomes generally more aware of mental illness diagnoses, prognoses, and pervasiveness, there is an increased focus on screening children for depression and other mental illnesses.[3] Medicaid requires that all Medicaid-eligible children be screened for mental illness per the Early and Periodic

[1] Am. Acad. of Pediatrics, *Health Screenings at School*, HEALTHYCHILDREN.ORG, https://www.healthychildren.org/English/ages-stages/gradeschool/school/Pages/Health-Screenings-at-School.aspx ("In some states these screening tests are mandated by law and may also include dental checks, scoliosis evaluations, blood pressure readings, and height and weight measurements. In school districts in which nurses are available for more thorough assessments, testing for tuberculosis and even physical exams may be conducted."); *see, e.g.*, Child Vision and Hearing Test Act, 410 Ill. Comp. Stat. Ann. 205/1; *see, e.g.*, Cal. Sch.-Based Health All., *List of Mandated Health Services,* SCHOOLHEALTHCENTERS.ORG, https://www.schoolhealthcenters.org/start-up-and-operations/school-health-program-models/mandated-health-services/list-of-mandated-health-services/.

[2] Am. Acad. of Pediatrics, Council on Sch. Health, *Policy Statement: Role of the School Nurse in Providing School Health Services,* 121 PEDIATRICS 1052, 1053 (2008).

[3] *See* Nat'l All. on Mental Illness, *Mental Health Screening*, https://www.nami.org/Learn-More/Public-Policy/Mental-Health-Screening (last visited Mar. 25, 2018) [hereinafter NAMI].

Screening, Diagnosis and Treatment (EPSDT) mandate.[4] Overall, there is a public interest in identifying children in need of services, and determining ways to prevent and resolve the potential negative outcomes of childhood mental illness.[5] The National Alliance on Mental Illness (NAMI) is an outspoken proponent for mental health screening in children, and advocates for assessments to be conducted in schools.[6] Similar to the benefits of physical health screenings, school mental health screenings allow for early identification of illness and conditions and can connect students with resources and treatment.[7] Propositions that support the oversight of, and responsibility over, children's mental health see schools as "the ideal setting for monitoring children's mental health and providing them with the services they need," especially in the wake of increasing school violence.[8]

While there are clear benefits to the early identification and treatment of mental illnesses,[9] mental health screenings in schools cannot currently be

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[4] *Id.*; Ctrs. For Medicare & Medicaid Servs., *Early and Periodic Screening, Diagnostic, and Treatment*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/benefits/epsdt/index.html (last visited Mar. 25, 2018) ("EPSDT is key to ensuring that children and adolescents receive appropriate preventative, dental, mental health, and developmental, and specialty services.").

[5] *See generally* Nat'l Inst. of Mental Health, *Child and Adolescent Mental Health*, NIMH.NIH.GOV, https://www.nimh.nih.gov/health/topics/child-and-adolescent-mental-health/index.shtml.

[6] *See* NAMI, *supra* note 3 (stating that NAMI advocates for the federal Mental Health in Schools Act of 2015 and supports professionals from around the country who encourage mental health screenings for children and adolescents).

[7] *See id.*

[8] *See, e.g.*, Tessa Heller, *Mandatory School-Based Mental Health Services and the Prevention of School Violence*, 24 HEALTH MATRIX: THE J. OF L.-MED. 279, 282-83, 293 (2014) (arguing for the implementation of mental health programs for children given that "the number of school shootings per year is higher now than it was in the 1990s. . . [and that experts] have determined that mental illness and social isolation are the two main factors that cause youth violence.").

[9] *See, e.g.*, NAMI, *supra* note 3 ("Mental health screenings are a key part of youth mental health. Approximately 50% of chronic mental health conditions begin by age 14 and 75% begin by age 24. At the same time, the average delay between when symptoms first appear and intervention is 8-10 years. Mental health screenings allow for early identification and intervention and help bridge the gap."); *see generally* Mark D. Weist et al., *Mental Health Screening in School*, 77 J. SCHOOL HEALTH 53, 53 (2007) (finding in its discussion of the importance of mental health screenings in schools, that "mental health screening in schools offers a number of benefits including enhancing outreach and help to youth in need, and mobilizing school and community efforts to promote student mental health while reducing barriers to their learning.").

approached in the same manner as physical health screenings. Identifying mental illness in children requires more dynamic and qualitative approaches than the quantitative measurements used for the assessment of physical illness. Mental Health diagnoses in children are reached differently than in adults.[10] However, despite the use of such a comprehensive approach, it is prone to mistakes.[11] "[Experts] note that normal adolescents are often moody and that overdiagnosis of major depressive disorder, which affects just 5.6% of teens, could lead to increased use of selective serotonin reuptake inhibitors, such as Prozac, that have been linked to an increased risk of suicide."[12] One such expert, Dr. Allen Francis, professor and chairman emeritus of the department of psychiatry and behavioral sciences at Duke School of Medicine, reflects on screening tools as "terrific in theory but terrible in practice."[13]

> For one thing, no screening method is discriminating enough to distinguish between normal sadness, which is very common in teens, and clinical depression, which is very rare. Even the screening methods recommended by the U.S. Preventive Services Task Force are by no means specific in diagnosing clinically significant depression. Many (probably most) teens deemed depressed by general screening will have normal sadness or transient and self-limited mild depression, not requiring diagnosis or treatment.[14]

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[10] *See* Eva Charlotte Merten et al., Review, *Overdiagnosis of Mental Disorders in Children and Adolescents (in Developed Countries)*, CHILD & ADOLESCENT PSYCHIATRY & MENTAL HEALTH 1, 6 (2017) ("Different to mental disorders in adults, mental disorders in children are established using a multi-informant approach [the child, parents, and other important caregivers are asked to describe the child's behavior].").
[11] *Id.* at 6-7.
[12] Brendan Borrell, *Pros and Cons of Screening Teens for Depression*, L.A. TIMES (Sep. 16, 2014), http://www.latimes.com/health/la-hew-depression-screening-pro-con3-2009aug03-story.html.
[13] Richard J. Chung & Allen Francis, *Big Issues in Health Care (A Special Report) – Should All Teens Be Screened for Depression?*, WALL STREET JOURNAL, April 11, 2016.
[14] *Id.*

Because a child's age and development manifests in different symptom expression, both clinicians and their diagnostic tools must be educated on those differences.[15]

Despite the benefits and effectiveness of childhood mental health screenings in identifying children in need of clinical care, mandating, or even encouraging, such screening tools be used in schools creates problems. This article will demonstrate that because of the stigma surrounding mental illness,[16] and the sensitive nature of the information, elementary and secondary school screening tools are currently too flawed to appropriately address the highly personal subject of potential or existing mental illness. It will first analyze the laws applicable to protecting students when the use of such tools occurs in public schools. By exploring and exemplifying the inconsistent use of these tools, and the societal stigma surrounding mental illness in children and the adults they will grow into, this article will then argue that using screening children in schools is not yet an appropriate step. Finally, as an interim solution, this article will reason that presently, schools should provide resources for identifying and addressing mental health concerns to students and their families. Educational efforts should take priority over school-based mental health screenings that may result in false positives and stigmatizing attention placed on vulnerable minors.

II. SCHOOL MENTAL HEALTH SCREENINGS AND THE LAW

As mental health screenings in public schools have gained popularity and controversy, governmental interest at the state and federal level have

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[15] Eva Charlotte Merten et al., *supra* note 10, at 8.

[16] "Stigma is another term for prejudice or negative stereotyping. In terms of mental illness, stigmas represent invalidating and poorly justified knowledge structures that lead to discrimination. . .Several themes recur in stigmatizing attitudes. Media analyses of film and print representations of mental illness have identified three common misconceptions: People with mental illness are homicidal maniacs who need to be feared, they have childlike perceptions of the world that should be marveled [sic], or they are rebellious, free spirits." Patrick W. Corrigan & David L. Penn, *Lessons from Social Psychology on Discrediting Psychiatric Stigma*, 54 AM. PSYCHOLOGIST 765, 766 (1999).

emerged to better regulate such tools.[17] In New Hampshire, House Bill 384 was introduced in 2013, as "[a]n Act requiring parental consent prior to a mental health examination in public schools."[18] Indiana's Senate Bill 435, which is currently under House review, would also require parental consent for mental health screenings as well as require the inclusion of mental health wellness education in school curriculum.[19]

Spurred by efforts to revise and amend the Public Health Service Act regarding children and violence, and to provide access to mental health programs in schools, the Mental Health in Schools Act of 2015 was introduced to Congress but never enacted.[20] The related Mental Health in Schools Act of 2017 was introduced on June 15, 2017 and indicates movement away from school-based screenings and more emphasis on educational efforts.[21] The proposed bill makes no mention of screening tools or the use of mental health testing in schools.[22]

A. FERPA

The Family Educational Rights and Privacy Act (FERPA) "is a federal law that protects the privacy of student education records."[23] The law applies

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[17] H.B. 384, *infra* note 18; H.B. 435, *infra* note 19; Mental Health in Schools Act of 2017, *infra* note 21.
[18] H.B. 384, 2013 Sess. (N.H. 2003).
[19] S.B. 435, 2017 Sess. (Ind. 2017).
[20] Mental Health in Schools Act of 2015, H.R. 1211, 114th Cong. (2015); *see also* Civil Impulse, LLC, *H.R. 1211 (114th): Mental Health in Schools Act of 2015*, GOVTRACK.US, https://www.govtrack.us/congress/bills/114/hr1211 (last visited Apr. 7, 2018) (stating that the "bill was introduced March 3, 2015, in a previous session of Congress, but was not enacted").
[21] *See* Mental Health in Schools Act of 2017, H.R. 2913, 115th Cong., § 581(b) (2017) (stating that activities under the program include "provid[ing] financial support . . . to implement a comprehensive culturally and linguistically appropriate, trauma-informed, and age-appropriate, school-based mental health program").
[22] *See id.* (outlining the general goals of the program without mention of "screening" or "testing" in its description of the types of activities supported by the bill).
[23] Family Educational and Privacy Rights, 20 U.S.C. § 1232g (2018); U.S. Dep't of Educ., *Family Educational Rights and Privacy Act (FERPA)*, https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html [hereinafter *FERPA*].

to all schools that receive federal funds from the Department of Education.[24] FERPA allows parents, and eventually adult students, to access, verify, and correct educational records.[25] Compliance with FERPA is paramount even without students' mental health information in the hands of school officials as the general boundaries limit disclosure without express written consent.[26] However, FERPA allows disclosure of education records without consent in certain circumstances, including when there is a legitimate educational interest, a health or safety emergency, and an audit and evaluation.[27]

The New Hampshire Department of Education provides the following to clarify how a school might define a legitimate educational interest:

> legitimate educational interest refers to the right of certain school officials to access student information and records for the purpose of (a) serving the student; (b) protecting the health, safety, and learning of this student and others; (c) maintaining operations of the school district; (d) obtaining payment for educational programs and services; and (e) other purposes as specified in Federal and state law.[28]

FERPA itself allows for the disclosure of identifying information at the discretion of schools.[29] In the instance of an articulable and significant threat to the "health or safety of a student or other individuals," a school may "disclose information from education records to any person whose

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[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] *Id.*
[28] N.H. Dep't of Educ., *Confidentiality and Public School Health Records*, EDUCATION.NH.GOV, https://www.education.nh.gov/instruction/school_health/faq_records.htm#legitimate (last visited Mar. 25, 2018) (citing NC SCHWAB ET AL., PROTECTING AND DISCLOSING STUDENT HEALTH INFORMATION: HOW TO DEVELOP SCHOOL DISTRICT POLICIES AND PROCEDURES (Am. Sch. Health Ass'n, 2005)).
[29] Disclosure in Health and Safety Emergencies, 34 C.F.R. § 99.36 (2009).

knowledge of the information is necessary to protect the health or safety of the student or other individuals."[30] The Department of Education defers to school judgement in such a situation if the school had a "rational basis for the determination."[31] However, the fear and stigma surrounding mental illness and school-based violence in children creates a large grey area of subjectivity for school officials.[32] If the environment in which a certain school operates supports an atmosphere of stigma, can that school's disclosure of mental health information be considered rationally-based? Even if the Department of Education were to later determine a disclosure inappropriate, and not rationally-based, the information cannot be "un-disclosed."

Stigma itself is not based in rational thought, nor in an examination of a person's true self.[33] We should not enable those school officials or teachers that harbor stigmatizing beliefs regarding mental illness, whether based in ignorance or otherwise, the opportunity to disclose student health information. Their professional education is not typically in medicine or advanced psychology.[34] What if a student suffers from, or is simply

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[30] *Id.*

[31] FERPA identifies the circumstances in which consent is not required for disclosure: when the school or district has determined that there is a "legitimate educational interests," "In an emergency "if knowledge of the information is necessary to protect the health or safety of the student or other individuals". . .[i]nstances of abuse or neglect[,] [m]andatory reporting of communicable diseases. . .[i]nformation that is required by a school to which the student is transferring[, and] [c]ertain legal situations including subpoenas or investigations of criminal offenses. *Id.*; If the Department of Education concludes that the information used to determine if one of those exceptions applied was "rational," it will not argue against the school's judgment. *Id.*

[32] *See* Heller, *supra* note 8, at 279-88 (discussing mental illness as a main factor contributing to youth violence); *see also* Bernice A. Pescosolido et al., *Perceived Dangerousness of Children with Mental Health Problems and Support for Coerced Treatment*, 58 PSYCHIATRY SERVS. 619, 619 (2007) (examining the public's belief and perceived dangerousness of children with mental illness regarding the potential for harm to self and others).

[33] *See* Corrigan & Penn, *supra* note 16, at 766 ("In terms of mental illness, stigmas represent invalidating and poorly justified knowledge structures that lead to discrimination.").

[34] U.S. Dep't of Labor, Bureau of Labor Stat., *Kindergarten and Elementary School Teachers,* BLS.GOV, https://www.bls.gov/ooh/Education-Training-and-Library/Kindergarten-and-elementary-school-teachers.htm (identifying the typical entry-level education for an elementary school teacher as a Bachelor's degree); U.S. Dep't of Labor, Bureau of Labor

suspected to have, Bipolar Disorder or Oppositional Defiant Disorder?[35] Educators are not, by trade, mental health professionals, and they should not be expected to handle or safeguard the health information traditionally not intended for them to access. Mandated mental health screenings in public schools allows the disclosure of those types of private health diagnoses at the discretion of school officials not expected to have significant mental health knowledge and/or training.

FERPA was enacted to protect children's personal information from unnecessary dissemination; however, its current status does not create the type of comprehensive coverage necessary to protect students' mental health information.[36] If, and when, schools attempt to broaden their healthcare services, they will push non-clinical school employees to attempt to provide health care. Schools traditionally have one regular health professional on staff, a nurse who is meant to facilitate, coordinate, and refer students to health care services rather than diagnose and treat major illnesses.[37] And while school districts do employ psychologists, the number of students each psychologist oversees can range from 600 to nearly 3,500.[38] The National

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Stat., *High School Teachers*, BLS.GOV, https://www.bls.gov/ooh/education-training-and-library/high-school-teachers.htm (identifying the typical entry-level education for a high school teacher as a Bachelor's degree); Psychologists, including those working in schools, require at least a Master's degree, but typically the profession requires a doctoral degree and licensure. U.S. Dep't of Labor, Bureau of Labor Stat., *Psychologists*, BLS.GOV, https://www.bls.gov/ooh/life-physical-and-social-science/psychologists.htm.

[35] Oppositional Defiant Disorder is a mental illness in children and adolescents that can present with excessive arguing, active defiance, deliberate attempts to upset people, frequent anger and resentment, and a spiteful and revenge-seeking attitude. Am. Acad. Child & Adolescent Psychiatry, *Children with Oppositional Defiant Disorder*, AACAP.ORG, https://www.aacap.org/App_Themes/AACAP/docs/facts_for_families/72_children_with_oppositional_defiant_disorder.pdf.

[36] *See* Rhoades v. Penn-Harris-Madison Sch. Corp., 3:05 CV 586, 2006 U.S. Dist. LEXIS 69446 *1 (N.D. Ind. Sep. 26, 2006) (illustrating that false positives for mental disorders may be detrimental to school children).

[37] *See* Am. Acad. of Pediatrics, *supra* note 2, at 1053 ("The school nurse is a *liaison* between school personnel,
family, health care professionals, and the community.") (Emphasis added).

[38] NAT'L ASS'N OF SCHOOL PSYCHOLOGISTS, RATIO OF STUDENTS PER SCHOOL PSYCHOLOGIST BY STATE: DATA FROM THE 2009-10 AND 2004-05 NASP MEMBERSHIP SURVEYS (2011).

Institute of Mental Health (NIMH) estimates that nearly fifty percent of children ages thirteen to eighteen suffers from a mental illness.[39] When contrasted against the ratios of school psychologists to students, sufficient attention for all children in need of psychological services seems highly improbable.

FERPA was signed into law in 1974.[40] Just seven years prior, Dr. Walter Freedman performed his last of approximately 2,500 transorbital lobotomies.[41] A transorbital lobotomy is an outdated and invasive procedure used for the treatment of "minor mental disorders" based on a poor understanding of mental health and illness.[42] In the over forty years since FERPA's enactment, it has been amended fewer than ten times, most recently over sixteen years ago in 2001.[43] In the same forty years, the Diagnostic and Statistical Manual of Mental Disorders (DSM) has been revised three times, and its most recent revision was published in 2013.[44] As a privacy law,

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[39] Nat'l Inst. of Mental Health, *Mental Illness; Prevalence of Any Mental Disorder Among Adolescents*, NIMH.NIH.GOV, https://www.nimh.nih.gov/health/statistics/mental-illness.shtml#part_155771.

[40] U.S. Dep't of Educ., *Legislative History of Major FERPA Provisions*, https://www2.ed.gov/policy/gen/guid/fpco/ ferpa/leg-history.html [hereinafter *FERPA Legislative History*].

[41] NPR, *A Lobotomy Timeline,* NPR.ORG, https://www.npr.org/templates/story/story.php?storyId=5014576.

[42] *See* Encyc. Britannica, *Lobotomy*, BRITANNICA.COM, https://www.britannica.com/topic/lobotomy#ref205578 (last updated Dec. 28, 2017). A transorbital lobotomy was a popular procedure "in which a picklike instrument was forced through the back of the eye sockets to pierce the thin bone that separates the eye sockets from the frontal lobes. The pick's point was then inserted into the frontal lobe and used to sever connections in the brain (presumably between the prefrontal cortex and thalamus). [Many lobotomized patients showed] apathy, passivity, lack of initiative, poor ability to concentrate, and a generally decreased depth and intensity of their emotional response to life. Some died as a result of the procedure." *Id.*

[43] *See FERPA Legislative History*, *supra* note 40 (listing a total of nine amendments from the earliest in 1974 to the most recent in 2001).

[44] "*The Diagnostic and Statistical Manual of Mental Disorders* (*DSM*) is the handbook used by health care professionals in the United States and much of the world as the authoritative guide to the diagnosis of mental disorders. *DSM* contains descriptions, symptoms, and other criteria for diagnosing mental disorders. It provides a common language for clinicians to communicate about their patients and establishes consistent and reliable diagnoses that can be used in the research of mental disorders. It also provides a common language for researchers to study the criteria for potential future revisions and to aid in the development of medications and other interventions." The DSM is reviewed and revised with new

FERPA was not developed in a time with great sensitivity to mental illness, and the medical knowledge into such conditions has far outgrown its reach. FERPA is not equipped to handle the current status, prevalence, and complexity of mental illness. Even in post-secondary institutions, where FERPA applies to health records in schools that provide health care, FERPA has not demonstrated a particular sensitivity to the social ramifications of disclosing information about mental health diagnoses.[45] In the wake of the 2009 Virginia Tech shooting, FERPA rules were altered to ensure that health information could be released without consent due to health and safety concerns.[46] That reactionary response showed no additional appreciation for the complexity of mental health information, and FERPA appears not to be proactive in its amendments. Without an in-depth knowledge of mental health diagnosis, treatment, and prognosis, such information in the hands of schools could lead to dangerous and violative outcomes.

B. HIPAA

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), from a mental health perspective, seeks to prohibit health information from unauthorized sharing.[47] In 2017, the Office of Civil Rights (OCR) released guidance speaking directly to HIPAA privacy and

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research and knowledge about mental disorders. Am. Psychiatric Ass'n., *DSM–5: Frequently Asked Questions*, PSYCHIATRY.ORG, https://www.psychiatry.org/psychiatrists/practice/dsm/feedback-and-questions/frequently-asked-questions (last visited Mar. 11, 2018); Am. Psychiatric Ass'n., *DSM History,* PSYCHIATRY.ORG, https://www.psychiatry.org/psychiatrists/practice/dsm/history-of-the-dsm (last visited Mar. 11, 2018) (presenting a timeline that shows that the DSM-II was used in 1974, followed by DSM-III, DSM-IV, and DSM-V revisions over the last four decades).

[45] *See generally* Gordon Block, *Mental Health Concerns Alter FERPA Rules,* COLLEGIATE TIMES, Apr. 2, 2009, http://www.collegiatetimes.com/news/mental-health-concerns-alter-ferpa-rules/article_d2ddec95-44a7-5464-a6e2-f18c875b7c9b.html.

[46] *Id.*

[47] *See* Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104–191 (1996).

information sharing regarding mental health.[48] The guidance speaks to adult mental health treatment and patient protections from unnecessary disclosures; however, with the exception of psychotherapy notes, mental health information is no more protected than general health information.[49] School mental health screenings do not create "psychotherapy notes," as they are not conducted by therapists or mental health professionals.[50] Therefore, children receiving mental health screenings in schools cannot have their screening results protected by the provisions of HIPAA.[51] The resulting information about highly stigmatized and private information is no more protected than a vision and hearing screening.[52]

Further, the Department of Health and Human Services (HHS) explicitly states: "In most cases, the HIPAA Privacy Rule **does not** apply to an elementary or secondary school."[53] Schools are not generally considered HIPAA covered entities.[54] Although "a school employs school nurses,

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[48] HHS Office for Civil Rights, *HIPAA Privacy Rule and Sharing Information Related to Mental* Health, HHS.GOV, https://www.hhs.gov/sites/default/files/hipaa-privacy-rule-and-sharing-info-related-to-mental-health.pdf (last updated Dec. 19, 2017) [hereinafter HHS *HIPAA Privacy Rule*]; "The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required the Secretary of [HHS] to develop regulations protecting the privacy and security of certain health information. To fulfill this requirement, HHS published what are commonly known as the HIPAA Privacy Rule and the HIPAA Security Rule. The Privacy Rule, or Standards for Privacy of Individually Identifiable Health Information, establishes national standards for the protection of certain health information." HHS Office for Civil Rights, *Summary of the HIPAA Security Rule,* HHS.GOV, https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html.

[49] HHS *HIPAA Privacy Rule*, *supra* note 48.

[50] *See* NAMI, *supra* note 3 (stating that the types of mental health screenings children receive in school are conducted by school staff rather than therapists. Other mental health screenings may also be performed by physicians or other physical health providers).

[51] Psychotherapy notes are given special protection because of the personal nature of the information they contain, and the fact that they are not required or useful in healthcare treatment, payment or operations beyond the creating therapist's use. HHS *HIPAA Privacy Rule, supra* note 48.

[52] *Id.*

[53] U.S. Dep't Health & Human Servs., *Does the HIPAA Privacy Rule Apply to an Elementary or Secondary School?*, HHS.GOV, https://www.hhs.gov/hipaa/for-professionals/faq/513/does-hipaa-apply-to-an-elementary-school/index.html (last visited Apr. 7, 2018) [hereinafter HHS *HIPAA*].

[54] *Id.* ("The HIPAA Privacy Rule only applies to health plans, health care clearinghouses, and those health care providers that transmit health information electronically in connection with certain administrative and financial transactions [covered entities].").

physicians, psychologists, or other health care providers, the school is not generally a HIPAA covered entity because the providers do not engage in any of the [HIPAA] covered transactions."[55]

Even in schools that conduct covered transactions, many schools are likely not required to comply as a HIPAA covered entity.[56] Schools maintain "health information only in student health records that are "education records" under FERPA and, thus, not "protected health information" under HIPAA.[57] Because student health information in education records is protected by FERPA, the HIPAA Privacy Rule excludes such information from its coverage."[58] Without HIPAA coverage, FERPA is left as the only coverage for health records in public elementary and secondary schools.[59] FERPA currently provides inadequate protection for those records. Its outdated status and lack of healthcare considerations does not allow it to include the type of coverage parents and guardians, schools, and students should demand for their private health information.

Steps have been made in government, society, and healthcare to recognize the importance of mental health treatment within a proper healthcare setting.[60] A child's public school is not the appropriate place for such

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[55] *Id.* (listing HIPAA covered transactions to include: transmitting health information electronically, submitting health care claims to health plans, and billing electronically).
[56] *See id.* (distinguishing HIPAA from FERPA by identifying the difference between protected health information and educational records).
[57] *Id.*
[58] *Id.*; *see also* 45 C.F.R. § 160.103 (2014) (specifying that "[p]rotected health information excludes individually identifiable health information. . .[i]n education records covered by the Family Educational Rights and Privacy Act").
[59] Ass'n of State and Territorial Health Officials, *Comparison of FERPA and HIPAA Privacy Rule for Accessing Student Health Date*, ASTHO.ORG, http://www.astho.org/programs/preparedness/public-health-emergency-law/public-health-and-schools-toolkit/comparison-of-ferpa-and-hipaa-privacy-rule/ (last visited Apr. 7, 2018) (recognizing no other federal law that govern health records besides FERPA and HIPAA).
[60] *See, e.g.*, Ctrs. for Medicare & Medicaid Servs., *The Mental Health Parity and Addiction Equity Act (MHPAEA)*, CMS.GOV, https://www.cms.gov/cciio/programs-and-initiatives/other-insurance-protections/mhpaea_factsheet.html (last visited Mar. 26, 2018) (summarizing and explaining the Mental Health Parity and Addiction Equity Act and its efforts to have mental health coverage equal to physical health coverage in American health plans).

meaningful health screenings to be conducted because the privacy concerns are presently too great a hurdle for schools to overcome given the overall societal view of mental illness in children.

III. RISKS OF INVOLVING SCHOOLS IN CHILDREN'S MENTAL HEALTH CARE

There is no governmental tracking tool regarding school mental health screenings, and the available tools vary in their intensity of services.[61] Sharon Stephan of the Center for School Mental Health commented that, "[n]o state is providing high-end services in all of their schools."[62] Without consistency and an equitable disbursement of resources and opportunities for mental health education, parents and guardians should not trust that public schools are prepared to protect private mental health information.

A high school student, Chelsea Rhoades, received a routine mental health screening at school.[63] Her "TeenScreen" results prompted a school counselor to pull her aside and provide Chelsea with what she and her parents identified as inappropriate diagnoses of Obsessive-Compulsive Disorder and Social Anxiety.[64] Consequently, Chelsea's parents sued the school district.[65] In their suit, the Rhoades alleged that Chelsea involuntarily took the screening test without parental consent (infringing on their liberty interest in making decisions about their child's health care and upbringing), and that the school

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[61] *See* Kelli Kennedy, *Controversy Plagues School Mental Health Screening*, USA TODAY (Jan. 13, 2014), https://www.usatoday.com/story/news/nation/2014/01/13/school-mental-health-screening/4454223/ ("The federal government does not keep track of school mental health screening, so it's all but impossible to say how many schools do or don't offer it.").
[62] *Id.*; "Baltimore and Chicago have robust screening and treatment programs. Teachers in one South Florida school district screen children as young as kindergarten by filling out a short questionnaire, while students in Minnesota answer anonymous surveys about drug use and depression. In Olympia, Wash., 21,000 students were screened for substance abuse and mental health issues in 2010, but that dropped to only 7,500 in 2012 due to lack of funding." *Id.*
[63] Rhoades v. Penn-Harris-Madison Sch. Corp., *supra* note 36, at *3.
[64] *Id.* at *4; TeenScreen Nat'l Ctr. for Mental Health Checkups at Columbia Univ., *About the TeenScreen National Center*, TEENSCREEN.ORG (July 18, 2013), https://web.archive.org/web/20130718212029/http://www.teenscreen.org: 80/about/ [https://perma.cc/9UQH-ACWB].
[65] Rhoades v. Penn-Harris-Madison Sch. Corp., *supra* note 36, at *5.

and test violated her privacy interest in the non-disclosure of personal information.[66] The court permitted the suit to proceed on the claims against the school regarding Chelsea's parents' liberty interest under the Fourteenth Amendment,[67] the school's failure to obtain affirmative parental consent for the screening, and the school's violation of the family's right to privacy by "extracting from Chelsea highly personal and private information . . . for the purpose of conveying a fallacious and highly damaging diagnosis of Chelsea's mental condition."[68] At the time of Chelsea's screening, parental consent was required; however, the school mailed her parents a form that only needed to be returned if they denied permission for Chelsea to participate.[69]

Chelsea's false positives likely became a part of her education record, protected only by FERPA's limited scope and ability to envelop private healthcare information.[70] Chelsea experienced the effects of societal stigma around mental illness despite having no formally diagnosed nor self-identified mental illness.[71] Because of the school's inadequate methods and capacity to diagnose and assist in the management of mental illness, Chelsea was damaged by the very tool her school employed to benefit her.

IV. WHY NOT NOW?: SAFEGUARDING CHILDREN FROM HARMFUL STIGMA

Despite the risks and precarious balance of children's privacy and public schools' integration with children's well-being, the proponents of mandatory testing raise valid points.[72] NAMI argues that childhood screenings will

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[66] *Id.* at *4.
[67] Legal Info. Inst., *14th Amendment*, LAW.CORNELL.EDU, https://www.law.cornell.edu/constitution/amendmentxiv (last visited Apr. 7, 2018).
[68] Rhoades v. Penn-Harris-Madison Sch. Corp., *supra* note 36, at *6, *27.
[69] *Id.* at *4.
[70] Family Educational and Privacy Rights, *supra* note 23 (identifying the scope of FERPA protections to include education records but not health diagnoses).
[71] Rhoades v. Penn-Harris-Madison Sch. Corp., *supra* note 36, at *3.
[72] *See, e.g.*, NAMI, *supra* note 3 (presenting the benefits of early mental health screening); *see generally* THE JED FOUNDATION, STUDENT MENTAL HEALTH AND THE LAW: A RESOURCE

"bridge the gap" between the onset of mental health symptoms and actual intervention.[73] With around half of "chronic mental health conditions [beginning] by age 14 and [three-quarters beginning] by age 24," childhood screenings seem to make the most sense.[74] Perhaps it could also be argued that eliminating mental health screenings in schools would create a downward spiral leading to the elimination of teachers and school officials as mandatory reporters.[75] While most school officials are mandatory reporters in instances of child behavior indicative of abuse or neglect,[76] the process of "mandatory reporting" should not be the same in the instance of suspected mental illness. We have reached a time in our society that we no longer ignore child abuse and neglect and label it a family's private concern.[77] The identification of such an issue elicits protective and nurturing instincts in the responsible adults in a child's life. Presently, diagnoses of mental illness still create a reaction of fear.[78] Until society can address a childhood diagnosis of mental illness as deserving of the same compassion as any physical medical condition or instance of abuse, mandated identification of mental illness in schools can create dangerous outcomes for the minor children identified by the tools initially intended to help them.[79]

FOR INSTITUTIONS OF HIGHER EDUCATION (2008) (recognizing that decisions in how to approach mental illness should be determined on a "case-by-case basis").

[73] NAMI, *supra* note 3.

[74] *Id.*

[75] Teachers, principals, and other school personnel are identified as mandatory reporters of suspected or actual child abuse in almost every state. A report is required when a mandated person knows or suspects that a child has suffered or threatened by mental or physical injury. Children's Bureau, *Mandatory Reporters of Child Abuse and Neglect*, CHILDWELFARE.GOV, https://www.childwelfare.gov/pubPDFs/manda.pdf.

[76] *Id.*

[77] *See id.* (providing extensive information on each state and American territory's regulations on reporting child welfare concerns).

[78] *See* Peggy Drexler, *Why Do We Fear Mental Illness?*, PSYCHOLOGY TODAY (Jan. 8, 2016), https://www.psychologytoday.com/blog/our-gender-ourselves/201601/why-do-we-fear-mental-illness ("[M]ost people shy away from or avoid someone experiencing a mental health emergency. They think whatever the person is going through is 'personal,' or that 'it's a family matter.'").

[79] *See, e.g.*, Rhoades v. Penn-Harris-Madison Sch. Corp., *supra* note 36, at *1 (illustrating that false positives for mental disorders may be detrimental to school children); *see, e.g.*,

By screening children in schools, perhaps we could begin to identify the true prevalence of mental illness in children and hope to destigmatize mental health in our communities. However, mandated screening, and the involvement of a child's school in his or her medical decisions, poses significant risks as the only privacy laws available to protect health information obtained by schools are inapplicable and inadequate in the case of mental illness.

V. WHAT SCHOOLS CAN DO NOW

It is a laudable objective to identify children at risk for, or already facing, mental illnesses. However, the example above and the present state of mental illness stigma do not indicate an accepting environment sensitive to the health needs of those children identified.[80] Maintaining or increasing such screenings in public schools despite their non-covered status under HIPAA,[81] and the inadequate protections of FERPA, is a step that would expose and possibly harm the vulnerable children we are intending to care for.[82]

Michael F. Cannon & Marie Gryphon, *Schools Shouldn't Play Doctor,* CATO INST. (July 4, 2010), https://www.cato.org/publications/commentary/schools-shouldnt-play-doctor-0 (detailing stories of children whose parents were accused of abuse when they stopped medicating their children for ADHD, putting the children at risk of losing a parent because of a school's determination that the child should be medicated).

[80] In a review of studies exploring stigma surrounding mental illness in the United states, "children with depression or ADHD were viewed as significantly more dangerous to others and themselves as compared to children with daily troubles or children with asthma. Similarly, children viewed peers with ADHD or depression as significantly more likely to be violent than peers with asthma. Adult respondents viewed adults with schizophrenia, depression, alcohol dependence, or drug dependence as more likely to be violent to others, compared to a person with 'normal' troubles. Adult respondents were also significantly more likely to report a person with mental illness or a person addicted to drugs as dangerous, as compared to a person in a wheelchair." Angela M. Parcesepe & Leopoldo J. Cabassa, *Public Stigma of Mental Illness in the United States: A Systematic Literature Review*, 40 ADMIN. POL'Y MENTAL HEALTH 384, 388 (2012) (citations omitted).

[81] *See* HHS *HIPAA*, *supra* note 53.

[82] *See generally* Weist et al., *supra* note 9, at 54 (noting that mental health screenings in schools have the *potential* to help in necessary early identification of mental illness but require "a coordinated and comprehensive school mental health program" (emphasis added)); *see, e.g.*, Rhoades v. Penn-Harris-Madison Sch. Corp., *supra* note 36.

In the United Kingdom, there is a program for primary and secondary schools encouraging education, open discussion, and the provision of resources centered around the topic of mental health and wellness.[83] The program provides materials for teachers and parents to help facilitate conversations about mental health at school and at home.[84] Such a program empowers students to talk about their feelings and emotions and gives students, teachers, and parents the appropriate resources to intervene if necessary. The program does not screen children nor encourage schools to take over the mental health care of their students. Although not based in the United States, such a program could revolutionize the American approach and conversation about mental health.

VI. CONCLUSION

"Education is the mission of schools. . ."[85] A push for mandated mental health screenings in schools jeopardizes the confidentiality of students' mental health information in a society where mental illness is poorly understood and highly stigmatized. There is a perpetual stereotype that children facing mental illness are prone to violence. Such stereotypes confine children hopeful to reach their full potential despite the obstacles of mental illness. The instincts of care and protectivity toward abused and neglected children can disappear from teachers and school officials when the child is being abused and neglected by his or her own brain. Elementary and

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[83] *See* Anna Freud Nat'l Ctr. for Children and Families, *The Talking Mental Health Project for Schools: Small words, Big Concepts*, ANNAFREUD.ORG (Sept. 28, 2017), https://www.annafreud.org/insights/blogs/2017/09/the-talking-mental-health-project-for-schools-small-words-big-concepts/ [hereinafter Anna Freud Primary]; *see also* Anna Freud Nat'l Ctr. for Children and Families, *Talking Mental Health with Secondary Pupils*, ANNAFREUD.ORG, https://www.annafreud.org/what-we-do/schools-in-mind/talking-mental-health-with-secondary-pupils/ [hereinafter Anna Freud Secondary] (introducing a booklet for teachers that offers introduction to mental health issues relevant to secondary school children).

[84] Anna Freud Primary, *supra* note 83; Anna Freud Secondary, *supra* note 83.

[85] Jamie Chamberlin, *Schools Expand Mental Health Care*, 40 MONITOR ON PSYCHOLOGY 64, 64 (2009).

secondary schools should focus on providing students and families with education and resources for identifying and addressing mental health concerns. Such educational efforts should be prioritized over school-based mental health screenings that allow schools to collect sensitive health information that current privacy laws are not equipped to protect.

Tax Cuts and Jobs Act of 2017: Economic Prosperity in Sacrifice of the Healthcare System?

Adrian Chan

I. INTRODUCTION

The adoption of the Affordable Care Act ("ACA")[1] in 2010 proved to be a significant policy left behind by the Obama presidency, but only time will tell if the ACA will continue to be part of President Obama's legacy. Healthcare and tax reform continue to dominate the U.S. political agenda, as evidenced by the passing of the Tax Cuts and Jobs Act of 2017.[2] A significant part of the legislation is the elimination of the individual mandate's penalty, a penalty imposed on those that do not comply with the requirement that U.S. citizens and noncitizens must have health insurance.[3] Coupled with the lowering of the corporate tax rate and the income tax rate reduction, there will be a substantial increase in the federal deficit.[4] In a recent analysis, the Congressional Budget Office ("CBO") stated that as many as thirteen million Americans would choose not to receive health

[1] Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 (2010); Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 [hereinafter Affordable Care Act].
[2] Tax Cuts and Jobs Act, PUB. L. NO. 115-97, 131 Stat. 2504 (2017).
[3] *Id*; CONG. BUDGET OFFICE, REPEALING THE INDIVIDUAL HEALTH INSURANCE MANDATE: AN UPDATED ESTIMATE, https://www.cbo.gov/system/files/115th-congress-2017-2018/reports/53300-individualmandate.pdf (last visited Mar. 17, 2018) [hereinafter AN UPDATED ESTIMATE].
[4] CONG. BUDGET OFFICE, RECONCILIATION RECOMMENDATIONS OF THE SENATE COMMITTEE ON FINANCE 1, https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/reconciliationrecommendationssfc.pdf (last visited Mar. 17, 2018) [hereinafter RECONCILIATION RECOMMENDATIONS] (stating that there will be a $1,414 billion increase in the deficit over the next 10 years).

insurance due to the repeal of the individual mandate's penalty.[5] Concurrently, the bill would reduce most income tax rates for individuals, increase the standard deduction and child tax credit and repeal deductions for personal exemptions, specific itemized deductions, and the alternative minimum tax (AMT).[6] For corporations, the bill would permanently modify the structure of the corporate income tax rates with the top rate of 35 percent under the current law to a reduction of a 21 percent rate.[7] The Joint Committee of Taxation ("JCT") estimates that this legislation would lead to an increase in the federal deficit by $1,414 billion over the next ten years.[8] Economists, health care analysts and other experts signal that this deficit will mean a reduction in the government's role in healthcare and a slash of funding to Medicare and Medicaid.[9]

This article discusses how the repeal of the individual mandate will increase health insurance premiums and individuals with lower health costs will, in turn, drop out of the insurance marketplace, thus creating pressure on the uncompensated care system and financial strain on Medicaid. The article then addresses the rise in federal deficit which will mean spending cuts to public programs, specifically Medicare and Medicaid. Finally, the article considers how while the Tax Cuts and Jobs Act of 2017 created great optimism for job growth and economic expansion, because of these changes

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[5] AN UPDATED ESTIMATE, *supra*, note 3.
[6] Tax Cuts and Jobs Act, PUB. L. NO. 115-97, 131 Stat. 2504 (2017) ("For example, the tax bill will lower individual tax rates to 37 percent, increase the standard deduction to $12,000 for singles and $24,000 to couples, increase the child tax credit to $2,000, eliminate the personal exemption, limit state and local tax deductions to $10,000 while repealing the overall limit on itemized deductions, and finally increase the exemption for the alternative minimum tax so fewer will pay it.").
[7] *Id.*
[8] *See* RECONCILIATION RECOMMENDATIONS, *supra* note 4.
[9] *See* David Blumenthal, *How the New U.S. Tax Plan Will Affect Health Care*, HARV. BUS. REV., https://hbr.org/2017/12/how-the-new-u-s-tax-plan-will-affect-health-care (last visited Mar. 26, 2018); Daniel Bush, *How will the tax bill impact health care? 5 experts weigh in*, PBS NEWS HOUR (Dec. 14, 2017), https://www.pbs.org/newshour/economy/making-sense/how-will-the-tax-bill-impact-health-care-policy-5-experts-weigh-in; Merrill Goozner, *10 healthcare predictions for 2018*, 48 MODERN HEALTHCARE; Chicago 26 (2018).

there will be major consequences to the quality of health and financial well-being of American citizens and added financial stress on states and American small businesses.

II. THE INDIVIDUAL MANDATE

Besides thirteen million fewer Americans having health insurance, the CBO and the JCT estimate that average premiums in the nongroup market will increase by about ten percent in the next decade.[10] The increase in premiums will likely occur because healthier, younger individuals will be less likely to obtain insurance and others will not purchase insurance due to these increased prices, thus, creating a concentrated market of higher premium paying, sicker individuals.[11] The CBO and JCT estimate that a repeal of the individual mandate would reduce the federal budget deficits by $416 billion between 2018 and 2026.[12] This would also decrease spending by $381 billion between 2018 and 2026 due to the drop in Medicaid enrollment, reduction of federal spending on subsidies for insurance purchased through the marketplace, and other effects.[13]

Critics argue that the individual mandate repeal will end the health care "calm"[14] and unnecessarily attack health care.[15] At the expense of damaging the health care system, they argue that the repeal's estimated federal

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[10] AN UPDATED ESTIMATE, *supra* note 3, at 1.
[11] *Id.*
[12] CONG. BUDGET OFFICE, REPEAL THE INDIVIDUAL HEALTH INSURANCE MANDATE (2016), https://www.cbo.gov/budget-options/2016/52232 [hereinafter REPEAL THE INDIVIDUAL HEALTH].
[13] *Id.*
[14] Timothy Stolzfus Jost, *Mandate Repeal Provision Ends Health Care Calm*, 37 CULTURE OF HEALTH, MEDICINE & MORE (Dec. 11, 2017), https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.1551.
[15] Linda Richmond, *New Tax law unnecessarily Attacks Health Care, Says APA*, PSYCHIATRIC NEWS (Jan. 12, 2018), https://psychnews.psychiatryonline.org/doi/full/10.1176/appi.pn.2018.1b24.

government savings of $416 billion between 2018 and 2026[16] gave Republicans the money needed to push tax cuts while following through on the promise made to repeal part of the ACA.[17] Proponents, however, point to the fact that the decision to obtain health insurance is a private matter that should be left to the individuals and not the federal government and, similarly, the associated penalties jeopardize the financial well-being of individuals.[18]

Regardless of whether an individual identifies healthcare as a right or as a privilege, a likely consequence will come in the form of uncompensated care where individuals who dropped insurance coverage shift a portion of the cost of their care onto others.[19] In the off-chance that a healthy, uninsured individual gets sick and needs health care, some may receive care without paying for it.[20] An example of this care is the federal Emergency Medical Treatment and Active Labor Act ("EMTALA"), EMTALA imposes a requirement on hospitals to screen patients entering the emergency room for medical conditions that require emergency treatment and then stabilize those patients regardless of whether they can pay for it.[21] The brunt of the cost of uncompensated care comes from the federal government with the help of state and local government programs.[22] The

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[16] REPEAL THE INDIVIDUAL HEALTH, *supra* note 12.
[17] Jost, *supra* note 14.
[18] REPEAL THE INDIVIDUAL HEALTH, *supra* note 12.
[19] Matthew Fiedler, *Repealing the Individual Mandate Would Do Substantial Harm*, THE BROOKINGS INST. (Nov. 21, 2017), https://www.brookings.edu/blog/up-front/2017/11/21/repealing-the-individual-mandate-would-do-substantial-harm/.
[20] *Id.*
[21] Harris Meyer, *Why patients still need EMTALA*, 46 MODERN HEALTHCARE 16, (2016) (discussing the importance of EMTALA in the healthcare sector and how the law remains essential in ensuring individuals receive basic treatment for emergencies. Tens of millions of Americans remain uninsured or underinsured despite the coverage expansion under the ACA. With the repeal of the individual mandate, the number of uninsured can be expected to significantly grow and forms of care required by acts such as EMTALA will be forced to take on a heavier burden).
[22] Teresa A. Coughlin et al., HENRY J. KAISER FAMILY FOUND., *Uncompensated Care for Uninsured in 2013: A Detailed Examination*, 14, 23 (2014) (stating that in 2013 the federal government was by far the largest funder of uncompensated care, about three-fifths ($34.8

government's role, particularly the federal government, in funding these programs should be expected to rise as the burdens of uncompensated care are expected to rise.[23] The Medicaid and Medicare programs account for an estimated total of 40.3 percent of uncompensated care, with Medicaid accounting for 25.3 percent and Medicare accounting for 15 percent.[24] Because the Medicare and Medicaid programs are such an integral part of funding for uncompensated care, it is critical to monitor how the ACA cutbacks of Medicaid and Medicare payments affect hospitals.[25] Therein lies the conundrum that could potentially reshape major areas of American life for the low and middle class. When Republican leaders are forced with the decision of whether to allocate more funding of the budget towards these public programs or to scale back these public programs, they often choose the latter.[26] Adding to the urgency of the situation, the federal deficit is expected to increase which will mean more cuts to programs like Medicaid and Medicare [27]

III. THE FEDERAL DEFICIT

Provisions in the legislation, specifically the reduction in corporate tax, are estimated to increase the federal deficit by $1,441 billion over the 2018-2027 period.[28] With the federal deficit expected to grow, Republican leaders

billion), through federal programs such as Medicaid, Medicare, and the Veterans Administration).

[23] *See* Fielder, *supra* note 19.

[24] *Id.* at 24.

[25] *Id.* at 15-17 (stating that the Medicaid program contains two major payments that help fund the cost of hospital uncompensated care: Disproportionate Share Hospital (DSH) payments and Upper Payment Limit (UPL) payments. The Medicare program is supported through Medicare DSH payments and its indirect medical education (IME) payments).

[26] Alan Rappeport, *Republicans May Use Cuts in Entitlement Programs to Reduce Deficit*, N.Y. TIMES (Nov. 15, 2017), https://www.nytimes.com/2017/11/15/us/politics/republicans-entitlement-programs-deficit.html?_r=0.

[27] *See* Longo*, infra* note 31.

[28] RECONCILIATION RECOMMENDATIONS, *supra*, note 4, at 1.

have hinted that they would like to see spending cuts and reform to public programs like Medicaid and Social Security.[29] As an entitlement program providing benefits primarily to low-income children, non-elderly adults, and Americans with disabilities, Medicaid is operated by the states but gets its funding from both state and federal governments.[30] For example, Senator Marco Rubio believes that in order to reduce the deficit and offset the cost of reform, one requirement is economic growth driving revenue but the other requirement is to bring spending under control.[31] For him, a large driver of debt is the structure of Medicare and he acknowledged that if these structural changes were to occur, future generations would be the ones to feel the changes.[32]

Debate over future budget policy normally surround entitlement programs like these because medical care costs are so high, promises to cost even more, and is largely paid for by the government.[33] Medicare and Medicaid together account for about $1.25 trillion in federal spending in 2016, which is about 30% of the federal budget, nearly one-half of which is publicly financed.[34] As the nation's largest single payer of long-term care services and supports, the federal government spent about $385 billion on Medicaid in 2017.[35]

IV. CONSEQUENCES OF SPENDING CUTS AND FEWER INSURED AMERICANS

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[29] *See* Rappeport, *supra* note 26.
[30] *See* Dept. of Health & Human Servs., *Medicaid & CHIP Coverage*, http://www.healthcare.gov/using-insurance/low-cost-care/medicaid/ (last visited Mar. 26, 2018).
[31] Tracy Longo, *Rubio: Offset Tax Cuts by Reducing Social Security, Medicare Benefits*, FA MAG (Nov. 29, 2017), https://www.fa-mag.com/news/rubio--offset-tax-cuts-by-reducing-social-security--medicare-benefits-35928.html.
[32] *Id.*
[33] EXEC. OFFICE OF THE PRESIDENT, COUNCIL OF ECON. ADVISERS, REFORMING THE HEALTH CARE SYSTEM 195, 198-99 (2017), https://obamawhitehouse.archives.gov/sites/default/files/docs/chapter_4-reforming_health_care_system_2017.pdf [hereinafter OFFICE OF PRESIDENT].
[34] *Id.*; *see also* Blumenthal, *supra* note 9.
[35] CONG. BUDGET OFFICE, AN UPDATE TO THE BUDGET AND ECONOMIC OUTLOOK: 2017-2027 tbl.2 (2017), https://www.cbo.gov/system/files/115th-congress-2017-2018/reports/52801-june2017outlook.pdf.

Generally, public programs receiving budget cuts and Americans losing or deciding against health insurance will mean fewer doctor visits, hospital visits, and drugs and medical devices sold.[36] David Blumenthal, the previous National Coordinator for Health IT for the Obama Administration, believes that the new tax bill will create a "de-stimulus."[37] More importantly, a de-stimulus like this will have a large effect on the American population's health[38], specifically the participants of these public programs. There have been many scientific studies conducted showing the link between having health insurance and health overall healthiness.[39] Comparing states that expanded health insurance coverage to those that did not, the states that had an influx of uninsured people gaining coverage resulted in significant health visits and a 23 percent point increase in the likelihood of being in excellent health.[40] Furthermore, adults with preexisting conditions saw improvements in both access and quality of care.[41] Thus, these spending cuts will mean a reduction in health of those American affected, particularly among the lower class and those suffering from chronic conditions.[42]

Even if the health of Americans is negatively impacted, what, if any, implications will occur from such a reduction in quality of health on their

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[36] *See* Blumenthal, *supra* note 9.
[37] *Id.*
[38] *Id.* ("The new Republican tax bill, which the House passed this afternoon and the Senate is expected to approve tonight, is complex, but what it will mean for health in the United States is simple: less. It will mean less health insurance for individuals; less coverage for elderly and poor Americans; less revenue for doctors, hospitals, and myriad health care businesses; and, quite possibly, a less-healthy, less-productive workforce.").
[39] Benjamin D. Sommers et al., *Three-Year Impacts of the Affordable Care Act: Improved Medical Care and Health Among Low-Income Adults*, 36 HEALTH AFFAIRS, 1119, 1124 (2017); Katherine Baicker et al., *The Oregon Experiment- Effects of Medicaid on Clinical* Outcomes, 368 N. ENGL. J. MED., 1713 (2013); Luojia Hu et al., *The Effect of the Patient Protection and Affordable Care Act Medicaid Expansions on Financial Wellbeing*, NAT'L BUREAU OF ECON. RESEARCH, Working Paper No. 22170, 2016.
[40] *See* Sommers et al., *supra* note 39, at 1124.
[41] *Id.*
[42] Benjamin D. Sommers et al., *Health Insurance Coverage and Health- What the Recent Evidence Tells Us*, 377 N. ENGL. J. MED. 586, 591 (2017).

financial well-being and overall economy? While prophesized by many of its supporters to revitalize the American economy[43], the tax bill will in fact create devastating, financial consequences specifically to those uninsured who are hit by unexpected illness or injury.[44] Those that find themselves with medical debt may be pursued by collection agencies, forced to file for bankruptcy, and have reduced access to credit.[45] Overall, for those hit by large, unexpected medical costs, these forms of financial strains will mean less savings, less financial independence, and less consumption of goods and services.[46]

Public debt, however, does not necessarily mean a reduction in economic growth.[47] This is particularly important to note because policymakers often assume a causal connection between high public debt and it hurting future growth.[48] That is not to say that high public debt has a positive effect on economic growth because there does exist a growing empirical literature showing the opposite, but those studies only show a non-linear correlation and correlation does not necessarily mean causation.[49] Thus, the worsening in quality of health's effect on the economy remains to be seen.[50]

Turning next to states' consequences due to budget cuts of public programs, specifically looking at Medicaid. Medicaid is funded jointly by the federal government and states.[51] In 2016, Medicaid accounted for 9.6 percent

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[43] United States House Committee on Ways and Means, https://waysandmeans.house.gov/taxreform/ (last visited Apr. 7, 2018).
[44] *See* Hu et al., *supra* note 39, at 3.
[45] *Id.*
[46] *Id.*
[47] Ugo Panizza & Andrea F. Presbitero, *Public debt and economic growth: Is there a causal effect?*, 41 J. OF MACROECON. 21, 36 (2014).
[48] Evan Bonsall, *The National Debt: A Social Justice Issue*, HARV. POL. REV. (Apr. 3, 2018), http://harvardpolitics.com/united-states/the-national-debt-a-social-justice-issue/.
[49] *See* Panizza & Presbitero, *supra* note 47; *but see* John H. Cochrane, *Understanding policy in the great recession: Some unpleasant fiscal arithmetic*, 55 EUR. ECON. REV. 2 (2011).
[50] Panizza & Presbitero, *supra* note 47, at 39.
[51] Laura Snyder & Robin Rudowitz, *Medicaid Financing: How Does it Work and What are the Implications?*, (May 20, 2015), https://www.kff.org/medicaid/issue-brief/medicaid-financing-how-does-it-work-and-what-are-the-implications/.

of the federal budget, the third-largest after Social Security and Medicare.[52] Medicaid currently operates under the basis of a state and federal partnership where the federal government matches the funds states expend on Medicaid spending.[53] With federal spending cuts to these programs to be anticipated and the financing structure of these programs susceptible to reform,[54] budgetary pressures may force states to respond to one urgent public policy epidemic while having to neglect another.[55] For example, in the case of an economic downturn, an epidemic (such as opioid addiction, HIV/AIDS), or a natural disaster (such as an flooding due to a Hurricane Katrina), medical costs will rise and because the federal funding that use to exist may no longer be available, states will struggle to fund the funds to cover these scenarios.[56]

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[52] Robin Rudowitz & Rachel Garfield, *10 Things to Know about Medicaid: Setting the Facts Straight* (Mar. 12, 2018), https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicaid-setting-the-facts-straight/.

[53] Synder & Rudowtiz, *supra* note 51.

[54] *See* Longo, *supra* note 31 (stating that federal spending cuts were imminent); In terms of Medicaid reform, Republicans support fundamentally changing the open-ended funding structure of the program. This entails restructuring the program as a "block grant" that would eliminate most federal rules regarding delivery and quality and would give states maximum flexibility to run their own program. The reasoning behind a block-grant program is that a cap on state and local tax deductions will increase pressure in high-tax states to curb spending and thereby result in grass-roots movements for single-payer systems. For Medicare, this could mean reforming the Medicare system or replacing government-run Medicare entirely. There are three basic models for reforming the Medicare system. First, the idea of retaining the basic design of Medicare as a social insurance system funded by a combination of payroll taxes, general revenues and premiums. Another option is dramatically replacing Medicare with a cash subsidy with which participants would purchase insurance in the private market. Finally, the plan of replacing traditional Medicare with a subsidy and changing the funding mechanism for a federal health care. *See* Howard Gleckman, *Healthcare and the Long-Term Fiscal Outlook*, 65 TAX L. REV. 835, 840 (2012); Merrill Goozner, *10 healthcare predictions for 2018*, 48 MODERN HEALTHCARE, Chicago 26 (2018); Paul N. Van de Water, *What You Need to Know About Premium Support*, CTR. ON BUDGET & POL'Y PRIORITIES (2012), http://www.cbpp.org/files/3-19-12health.pdf.

[55] *See* Snyder & Rudowitz, *supra* note 51; *see also* John Holahan et al., *National and State-by-State Impact of the 2012 House Republican Budget Plan for Medicaid*, KAISER FAMILY FOUNDATION'S COMMISSION ON MEDICAID AND THE UNINSURED (Oct. 2012), https://kaiserfamilyfoundation.files.wordpress.com/2013/01/8185-02.pdf (finding that the 2012 House Budget Committee's proposal to spending cuts on Medicaid to have significant effects on Medicaid, such as states reducing enrollment by 14.3 million and those that lose coverage to become uninsured).

[56] *See* Snyder & Rudowitz, *supra* note 51.

Moreover, state Medicaid programs will be less responsive to their states' demographic and economic shifts as well as coverage needs.[57] In conclusion, the rise in the federal deficit will likely lead to reform of public programs like Medicaid, forcing states to make public policy decisions and prioritize policies of health care, education, law enforcement, and prisons.[58]

Fewer people being uninsured and the strain on public programs such as Medicaid will affect American small businesses because the owners of these businesses have to provide health insurance to their workers and also for themselves.[59] Half of businesses with 3 to 9 workers offer health benefits while 73 percent of businesses with 10 to 24 workers provide health benefits.[60] Those that work for small businesses who don't offer health insurance have to either buy insurance in the individual market or decide to go uninsured.[61] The same choices apply to the owners of these small businesses.[62] In deciding their health insurance, these small business owners take into consideration factors in the individual insurance market such as guaranteed access to coverage, the requirement to be insured, and tax credits to make premiums more affordable. With the repeal of the individual mandate and incoming changes likely for how states operate their health care exchanges and public programs, these small business owners may decide to go the direst route of being uninsured.[63]

The Tax Cuts and jobs Act of 2017's repeal of the individual mandate and the increase in federal deficit will create ever-increasingly burdened public programs which, in turn, will cause the quality of health and financial well-

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[57] *See* Rudowitz & Garfield, *supra* note 52.
[58] *See* Snyder & Rudowitz, *supra* note 51.
[59] Larry Levitt, Anthony Damico, & Gary Claxton, *How Small Business Owners Get Health Insurance*, (Sept. 28, 2012), https://www.kff.org/health-reform/perspective/how-small-business-owners-get-health-insurance/.
[60] *Id.*
[61] *Id.*
[62] *Id.*
[63] *Id.*

being of individuals to worsen, states to minimize the coverage of their public programs, and American businesses left with less options in the health care exchange. Only time can tell if the tax bill's promises' of economic growth and job prosperity occur but evidence suggests that the healthcare system will face the brunt of the less understood consequences of an increased federal deficit and stressed public programs.

V. CONCLUSION

Congress will enact budget cuts to public programs like Medicaid and Medicare because of the looming rise in the federal deficit.[64] Moreover, the Tax Cuts and Jobs Act of 2017's repeal of the individual mandate will exert a substantial burden on these same public programs due to the inevitable rise of uncompensated care.[65] These public programs will be inadequately funded and as a result, the American health care system will be forced to undergo a strenuous transformation. As scientific literature shows that there is an increasingly strong link between health insurance and health status, those left uninsured will face the brunt of an in impending crisis along with the financial consequences of being uninsured.[66] With federal spending cuts to public programs likely, states will be forced to make tough public policy decisions. Finally, small businesses will also face a dire scenario with the choices left by health care system.

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[64] *See* Rappeport, *supra* note 26.
[65] *See generally* Coughlin et al., *supra* note 22.
[66] *See* Sommers et al., *supra* note 42.

Navigating the Insurance Approval Process for Medicare and Private Insurers

Chloe Cunningham

I. INTRODUCTION

The insurance market plays a critical role in managing risk.[1] Life's uncertainty makes people utilize insurance to protect themselves from financial collapse in times of adversity.[2] Generally, health insurance functions as a safety net to protect the lives of those it covers.[3] However, this safety net is not absolute. Coverage depends on the terms of the contract created between the policyholder and insurer, and ultimately the interpretation of the contractual language.[4] When an insurer denies a claim for coverage, whether by denying a prior authorization request or rejecting the claim entirely, a policyholder has the right to appeal the insurance plan's decision. The Patient Protection and Affordable Care Act ("ACA") established this right for policyholders to appeal health insurer coverage

[1] *See* Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519, 548 (2012) (discussing how the ACA sought to manage the risk pools for health insurance by increasing health insurance participation among healthier populations).
[2] *See* Bill Conerly, *Uncertainty and Risk Management: What to do about Black Swans?*, FORBES (Feb. 20, 2013), https://www.forbes.com/sites/billconerly/2013/02/20/uncertainty-and-risk-management-what-to-do-about-black-swans/#2e07df1e5768.
[3] Irwin Redlener & Roy Grant, *America's Safety Net and Health Care Reform – What lies Ahead?*, N. ENGL. J. MED. (Dec. 3, 2009), http://www.nejm.org/doi/full/10.1056/NEJMp0910597.
[4] Brendan S. Maher & Radha A. Pathak, *Enough About the Constitution: How States Can Regulate Health Insurance Under the ACA*, 31 YALE L. & POL'Y REV. 275, 284 (2013).

decisions,[5] but the process of appeal is still arduous and often results in poor health outcomes due to timely lapses in coverage.[6]

When an insurer denies an individual's health insurance claim, he or she is often left in a precarious situation – tasked with navigating the insurance appeals processes set forth by administrative agencies, while confronting taxing health dilemmas.[7] The process of review for the appeal varies greatly depending on whether a patient is covered by a private insurer or public insurer, and which administrative body governs the insurance appeals process.[8] For example, Medicare, a public insurance provider, is administrated by the Centers for Medicare & Medicaid Services ("CMS"). Medicare is federally regulated; accordingly, all Medicare policyholders nationwide adhere to a uniform five level appeals process, established by the Social Security Act of 1935.[9] The federal courts also have jurisdiction over disputes that involve employee benefit plan denials under ERISA, which only applies to private employers that offer employer-sponsored health insurance coverage.[10] On the other hand, private individual insurers and Medicaid are regulated at the state level, meaning state administrative agencies – sometimes in conjunction with private insurers – set the administrative standards for the health insurance appeals process.[11] This

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[5] *Right to Health Insurance Appeals Process*, NAT'L CONFERENCE OF STATE LEGISLATURES (Feb. 2011), http://www.ncsl.org/documents/health/hrhealthinsurapp.pdf.
[6] *See* Bridget Montgomery, *Access Denied and What You Can Do When Life Saving Treatments Are Denied*, THE DIABETES COUNSEL (Jan. 15, 2018), https://www.thediabetescouncil.com/access-denied-and-what-you-can-do-when-life-saving-treatments-are-denied/ (demonstrating the life-threatening choices patients are faced with when confronted with a significant lapse in critical treatment).
[7] *See* Linda Dahlstrom, *9 Things Insurers Don't Want You to Know*, NBC NEWS (July 15, 2007), http://www.nbcnews.com/id/20186938/ns/health-health_care/t/things-insurers-dont-want-you-know/#.Ws0ilGbMyYU.
[8] *Right to Health Insurance Appeals Process*, *supra* note 5.
[9] 42 U.S.C. §§1395ff (pertaining to Medicare Parts A and B).
[10] Albert Feuer, *When Do State Laws Determine ERISA Plan Benefit Rights?*, 47 J. MARSHALL L. REV. 145, 154 (2014) ("The broad preemption of ERISA insures that state law will neither diminish nor enhance its protections.").
[11] Maher & Pathak, *supra* note 4, at 283.

patchwork of administrative oversight leads to a variance of procedural processes, some of which are inefficient and inequitable.[12]

The administrative laws surrounding the health insurance appeals process play a critical role in patient health.[13] In health insurance, every day of denied coverage means a day of lost access to proper medical treatment.[14] When facing a serious health issue, such as diabetes or even rehabilitation for an eating disorder or stroke, a day of lost treatment can have devastating effects on one's health.[15] This is not a small problem. A 2017 study revealed that health insurers denied "nearly one-quarter [24%] of the claims for treatment of a chronic or persistent illness" and of these denied claims, 70% of the treatments were for "serious" conditions.[16] Perhaps even more troubling is that on average over 50% of these claims are successfully appealed, meaning individuals are unnecessarily faced with a complicated and burdensome appeals process while often amidst a significant health condition.[17] Thus, the administrative inefficiencies and inequities throughout different health insurance appeals processes not only place a financial burden on policy holders to cover costs out of pocket, but jeopardize their health by impeding their access to pertinent care.[18]

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[12] Juliette F. Espinosa, *Strengthening Appeals Rights for Privately Insured Patients: The Impact of the Patient Protection and Affordable Care Act*, PUBLIC HEALTH REP. (July-Aug. 2012).
[13] *Id.*
[14] Elizabeth S. Rowe, *Pre-Authorizations: The New Barrier to Health Care*, ROWE NEUROLOGY INST., http://www.neurokc.com/healthcare-advocacy/pre-authorizations-the-new-barrier-to-health-care/ (last visited Apr. 10, 2018).
[15] *Id.* (explaining the time required for pre-authorization requests for every individual test can lead to "life threatening injury").
[16] *Not What the Doctor Ordered, Barriers to Healthcare Access for Patients*, THE DOCTOR-PATIENT RIGHTS PROJECT (Aug. 2017), http://doctorpatientrightsproject.org/wp-content/uploads/2017/08/DPRP-Report_Not-What-the-Doctor-Ordered_August-2017.pdf.
[17] *Id.*
[18] *See* Jason J. DeJonker, *Medicare Appeals and Interpretation: Meeting the Reasonable Expectations of Medicare Users Through a Comparison to Private Health Insurance*, 8 ELDER L.J. 103, 130 (2000); *see also* Stacey L. Worthy et al., *Now or Never: The Urgent Need for Action Against Unfair Coverage Denials for Quality Health Care*, 48 LOY. U. CHI. L.J. 1041 (2017).

This Article explores the harmful inefficiencies of the current health insurance appeals process and advocates for a more uniform set of procedures that allows policyholders to appeal in a timelier manner. The first part of this Article examines the current state of health insurance appeals, first analyzing Medicare's five-step appeals process and then evaluating the administrative procedures of private insurance appeals. The Article concludes with proposed strategies for reforming both systems in order to create a more efficient process for patient appeals, ultimately increasing access to health care.

II. THE CURRENT LANDSCAPE OF HEALTH INSURANCE APPEALS ADMINISTRATION

Implemented in July 2010, § 2 of the ACA mandates internal and external review processes for coverage determinations and claims.[19] An internal review involves the insurance provider conducting a "full and fair review of its decision."[20] Conversely, an external review requires an independent third party to review the decision.[21] These regulations apply to group health markets, individual health markets and the insured and self-insured, but do

[19] Timothy Jost, *Implementing Health Reform: The Appeals Process*, HEALTH AFFAIRS (July 25, 2010), https://www.healthaffairs.org/do/10.1377/hblog20100725.006019/full/.
[20] *Appealing Health Care Decisions*, HHS.GOV, https://www.hhs.gov/healthcare/about-the-law/cancellations-and-appeals/appealing-health-plan-decisions/index.html (last updated Jan. 31, 2017); *see also Internal Claims and Appeals and External Review Process Overview*, CTRS FOR MEDICARE & MEDICAID SERVS. (Apr. 12, 2017), https://marketplace.cms.gov/technical-assistance-resources/internal-claims-and-appeals.pdf (explaining that the right to a full and fair review means a "[c]laimant has opportunity to see and respond to any evidence/rationale under consideration" and that there is "no conflict of interest for reviewers").
[21] *Id.*

not pertain to grandfathered plans.[22] Grandfathered plans are "individual health insurance [policies] purchased before March 23, 2010."[23]

A. Medicare Appeals Process

The appeal process for Medicare, is the most procedurally streamlined and patient friendly. The Social Security Act of 1935 established a five-level appeals process for Medicare: (1) redetermination by a Medicare Administrative Contractor ("MAC"), (2) reconsideration by a Qualified Independent Contractor ("QIC"), (3) hearing before an Administrative Law Judge ("ALJ"), (4) review by the Medicare Appeals Council, and (5) Judicial Review in the United States District Court.[24]

As the first administrative step of the Medicare appeals process, redetermination "is a review of the claim by [MAC] personnel not involved in the initial claim determination."[25] An individual has 120 days from the original MAC determination to file for reconsideration.[26] Once reconsideration is received, the next set of MAC personnel has 60 days to issue a decision for payment request or 30 days for a standard service request.[27] It is important to note that there is also an expedited appeals process for qualifying services such as a hospital service, skilled nursing

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[22] Jost, *supra* note 19.
[23] *Grandfathered Health Plan*, HEALTHCARE.GOV, https://www.healthcare.gov/glossary/grandfathered-health-plan/, (last visited Apr. 10, 2018).
[24] *HHS Primer: The Medicare Appeals Process*, HHS.GOV 1, https://www.hhs.gov/sites/default/files/omha/files/medicare-appeals-backlog.pdf (last visited Apr. 10, 2018); *see also* Jeffrey S. Wolfe, *Civil Justice Reform in Social Security Adjudications*, 64 ADMIN. L. REV. 379 (2012) (providing an explanation of the administrative judge system).
[25] *First Level of Appeal: Redetermination by a Medicare Contractor*, CMS.GOV, https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/RedeterminationbyaMedicareContractor.html (last updated Feb. 1, 2018).
[26] *Medicare health plan appeals – Level 1: Reconsideration*, MEDICARE.GOV, https://www.medicare.gov/claims-and-appeals/file-an-appeal/medicare-health-plan/health-plan-appeals-level-1.html (last visited Apr. 10, 2018).
[27] *Id.*

facility, home health, hospice or comprehensive outpatient rehabilitation facility.[28] Under the expedited process, an individual must request expedited review by noon the day after receiving notice of a denied claim, but the individual receives a decision from MAC within 72 hours.[29]

The second level of Medicare appeals allows an individual to request a reconsideration of the redetermination. In reconsideration, a QIC conducts an independent review of the administrative record, including the initial determination and redetermination.[30] Once an individual files for redetermination, the QIC has 60 days to issue a reconsideration decision.[31] In the case of expedited review, the QIC has 72 hours.[32] Level 3 of the appeals process allows any individual "dissatisfied with the reconsideration decision to request a hearing before an ALJ."[33] The Office of Medicare Hearing and Appeals ("OMHA") is responsible for the administration of Level 3 appeals.[34] This level of the appeals process is very patient friendly.[35]

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[28] *New Medicare Expedited Appeals Rights: What Do Beneficiaries Gain?*, CTR. FOR MEDICARE ADVOCACY, INC. (2004), http://www.medicareadvocacy.org/oldsite/News/WeeklyAlerts/AlertPDFs/2004/CMA_Weekly_Alert_12.09.04_Expedited_Appeals.pdf.

[29] *Medicare Appeals*, MEDICARE.GOV 1, 36, https://www.medicare.gov/Pubs/pdf/11525.pdf (last visited Apr. 10, 2018).

[30] *Second Level of Appeal: Reconsideration by a Qualified Independent Contractor*, CMS.GOV, https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/ReconsiderationbyaQualifiedIndependentContractor.html (last modified Feb. 1, 2018); *see Appeals Level 2: Qualified Independent Contractor (QIC) Reconsideration*, CMS.GOV, https://www.medicare.gov/claims-and-appeals/file-an-appeal/original-medicare/original-medicare-appeals-level-2.html (last visited Apr. 10, 2018) (defining QIC as "an independent contract that didn't take part in the level 1 decision").

[31] *Medicare Appeals*, *supra* note 29, at 36.

[32] *Id.*

[33] *Third Level of Appeal: Decision by Office of Medicare Hearings and Appeals (OMHA)*, CMS.GOV, https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/OMHA-ALJ-Hearing.html (last modified Feb. 7, 2018) [hereinafter *Third Level of Appeal*].

[34] *Id.*

[35] *See, e.g.*, *Administrative Law Judge Hearings for Medicare Advantage Plans and Prescription Drug Plans*, MEDICARE RIGHTS CTR. (2018), http://www.medicarerights.org/fliers/Rights-and-Appeals/ALJ-Packet.pdf?nrd=1 [hereinafter *ALJ Hearings for Medicare*] (demonstrating the ALJ proceedings instructions given to policyholders).

Unlike a typical hearing, there are no steadfast rules of evidence or procedure.[36] This allows patients to navigate the process without needing to seek legal counsel.[37] Additionally, these hearings are most commonly held over the telephone with a more conversational tone as opposed to a formal proceeding.[38] However, at this level, there is no longer an expedited process and there is a minimum amount in controversy requirement of $160.[39]

Level 4 allows "[a]ny party that is dissatisfied with OMHA's decision or dismissal [to] request a review by the Medicare Appeals Council."[40] This level is essentially the appellate administration court within Medicare and has a 90-day time limit.[41] Lastly, Level 5 allows individuals to request review in Federal Court.[42] As of 2018, the amount in controversy requirement for level five is $160,000.[43]

These five levels of appeal aim to provide policyholders with a timely and efficient procedure for appeals, but in practice, there is a massive administrative delay within the system.[44] At the third level, OMHA faces a

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[36] *Issue Brief: CMS Issues New Rules Governing Medicare Appeals*, CTR. FOR MEDICARE ADVO. (Feb. 8, 2017), http://www.medicareadvocacy.org/issue-brief-cms-issues-new-rules-governing-medicare-appeals/ (reflecting that CMS sets the administrative rules governing the appeals process, rather than having a formalized evidence rules set by legislation).
[37] *ALJ Hearings for Medicare*, *supra* note 35 ("If you think you need help preparing for the hearing or represent yourself, you can appoint a representative to represent you during the hearing. The representative can be a friend, family member, doctor or lawyer.").
[38] *Id.*
[39] *Third Level of Appeal*, *supra* note 33.
[40] *Fourth Level of Appeal: Review by the Medicare Appeals Council*, CMS.GOV, https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/05AppealsCouncil.html (last modified Feb. 1, 2018).
[41] *Id.*
[42] *Fifth Level of Appeal: Judicial Review in Federal District Court*, CMS.GOV, https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/Review-Federal-District-Court.html (last modified Feb. 1, 2018).
[43] The amount in controversy requirement for level five is determined annually. *Id.*
[44] Amy H. Kearbey & Nicholas F. Alarif, *Medicare Appeals Backlog: A Setback and New Opportunities for Providers*, MCDERMOTT WILL & EMERY (Sept. 26, 2017), https://www.mwe.com/en/thought-leadership/publications/2017/09/medicare-appeals-backlog.

rapidly increasing backlog of cases.[45] In June 2017, the OMHA had 607,402 cases waiting for disposition with an estimated wait time of three years to be heard by an ALJ.[46] This number is predicted to grow to 950,520 pending cases by the end of 2021.[47]

Yet, despite this concerning backlog, the Medicare system has one critical defining procedural policy that private insurers lack – Medicare very rarely requires prior authorization.[48] Prior authorization requires a health care provider to obtain authorization from an insurer before performing a service.[49] Medicare only requires prior authorization "for limited items of Durable Medical Equipment and physicians' services."[50] Medicare's absence of a prior authorization requirement hugely impact patients' access to treatment because it allows patients to receive timely treatment with no authorization barriers. However, while this policy may benefit patients, it can create large economic burdens for treating hospitals and physicians, because if Medicare rejects the claim, they are often left to pay out of pocket.[51]

B. Individual Private Insurers Process

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[45] Scot T. Hasselman, *Can CMS Curtail The Medicare Appeals Backlog?*, LAW 360 (Aug. 11, 2016), https://www.law360.com/articles/827040.
[46] Kearbey & Alarif, *supra* note 44.
[47] *Id.*
[48] *Medicare Prior Authorization*, CTR. FOR MEDICARE ADVO., http://www.medicareadvocacy.org/prior-authorization/ (last visited Apr. 10, 2017).
[49] *Id.*
[50] *Id.* ("Traditional Medicare, historically, has rarely required prior authorization. Originally, the Social Security Act did not authorize any form of "prior authorization" for Medicare services, but the law has subsequently been changed to allow prior authorization for limited items of Durable Medical Equipment and physicians' services. Despite this change, there are still very few services requiring Prior Authorization in traditional Medicare.").
[51] Ilene MacDonald, *Increased Claim Denials Cost Hospitals as much as $3.5M, New Report Shows*, FIERCE HEALTHCARE (Nov. 15, 2017, 8:43 AM), https://www.fiercehealthcare.com/finance/increased-claim-denials-cost-hospitals-as-much-as-3-5m-new-report-shows ("[A] median 350-bed hospital would have lost $3.5 million to increased denial write-offs from healthcare payers over the past four years.").

Unlike Medicare which is federally administered, state regulation governs individual private insurers.[52] Accordingly, the appeals process for each private insurer may vary from state to state.[53] Unlike the government-consumer relationship, which is one of statutory regulation, the private insurer-consumer relationship is one of contractual duty.[54] When a consumer enrolls in a private insurance, he or she contractually consents to the terms of the insurance set by the private carrier.[55] Part of this agreement is the appeals process terms.[56] Accordingly, consumers "must rely on a contract that defines the medical services covered and reimbursed and services not covered."[57] Each carrier has a different appeals process, which can often be ambiguous and difficult for a consumer to navigate.[58] A consumer's appeal

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[52] *See generally* Daniel Schwarcz, *Transparency Opaque: Understanding the Lack of Transparency in Insurance Consumer Protection*, 61 UCLA L. REV. 394 (2014) (critiquing state regulation of insurance for lack of transparency and consumer protection).
[53] *Health Insurance Regulations State-by-State*, HEALTH INSURANCE, http://www.healthinsuranceindepth.com/individual-state-guides.html (last visited Apr. 10, 2018) (providing information on each state's insurance laws).
[54] *A Patient's Guide to Navigating the Insurance Appeals Process*, PATIENT ADVOCATE FOUND., www.patientadvocate.org/requests/publications/Guide-Appeals-Process.pdf (last visited Apr. 10, 2018).
[55] *See, e.g.*, *Health Care Insurer Appeals Process Information Packet*, UNITED HEALTHCARE https://www.uhc.com/content/dam/uhcdotcom/en/Legal/PDF/AZ_appeals.pdf (last visited Apr. 10, 2018) (providing United HealthCare's appeals process form); *Request for Health Care Professional Payment Review*, CIGNA, https://www.cigna.com/assets/docs/health-care-professionals/MM_002_appeal_request_for_provider_payment_review.pdf?WT.z_nav=healthcare-professionals%2Fresources-for-health-care-professionals%2Fclinical-payment-and-reimbursement-policies%2Fclaim-policies-procedures-and-guidelines%2Fclaim-adjustment%3Baccordion%3BHow%20to%20initiate%20an%20appeal%3BRequest%20for%20Health%20Care%20Professional%20Payment%20Review%20form (last visited Apr. 10, 2018) (providing United HealthCare's appeals process form).
[56] *A Patient's Guide to Navigating the Insurance Appeals Process, supra* note 54, at 2.
[57] *Right to Health Insurance Appeals Process*, *supra* note 5.
[58] *See* Janet W. Battaile, *Insurance Nightmare: We Need a Better* System, NBC NEWS (Feb. 25, 2010, 1:14 PM), http://www.nbcnews.com/id/35584865/ns/politics-politics_daily/t/insurance-nightmare-we-need-better-system/#.WsZZj9MbPBI (examining a policy holder's difficult experience communicating with Blue Cross Blue Shield during an insurance appeal); *see also Claim Adjustment and Appeal Guidelines*, CIGNA, https://www.cigna.com/healthcare-professionals/resources-for-health-care-professionals/clinical-payment-and-reimbursement-policies/claim-policies-procedures-and-guidelines/claim-adjustment (last visited Apr. 10, 2018) (displaying Cigna's guidelines for submitting an appeal claim as an example).

path often depends on the type of appeal, applicable state regulations, and the carrier's individual appeals process. Because the ACA mandates individual insurance markets to comply with either states' external review processes or the federal external review process for appeals, private insurers must behave somewhat uniformly in establishing their appeals processes.[59]

On average, private insurance contains three levels of appeals.[60] Under the first level of appeal, a policyholder or his or her physician may contact the insurance company and request reconsideration. At this stage, the physician "may also request to speak with the medical reviewer of the insurance plan as part of a 'peer to peer review' in order to challenge the decision which could resolve the issue."[61] Unlike the Medicare process, this initial step allows physicians to speak to the reviewing parties directly and promptly.[62] Additionally, physicians are often permitted to contact medical reviewers directly via phone.[63] This streamlines the communication between the parties, making the process more efficient.

At the second level, the appeal is typically filed formally and then reviewed by a medical director, appointed by the insurer, who was not

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[59] Michelle Andrews, *Your 2018 Health Plan Must Comply With ACA Rules Or You Risk Tax Penalties*, NAT'L PUBLIC RADIO (Feb. 27, 2018, 5:00 AM), https://www.npr.org/sections/health-shots/2018/02/27/588950615/your-2018-health-plan-must-comply-with-aca-rules-or-you-risk-tax-penalties; *see Right to Health Insurance Appeals Process*, *supra* note 5 ("Group health plans and health insurance issuers must comply with the applicable state external review process that, at a minimum, 'includes the consumer protections set forth in the Uniform External Review Model Act promulgated by the National Association of Insurance Commissioners (NAIC).").

[60] *A Patient's Guide to Navigating the Insurance Appeals Process, supra* note 54, at 13.

[61] *Id.*

[62] *See, e.g.*, *Florida Medicaid Provider Handbook*, HUMANA, http://apps.humana.com/marketing/documents.asp?file=3058978 (last visited Apr. 10, 2018) ("We encourage the member or member's representative to explore the informal complaint process first in attempt to work out the issue directly with the care manager and/or the supervisor. If the concern or complaint was not resolved satisfactorily with the care manager, a grievance or appeal may be filed with Humana Ling-Term Care Plan.").

[63] *Id.*

involved in the initial determination.[64] Again, one advantage of this step is the direct line of communication between the physician and medical director. The last level is an independent review process mandated by the ACA.[65] A physician conducts these reviews in the same specialty as the patient's physician, and in cooperation with a third-party independent reviewer.[66]

While these general steps provide the advantage of direct communication, private insurers often place a lofty administrative barrier in front of patients seeking access to health care – prior authorization. A study conducted by the American Medical Association ("AMA") reflected that over 50 percent of physicians waited one to five days after submitting a request for authorization before hearing back from insurers.[67] 90 percent of the physicians reported that this process delayed patients' necessary care.[68]v This means that when a patient goes to a hospital or rehabilitation facility, they must wait hours, often days, before they can receive treatment. By contrast, Medicare patients may be admitted into a hospital or healthcare facility *without* acquiring prior authorization, meaning treatment begins immediately.[69] This is critical for patients confronting threatening health problems such as stroke recovery, eating disorders, and mental illness, where every minute is vital to recovery. Not only does the prior authorization requirement impede patient access

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[64] *A Patient's Guide to Navigating the Insurance Appeals Process*, *supra* note 54, at 13.
[65] Jost, *supra* note 19.
[66] *A Patient's Guide to Navigating the Insurance Appeals Process*, *supra* note 54, at 13.
[67] Kevin B. O'Reilly, *Survey Quantifies Time Burdens of Prior Authorization*, AMA WIRE (Jan. 30, 2017), https://wire.ama-assn.org/practice-management/survey-quantifies-time-burdens-prior-authorization.
[68] *Id.*
[69] *See Physician Frustration With Prior Authorizations Hits New High*, AM. ACAD. OF FAM. PHYSICIANS (June 9, 2017, 3:20 PM), https://www.aafp.org/news/practice-professional-issues/20170609priorauth.html ("Health plan demands for prior approval for physician-ordered medical tests, clinical procedures, medications and medical devices ceaselessly question the judgment of physicians, resulting in less time to treat patients and needlessly driving up administrative costs for medical groups.").

directly, but it places a substantial administrative burden on health care professionals who must complete the forms.[70]

III. A NEW APPEALS PROCESS

The current administrative system governing health insurance appeals places dangerous barriers to access to health care.[71] Medicare is facing a rising backlog of appeals with no relief in sight, while private insurers battle scrutiny for the ethicalness of their procedures.[72]

Medicare's process provides patients with clear steps to appeal, but not all of these steps are necessary, causing a delayed and untimely appeals process.[73] The first level of appeal for Medicare requires a review by the same party that made the initial determination.[74] As one might infer, appeals at this level are typically unsuccessful. In 2012, only 24 percent of Medicare Part A appeals were successful at the first level, compared to 50 percent in 2008.[75] This could be partly due to the fact that the same party making the initial determination is conducting the review for the first level appeal. Given that the majority of appeals are still reaching level three, leading to serious backlogs, it would be more efficient to either cut unnecessary additional steps or make proceeding steps more efficient. Thus, eliminating the first level,

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[70] *Id.*
[71] *See generally* Worthy et al., *supra* note 18; *see also VA and GAO Agree: Appeals Reform Needed*, U.S. DEPT. OF VETERAN AFFAIRS (Mar. 23, 2017, 1:18 PM), https://www.va.gov/opa/pressrel/pressrelease.cfm?id=2874 (addressing the three year average delay for Veteran appeals and stating that the "[t]here is board consensus that the current VA appeals system is broken and in urgent need of reform").
[72] Kearbey & Alarif, *supra* note 44; *see* Shelby Livingston, *Two States Question Aetna's Prior-Authorization Practices Amid CVS Merger*, MODERN HEALTHCARE (Feb 13, 2018) http://www.modernhealthcare.com/article/20180213/NEWS/180219975 (discussing the allegation that Aetna's reviewing medical directors were reviewing appeals claims without consulting the patient's medical records).
[73] DeJonker, *supra* note 18.
[74] *First Level of Appeal: Redetermination by a Medicare Contractor*, *supra* note 25.
[75] James Swann, *Medicare Appeal Success Rates Trending Down*, BLOOMBERG HEALTH CARE BLOG (Oct. 4, 2013), https://www.bna.com/medicare-appeal-success-b17179877599/.

which is repetitive of the initial determination, would improve efficiency in the appeals system.

Another area of reform within Medicare's appeal process is improving the communication barriers between physicians and reviewers. As Medicare's appeal system stands, there is no consistent point of contact throughout the appeals process for physicians to address concerns or questions to.[76] For fast tracked review, Medicare privately contracts with health advisory groups to serve as Medicare Quality Improvement Organizations (QIO).[77] These contractors vary between states, but serve to provide patients with assistance in the appeals process.[78] However, these private contracts offer limited to communication between the reviewing parties and the physician, often providing only one direct point of contact for multiple states.[79] This communication barrier between physicians and reviewers reduces transparency and complicates the appeals process.[80] Adopting a case manager approach, similar to models most private insurers have adopted, would alleviate this problem. A case manager approach is more personalized and allows for quicker more direct communication, which in turn allows for

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[76] *See, e.g.*, *Medicare Appeals*, *supra* note 29 (showing the Medicare appeals contact number is the same general line for various types of concerns and appeals, there is not direct point of contact assigned).

[77] *See Health Services Advisory Group Assumes Work Under Medicare Contract*, CMS.GOV (Dec. 15, 2008), https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2008-Press-releases-items/2008-12-15.html.

[78] *Quality Improvement Organizations*, CMS.GOV, https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs/index.html (last updated Apr. 19, 2018).

[79] *See Quality Improvement Organization (QIO) Program Changes*, HEALTH SERVS. ADVISORY GROUP, https://www.hsag.com/es/patients-families/quality-improvement-organization-qio-program-changes/ (last visited Apr. 25, 2018) (displaying the helpline phone numbers).

[80] *See Grassley Expresses Renewed Concern Over Medicare Quality Improvement Organizations*, U.S. SENATE COMMITTEE ON FIN. (Mar. 7, 2006), https://www.finance.senate.gov/chairmans-news/grassley-expresses-renewed-concern-over-medicare-quality-improvement-organizations (quoting Grassley, "The services of QIOs are intended for the protection of Medicare beneficiaries and the improvement of the quality of care. Unfortunately, there is a lack of information on the value of these services and whether or not QIOs are in fact meeting their mission.").

better care. Under this approach, every patient appealing would be assigned a case manager that would serve as a point of contact throughout the entire appeals process. Physicians could also contact the case managers directly, resulting in streamlined communication and faster solutions.

For private insurers, eliminating the prior authorization requirement would be ideal for improving health outcomes. The American Medical Association recently urged attorney generals throughout the United States to work with insurers in suspending prior authorization requirements for medication-assisted treatment for opioid addictions.[81] New York's Attorney General reached settlements with Anthem and Cigna, to eliminate prior authorizations for patients seeking opioid treatment.[82] The serious health consequences associated with prior authorization requirements are clear, but it is unlikely that insurers will eliminate the policies in the near future.

While it is unlikely that prior authorizations will be eliminated anytime soon, health care groups are working to minimize the care disruption created by these requirements. Health care industry leaders released a collaborative plan to improve the prior authorization process in 2018.[83] First, they aim to reduce prior authorization requirements by limiting the number of health care professionals that are subject to the requirements based on performance, value-based care agreements, or "adherence to evidence-based medical practices."[84] The group also proposes to "[r]egularly review the services and medications that require prior authorization and eliminate requirements for

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[81] Jacqueline Belliveau, *AMA: Eliminate Prior Authorization for Opioid Abuse Treatment*, REVCYCLE INTELLIGENCE (Feb. 8, 2017), https://revcycleintelligence.com/news/ama-eliminate-prior-authorization-for-opioid-abuse-treatment.
[82] *Id.*
[83] Joint Press Release, *Health Care Leaders Collaborate to Streamline Prior Authorization and Improve Timely Access to Treatment* (Jan. 17, 2018), https://www.ahip.org/wp-content/uploads/2018/01/Joint-News-Release-Prior-Authorization-Consensus-Statement.pdf.
[84] *Id.*

therapies that no longer warrant them."[85] Additionally, the group aims to improve communications between insurers, physicians, and patients in order to minimize delays in care and promote transparency.[86] Thus, while eliminating prior authorization may not be a plausible solution for now, working to expand the exceptions for prior authorization is a step that can be taken to increase the efficiency and quality of health care delivery.

Another area for reform within private health insurance, is improving the communication within the case management system. While most private insurers already offer physicians and patients a direct line of communication to their case managers,[87] the communications are most often limited by hours of operation and set to Eastern Standard Time.[88] Limiting the hours of operation to business hours creates a huge barrier for patients and providers working to appeal approval or coverage determinations, especially in the context of prior authorization. Health care, especially in a hospital setting, is not limited to business hours so it is inconsistent for health insurance providers to only offer appeal and approval assistance in a limited time frame. Some providers do offer emergency lines for fast tracked appeals, however these lines are very limited. There is also the compounded problem of the majority of insurers basing their hours of operation on Eastern Standard Time. This severely limits communication for patients and providers operating in western time zones. Just as health care providers work at all hours of the day, health insurance approval and appeals centers should to. The private insurers and Medicare could both be significantly improved by establishing 24/7 lines of communication between insurance providers, physicians and patients.

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[85] *Id.*
[86] *Id.*
[87] *See, e.g.*, *Florida Medicaid Provider Handbook*, *supra* note 62.
[88] *Id.* ("Office hours for the grievance and appeals review department are from 8a.m – 8p.m. Eastern time, Monday – Friday.").

IV. CONCLUSION

The current administrative inefficacies plaguing the insurance system's appeals processes are placing unduly burdens on patients and health providers, diminishing patient care and access. While Medicare aims to offer a patient friendly, uniform appeals process, there are still many issues with the system's efficiency and transparency. The Medicare appeals system could be improved by eliminating the first step of its appeals process, which is monotonous of the initial determination. Additionally, Medicare's complicated five step appeals process could be made more efficient and easier to navigate if care managers were assigned to individual cases, allowing for more personalized responses. One of Medicare's greatest administrative strengths is having no prior authorization requirements that delay the delivery of health care. Modeling this approach, private insurers could strive for more timely treatment by eliminating prior authorization requirements. As a whole, transparency and communication need to be improved in order to minimize critical delays in treatment. Both administrative systems expanding their operations of contact to any time, any day would significantly improve communication and efficacy. The current insurance appeals system is riddled with costly inefficiencies; reform in this administrative system is critical to improving patients' access to critical care.

Healthcare While Incarcerated: An Argument Against Co-pays

Abigail Elmer

I. INTRODUCTION

Those incarcerated by the state have had their liberty taken away from them; their physical mobility is completely limited and controlled.[1] Many do not make money, and when they are able to have jobs in prison, they are paid only between fourteen and sixty-two cents an hour.[2] The only other source of funds that a prisoner can access is a commissary account funded by the prisoners' friends and families outside the prison.[3] Considering the impoverished background of most prisoners, many of their friends and family are not able to provide large sums of money, if any at all.[4] And yet, when prisoners need medical attention, they are expected to pay a co-pay for the services.[5] Prisoners can be charged co-pays amounting anywhere from $1 to around $100 for medical care.[6] While this may not seem like a lot in the general public healthcare system, it is a huge burden on prisoners who have very little money that they can access.[7] These co-pays are contrary to our

[1] Lauren-Brooke Eisen, *Charging Inmates Perpetuates Mass Incarceration*, BRENNAN CTR. FOR JUSTICE 4 (July 31, 2014).
[2] Wendy Sawyer, *The Steep Cost of Medical Co-pays in Prison Puts Health at Risk*, PRISON POLICY INITIATIVE (Apr. 19, 2017), www.prisonpolicy.org/blog/2017/04/19/copays/ [hereinafter *The Steep Cost of Medical Co-pays*].
[3] Ryan Cooper, *American Prisons' Cruel and Unusual Health Care*, THE WEEK (Apr. 19, 2017), http://theweek.com/articles/692864/american-prisons-cruel-unusual-health-care.
[4] *Id*.
[5] Michelle Andrews, *Even in Prison, Health Care Often Comes with a Copay*, NAT'L PUB. RADIO (Sept. 30, 2015), https://www.npr.org/sections/health-shots/2015/09/30/444451967/even-in-prison-health-care-often-comes-with-a-copay.
[6] *Id*.
[7] *Id*.

basic principles as a free market society. When someone from the general public needs medical care, they have the option of finding the cheapest choice. If they do not want to pay a certain co-pay, they can find a different healthcare plan or provider that charges a reduced fee. This is not the case for prisoners.[8] Their only option is the healthcare provided by the government; they cannot shop around like the general public.[9] While paying their debts to society, prisoners' lives are controlled by the state, because "the community as a whole has chosen to remove these individuals from society … society should be prepared to pay the costs of feeding, housing, and providing medical attention for inmates. As a collective decision, society should bear the collective cost."[10] These prisoners have little to no income and mostly rely on their families for funds.[11] This reality is further reason that it is the states' responsibility to pay inmate medical fees.[12]

In *Estelle v. Gamble*, the Supreme Court ruled that failure to provide adequate healthcare to prisoners constituted cruel and unusual punishment, thus violating the Eighth Amendment.[13] Various state appellate courts and federal circuit courts that have taken up the issue of co-pays have found that they do not violate the constitution or the standard set by *Estelle.*[14] The

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[8] *See* Eisen, *supra* note 1 (arguing that "inmates are 'involuntary consumers' and 'correctional
clients are not permitted to forego the services, consume less of them, or obtain them elsewhere,'" so they should not be required to pay fees for their services).
[9] *Id*.
[10] *Id*.
[11] Eisen, *supra* note 1.
[12] *See id.* ("Another compelling reason not to charge inmates is the burden on families. Experts estimate that at least 80 percent of individuals in jail are indigent. And, in most cases, the inmates' families pay these fees, a reality that makes it difficult for families already suffering from the loss of income from an incarcerated family member.")
[13] Estelle v. Gamble, 429 U.S. 97, 97 (1976); U.S. Const. amend. VIII ("Excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted.").
[14] Estelle, 429 U.S. at 97; McCall v. Johnson County Sheriff's Dep't., 71 Fed. Appx. 30 (2003) (holding that a detention center's policy of charging a co-pay for medical services and a monthly charge for medication did not inflict cruel and unusual punishment); Mourning v. Correctional Medical Services (CMS) of St. Louis, Mo, 300 N.J. Super. 213 (Super. Ct. App. Div. 1997) (finding that a state statute allowing co-pays did not violate the

Supreme Court should address this issue and reverse the decision of circuit courts; they should find that charging co-pays for healthcare of incarcerated people goes against the holding in *Estelle* and violates the Eighth Amendment.

This article will first address how the healthcare system is set up in American prisons, from the importance of prisoner healthcare to the effect of co-pays and the problems they cause. It will next cover the relevant Supreme Court and lower court holdings on prison healthcare. Finally, this article will discuss proposed solutions to the problem of co-pays in the prison healthcare system. These proposed solutions include policy change, meaning that state and federal legislatures would make the practice illegal, and litigation, having the Supreme Court take up the issue and find that co-pays are unconstitutional under the Eight Amendment and the decision in *Estelle v. Gamble.*

II. HEALTHCARE IN THE AMERICAN PRISON SYSTEM

A. Importance of Prisoner Healthcare

While incarcerated, prisoners do not concede all of their constitutional rights.[15] The Supreme Court has failed to extend some constitutional rights to prisoners, but in *Estelle v. Gamble*, discussed further below, the Supreme Court found that inadequate healthcare in prisons violated the Eighth Amendment and constituted cruel and unusual punishment.[16]

Eighth Amendment); Poole v. Isaacs, 703 F.3d 1024 (2012) (finding that a modest fee for medical services provided to inmates with adequate resources to pay fee does not violate United States Constitution).

[15] Legal Information Institute, *Prisoner's Rights*, CORNELL LAW SCH., https://www.law.cornell.edu/wex/prisoners_rights (last visited Mar. 19, 2018).

[16] Estelle, 429 U.S. at 97.

Not only do prisoners have a constitutional right to adequate healthcare, but it is necessary for their rehabilitation and re-entry to society process.[17] The provision of healthcare not only benefits the prisoner but society as a whole.[18] Treatment and discharge plans for those with substance abuse disorders, mental illnesses, and infectious diseases are important for anti-recidivism efforts and for the health of the communities the prisoners enter back into.[19] Ninety-five percent of incarcerated individuals re-enter society, and health problems follow the individuals after they leave prison.[20] Without adequate healthcare in prisons, these lingering health problems will risk the health of their communities and could prevent individuals from staying out of prison in the future.[21]

One aspect where healthcare while in prison affects the prisoner's life after release is with drug overdoses.[22] During the period post-release, ex-prisoners are 129 times more likely to die from drug overdoses than the general population.[23] Medical care in prisons, along with overdose education and other drug abuse programs prior to release, could dramatically reduce this risk of overdose.[24] Unfortunately, this medical care is likely only available through a co-pay, meaning that many will be deterred from seeking this sort of treatment.[25]

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[17] April Dembosky, *Health Care Can be Key to a Better Life for Former Inmates*, NAT'L PUB. RADIO (Jun. 12, 2014), https://www.npr.org/sections/health-shots/2014/06/12/317443878/health-care-can-be-key-to-a-better-life-for-former-inmates.
[18] *Prison Health Care Costs and Quality*, THE PEW CHARITABLE TRUSTS (Oct. 18, 2017), http://www.pewtrusts.org/en/research-and-analysis/reports/2017/10/prison-health-care-costs-and-quality.
[19] *Id*.
[20] Alexandria Macmadu & Josiah D. Rich, *Correctional Health is Community Health*, 32 ISSUES IN SCI. & TECH. (2015).
[21] *Id*.
[22] *Id*.
[23] *Id*.
[24] *Id*.
[25] Andrews, *supra* note 5.

B. The Effect of Co-Pays

Requiring inmates to pay a co-pay for health services is contrary to the states' interests in successfully rehabilitating prisoners and having them successfully re-enter society. Like those in the general population, co-pays and high healthcare costs discourage inmates from getting the healthcare that they need.[26] This failure to receive necessary treatment will not only hinder their health at the time but will also make them less able to thrive when back in the general population, along with risking the spread of health problems to the communities involved.[27]

At least 36 states and the federal prison system have implemented prison co-pay systems through legislation or administrative directive.[28] These fees are not court-ordered, they are not fines, and they are not a part of the inmate's sentence or punishment.[29] Instead, these co-pays are user fees for the facilities and services that come with being incarcerated.[30] Since the criminal justice system and prisons play an important role in our society and are necessary, prisoners should not be charged the costs of services they are constitutionally entitled to.[31] These co-pays do not contribute to sentencing

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[26] *Id.*
[27] Cooper, *supra* note 3.
[28] Michael B. Mushlin, *§4:40 Prison Copayment Plans for Medical Care*, 1 RIGHTS OF PRISONERS §4:40 (5th ed. 2017) (listing the following states in footnote 1 that have co-pay systems: Arizona, Alaska, California, Georgia, Illinois, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Nevada, New Hampshire, New Jersey, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Washington, West Virginia, and Wisconsin. The listed states show that this issue is a national problem and not confined to one region of the country or historically red or blue states).
[29] Dembosky, *supra* note 17; Andrews, *supra* note 5.
[30] Andrews, *supra* note 5.
[31] Eisen, *supra* note 1; *see* Estelle, 429 U.S. (holding that prisoners have constitutional right to adequate healthcare).

and are not a part of a prisoner paying their debt to society; instead, they are only used to raise revenues for the prison system.[32]

Prisoners make very little money, if they make any at all.[33] In West Virginia, prisoners are paid only 4 cents an hour.[34] At that rate, a $5 co-pay would cost almost a month's worth of wages.[35] The equivalent co-pay by a minimum wage earner in the same state would be $1,093.[36] The wages for prison labor are decreasing as well, meaning that affording healthcare will only more difficult.[37] In other states, such as Alabama, Arkansas, Florida, Georgia, Mississippi, South Carolina, and Texas, prisoners are paid nothing for their labor.[38] Prisoners are often left to depend on their family and friends outside of prison to help them pay the co-pays.[39] This is a problem because many prisoners are indigent and their community outside of prison is as well, meaning that these co-pays put financial strain on communities that cannot afford them.[40]

These co-payments keep inmates from getting the medical help that they need, such as mental health services, substance abuse help, and medication for infectious diseases.[41] Along with these barriers to re-entering society, the co-pays also add to the debt that prisoners face when they return to society.[42] Co-pays are not the only living charges put on inmates; they also are charged

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[32] Eisen, *supra* note 1.
[33] *See The Steep Cost of Medical Co-pays*, *supra* note 2 (stating that in most states, prisoners are paid between 14 and 62 cents per hour for their labor).
[34] Nick Wing, *Prisons and Jails are Forcing Inmates to Pay a Small Fortune Just to See a Doctor*, HUFFINGTON POST (Apr. 19, 2017), https://www.huffingtonpost.com/entry/prison-jail-medical-copays_us_58f64bdbe4b0b9e9848ee23e.
[35] *Id*.
[36] *The Steep Cost of Medical Co-pays*, *supra* note 2.
[37] Wendy Sawyer, *How Much Do Incarcerated People Earn in Each State?*, PRISON POLICY INITIATIVE (Apr. 10, 2017), https://www.prisonpolicy.org/blog/2017/04/10/wages/ [hereinafter *How Much Do Incarcerated People Earn*].
[38] Wing, *supra* note 34.
[39] *Id*.
[40] *Id*.
[41] *Prison Health Care Costs and Quality*, *supra* note 18.
[42] Eisen, *supra* note 1.

fees for using a public defender, for probation services, and for phone calls home.[43] These fees add up quickly and leave prisoners with insurmountable debt when they leave prison.[44] They are unable to pay for food and housing and other basic necessities because of the debt they incurred while part of the criminal justice system.[45] By making re-entry to society harder, co-pays and other fees make recidivism more likely and are perpetuating mass incarceration.[46]

Some may argue that even though the fees incurred by prisoners are not court-ordered, it should still be their responsibility to pay them, instead of the cost being passed onto the innocent taxpayer. Some may argue that prisoners have put themselves in this position by committing criminal actions, and that the monetary consequences are of their own doing. However, these co-payments are bad policy for the reasons already argued.[47] When the state takes someone's liberty away and locks them up in a state facility, it should be the state's responsibility to pay for necessities such as healthcare.[48] Also, many of the prisoners make little to no money, thus co-pays pass the cost onto their families, who are also impoverished.[49] These fees are also too much of a deterrent to getting care, especially when considering that an estimated 80% of prisoners are indigent.[50]

III. PRISON HEALTHCARE CASELAW

[43] *Id*.
[44] *Id*.
[45] *Id*.
[46] *Id*.
[47] *Id.*
[48] *Id.*
[49] *Id.*
[50] Andrews, *supra* note 5.

A. Estelle v. Gamble

The leading Supreme Court case on access to healthcare for inmates is *Estelle v. Gamble.*[51] This case was brought by an inmate as a civil rights action under 42 U.S.C. 1983 against a state corrections department medical director and two correctional officials.[52] The inmate claimed that the officials violated his Eighth Amendment right to be free from cruel and unusual punishment for inadequate treatment of a back injury he sustained while in prison.[53] The Supreme Court ultimately held that deliberate indifference by prison personnel to an inmate's serious illness or injury is cruel and unusual punishment in violation of the Eighth Amendment.[54] Though the Court ultimately found against the plaintiff in *Estelle*, the case set a new standard for the quality of healthcare to which prisoners are constitutionally entitled.[55]

Estelle holds that there is an established government obligation to provide treatment to those whom the state is punishing by incarceration.[56] Part of this reasoning is that prisoners rely on the prison system to provide medical services; if this system fails, or if they cannot afford the treatment, there is nowhere else for the inmates to turn.[57] When the government controls the prisoner's medical care, it is not the prisoner's responsibility to provide his or her own medical treatment, but the government's responsibility.[58] The *Estelle* opinion argues that "it is but just that the public be required to care

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[51] Estelle*,* 429 U.S. at 97.
[52] *Id*. at 98; 42 U.S.C. §1983 (providing a cause of action when any "person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws").
[53] *Id*. at 101.
[54] *Id*. at 97.
[55] *Id*.
[56] Estelle, 429 U.S. at 103.
[57] *Id*. at 103.
[58] *Id*. at 104.

for the prisoner, who cannot by reason of the deprivation of his liberty, care for himself."[59] The standard for an *Estelle* violation of the Eighth Amendment is "deliberate indifference to serious medical needs of prisoners," and can be evidenced by prison doctors failing to respond to prisoners' needs, prison guards intentionally denying or delaying access to care, or intentional interference with treatment once prescribed.[60] Regardless of who on the prison staff actually caused the deliberate indifference, the failure to provide adequate healthcare is a legitimate cause of action under 42 U.S.C. 1983.[61]

B. Recent Holdings

The Supreme Court has yet to hear a case regarding prisons charging inmates co-pays for medical treatment. However, such cases have been heard at the Federal Circuit Courts and in State Supreme Courts.[62] These cases have been unanimous in holding that co-pays do not violate the standard set out in *Estelle.*[63]

In *McCall v. Johnson County Sheriff's Department*, the Tenth Circuit Court of Appeals found that it is "constitutionally acceptable to charge inmates a small fee for healthcare when indigent inmates are guaranteed medical care regardless of ability to pay."[64] The Court held that a state statute that would not allow for exceptions to a co-payment requirement for those

[59] *Id*.
[60] *Id*. at 105.
[61] *Id*. at 106.
[62] McCall, 71 Fed. Appx. at 30; Mourning, 300 N.J. Super. at 213; Poole, 703 F.3d at 1024.
[63] McCall, 71 Fed. Appx. at 30; Mourning, 300 N.J. Super. at 213; Poole, 703 F.3d at 1024.
[64] McCall, 71 Fed. Appx. at 31.

who could not afford it would be unconstitutional, but that was not the issue in that case.[65]

The New Jersey Supreme Court took up the same issue in *Mourning v. Correctional Medical Services (CMS) of St. Louis, Mo*.[66] The Court found that a law allowing for co-payments is not unconstitutional, so long as medical treatment is guaranteed despite ability to pay.[67] The court went so far as to say that there is no violation of the deliberate indifference standard in the Eighth Amendment even if the co-payments discourage inmates from seeking medical care.[68]

In *Poole v. Isaacs*, the Tenth Circuit Court of Appeals found that "as long as the governmental entity ensures that the medical care needed is in fact provided, the constitution does not dictate how the cost of that care should be allocated as between the entity and the provider of the care."[69] The Court held this way even though treatment was withheld until the plaintiff agreed to pay because he was in fact able to afford the co-pay, and if the plaintiff was truly indigent, he would have been exempt from the requirement.[70] Other state courts and federal circuit courts have held the same, finding that charging co-payments are not unconstitutional, so long as there are exceptions for indigent inmates.[71]

IV. PROPOSED CHANGES

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[65] *Id*. at 31.
[66] Mourning, 300 N.J. Super. at 225.
[67] *Id*.
[68] *Id*.
[69] Poole, 703 F.3d at 1027.
[70] *Id*.
[71] *See, e.g.*, Reynolds v. Wagner, 128 F.3d 166 (3d Cir. 1997); Tillman v. Lebanon Cnty. Corr. Facility, 221 F.3d 410, 418–19 (3d Cir. 2000); *see also* Shapley v. Nev. Bd. of State Prison Comm'rs, 766 F.2d 404, 408 (9th Cir. 1985); Negron v. Gillespie, 111 P.3d 556, 558–59 (Colo. App. 2005).

A. Policy

A primary reason that co-payments should not exist in the American prison system is because, from a public policy perspective, co-pays are just bad policy.[72] The Commission on Safety and Abuse in America's Prisons made a report recommending the end of the co-payment system in prisons.[73] The Commission argued that many of the short-term savings used to justify the co-payment system have long-term negative consequences.[74] While there may be short-term savings by distributing some of the medical costs to the prisoners, in the long run the co-payments discourage sick prisoners from seeking medical care early on.[75] When medical care is delayed, the treatment only becomes more expensive and less effective.[76] Research has found that co-payment systems reduce sick calls in prisons between sixteen and fifty percent.[77] By delaying treatment, medical costs increase, and the risk increases that disease will spread to other inmates, putting further financial strain on the system.[78]

The American Bar Association (ABA) has also taken the view that fees should not be charged for necessary healthcare procedures for prisoners.[79]

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[72] *See* Mushlin, *supra* note 28 (arguing that co-payments are bad public policy because "while the system of copayments seems reasonable at first glance, "they cost more in the long run by discouraging sick prisoners from seeking care early on, when treatment is less expensive and more effective and before disease spreads"); *see* Eisen, *supra* note 1 (arguing that co-payments are bad public policy because these charges are the government's responsibility, the financial burden is shifted to the inmate's family, and because of the deterent effects the payments have).
[73] Mushlin, *supra* note 28.
[74] *Id*.
[75] *Id*.
[76] *Id*.
[77] *Id*.
[78] *Id*.
[79] *Id*.

The ABA took this stance for the same reasons already articulated in this article, including the deterrent effect of the co-payments and prisoners' lack of funds.[80] The ABA's argument provides additional reasoning and support for eliminating co-payments. The ABA relies on the American Public Health Association's reasoning that co-payments deter prisoners from seeking healthcare, making the fees a "barrier to health care".[81] They cite to additional support from the United Nations, which argues that "medical care and treatment shall be provided whenever necessary … free of charge."[82]

Judicial decisions are not the only way to abolish the co-payment system in prisons. One possible solution for the problems set out in this article would be for states to withdraw co-payment laws or to enact new legislation prohibiting charging prisoners fees for medical care. This would be an effective solution because it does not require the Supreme Court to reach the high burden of finding that co-payments violate the constitution. It is worth noting that the lower courts that have taken up this issue have found that this decision is one that is better left to state legislators, not Congress.[83] This means that this issue could not just be decided by one legislative body; Congress could not change their policy and require all states to follow it. Instead, to rid every state of prison co-payments the decision would have to be made state by state. Completely abolishing prisoner co-pays would require legislative action by all 50 states. This sort of collective action seems incredibly difficult, if not impossible; legislative action is probably not the best solution.

B. An Issue for the Supreme Court

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[80] American Bar Association, Standards for Criminal Justice, Treatment of Prisoners, Section 23-6.1 (b),
commentary at 156 (2010).
[81] *Id.*
[82] *Id.*
[83] Mourning, 300 N.J. Super. at 227.

Another path to abolishing co-payments in prisons is through continued litigation. In some ways, this solution would be simpler. Only one decision, by the Supreme Court, could end co-payments across the country. In other ways, this solution is more complicated and less practical, with lower courts already holding that there is no constitutional violation in these policies. While lower federal courts and state courts are currently in agreement that these fees do not violate the constitution, the Supreme Court has not decided the issue.

The Supreme Court should take up the issue and reverse previous holdings, finding that charging inmates fees for healthcare violates their Eighth Amendment rights. Many scholars have disagreed with the current court consensus, arguing that medical co-payments impose cruel and unusual punishment on prisoners.[84] It is also argued that if co-pay laws were implemented in a way that discouraged inmates from seeking healthcare, it would deprive them of a meaningful access to such care and violate the Eighth Amendment.[85] These arguments should be affirmed by the Court. A crucial element of the *Estelle* standard is that a prisoner's right to medical care is not influenced by treatment costs.[86] Lower courts have used this holding to find that a lack of funds does not justify an unconstitutional level of medical treatment for inmates.[87] Due to this aspect of *Estelle*, courts should find that co-payments are unconstitutional. The stated legislative justification for these systems is to alleviate the costs of prisoner healthcare,

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[84] Mushlin, *supra* note 28 (citing scholars who believe co-payments constitute cruel and unusual punishment and noting that the fees are bad public policy because "[m]any short-term cost saving measures imposed by local, state, and federal legislatures have long-term negative consequences").
[85] *Id*.
[86] Jessica Wright, *Medically Necessary Organ Transplants for Prisoners: Who is Responsible for Payment?*, 39 B.C. L. REV. 1251, 1269 (1998).
[87] *Id*. at 1270.

but under *Estelle*, it is up to the government, not the prisoners, to fund healthcare, no matter the costs.[88]

Further, *Estelle* states that there is a violation of the cruel and unusual punishments clause when the deliberate indifference to medical needs is "manifested by prison doctors in their response to the prisoner's needs or by prison guards in intentionally denying or delaying access to medical care or intentionally interfering with the treatment once prescribed."[89] To rid the prison system of co-payments, the Court should interpret them as "intentionally interfering" with medical treatment, and should expand this rule to apply to all treatment, and not only treatment once it is prescribed. This would not be a far deviation from the current stated rule and would fulfill the same purpose.

Estelle guarantees the right to medical care to prisoners, without deliberate interference or delay once the treatment is prescribed.[90] There is no reason that this should not apply before the treatment is prescribed. Prisoners with health conditions that have not yet had treatment prescribed deserve healthcare services just as much as those who have already been seen by a doctor.

Further, co-payments are "deliberate interference or delay" of healthcare.[91] Prisons state that the purpose of the co-payments is deter prisoners from obtaining what they see as "frivolous" healthcare.[92] Actively putting up a barrier to deter healthcare cannot be seen as anything other than deliberate interference in providing care. This is a position further supported by the American Bar Association, which considers co-payments "a barrier to

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[88] Estelle, 429 U.S. at 97.
[89] *Id.* at 104.
[90] *Id*.
[91] *See* Estelle, 429 U.S.
[92] Andrews, *supra* note 5 (according to Dr. Greifinger, who was a chief medical officer of the New York Department of Corrections and has also worked as a correctional consultant).

health care."[93] Finally, co-payments are a delay in the providing of healthcare. Services are delayed when prisoners refuse to pay the fees or are unable to pay them, and care is not provided until the prisoners comply.[94] Because the co-payments are deliberate interference and delay, these fees violate the *Estelle* standard for what constitutes Eighth Amendment cruel and unusual punishment.

V. CONCLUSION

Around 80% of the incarcerated population is poor, and while in prison they make little to no money for their labor.[95] Yet, in at least thirty-six states and the federal prison system, these inmates are charged co-pays for routine and necessary healthcare.[96] This policy discourages inmates from seeking treatment, which adversely affects not only the individual prisoner, but the population that they re-enter after serving their sentence.[97] This policy must be changed, either through policy or through a decision by the Supreme Court. While a policy change would not require the difficulties of finding a policy unconstitutional, it would require a decision by every state in the country. This causes a collective action problem by requiring fifty legislative bodies to outlaw the policy for co-payments to be completely abolished. The easier and more permanent path forward will be a decision by the Supreme Court. The Court should find that these co-payments are in violation of the Eighth Amendment under the *Estelle* standard of intentional interference or delay with healthcare.

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[93] American Bar Association, *supra* note 80.
[94] Poole, 703 F.3d at 1024.
[95] Andrews, *supra* note 5; Wing, *supra* note 34.
[96] Mushlin, *supra* note 28.
[97] Andrews, *supra* note 5.

The Impact of Merger & Acquisitions on Smaller Pharmacy Market Participants and Consumers

John Gitta

The U.S. pharmaceutical industry has experienced an explosion in mergers and acquisitions (M&A) over the past 10 years.[1] In 2014, there were 188 total mergers totaling more than $213.3 billion.[2] This increased activity has resulted in numerous drug manufacturer consolidations, followed by an exponential rise of revenues, with annual profits of the top drug manufacturers increasing by 252 percent.[3] These booming revenues are in stark contrast with drug manufacturers' industry counterparts—CVS Pharmacy closed 200 stores across the nation through 2017, Walgreens closed 600 pharmacy locations subsequent its acquisition of Rite Aid in 2017,[4] and over 17,000 independent pharmacies in rural and urban areas have closed since 2000.[5] These closures carry serious consequences for patients, limiting their access to care in the rapidly consolidating healthcare market. These industry trends have impacted downstream participants—particularly drug suppliers—leading to an increase in horizontal mergers that have transformed a once competitive industry, characterized by a balanced mixture

1. INST. FOR HEALTH & SOCIO-ECONOMIC POLICY, MARCHING TOWARD MONOPOLY – MERGERS AND ACQUISITIONS IN THE PHARMACEUTICAL INDUSTRY, 2, 16 (2016) [hereinafter MARCHING TOWARD MONOPOLY].

2. ELEANOR B. MEREDITH, HEATH CARE MERGERS & ACQUISITIONS IN THE 21ST CENTURY (2d ed., 2017), https://s3.amazonaws.com/levin-publications/HC21_2016_web.pdf.

3. MARCHING TOWARD MONOPOLY, *supra* note 1, at 3.

4. Phil Wahba, *Walgreens to Shutter Almost 600 Rite Aid Stores as Part of Megadeal,* FORTUNE (Apr. 5 2018), http://fortune.com/2017/10/25/walgreens-rite-aid-5/.

5. First Bank, *How the Small, Neighborhood Pharmacy Prevails*, TRIANGLE BUS. J. (Apr. 25, 2017). https://www.bizjournals.com/triangle/news/2017/04/24/how-the-small-neighborhood-pharmacy-prevails.html

of big chain and independent pharmacies, into an industry dominated by a handful of consolidated "big chain" pharmacies.[6] This seemingly unrestrained consolidation has resulted in a marketplace devoid of competition and access as independent pharmacies continue to be edged out of the retail pharmacy industry. While the increase in M&A activity among mid-market big chain pharmacies has been a successful response to upstream market pressures, it has had a detrimental impact on consumers, whose primary access to healthcare depends upon the continued availability of independent pharmacies.

This Article explores the overlooked consequences to access inherent in the rapidly consolidating healthcare market by examining the recent closures of chain and independent pharmacies in primarily low-income, minority communities. Part I will provide an overview of the changing landscape within the pharmacy industry by examining the detrimental impact of M&A activity on independent pharmacies. Next, Part II explores retail pharmacy business growth strategy and the downstream impact of horizontal mergers by contrasting the financial objectives driving restructurings that result in barriers to health care in underserved communities. The remainder of the Article will attempt to reconcile the balance between retail pharmacies' business objectives and the potential impacts such objectives on underserved communities by presenting possible solutions to improve pharmacy accessibility.

I. A CHANGING LANDSCAPE IN THE RETAIL PHARMACY MARKETPLACE

Historically, retail pharmacies have served as the primary points of contact between consumers and their supply of most medications.[7] Comprised of large chain pharmacies, food stores, mail order and independent pharmacies,

6. Pengcheng Zhu & Peter Hilsenrath, *Mergers and Acquisitions in U.S. Retail Pharmacy*. 41 J. OF HEALTH CARE FINANCE, 1, 2–20 (2014).

7. MARCHING TOWARD MONOPOLY, *supra* note 1, at 1–16.

the retail pharmacy sector provided consumers a wide range of selection and access to medication, while creating a competitive market for parties across the supply chain, including drug manufacturers and suppliers.[8] Over the past decade, however, the competitive landscape within retail pharmacy sector has undergone a transformation whereby large pharmacies have used M&A growth strategies to dominate the highly lucrative retail pharmacy market by either buying or squeezing out smaller independent pharmacies.[9] Since 2008, there have been at least a hundred announced mergers or acquisitions within the retail pharmacy sector, with six years boasting 150 acquisitions or more.[10] Spearheaded by five firms—which presently control nearly seventy percent of the retail pharmacy revenue—M&A activity has shifted market competition in favor of larger, big chain pharmacies to the detriment independent pharmacies and, consequently, consumers.[11]

Opponents of this pharmacy market consolidation trend cite the lack of access that has resulted from recent pharmacy closures, while promoting the pivotal role of independent pharmacies in maintaining access and efficacy within healthcare administration.[12] Further, recent pharmacy closures have particularly impacted lower income, segregated areas leading to an increased lack of access to care.[13] Chicago's West and South Sides' together

8. Zhu & Hilsenrath, *supra* note 6, at 7.

9. MADELINE HURLEY & JONATHAN HADAD, IBIS WORLD, INCREASED M&A WILL PROPEL THE RETAIL SECTOR FORWARD 1 (2017), https://www.ibisworld.com/media/wp-content/uploads/2017/07/retail-MandA-pdf.pdf.

10. MEREDITH, *supra* note 2, at 42.

11. Rodey Wing et al., *M&A Activity Heats up in Specialty Pharmacy*, CHAIN DRUG REV. (July 3, 2017), https://www.chaindrugreview.com/ma-activity-heats-specialty-pharmacy/.

12. *See, e.g.*, Fred Gebhart, *Top 7 Challenges (and Opportunities) For Pharmacy in 2018*, DRUG TOPICS (Jan. 11, 2018), http://drugtopics.modernmedicine.com/drug-topics/news/top-7-challenges-and-opportunities-pharmacy-2018?page=0%2C2 (noting the criticism that "[p]atients are being limited more and more in where they can go[,]" because "[patients] want to [go to a smaller pharmacy], but it's a challenge when they have to pay more. Growing consolidation and ever more-restricted networks is frustrating for patients and frustrating for [smaller, independent pharmacy owners").

13. Dima Qato et al., '*Pharmacy Deserts' Are Prevalent in Chicago's Predominantly Minority Communities*, *Raising Medication Access Concerns*, 33 HEALTH AFFAIRS, 1958,

represented fifteen percent of the seventy pharmacies that Walgreens decided to close nationally in 2017.[14] As a result of these closures, many west and south side residents no longer have a pharmacy within two miles of their homes, a burden felt most severely by the elderly.[15]

It is facile not to see how a lack of access to health care quickly transforms into a broader, public policy issue. Dr. Dima Qato, a professor at the University of Illinois-Chicago College of Pharmacy, examined the resultant costs of these closures from a public policy perspective.[16] She observed that the lack of retail pharmacies in underserved communities is akin to food deserts.[17] This observation is supported by the fact that residents who live in communities without retail pharmacies face the same challenges of accessing necessary preventative services—in the pharmacy context, in the form of over-the-counter drugs and prescriptions—that treat or even prevent chronic conditions.[18]

In addition to serving as cornerstone access point for primary care, pharmacists contribute many services to communities, serving as patient educators and as accessible reference points for minor health issues.[19] Pharmacists' personal knowledge of communities and their residents help with healthcare administration as patients are more comfortable with sharing health information that they may withhold from their doctors.[20] A recent study by the American Pharmacists Association (APA) highlighted how

1959 (2014) (noting that although the study was limited to Chicago, the findings are likely relevant to other major urban areas – such as Detroit, New York City, Los Angeles, Atlanta, and Philadelphia – that have similar persistent race or ethnic residential segregation.)

14. *See* Ese Olumhense & Nausheen Husain, *'Pharmacy Deserts' a Growing Health Concern in Chicago, Experts, Residents Say,* CHI. TRIB. (Jan. 22, 2018), http://www.chicagotribune.com/news/local/breaking/ct-met-pharmacy-deserts-chicago-20180108-story.html.

15. Qato et al., *supra* note 13, at 1958.

16. *Id*.

17. *Id*.

18. *Id*.

19. Andrew Traynor et. al., *The Main Street Pharmacy: Becoming an Endangered Species*, 2 RURAL MINN. J. 83, 85 (2005).

20. *Id*. at 86.

independent pharmacists' unique combination of knowledge, central location, and often easier accessibility to patients positions them to serve as the perfect health care administrators in the medication-use process.[21]

In tandem with improving efficacy, independent pharmacists play an important role in addressing chronic diseases, which are the leading causes of healthcare costs in the United States.[22] A 2010 study focusing on pharmacists' role towards positive healthcare outcomes demonstrated that the cost of clinical pharmacy services far exceeds the costs of providing the service, regardless of practice setting.[23] In fact, certain studies have found that for every dollar invested in clinical pharmacy services for the treatment or prevention of chronic diseases, the clinical pharmacist providing the services will see more than four dollars in benefits and savings.[24] Given these positive outcomes, increasing pharmacy availability, especially in communities with the highest rates of chronic diseases, would help reduce the cost of healthcare across the market by reducing (or removing) chronic diseases which are ultimately paid for at a higher cost when addressed only during end of life treatment.[25]

Advocates of consolidations within the retail pharmacy sector present cost-cutting and increased efficiency as benefits that help parties across the entire supply chain; however, these assertions present a short-sighted view of the full impacts of mergers by assuming that all participants have equal

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21. David Steeb et. al., *Improving Care Transitions: Optimizing Medication Reconciliation*, 52 AM. PHARM ASSOC. 1, 8 (2012).

22. Patti Gasdek Manolakis & Jann B. Skelton, *Pharmacists' Contributions to Primary Care in the United States Collaborating to Address Unmet Patient Care Needs: The Emerging Role for Pharmacists to Address the Shortage of Primary Care Providers*, 74 AM. J. PHARM. EDUC. 1, 9 (2010).

23. *Id*. at 2.

24. *Id.*

25. *Id.*; *see, e.g.*, *Community Pharmacists Can Help Lower Overall Health Care Costs*, NAT'L CMTY. PHARMACISTS ASS'N, http://www.ncpanet.org/advocacy/federal-advocacy/medicare-issues/community-pharmacists-can-help-lower-overall-health-care-costs (last visited Apr. 10, 2018).

bargaining power and a competitive insurance market.[26] First, while it is uncontested that big chain pharmacy consolidations increase their buying power when negotiating with equally large drug manufactures, the high degree of consolidation, especially in the form of horizontal mergers, destroys smaller participants' ability to compete, a factor evidenced by the acquisition or closure of smaller independent pharmacies.[27] Additionally, due in part to their buying power and ability to "attract consumers with their wide selection of non-pharmaceutical inventory, big chain pharmacies can earn higher profit margins," which accordingly allow them to negotiate lower drug prices.[28]

Finally, support for value-creation by consolidation through cost cutting and efficacy "hinges on the degree of competition within the health insurance marker, absent which, consumers will not see benefits passed down the form of lower prices."[29] In a recent summary by the House Judiciary Subcommittee on Regulatory Reform regarding a proposed merger between CVS Health and Aetna, the subcommittee concluded that mergers that concentrate purchase power within the healthcare industry will result in an increase in firm profits rather than consumer welfare due to the lack of a competitive insurance market.[30]

The subcommittee's findings that retail pharmacy consolidations may be driven more by the motivation to earn profits than by the intention to lower

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26. *Competition in the Pharmaceutical Supply Chain: The Proposed Merger of CVS and Aetna: Hearings Before the Sub Comm. On Regulatory Reform, Commercial and Antitrust Law, 115th Cong*. (2018) (statement of Prof. Craig Garthwaite) [hereinafter Garthwaite Statement].

27. MATTHEW NATTINGER ET AL., RUPRI CENTER FOR RURAL HEALTH, CHARACTERISTICS OF RURAL COMMUNITIES WITH A SOLE, INDEPENDENTLY OWNED PHARMACY 2 (Mar. 11, 2018). https://www.publichealth.uiowa.edu/rupri/publications/policybriefs/2015/Sole%20Independent%20Pharmacies.pdf

28. David Reich-Hale, *Independent Pharmacies Battle Big Chains, Mail Order Services*, NEWSDAY (Mar. 5, 2018), https://www.newsday.com/business/independent-pharmacies-battle-big-chains-mail-order-services-1.13195404.

29. Wing et al., *supra* note 11, at 17.

30. *Id*. at 2.

consumer prices or to respond to upstream market pressures are supported by restructurings in the form of pharmacy closures that appear to be strategically influenced by profit margins. Studies show that following consolidations among large retail pharmacies—either via horizontal mergersbetween large chains or acquisitions of smaller pharmacies[31] —the newly formed entity often closes pharmacies as to remain within regulatory antitrust compliance limits.[32] Even though evidence suggests otherwise,[33] pharmacies involved in these restructurings often cite this as the determinative factor when explaining post-merger pharmacy closures in primarily low-income and often minority communities.[34] A recent study about the availability of pharmacies revealed that recent pharmacy closures were mainly concentrated in Chicago in predominantly segregated black or Latino communities, as well as in federally "Medically Underserved Areas."[35] Coining areas without pharmacies "Pharmacy Deserts,"[36] the study revealed that fifty-four percent

31. *See generally*, WACHTELL, LIPTON, ROSEN & KATZ, TAKE OVER LAW AND PRACTICE 79 (2017) (discussing horizontal mergers of equals (MOEs)).

32. *Competition in the Pharmaceutical Supply Chain: The Proposed Merger of CVS and Aetna: Hearings Before the Sub Comm. On Regulatory Reform, Commercial and Antitrust Law, 115th Cong*. (2018) (statement of the Am. Med. Assoc.) [hereinafter AMA Statement].

33. MARCHING TOWARD MONOPOLY, *supra* note 1, at 3 (noting that increasing M&A activity also closely correlates to the relentless growth of profits for the to 50 pharmaceutical corporations); *see also* AMA Statement, *supra* note 32, at 2 (confirming that CVS's understated its competitive significance in relation to what they called "the appearance of market power", even though they to disclosed 10K's acknowledging antitrust risks: "To the extent that we appear to have actual or potential market power in a relevant market or CVS pharmacy or CVS specialty plays a unique or expanded role in a PMB product offering, our business arrangements and uses of confidential information may be subject to heightened scrutiny from an anti-competitive perspective and possible challenges by state or federal regulators or private parties".)

34. Kim Bellware, *A Wave of Closures has left some Neighborhoods in a 'Pharmacy Desert'*, CHI. MAG. (Oct. 26, 2017), http://www.chicagomag.com/city-life/October-2017/A-Wave-of-Closures-Has-Left-Some-Neighborhoods-in-a-Pharmacy-Desert/.

35. Qato et al., *supra* note 13, at 1959 (noting that often federally designated "high needs areas" were often also predominantly African America or Hispanic)

36. For a definition of pharmacy deserts, see Zach Schaledetsky, *Trend: What is a Pharmacy Desert?*, TELEPHARM (Apr. 8, 2017), http://blog.telepharm.com/what-is-a-pharmacy-desert (defining an urban pharmacy desert as "a low-income community or neighborhood with no pharmacy within a half-mile for those with limited vehicle access. For low-income communities with adequate vehicle access, the defining radius extends to a mile[,]" and a rural pharmacy desert as a "any area within a 10-mile radius without ready

of the 287 segregated black communities and thirty-four percent of segregated Hispanic communities were located in deserts.[37] These findings were focused on Chicago, and arguably contradicted the notion that post-merger pharmacy closures were primarily driven by regulatory compliance: "between 2000 and 2010 there was a 20 percent increase in the number of pharmacies in white communities, with no such expansion in minority communities."[38] Further, the discrepancies found in the preceding study were not explained by differences in surveyed communities' population densities; this appears to correspondingly indicate that fewer pharmacies were located in minority communities, despite surveyed population changes.[39]

Studies akin to those described *supra* suggest that consolidating big chain pharmacies have profit motivations that drive restructurings, which resultantly lead to pharmacy closures. Nevertheless, a difficulty arises when the question of legal duty to provide services is presented, because pharmacy companies have fiduciary duties to their shareholders to maximize profits, but not necessarily legal (or ethical) duties to ensure access to healthcare. Distinguishing the above views would be easier absent mitigating factors; however, an argument could be made here that regulatory bodies, as a matter of public policy, have implemented policy to curtail profit-driven restructurings. By way of illustration, a recent report by the Federal Trade

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access to a pharmacy (for those that have access to transportation)").

37. *Id.* at 1960; *see also 'Pharmacy Deserts' a Growing Health Concern in Chicago, Experts, Residents Say*, AM. PHARMACISTS ASS'N (Jan. 22, 2018), https://www.pharmacist.com/article/pharmacy-deserts-growing-health-concern-chicago-experts-residents-say (reiterating Dr. Qato's findings).

38. *Id*.; Qato et al., *supra* note 13, at 1962-63 (highlighting how, despite an increase in pharmacies in Chicago, disparities in the availability of pharmacies worsened between 2000 and 2010, especially for segregated black communities).

39. *Id.* at 1963; *but see* Phil Galowitz, *When Hospitals Move, Who Gets Left Behind,* THE ATLANTIC (Apr. 25, 2015) (noting that a growing number of hospitals and pharmacies are relocating to wealthier towns, citing financial necessity, but many see it as a choice to abandon the residents of poorer areas, suggesting that race is not the only factor driving the closure of pharmacies in minority communities) https://www.theatlantic.com/health/archive/2015/04/when-hospitals-move-who-gets-left-behind/391412/.

Commission (FTC) shows that the federal government continues to monitor the spike in retail pharmacy restructurings, especially where horizontal mergers are between direct competitors.[40]

II. REGULATING AND INCENTIVIZING THE RETAIL PHARMACY INDUSTRY

Given the complexity of the health care industry, reconciling the various conflicts of interest that impede access to health care in underserved communities requires a combination of factors from both inside and outside the retail pharmacy industry. Possible solutions include increased federal and state government regulation, as well as private solutions from e-commerce. Recent mergers within the pharmacy industry against the backdrop of rapidly closing retail pharmacies (both family owned and chained-based) seems to have raised alarms to warrant federal attention, resulting in actions by the FTC as well as bill proposals by the legislature.[41] A recent report by the FTC shows that the federal government continues to monitor the spike in retail pharmacy restructurings, especially where horizontal mergers are between direct competitors.[42] Furthermore, driven in part by concerns about unfair competition and the eventual detrimental impacts on consumers, since 2014 the FTC has rejected 13 proposed mergers between direct retail pharmacy competitors.[43]

Moreover, in early 2017, Rep. Brett Guthrie of Kentucky introduced the Pharmacy and Medically Underserved Areas Enhancement Act.[44] This bipartisan legislation aims to amend section 1861(s)(2) of the Social Security

40. MARKUS MEIER ET AL., FED. TRADE COMM'N, OVERVIEW OF FTC ACTIONS IN PHARMACEUTICAL PRODUCTS AND DISTRIBUTIONS 64, 92 (2017), https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_april_2017.pdf.

41. Pharmacy and Medically Underserved Areas Enhancement Act, H.R.592, Cong. (as reported by H. Comm. on Energy and Commerce, (Jan 20, 2017) [hereinafter Pharmacy Act].

42. Meier et al., *supra note* 40, at 92.

43. *Id.*

44. *Id; see generally* Pharmacy Act, *supra* note 41.

Act (SSA) to include pharmacists on the list of recognized healthcare providers.[45] Presently, the SSA does not recognize pharmacists as "healthcare providers," and as such insurance companies sometimes do not cover healthcare services provided by pharmacies.[46] Supporters of the Act hope that if pharmacies are federally recognized "healthcare providers" as defined by the SSA, then insurance companies are more likely to cover provided services.[47] The Act and its corresponding amendment will directly target this issue by increasing health care access to underserved communities by incentivizing chain and independent retail pharmacies towards the goal of increasing access to healthcare through providing preventative services.[48]

In addition to recognizing pharmacies as health care providers, another way of increasing parity between independent and big chain pharmacies would be to streamline Medicare reimbursement by amending Medicare Part D.[49] A recent survey by the National Community Pharmacists Association revealed that because of retroactive direct and indirect remuneration fees, "84% of independent pharmacy owners polled said they don't know what their final reimbursement will be at the point of sale, and 77% said it takes four to 12 months before they find out that figure."[50] In addition to reimbursement uncertainties, the study found that pharmacists were also concerned that the slow payments made it more challenging to plan for the future of their business because of the inability to predict cash flow for

45. *Id.*

46. Benjamin M. Blum, *Consortium Recommendations for Advancing Pharmacists' Patient Care Services and Collaborative Practice Agreements*, 53 J. AM. PHARMACISTS ASS'N, 132, 137 (2013).

47. *Id.*

48. *Pharmacy Act, supra* note 41.

49. *See generally* DONALD KLEPSER ET. AL,, RUPRI CENTER FOR RURAL HEALTH, INDEPENDENTLY OWNED PHARMACY CLOSURES IN AMERICA, POLICY BRIEF #2008-2 1, 4 (2008), http://www.ncpanet.org/pdf/leg/feb13/rural_pharmacy_closures.pdf (discussing pharmacy closures due in part to poor reimbursement rates).

50. CDR Blog & Drug Chain Review, *Pharmacies Feel the DIR Fee Pain,* CHAIN DRUG REV. (Feb. 9, 2018), https://www.chaindrugreview.com/pharmacies-feel-the-dir-fee-pain/.

operating revenue.[51]

While both big chain and independent pharmacies face these challenges, independent pharmacies endure harsher consequences because—unlike their big chain counterparts—they lack the operating capital to cope with the delayed payments, not to mention the inability to independently negotiate preferable prescription drug discounts with insurance companies through Pharmacy Benefit Managers (PBMs).[52] A recent bill introduced by Rep. Griffin Morgan of Virginia should hopefully pave the way for a solution the payment uncertainties.[53] Entitled the "Transparency and Accuracy in Medicare Part D Spending Act," the bill attempts to solve this issue by "amend[ing] title XVIII [(Medicare)] of the Social Security Act to prohibit [Medicare] Prescription Drug Plan sponsors and MA–PD organizations from retroactively reducing payment on clean claims submitted by pharmacies," while simultaneously providing pharmacies an itemized list of costs.[54]

III. ALTERNATIVE SOLUTIONS

Pharmacy closures due to horizontal consolidation has resulted in a

51. *Id.*

52. Joanna Shepherd*, The Fox Guarding the Henhouse: The Regulation of Pharmacy Benefit Managers by a Market Adversary,* 9 NW. J. L. & SOC. POL'Y. 1, 3 (2013) (noting that PBMs are direct market adversaries of pharmacies in several segments of the prescription drug market because they negotiate price discounts for network pharmacies leading to direct pressures on the profits of both network and non-network pharmacies).

53. *See* Improving Transparency and Accuracy in Medicare Part D Spending Act, H.R.1038, Cong. (as reported by H. Comm. On Energy & Commerce, (Feb. 14, 2017) ("IN GENERAL.—Section 1860D–12(b)(4)(A) of the Social Security Act (42 U.S.C. 1395w–112(b)(4)(A)) is amended by adding at the end the following new clause:
'(iv) PROHIBITING RETROACTIVE REDUCTIONS IN PAYMENTS ON CLEAN CLAIMS.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall provide that after the date of receipt of a clean claim submitted by a pharmacy, the PDP sponsor (or an agent of the PDP sponsor) may not retroactively reduce payment on such claim directly or indirectly through aggregated effective rate or otherwise except in the case such claim is found to not be a clean claim (such as in the case of a claim lacking required substantiating documentation) during the course of a routine audit as permitted pursuant to written agreement between the PDP sponsor (or such an agent) and such pharmacy. The previous sentence shall not prohibit any retroactive increase in payment to a pharmacy pursuant to a written agreement between a PDP sponsor (or an agent of such sponsor) and such pharmacy.'").

54. *Id.*

detrimental effect on patients' access to care, especially in socio-economically disadvantaged areas where an independent pharmacy may have been the only one accessible to patients without the means to travel to a pharmacy further away. For instance, in the West and South Side neighborhoods of Chicago, this problem has been recognized and addressed from a public health perspective, which has attempted to quantify and qualify the loss due to lack of healthcare access. As discussed in more detail in Part I of this Article, Dr. Qato's studies predict that if the disparities in pharmacy accessibility continued to be ignored, improvements population health may continue to worsen.[55] Dr. Qato's study offers distinct policy solutions, including "economic incentives similar to those implemented to address the shortage of primary care providers and the existence of food deserts."[56] This solution embraces a private-public approach, which accepts the expanding scope of services offered by consolidated pharmacy chains, including retail minute clinics, immunizations, and medical therapy management programs.[57] To succeed, this plan depends on the achievement of a streamlined Medicare reimbursement system, where *all* pharmacies, including now-consolidated big chain pharmacies, are incentivized to move back to underserved communities with the promise of market-based

55. Qato et al., *supra* note 13 at 1964.

56. *Id*. at 1963; *cf.* David C. Holzman, *White House Proposes Healthy Food Financing Initiative*, 118 Envtl. Health Persp. A156, A156 (2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2854743/pdf/ehp-118-a156.pdf (summarizing Obama-era public policy solution to food deserts).

57. Qato et al., *supra* note 13 at 1963; *but see* Garthwaite Statement, supra note 26 (addressing the possibility that the convenience of retail clinics that offer subsidized healthcare with additional services in underserved neighborhoods might *actually* increase spending in the long run by changing the number of visits at the extensive margin . . .meaning that individuals may not have seen a provider - and therefore incurred no cost- would not see a provider and have increased health spending. Because visits to retail clinics are less expensive than similar visits to other providers, the aggregate impact of access is increased rather than decreased healthcare spending. Ultimately, for the program to work, the market must avoid a moral hazard problem, whereby healthcare is consumed at or above its market value where consumers bear the direct financial costs of each visit, and therefore are more likely to guard against overconsumption).

returns.[58]

Alternatively, there is the private solution of the inclusion of locally owned independent pharmacies in preferred networks, which could also provide independent pharmacies an incentive to remain with communities.[59] Specifically, this solution would address the problem of price discrimination, whereby in-network big chain pharmacies have superior leverage to negotiate fairer terms for lower wholesale prescriptions, allowing PBMs to provide incentives like lower copays to steer patients to their own pharmacies.[60] This is in stark contrast to PBMs' strategy with independent pharmacies, to which they offer adhesive contracts that force the pharmacies to choose between losing money on many filled prescriptions or being excluded from an insurer's network altogether.[61] Most independent pharmacies have accepted this limited offer, due to their belief that joining nationwide independent purchasing groups is the only way to gain a superior bargaining position on par with big chain pharmacies.[62] Essentially, independent pharmacies are facing a Sophie's choice between their independent survival and livelihood versus closing their doors and consequently leaving their communities without access to health care.[63]

For the aforesaid private solution to succeed, it would require support from the public sector through public health-driven policies enacted to counter the

58. Kevin Schweers, *Study Highlights Independent Pharmacies' Role in Caring for Underserved Patients*, NAT'L COMMUNITY PHARMACISTS ASS'N: THE DOSE (Nov. 10, 2014), http://www.ncpanet.org/newsroom/ncpa's-blog—-the-dose/2014/11/10/study-highlights-independent-pharmacies-role-in-caring-for-underserved-patients.

59. *See generally* STACY MITCHELL, INST. FOR LOCAL SELF- RELIANCE, MONOPOLY POWER AND THE DECLINE OF SMALL BUSINESS: THE CASE FOR RESTORING AMERICA'S ONCE ROBUST ANTITRUST POLICIES (2016), https://ilsr.org/wp-content/uploads/downloads/2016/08/MonopolyPower-SmallBusiness.pdf.

60. Hearing on H. 97 Before the S. Comm. On Welfare and the H. Comm. on Health, 2015-16 Sess. (VT. 2015) (PBM Presentation by David Balto) [hereinafter Balto, PBM Presentation Testimony].

61. N.D. CENT. CODE § 43-15-32 (2015); *see generally* Balto, PBM Presentation Testimony, *supra* note 60.

62. *See* Reich-Hale, *supra* note 28, at 6.

63. *Id.*

impacts of horizontal market compression caused by big-chain pharmacy mergers. One successful state initiative on this subject is North Dakota's 1963 law, N.D. Century Code § 43-15-32, which mandates that only drugstores owned by pharmacists may operate in the state, effectively banning chain stores from owning pharmacies.[64] While drastic in scope, this law has ensured that North Dakota has the most pharmacies per capita than any other state, and there is not a single Walgreens, Walmart, or other big chain pharmacy among them.[65] This 1965 state law essentially set out to solve—and appears to have succeeded at a small, intrastate scale—the problems caused by merging big chain pharmacies, namely decreased competition and the closure of independent pharmacies.[66] By creating an artificial barrier to entry, North Dakota's law has in effect filled a "vacuum left by the failure of antitrust policy to promote and maintain an open an open and competitive market."[67] Even laws not as drastic as North Dakota's could effectively create a more even playing ground, whereby independent pharmacists have some leverage to negotiate fairer terms with PBMs, which intimately results in health markets where pharmacies are not forced to adjust to market compressions by passing down costs to consumers.[68]

Finally, the expanding role of e-commerce and telemedicine in the retail pharmacy sector might be a welcome disrupter that frees healthcare consumers from strict dependence on the pharmacy industry. By providing a way for patients to get medication directly from manufacturers while simultaneously cutting out the retail pharmacy middleman, e-pharmacies will

64. *See, generally* Tony Alesandra, *North Dakota's Pharmacy Ownership Law: An Analysis of the Strictest Pharmacy Law in the United States*, 86 N. DAKOTA LAW REV. 335, 335 (2010).

65. MITCHELL, *supra* note 59.

66. N.D. CENT. CODE § 43-15-32.

67. MITCHELL, *supra* note 59, at 7.

68. OLIVIA LAVECCHIA & STACY MITCHELL, INST. FOR LOCAL SELF-RELIANCE, NORTH DAKOTA'S PHARMACY OWNERSHIP LAW ENSURING ACCESS, COMPETITIVE PRICES, & QUALITY CARE 1, 22 (2014).

empower the consumer while also increasing access to healthcare.[69] A potential partnership here would be Amazon.com, Inc. (Amazon): with its expansive e-commerce platform, Amazon is the best-positioned candidate to undercut big chain, commercial giants such as CVS and Walgreens because of the large market footprint, which should enable them to independently bargain for lower prices.[70]

To further address problems of patient access, telehealth and telemedicine services have emerged as gap-fillers following pharmacy closures.[71] For instance, companies like TeleCounsel and TeleCheck have created proprietary online platforms to allow centrally located pharmacists to provide offsite services at long-term care facilities, patient's homes and doctor's offices.[72] If implemented correctly with ample support from public representatives, these private sector services will be the perfect tool to improve patient care, though lower costs and increased healthcare accessibility for those often underserved communities.

IV. CONCLUSION

Ultimately, it should not matter if the solution to pharmacy inaccessibility results from exclusively private, public or joint-effort ventures. Instead, what matters the most is that consumers have some access to pharmacies. However, for any solution to succeed, public and private stakeholders must conclude that increasing access to health resources will benefit all market participants in the long run, even at the cost of profit margins.

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69. Annie Palmer, *Why Some Think It's 'Prime Time' for Amazon to Enter the Pharmacy Market,* THE STREET (Oct. 2017, 3:40 PM EDT), https://www.thestreet.com/story/14340895/1/amazon-pharmacy-market-next.html.

70. *Id.*

71. Eileen Oldfield, *Telemedicine Fills Pharmacy Services Gap Following Rural Store Closures*, PHARMACY TIMES (Sept. 4, 2014), http://www.pharmacytimes.com/news/telemedicine-fills-pharmacy-services-gap-following-rural-store-closures.

72. *Id.*

Antitrust: How an Online Retailer Could Enter the Healthcare Market

Mary Hannosh

Recently, Amazon announced its partnership with Berkshire Hathaway and JP Morgan to enter the healthcare market and create solutions to combat the rising healthcare costs.[1] The announcement did not contain many details as to how the companies were going to accomplish this goal, but together, the three companies will be able to highly influence the industry.[2] While Amazon confines the details regarding the partnership, imagine, a fictional entity named SEBCorp. SEBCorp is a large, predominantly online retail company that is continuously growing and looking to expand. The company is a "marketing platform, a delivery and logistics network, a payment service, a credit lender, an auction house, a major book publisher, a producer of television and films, a fashion designer, a hardware manufacturer, and a leading provider of cloud server and computing power."[3] SEBCorp continues to expand into new markets by acquiring companies within the specific market it is aiming to enter. SEBCorp's business strategy is to acquire companies by constantly reinvesting its profits to purchase those companies, growing as a corporation overall to generate profits, and then reinvest into a new market. This business strategy of purchasing other companies within its supply-chain is commonly referred to as vertical integration.[4] This cyclical

1. Cara Lombardo et al., *Amazon, Berkshire Hathaway, JPMorgan Join Forces to Pare Health-Care Costs*, WALL ST. J. (Jan. 30, 2018), https://www.wsj.com/articles/amazon-berkshire-hathaway-jpmorgan-to-partner-on-health-care-1517315659.

2. *Id.*

3. Lina M. Khan, *Amazon's Antitrust Paradox*, 126 YALE L.J. 710, 713 (2017).

4. *Competitive Effects*, FED. TRADE COMM'N, https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/mergers/competitive-effects (last visited

process has allowed SEBCorp to continue growing and become a large competitor across several industries in the nation. SEBCorp is eager to expand again, and recently announced that it will begin testing its entry into the healthcare market.

However, SEBCorp may find itself in more trouble than it realizes with its move into the healthcare sphere. Not only is healthcare a highly regulated space, but as the healthcare market consolidates through mergers and acquisitions, it has come under intense scrutiny by antitrust laws.[5] Antitrust laws were initially passed to encourage competition in the marketplace and protect consumers from large corporations.[6] The laws ensure that large corporations do not obtain such an excessive amount of market power that they can control the market as whole.[7] Companies that want to acquire or merge with other companies need to follow the antitrust guidelines set forth in the Sherman Act, the Clayton Act, the Federal Trade Commission Act, state law, and Federal Trade Commission (FTC) guidelines to confirm that the market competition is fair for all companies.[8] These laws and guidance ensure that the acquisition and merger transactions taking place do not hurt the consumer market.[9] For example, the transactions can hurt the market by creating barriers to entry or fixing prices to overcharge consumers.[10] The FTC and Department of Justice (DOJ) work together to stop transactions in markets if those transactions would cause problems that antitrust laws seek to prevent.[11] Antitrust laws apply to every market, including healthcare, which means that SEBCorp will have to comply.

Apr. 24, 2018).

5. Jeff Miles, *Healthcare Antitrust Mergers and Merger Guidelines Revision: What Might It Mean for Healthcare Firms*, 22 HEALTH L. 36 (2009).

6. BARRY R. FURROW ET AL., HEALTH LAW CASES, MATERIALS AND PROBLEMS 1163 (7th ed. 2013).

7. *Id.*

8. *Id.*

9. *Id.* at 1164-65.

10. *Id.*

11. *Id.* at 1165.

SEBCorp will have to overcome hurdles from the antitrust field to enter the healthcare market. Part I of this paper will explain what antitrust law is and the consequences a company may face if it violates the antitrust laws. Part II will explain how antitrust laws apply to the healthcare market. This includes the history of how antitrust and health law grew to be what they are today. Part III will address the antitrust barriers that SEBCorp will face and propose different types of transactions that would allow the company to best enter the healthcare market.

I. INTRODUCTION TO ANTITRUST LAW

Antitrust laws oversee transactions affecting market structures as they evolve, to protect the competitive marketplace.[12] They are concerned with the market power a corporation or set of corporations have within the marketplace.[13] The three major antitrust laws are the Sherman Act, the Clayton Act, and the Federal Trade Commission Act.[14] These three statutes provide broad guidance, leaving it to the federal courts to create antitrust common law.[15]

The Sherman Act contains two sections that are important to understand how corporations evolve in the marketplace.[16] Section One requires two elements for an antitrust violation: an agreement between the two parties and the agreement must unreasonably restrain trade in the marketplace.[17] Although the term "unreasonable" cannot be found in the text of Section 1 of the Sherman Act, courts have added this requirement.[18] The courts subsequently determined a list of agreements that unreasonably restrain trade,

12. FURROW ET AL., *supra* note 6, at 1163.
13. *Id.*
14. *Id.* at 1164.
15. *Id.*
16. 15 U.S.C. §§ 1-2 (2004) (naming the two sections mostly referred to in the antitrust field as § 1, Restraints of Trade, and § 2, Monopolization and Attempted Monopolization).
17. FURROW ET AL., *supra* note 6, at 1164-65.
18. N. Pacific. Railroad Co. v. United States, 356 U.S. 1, 5 (1958)

called per se violations.[19] The list includes price fixing, market division, exclusive dealing, group boycotts, and tying arrangements.[20] If a merger or acquisition agreement between two corporations is one of the per se violations, then the parties have violated antitrust laws.[21]

If the agreement between the two parties is not a per se violation, then the courts will analyze the agreement under a balancing test called "the rule of reason."[22] Using the rule of reason analysis, courts weigh the pro-competitive benefits of the challenged transaction against any anticompetitive effects. If competition in the marketplace is strengthened rather than restrained, the transaction passes the rule of reason test, thus no antitrust violations are present.[23] To determine if competition is strengthened, the courts answer three questions: "(1) how does the restraint harm competition; (2) what is the nature and magnitude of the activity's 'redeeming virtues'. . . and (3) are there 'less restrictive alternatives' that could achieve the legitimate objectives with less harm to competition?"[24] Although courts do still use the rule of reasoning test,[25] in reality, courts rely on other forms of analyses to determine whether or not the restraint on trade harms competition.[26]

In addition to the Sherman Act, Section Seven of the Clayton Act prohibits mergers and acquisitions whose effect is "substantially to lessen competition" or "to tend to create a monopoly."[27] The FTC and DOJ first assess whether the agreement between two corporations will increase its market power, by defining "relevant markets and calculate market shares and

19. FURROW ET AL., *supra* note 6, at 1165.
20. *Id.*
21. *Id.* at 1167.
22. *Id.*
23. *Id.*
24. David Marx Jr., *Antitrust Issues*, AM. HEALTH LAWYERS ASS'N 1, 4 (2003).
25. *See* Leegin Creative Leather Prod., Inc. v. PSKS, Inc., 551 U.S. 877, 885 (2007).
26. *See* Fed. Trade Comm'n v. Advocate Health Care, No. 15 C 11473, 2017 WL 1022015, at *3 (N.D. Ill. Mar. 16, 2017); *see* United States v. Anthem, Inc., 236 F. Supp. 3d 171, 196 (D.D.C. 2017).
27. 15 U.S.C. § 18 (1996).

concentration."[28] If the agreement does, then it poses a risk to competition.[29] Section Seven also requires transactions over a certain amount to file a premerger notification report to authorities, which allows enforcement agencies to review the transaction and determine if it violates the Clayton Act.[30]

Lastly, the Federal Trade Commission Act prohibits "unfair methods of competition," which courts have interpreted to mean all violations of the Sherman Act and the Clayton Act.[31] The Federal Trade Commission Act also gives the FTC the power to enforce antitrust statutes.[32] As a regulatory agency, the FTC does not have criminal prosecution powers, but the agency can still pursue civil actions.[33] The Sherman Act and the Clayton Act provide the antitrust laws that the individual markets must comply with, while the Federal Trade Commission Act provides guidelines to clarify what activities and market breadth constitute an antitrust violation. Corporations, such as SEBCorp, must consider these three statutes when engaging in mergers and acquisitions to increase their market share.

A company may end up in court in a suit against the FTC for potential antitrust violations if the FTC finds in its investigations that a company violated one of the antitrust laws.[34] The FTC may begin to investigate a

28. FED. TRADE COMM'N & DEP'T OF JUSTICE, ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS (April 2000) https://www.ftc.gov/sites/default/files/documents/public_events/joint-venture-hearings-antitrust-guidelines-collaboration-among-competitors/ftcdojguidelines-2.pdf (citing Eastman Kodak Co. v. Image Technical Services, Inc., 504 U.S. 451, 464 (1992)).

29. *Id*.

30. Marx, *supra* note 24, at 3; Press Release, Fed. Trade Comm'n, FTC Announces Annual Update of Size of Transaction Thresholds for Premerger Notification Filings and Interlocking Directorates (Jan. 26, 2018) (online at https://www.ftc.gov/news-events/press-releases/2018/01/ftc-announces-annual-update-size-transaction-thresholds-premerger) (announcing the 2018 price threshold that would require a premerger notification is $84.4 million).

31. FURROW ET AL., *supra* note 6, at 1165.

32. 15 U.S.C. § 45(a)(2) (2006).

33. FURROW ET AL., *supra* note 6, 1165.

34. *The Enforcers*, FED. TRADE COMM'N, https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/enforcers (last visited March 18, 2018) [hereinafter

merger or acquisition agreement between two companies based on either "premerger notification filings, correspondence from consumers or businesses, congressional inquiries, or articles on consumer or economic subjects."[35] After the investigation is completed and the FTC concludes that a company's proposed merger "unreasonably restrains trade," the FTC will offer a company a consent agreement that binds a company to comply with the antitrust laws.[36] If a company chooses to sign the consent agreement and violates it, then the FTC can pursue civil penalties or an injunction against that company.[37] If a company chooses not to sign the consent order, the FTC will pursue an administrative order or seek an injunction on the transaction to completely stop it from taking place.[38]

II. HOW HEALTHCARE INTERSECTS WITH ANTITRUST LAW

Due to lawmakers writing the antitrust statutes generally, federal courts have defined what antitrust violations are and how the statutes apply.[39] As a result of these cases arguing the application of the statutes, defenses to antitrust violations have emerged in the healthcare market.[40] One of these proposed defenses is that antitrust laws do not apply to the healthcare market.[41] In *Goldfarb v. Virginia State Bar,* the plaintiff argued that the medical field was a "learned profession" and that antitrust laws were not intended to apply to physicians because "learned professions" did not constitute as trade or commerce.[42] However, the Supreme Court explained that it could not find support that learned professions were exempt from the

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Enforcers].

35. *Id.*
36. *Id.*
37. *Id.*
38. *Id*.
39. FURROW ET AL., *supra* note 6, at 1165.
40. *Id.* at 1166.
41. Spencer Weber Waller, *How Much of Health Care Antitrust is Really Antitrust?*, 48 LOY. U. CHI. L.J. 643, 644 (2017).
42. Goldfarb v. Va. State Bar, 421 U.S. 773, 787 (1975).

Sherman Act.[43] Furthermore, the Court stated that Congress intended the Sherman Act to be extremely broad and to grant an exemption from it would contradict the purpose of the Sherman Act being written so broadly.[44] Thus, the defense that antitrust law does not apply to learned professions, such as the healthcare field, was not valid.[45]

Case law applying antitrust to healthcare continued to build from that point. In *Arizona v. Maricopa City Medical Society*, the Supreme Court reviewed the per se violation rule and the rule of reasoning in the context of the healthcare field.[46] The respondent argued that even though the case dealt with price fixing, there were procompetitive justifications to the price fixing, thus it did not violate antitrust laws.[47] However, the Supreme Court rejected this argument and said that because price fixing is a per se violation, the Court would not consider the procompetitive justifications because price fixing was inherently a violation of antitrust laws.[48] While there are several other cases involving antitrust and healthcare, these two cases lay the foundation of how antitrust applies to the healthcare market.

III. SEBCORP ENTERING THE HEALTHCARE MARKET

Considering the foregoing, SEBCorp will need to remain conscious of antitrust issues when entering the healthcare market. Its goal as a corporation is to become a large competitor in several different markets and entering the healthcare market is its next mission. While accomplishing this task, SEBCorp wants to earn a large amount of profit quickly, as it has done while entering other markets. Currently, SEBCorp does not contain an interest in any healthcare company and will likely enter the healthcare market through

43. *Id.*
44. *Id.*
45. *Id.*
46. Ariz. v. Maricopa Cnty. Med. Soc'y, 457 U.S. 332 (1982).
47. *Id.*
48. *Id.* at 351.

one of two options: (1) acquire a healthcare company and incorporate it into its online retail scheme or (2) choose to build its own healthcare company. There are benefits and drawbacks to both options. While the choice of strategy changes the antitrust math, it does not alter the fact that antitrust law applies. Based on its business needs to earn profit quickly and the ability to avoid violating antitrust violations, SEBCorp should consider acquiring an already existing healthcare company in order to be considered a competitor by other big healthcare companies.

A. Acquiring a Healthcare Company

The first option to entering the healthcare market would be for SEBCorp to merge with or acquire an already established healthcare company. An example of this would be for SEBCorp to invest in the pharmaceutical industry and acquire a pharmacy. The major benefit to this option is that SEBCorp will not have to be concerned with establishing itself within the healthcare market; the corporation that it acquires will already be established, and SEBCorp will simply take its consumers and add them to their client base. Additionally, this option is cost effective for SEBCorp because it will not have to build an inventory from the ground up. Rather, it can take the purchased corporation's inventory and incorporate it within their online shop by selling drugs online. However, throughout the acquisition, SEBCorp will have to comply with the antitrust laws and common law that were previously discussed in order to avoid facing the consequences of violating antitrust laws.

The major concern inherent in this route is that if SEBCorp purchases an already established healthcare company, the acquisition may be large enough that it will be required to submit a premerger filing to the FTC under Section Seven of the Clayton Act.[49] This will alert the FTC of the acquisition and

49. 15 U.S.C. § 18 (1996).

permit it to review the acquisition by conducting an investigation.[50] Depending on the result of the investigation, the FTC may seek an injunction on the acquisition if any antitrust laws are violated.[51] The FTC may pursue the injunction if it thinks that this acquisition will hurt consumers and give SEBCorp too much market power.[52]

However, SEBCorp may be able to defend the transaction against the FTC for several reasons. First, this is not a per se violation because it does not fall into one of the categories the courts established as a per se violation.[53] Although it was previously mentioned that courts refer to other forms of analysis rather than referring to the rule of reasoning tests, it is still possible for the court to use that analysis for SEBCorp due to the lack of per se violation. SEBCorp will likely be able to prove that it has more procompetitive than harmful effects to the consumer market for a few reasons. Mainly, SEBCorp will be expanding the market by entering it. Currently, consumers purchase their prescription drugs from a storefront pharmacy, but SEBCorp will begin selling prescription drugs online and using its large delivery service to get prescriptions to consumers. This will expand the pharmaceutical industry and influence other pharmaceutical companies to offer competitive services. Furthermore, because the delivery structure already exists within SEBCorp, it may be possible to reduce costs, which is beneficial for consumers.

The second defense that SEBCorp can present is that it is engaging in a vertical merger. As previously mentioned, the courts may use other forms of analysis to determine whether or not the acquisition violates the antitrust statutes, however, the other forms of analysis are predominantly for

50. 15 U.S.C. § 45(a)(2) (2006).
51. *Enforcers*, *supra* note 34.
52. 15 U.S.C. § 45(a)(2) (2006).
53. FURROW ET AL., *supra* note 6, at 1165 (listing per se violations as price fixing, market division, exclusive dealing, group boycotts, and tying arrangements).

horizontal mergers.[54] Unlike horizontal mergers, vertical mergers are a type of integration that antitrust law fails to sufficiently account for when considering market power of a corporation.[55] A horizontal merger is when a company merges with its competitor.[56] Horizontal mergers are heavily scrutinized by the FTC because they harm competition by eliminating one (possibly large) competitor in a market.[57] On the other hand, a vertical merger involves a buyer-seller relationship.[58] For example, a grocery store that purchases its produce from a specific farm decides to buy the farm. The grocery store is the final step in the supply chain before selling to consumers and it integrated a different part of the supply chain into its business. Vertical mergers are not scrutinized as much as horizontal mergers because they offer benefits to consumers since they "can generate significant cost savings and improve coordination of manufacturing or distribution."[59]

If SEBCorp chooses to purchase a pharmaceutical company or another health entity, it would be engaging in a vertical merger rather than a horizontal merger. It is a vertical merger because SEBCorp is acquiring a company from a market that it does not engage in yet, and thus, the health entity would not be its competitor. SEBCorp would be purchasing the supplier of the drugs and integrating it into its business in order to sell to consumers. Even though some vertical integrations make it difficult for competitors to access certain products or have other anticompetitive effects,[60] there is a gray area within antitrust laws that allows corporations, such as SEBCorp, to continue growing and gaining more market power. This gray area is a result from the lack of enforcement of antitrust laws against vertical

54. *See* FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES (Aug. 19, 2010) https://www.ftc.gov/sites/default/files/attachments/merger-review/100819hmg.pdf.
55. Khan, *supra* note 3, at 792.
56. *Competitive Effects*, *supra* note 4.
57. Waller, *supra* note 41, at 659.
58. *Competitive Effects*, *supra* note 4.
59. *Id.*
60. *Id.*

integration due to the procompetitive effects that it may have on the market.[61] Therefore, SEBCorp's acquisition is most likely to pass all the tests involved for determining if the transaction violates any antitrust laws and provides benefits to consumers.

B. Creating its Own Healthcare Company

The second option that SEBCorp could pursue to enter the healthcare market would be to create its own healthcare company. Creating a company from scratch would be a new process for SEBCorp, since SEBCorp's business strategy is to acquire already-established companies when entering new markets in the past.[62] SEBCorp would be less concerned with antitrust laws in this scenario because this route does not pursue a merger or acquisition—SEBCorp would be building up a market share, rather than simply acquiring one. Therefore, there should not be a concern with SEBCorp taking over the market and violating the antitrust statutes. Moreover, this would be a procompetitive move because a completely new company entering the healthcare market would create new options for consumers rather than limit options.

However, this strategy is not an optimal choice for SEBCorp. This option does not align with SEBCorp's business strategy it historically used when entering new markets to expand. Therefore, it may be a burden because it would be a large cost to enter the market and not provide substantial profits from the business as quickly as SEBCorp had done in the past. Additionally, since SEBCorp's strategy is to buy a company that is already established in the specific market with its own clients, this route would require SEBCorp to establish new clients. This may prove to be difficult for SEBCorp because it may require more time and money that the company is willing to invest.

61. Khan, *supra* note 3, at 732-36.
62. *Id.* at 748-47.

Overall, this option results in a larger burden than SEBCorp may be willing to inherit.

IV. CONCLUSION

A large, online corporation like SEBCorp trying to enter the healthcare market needs to consider antitrust laws when doing so. The company will need to take into account whether it is participating in a horizontal merger or engaging in an acquisition that will appear to stifle competition.[63] If so, the company is more likely to violate antitrust laws than a company that is engaging in a vertical merger. If the corporation needs to defend the transaction, then it would need to discuss the procompetitive benefits that it is providing for the healthcare market.[64] If SEBCorp chooses to pursue the recommended route, then it will most likely get past these concerns.

Similar to SEBCorp, Amazon may consider the two options as part of their plan to enter the healthcare market. However, since the announcement that Amazon released in January was vague in terms of how Amazon plans to enter the healthcare market,[65] it is unclear what the company will ultimately decide. Although SEBCorp is a fictional entity, the antitrust implications it hypothetically faces are the same as those faced by Amazon. As similarly-situated corporations eye the profits and pitfalls of the healthcare market, they should consider many strategies to be able to adapt and change.

63. *See* 15 U.S.C. § 18 (1996).
64. *See* FURROW ET AL., *supra* note 6, at 1167.
65. Lombardo et al., *supra* note 1.

Health Insurance in Collegiate Athletics: Why it should be Nationally Regulated

Brianna Jenkins

I. INTRODUCTION

Sports fanatics know more today about their favorite athletes' injuries than ever before, which places great weight on the ways in which colleges and universities care for their athletes. To understand the impact this issue has had at the college level, we must first understand the body that governs intercollegiate athletics and the policies in place for handling student-athlete injuries. The National Collegiate Athletic Association (NCAA) governs intercollegiate athletics,[1] it was founded in 1906 to protect college students from dangerous and exploitative athletic practices.[2] The NCAA is a member-led organization made up of colleges and universities tasked with maintaining intercollegiate athletics, as well as assuring that student-athletes prioritize their academics over their sport,[3] so states the NCAA on its official website.[4]

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[1] *College Athletics – The National Collegiate Athletic Association*, STATE UNIVERSITY.COM, http://education.stateuniversity.com/pages/1851/College-Athletics-NATIONAL-COLLEGIATE-ATHLETIC-ASSOCIATION.html (last visited Feb. 23, 2018) [hereinafter *College Athletics*].
[2] Dan Treadway, *Why Does the NCAA Exist?*, https://www.huffingtonpost.com/daniel-treadway/johnny-manziel-ncaa-eligibility_b_3020985.html (last updated Dec. 6, 2017).
[3] *See College Athletics*, *supra* note 1.
[4] *What is the NCAA?*, NCAA, http://www.ncaa.org/about/resources/media-center/ncaa-101/what-ncaa (last visited Apr. 27, 2018).

In the early 1900s in response to public outcry that football was too dangerous the NCAA was formed to improve the safety of college athletes.[5] Naturally, building off of their whole basis for existing the NCAA created rules governing insurance policies for athletes involved in intercollegiate sports.[6] Student-athletes, before they can participate in any collegiate sport, must have insurance covering injuries sustained during practice or competition.[7] This insurance can either come from a parent, the school, or it may be left up to the student-athlete to purchase a policy.[8] The NCAA's catastrophic insurance plan covers a student-athlete's injuries arising from practice or competition, but only in the event that the expenses for the injury reach $90,000.[9]

While the NCAA has the catastrophic insurance plan, it is still at the discretion of every college and university to create their own health insurance policy regarding the coverage of sport injury-related expenses.[10] Because some schools accept responsibility, but others do not, and are not required to be transparent on this issue, it can leave athletes and their families confused, frustrated, and oftentimes, floating the bill.[11] Not to mention, the

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[5] *See* Treadway, *supra* note 2.
[6] *Question…Is Health Coverage-Insurance Provided for NCAA College Athletes?*, https://www.athleticscholarships.net/athleteshealth.htm (last visited Feb. 23, 2018).
[7] *Insurance Coverage for Student-Athletes*, NCAA, http://www.ncaa.org/about/resources/insurance/insurance-coverage-student-athletes (last visited Feb. 23, 2018).
[8] Jon Solomon, *College Athletes' Rights: NCAA Requires Health Insurance, but Schools Decide What to Pay*, (Feb. 19, 2012, 7:55 AM), http://www.al.com/sports/index.ssf/2012/02/college_athletes_rights_ncaa_r.html [hereinafter *College Athletes' Rights*] (stating that schools such as the University of Alabama and Auburn are among few schools to provide information showing that they take responsibility for all medical expenses regarding injury); *see also* Kristina Peterson, *College Athletes Stuck With the Bill After Injuries*, (July 15, 2009), https://www.nytimes.com/2009/07/16/sports/16athletes.html (providing examples of colleges that pay medical expenses for injured athletes, in addition to those that do not and the associated hardships plaguing injured athletes whose schools does not pay medical expenses).
[9] *Insurance Coverage for Student-Athletes*, *supra* note 7.
[10] *Question…Is Health Coverage-Insurance Provided for NCAA College Athletes*, *supra* note 6.
[11] *College Athletes' Rights*, *supra* note 8.

catastrophic insurance plan does not completely protect athletes who were severely hurt in school, and suffer lasting effects after leaving their college or university.[12] Additionally, many insurance plans may not cover much of a bill when an athlete is injured playing varsity sports, it may exclude varsity sports injuries all together, and they may even limit out-of-state treatment.[13]

There needs to be further regulation of health insurance for student-athletes, either at the state or federal level. First, this article will address the policies that universities have in place regarding student-athlete health insurance. Next, it will explore remedies such as a state statutory mandate to require colleges to cover all medical expenses regarding athletic injuries, the improvement of the scholarship format, consisting of requiring multi-year scholarships to avoid universities revoking student-athlete scholarships in situations where they are not healthy enough to play and briefly touching on paying players. Last, this article will briefly examine insurance for athletes after they have left school and discuss current practices and policies at the state level.

II. UNIVERSITY POLICIES ON STUDENT-ATHLETE HEALTH INSURANCE

Majority of student-athletes are on scholarship, but what many of them do not know is that if they are injured, not only can their scholarships be revoked, but those same scholarships do not cover medical expenses and schools are not required to do so.[14] Today, the NCAA has put in place the catastrophic insurance program to provide medical care for "student-athletes, student coaches, student managers, student trainers or student cheerleaders

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[12] *Id.*
[13] *See* Peterson, *supra* note 8.
[14] Smriti Sinha, *The NCAA's Shameful Failure to Insure Its Athletes*, VICE SPORTS (Nov. 5, 2014, 11:50 AM), https://sports.vice.com/en_us/article/pg54gg/the-ncaas-shameful-failure-to-insure-its-athletes.

who are injured catastrophically during a covered event."[15] However, this is a disservice to student-athletes because the NCAA's catastrophic insurance program, not only goes into effect once expenses reach an amount greater than $90,000,[16] but also requires that every student-athlete who plans to participate in a collegiate sport have insurance covering sports-related injuries.[17] However, NCAA member schools are not required to pay for that insurance.[18] Because schools are not legally obligated to offer assistance to athletes they are often left to cover medical expenses that reach into the thousands.[19]

Some schools, however, have chosen to cover medical expenses and much more, like the University of Alabama, which covers medical, dental, and rehabilitation expenses for student-athletes.[20] Unfortunately, there are schools that cannot afford to completely cover the medical expenses of their athletes, for instance, before school coverage can kick in, the University of Maine requires student-athletes to be responsible for co-pays, deductibles, and other expenses up to $10,000.[21]

Moreover, it is equally important to note that not only do schools have the right to decide to cover medical expenses, but also to offer multi-year or one-year renewable scholarships.[22] The type of scholarships schools offer are important when discussing health coverage for student-athletes because with

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[15] Corry McCune, *NCAA Policies for Student-Athlete Medical Insurance Breakdown*, BLEACHER REPORT (Apr. 8, 2013), http://bleacherreport.com/articles/1595326-ncaa-policies-for-student-athlete-medical-insurance-breakdown.
[16] *Id.*
[17] Sinha, *supra* note 14.
[18] *Id.*
[19] *Id.*; *see also* Justin Brown, *The Ins and Outs of NCAA Student Athlete Insurance*, PROPERTY CASUALTY 360 (Mar. 24, 2014), https://www.propertycasualty360.com/2015/03/24/the-ins-and-outs-of-ncaa-student-athlete-insurance/ (explaining how families are left in in the gap between what, if anything, the school pays and what their insurance covers).
[20] Chelsea L. Dixon, *When Student-Athletes Get Injured, Who Pays*, NOODLE (Oct. 27, 2015), https://www.noodle.com/articles/when-student-athletes-get-injured-who-pays134.
[21] *Id.*
[22] *Id.*

one-year renewable scholarships, schools, at the end of the year can decide whether or not to release a player, usually an injured player from scholarship, in turn leaving them with any sport injury-related expenses.[23] On the other hand, if schools were required to offer multi-year scholarships the practice of releasing injured players would be obsolete because multi-year scholarships guarantee a player a scholarship for at least four years.[24]

III. SOLUTIONS/REMEDIES

Schools need to be held accountable because it is up to them to ensure the well-being of their athletes. In 2012, both the Pacific 12 Conference (Pac-12) and Big 10 Conference promised guaranteed, four-year scholarships and health insurance improvements.[25] The Pac-12 went as far as to say that "student athletes who receive scholarships will have four years of funding regardless of the sport a student plays, which can't be reduced or canceled for any reason so long as the student remains in good academic standing and fulfills the terms of their scholarship."[26] Guaranteed, four-year scholarships are an important starting point, but the issue is whether these institutions will honor their commitments. Because conferences are not required to offer more than one-year scholarships, universities are not bound to follow through on their promises.[27] Therefore, the best way to guarantee change is to pass a binding requirement mandating that all NCAA member institutions offer four-year scholarships.[28]

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[23] *Id.*
[24] *Id.*
[25] Sinha, *supra* note 14; *see also* BIG TEN CONFERENCE, http://www.bigten.org/school-bio/delany-bio.html (last visited Apr. 27, 2018) (discussing reform to scholarship format and health insurance); PAC-12 CONFERENCE, http://pac-12.com/article/2014/10/27/pac-12-universities-adopt-sweeping-reforms-student-athletes-guaranteeing (last visited Apr. 27, 2018) (highlighting promise to improve student-athlete health insurance and reform scholarship format).
[26] Dixon, *supra* note 20.
[27] Sinha, *supra* note 14.
[28] *Id.*

Further, in the interest of protecting its student-athletes, the NCAA could also look to revise its policies regarding student-athlete insurance coverage.[29] Paying partial or no medical expenses and offering one-year renewable scholarships is not in the best interest of the student-athlete. I propose that there be a mandate placed on all NCAA institutions to provide four-year scholarships and in a provision within the scholarship outlining a full health care coverage plan, which will be discussed in part B of this section.

A. Multi-Year Scholarships

Since 2012, the NCAA has permitted, but not required, institutions to offer multiyear scholarships.[30] However, after a recent vote amongst the five major Division I sports conferences (the Power Five), which includes the Southeastern Conference (SEC), Atlantic Coast Conference (ACC), Pac-12, Big 10 and Big 12 Conference, their member schools agreed to provide guaranteed, four-year athletic scholarships.[31] However, student-athlete participation does not stop with those five conferences, the NCAA's Division I is made up of nearly three-hundred and fifty universities, more than 6,000 athletic teams, and 170,000 athletes.[32] The Power Five only makes up sixty-five of those universities and one-hundred nine of those teams.[33] Thus the Power Five's decision to mandate guaranteed, four-year athletic scholarships is a move forward in ensuring the well-being of their athletes, but it nonetheless benefits a minority of NCAA member schools offering

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[29] Dixon, *supra* note 20.
[30] Jon Solomon, *Schools can give out 4-year athletic scholarships, but many don't*, CBS SPORTS (Sept. 16, 2014), https://www.cbssports.com/college-football/news/schools-can-give-out-4-year-athletic-scholarships-but-many-dont/.
[31] Rick Allen, *The Facts About "Guaranteed" Multi-year NCAA DI Scholarships*, INFORMED ATHLETE (June 12, 2015), https://informedathlete.com/the-facts-about-guaranteed-multi-year-ncaa-di-scholarships/.
[32] *NCAA Division I*, NCAA, http://www.ncaa.org/about?division=d1 (last visited Apr. 30, 2018).
[33] *Id.*; *see also Power 5 Conferences Schools*, LIST CHALLENGES, https://www.listchallenges.com/power-5-conferences-schools/checklist/2.

scholarships.[34] A majority of schools may still revoke a scholarship at the end of the year without cause, and for injured players, that can prove to have serious monetary consequences.[35] Though it may be unusual for a student-athlete to lose his or her scholarship due solely to injury, it is a possibility and thus to avoid scholarships being revoked after one-year we need to require multi-year scholarships.[36] Ultimately, absent a scholarship, a student-athlete would potentially be left responsible for the entirety of his or her own medical bills – which may be in the thousands of dollars - out of pocket.[37] Thus, the reward of a free education that many base their arguments against multi-year scholarships off of means nothing if left to the discretion of a coach who could revoke a scholarship without cause.[38] Nonetheless, the current trend today is optimistic, from 2012 where the NCAA encouraged the use of multi-year scholarships,[39] to the Power Five vote to require them,[40] to hopefully it becoming the standard throughout the NCAA via a legally binding requirement.

While allowing institutions to offer multi-year scholarships and actually having conferences do just that is a step in the right direction, it is still lacking in actual progress because NCAA conferences and subsequently their schools are still given the option not a requirement. The same problem remains – schools have a choice whether to act fairly, not a requirement.[41]

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[34] Solomon, *supra* note 30.
[35] *Id.*
[36] Ben Strauss, *A Fight to Keep College Athletes from the Pain of Injury Costs*, N.Y. TIMES (Apr. 24, 2014), https://www.nytimes.com/2014/04/25/sports/a-fight-to-keep-college-athletes-from-the-pain-of-injury-costs.html.
[37] Sinha, *supra* note 14.
[38] Josh Levin, *The Most Evil Thing about College Sports*, SLATE (May 17, 2012, 7:50 PM), http://www.slate.com/articles/sports/sports_nut/2012/05/ncaa_scholarship_rules_it_s_morally_indefensible_that_aathleti_scholarships_can_be_yanked_after_one_year_for_any_reason_.html.
[39] Sinha, *supra* note 14.
[40] Allen, *supra* note 31.
[41] Sinha, *supra* note 14.

B. Full Health Insurance Coverage

One possible change is for conferences and their participating schools to provide full health insurance coverage. In this context, full health insurance coverage would look something like the University of Alabama's coverage plan. Alabama covers the complete cost of medical, rehabilitation and custodial care expenses for injuries resulting from an official team activity, conditioning or practice session.[42] Basically, health insurance is through the scholarship and the school's insurance plan would then become the athletes' primary provider. Further, to be transparent, these schools should recommend that their players carry accident/illness insurance to cover issues not related to athletic events, because injuries not sustained in an athletic activity will not be covered under the school's primary medical coverage.

C. Pay for Play

Paying student-athletes is another commonly-discussed solution to the issue of insurance for amateur athletics. In reality, the prospect of considering student-athletes as employees is a major hurdle with many obstacles.[43] There was a small victory for college athletes in the North Western ruling, where the Chicago District (Region 13) of the National Labor Relations Board (NLRB) ruled that Northwestern University football players qualified as employees and can unionize and bargain collectively.[44]

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[42] *College Athletes' Rights*, *supra* note 8.
[43] Kathryn Kisska-Schulze & Adam Epstein, *"Show Me the Money!"—Analyzing the Potential State Tax Implications of Paying Student-Athletes*, 14 VA. SPORTS & ENT. L.J. 9, 13 (2014) (stating that some major obstacles include the classification from student-athlete to employee, the tax implications to the schools and players, as well as school shopping, in the sense that athletes would be more prone to shop for the schools that can offer them more money); *see also* Editorial Board, *Pay for Play and Title IX*, N.Y. TIMES (Mar. 22, 2014), https://www.nytimes.com/2014/03/23/opinion/sunday/pay-for-play-and-title-ix.html (discussing how to accommodate Title IX in the pay for play scheme).
[44] Brian Bennett, *Northwestern Players Get Union Vote*, ESPN (Mar. 27, 2014), http://espn.go.com/college-football/story/_/id/10677763/northwestern-wildcats-football-players-win-bid-unionize.

However, that ruling has since been overturned on appeal, preserving one of the NCAA's core principles: that college athletes are primarily students.[45]

IV. POST-COLLEGE HEALTH BENEFITS

Not only is health insurance for enrolled student-athletes a major concern, but there is also a concern for the health and well-being of student-athletes after graduation. It would be remiss not to note that the NCAA in regard to career ending injuries and lingering effects have implemented two programs, the Exceptional Student-Athlete Disability Insurance Program (ESADIP) and the enhancement of the catastrophic insurance program. However, why it is not enough will be discussed in this section.

Athletes may not only be responsible for medical expenses incurred during enrollment in school, but may also amass health care expenses related to injuries even after leaving school.[46] Generally, once an athlete leaves school any lingering effects from injuries sustained while playing is not covered by a university's or the NCAA's medical insurance.[47] Schools have the choice to pay for medical expenses, and since college athletes are not considered employees, there is no workers' compensation when they get injured and can no longer play.[48] Many of these colleges generate massive profits through college athletics, like the University of Louisville, which generated more than $40 million through its basketball program in 2012,[49] or Texas A&M, which generated $37 million in exposure in 2013 due to Heisman trophy

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[45] Ben Strauss, *N.L.R.B. Rejects Northwestern Football Player's Union Bid*, (Aug. 17, 2015), https://www.nytimes.com/2015/08/18/sports/ncaafootball/nlrb-says-northwestern-football-players-cannot-unionize.html.
[46] Bill Pennington, *When Injured Athlete Leaves Campus, College's Responsibility Ends*, N.Y. TIMES (Apr. 4, 2013), http://www.nytimes.com/2013/04/05/sports/ncaabasketball/broken-leg-renews-focus-on-college-athletes-health-insurance.html.
[47] *Id.*
[48] *Id.*
[49] *Id.*

winner Johnny Manziel.[50] However, if Manziel was to get injured and could no longer play, and suffered from long-term effects, the school has no legal obligation to help with any medical expenses.[51] This is one of the biggest loopholes for the NCAA and its member schools – they do not have to pay any medical expenses for a former student-athlete once that athlete is no longer enrolled and under scholarship.[52]

This is why this past January the power five conferences got together to make changes to everything from medical care to basketball during the holidays.[53] In regard to medical coverage, these conferences voted in favor of extending medical coverage two-years post-college for players who suffered injuries during their college careers.[54] This was a huge move in the right direction, however, the first of two concerns is that student-athletes in the power five conference don't make up all of student-athletes, there needs to be some consideration to schools outside of the richest conferences. Meaning, what about those athletes at schools with less money, the costs of a change of this magnitude for such school may be prohibitive, thus the NCAA may need to step in and assist in helping those schools implement such a change.[55] The second concern is in the time limit, two-years is not enough, the Pac-12 had the right idea in extending help four-years post college, the same amount as player eligibility. Though this is a move forward, there are still small tweaks that can be made to ensure athletes are well protected.

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[50] Treadway, *supra* note 2.
[51] Pennington, *supra* note 46.
[52] Corry McCune, *NCAA Policies for Student-Athlete Medical Insurance Breakdown*, BLEACHER REP. (Apr. 8, 2013), http://bleacherreport.com/articles/1595326-ncaa-policies-for-student-athlete-medical-insurance-breakdown.
[53] Michael Marot, *Power Five conferences approve 11 new measures, including medical benefits extension and holiday break for hoops*, (Jan. 19, 2018, 6:20 PM), http://www.chicagotribune.com/sports/college/ct-power-five-conferences-approve-medical-benefits-extension-20180119-story.html.
[54] *Id.*
[55] *Id.*

Further, in the past two years, the NCAA has also made changes in creating the Exceptional Student-Athlete Disability Insurance Program (ESADIP), supplementing the catastrophic insurance coverage, and also enhancing the catastrophic insurance coverage for athletes who suffered from debilitating injuries.[56] The ESADIP was created for student-athletes that are projected to be selected in the first three rounds of the NFL, MLB, WNBA drafts or drafted at all for the NBA, since there are only two rounds.[57] The ESADIP allows for student-athletes who meet the criteria to get disability insurance with pre-approved financing.[58] However, this program excludes those student-athletes that aren't drafted during those first three rounds, as well as those that aren't drafted at all.[59] Then, there is the catastrophic insurance program, which was enhanced to include lifelong coverage to student athletes suffering from a permanent physical disability with medical bills expected to exceed $90,000.[60] The problem here is that this enhancement excludes athletes who don't quite suffer from a serious debilitating injury, such as a spinal cord injury, which left one player unable to operate a vehicle, but the player is injured enough to have lasting effects and/or any athlete whose medical bills do not exceed $90,000.[61]

Although the ESADIP and the enhancement of the catastrophic insurance program represents a move in the right direction, improvements still need to be made to better serve student-athletes. First, it may be best to extend the ESADIP to all athletes, not just those who are projected to turn pro, all athletes deserve to be protected from debilitating injuries, however for

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[56] McCune, *supra* note 52.
[57] *Id.*
[58] *Id.*
[59] *Id.* (stating that the rationale behind the ESADIP in protecting the high draft pick players was "to keep the student-athletes away from agents that would promise them insurance if the student-athlete would sign with them when they went pro").
[60] Brian Burnsed, *NCAA Catastrophic Injury Coverage Enhanced*, NCAA (Aug. 9, 2016, 10:00 AM), http://www.ncaa.org/about/resources/media-center/news/ncaa-catastrophic-injury-coverage-enhanced.
[61] *Id.*

smaller institutions it may not be affordable and there is also skepticism regarding if the ESADIP actually provides the "help" it sets out to.[62]

Second, the enhancement of the catastrophic insurance program would be better modeled after the PAC 12's mandate that coverage will extend to four years (amount of player eligibility) post-attendance for athletes who suffer from lasting effects of injury.[63] Basically, the student-athletes would have post-college coverage for the same number of years that they are eligible for competition. This means that majority of the athletes will receive at least four years of post-coverage.

A third option would be to follow the NFL's insurance benefits package. The NFL's insurance benefits package, which was created specifically to protect players, could serve as an excellent model. That package includes: The Player Insurance Plan, the Health Reimbursement Account (HRA) Plan, the Long-Term Care Insurance Plan and the Former Player Life Improvement Plan.[64] Each plan was designed to benefit the player in the long-term. For instance, the Player Insurance Plan provides players with life insurance, medical coverage, dental coverage, and wellness benefits.[65] One important aspect of the wellness benefits that should be noted is that players are given access to clinicians for mental health, alcoholism and substance abuse, which all have been major concerns when dealing with athletes.[66]

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[62] *but cf.* Marc Isenberg, *The "Student-Athlete Disability Insurance Program" Isn't What The NCAA Cracks It Up To Be*, COACHING FOR SUCCESS (Mar. 20, 2013), http://coachgeorgeraveling.com/the-student-athlete-disability-insurance-program-isnt-what-the-ncaa-cracks-it-up-to-be/ (explaining that the ESADIP may not actually help like it states it does).

[63] Dixon, *supra* note 20.

[64] Christopher R. Deubert et al., *Comparing Health-Related Policies & Practices in Sports: The NFL and Other Professional Leagues*, FOOTBALL PLAYERS HEALTH STUDY AT HARVARD UNIV. 107, 127 (2017), https://footballplayershealth.harvard.edu/wp-content/uploads/2017/05/Harvard-Comparative-League-Analysis-5.15.17.pdf. (stating that their benefits package includes: "(1) retirement benefits; (2) insurance benefits; (3) disability benefits; (4) workers' compensation benefits; (5) education-related benefits; and, (6) the existence of health-specific committees jointly run by the league and players association").

[65] *Id.* at 113.

[66] *Id.*

The Health Reimbursement Account (HRA) Plan, helps to pay out-of-pocket healthcare expenses after a player is no longer employed by an NFL team and the coverage under the Player Insurance Plan has ended.[67] The Long-Term Care Insurance Plan provides medical insurance to cover the costs of long-term care for former NFL players, and was mainly created for players who suffer debilitating injuries by providing a maximum of $150 a day for four years.[68] Finally, the Former Player Life Improvement Plan "permits qualifying former players (and in some cases their dependents) not otherwise covered by health insurance to receive reimbursement for medical costs for 'joint replacements, prescription drugs, assisted living, Medicare supplemental insurance, spinal treatment, and neurological treatment.'"[69]

The NCAA has options – they can provide medical care for up to the amount of player eligibility or they can take what the NFL has laid out and rework it to fit in a collegiate framework. The NCAA could also pitch in and help out the schools who are less fortunate, so they too can extend medical coverage. There are too many injured student-athletes who can no longer do what they love and cannot afford their medical expenses - it is up to the universities and colleges to do more and for the NCAA to back them in doing so.

V. PROPOSED INTERVENTION AT THE STATE LEVEL

Ultimately, there needs be some outside force regulating how health insurance is handled for student-athletes. Leaving it up to the discretion of the schools does not benefit the athletes. Regulation at the state level would ensure that schools are not given a choice, but rather a requirement to improve health insurance for student-athletes. The state of Connecticut, for example, started in the right direction by adopting laws requiring public

[67] *Id.*
[68] *Id.* at 114.
[69] *Id.*

schools to put their medical policies in writing.[70] This allows for transparency between the schools that are recruiting these players and their families, who are now able to see what the school will pay if there is an injury, the costs of premiums, as well as deductibles and co-payments.[71] It will also show them how long medical expenses are covered after an athlete's eligibility expires.[72] This eliminates confusion and frustration for athletes and their families when it comes to knowing what the school will cover and what families will have to pay, but it does nothing to help student-athletes whose schools choose not to pay for anything.

Connecticut is not the only state to enact regulation regarding student-athlete health insurance, California enacted the Student-Athlete Bill of Rights.[73] The Student-Athlete Bill of Rights holds colleges and universities that generate more than $10 million in athletic media revenue responsible for paying deductibles for student-athletes who suffer sports-related injuries, and further requires these schools to offer guaranteed scholarships.[74] The legislation assures student-athletes that in the event that their scholarship is revoked due to a debilitating injury or illness, the university must provide them with an academic scholarship of equal value.[75] Furthermore, if an athlete is injured in the course of their duties the college is responsible for insurance deductibles as well as, insurance premiums for low-income student-athletes.[76] California understood that these athletes are risking their health and wellness, and thus require greater protection.[77]

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[70] *College Athletes' Rights*, *supra* note 8.
[71] *Id.*
[72] *Id.*
[73] Michelle A. Winters, *In Sickness and in Health: How California's Student-Athlete Bill of Rights Protects Against the Uncertain Future of Injured Players*, 24 MARQ. SPORTS L. Rev. 295, 297 (2013).
[74] Dixon, *supra* note 20.
[75] Winters, *supra* note 73, at 297.
[76] *Id.*
[77] *Id.* at 299.

With California's new bill, student-athletes at schools with more than $10 million in media revenue have the assurance that if they sustain an injury while participating in college athletics, they will receive proper medical care, which they do not have to worry about paying for.[78] Not only will they receive proper medical care while enrolled in school, but also schools are required to provide necessary medical treatment or health insurance for injuries that require continuous treatment, which will continue for a minimum of two years following the student-athlete's graduation or separation from the institution.[79] Knowing that medical expenses will be taken care of allows the players to play without fear of losing their access to healthcare, and gives coaches something they can use as a recruiting tool to show the superiority of their school.[80]

However, the Student-Athlete Bill of Rights falls short on three major points. First, coverage only extends two years post-college.[81] The same problem with the power five conferences extension of medical coverage. Perhaps it would be better if it extended to four years, such as in the Pac-12's mandate, where coverage length is based in the amount of eligibility a player normally receives.[82] Second, this bill is mostly helpful to Division I athletes whose schools received more than $10 million in media right deals and have wide profit margins. It does not address nor really help smaller schools that may not have received mega media deals or schools who did not turn a profit, but whose players are still putting their bodies on the line. In 2010, only twenty-two schools actually returned a profit.[83] This bill should apply to schools without consideration of profit margins and media revenue. Though, there is some concern to whether or not these smaller schools can actually

[78] *Id.*
[79] *Id.*
[80] *Id.* at 320-21.
[81] *Id.* at 318.
[82] Dixon, *supra* note 20.
[83] Winters, *supra* note 73, at 321.

afford such an insurance program since they do not have the media deals or profits to support it. However, there is no perfect solution, but this is a step in the right direction and an improvement on what is in place nationally now. This bill unequally depends on the wealth of the athletic program, which in the end harms athletes participating in Division II or III programs. In the end it should not matter how much money the school brings in, at a minimum all NCAA institutions should provide medical care paid for by the school, especially for sports where injury is inevitable, and that sport brings in millions to the institution. Lastly, this bill unfortunately will become inoperative on January 1, 2021, and all the benefits it brings will cease.[84]

Though the Student-Athlete Bill of Rights can be improved, it still gives student-athletes protection. Like California, other states should be involved in ensuring that these young athletes have health insurance and scholarship protection.

Pointing out the shortcomings of these laws is not meant to take away from the benefits they will bring to student-athletes. The California bill will greatly reduce the costs to players and give athletes who can no longer play the opportunity to still pursue their education. The Connecticut law may help force some schools to come up with better health insurance policies since they will have to put them in writing and show them to potential players and their families. Both of these states are paving the way for future legislation, hopefully in many more states to come.

VI. CONCLUSION

State involvement is vital in collegiate athletics, especially in the more dangerous sports, like football. California and Connecticut requiring public schools to follow a specific set of rules when it comes to injured student-

[84] *Id.* at 318.

athletes helps regulate health insurance and benefits for student-athletes. Without state laws regulating universities, the well-being of student-athletes will continue to be at the discretion of schools, that can choose to prioritize their athletes' health, or continue to ignore it. These educational institutions and the NCAA should be required to do more when it comes to student-athletes who are putting their bodies in harm's way on a daily basis in order to keep a scholarship that may or may not be taken away with injury. It is not enough to leave health insurance plans for student-athletes up to individual colleges or universities. Requirements for these plans must be mandated uniformly, and the best way to begin is with state legislation.

Authorized Generics through the Hatch Waxman Act—Smart Business Plan of Big Pharma or Denial of Cheaper Pharmaceuticals for Consumers?

Sarah Johnson

When the Hatch-Waxman act was passed in 1984,[1] it revolutionized the pharmaceutical industry in a number of ways. Primarily, it allowed generic drugs faster entry into the market and an exclusive marketing period if they were the first generic to be approved through the FDA.[2] These provisions resulted in major competition for the name-brand pharmaceutical companies[3] and left them without reprise to fix this deficit, or so they thought. In recent years, the name-brand companies are finding a loophole that is incredibly useful for their business—authorized generics.[4]

Authorized generics are generic pharmaceuticals that are either manufactured by the name-brand pharmaceutical company themselves or generic pharmaceuticals that the name-brand company contracts with a generic manufacturer to produce.[5] This system allows the brand-name manufacturer to lead the charge on the generic market and thus discourages independent generic pharmaceutical companies from producing their own

1. Lisa BARONS PENSABENE & DENNIS GREGORY, HATCH-WAXMAN ACT: OVERVIEW 1 (2013), https://www.fitzpatrickcella.com/wp-content/uploads/Hatch-Waxman-Act-Overview-lpensabene_dgregory.pdf.

2. *Id.*

3. Margaret Hamburg, *Celebrating 30 Years of Easier Access to Cost-Saving Generic Drugs*, FDA VOICE (Sept. 24, 2014), https://blogs.fda.gov/fdavoice/index.php/tag/drug-price-competition-and-patent-term-restoration-act-of-1984/.

4. Martha Rumore, *The Hatch-Waxman Act—25 Years Later: Keeping the Pharmaceutical Scales Balanced*, PHARMACY TIMES (Aug. 5, 2009), http://www.pharmacytimes.com/publications/supplement/2009/genericsupplement0809/generic-hatchwaxman-0809.

5. *Id.*

drugs and facing a net loss in profit.[6] This loss of profit may render devastating financial problems for generic pharmaceutical companies. In addition, there are antitrust implications because the generic companies are unable to compete in the market, which leads to the big name-brand pharmaceutical companies controlling and monopolizing the market.[7] Furthermore, the Hatch-Waxman Act leads to trouble in patent law as it relates to the 180-day exclusivity grant.[8] If these large companies can pay big money in reverse settlements to ensure they never need to go to court for patent litigation suits they will effectively be given patent rights with little to no chance a non-authorized generic will be able to challenge them. In this article, I will argue that authorized generics should be more tightly regulated to avoid the patent and antitrust problems that arise from their allowance. Part I gives more detailed background on the Hatch-Waxman Act. Part II provides background on authorized generics. Part III details the antitrust problems introduced in this paragraph while Part IV discusses patent problems that have resulted from authorized generics. Finally, in Part V I will introduce practical solutions in this field.

I. THE HATCH-WAXMAN ACT

The Drug Price Competition and Patent Term Restoration Act was passed in 1984 and is commonly known as the Hatch-Waxman Act.[9] It is named for Senator Orrin Hatch and Representative Henry Waxman, who drafted the law.[10] Before the Hatch-Waxman Act, there was no separate provision to

6. *Id.*

7. Philip A. Proger & Michael H. Knight, *Antitrust Alert: FTC Releases Report on Authorized Generics*, JONES DAY, (Sept. 23, 2011), http://www.jonesday.com/Antitrust-Alert—FTC-Releases-Report-on-Authorized-Generic-Drugs-09-23-2011/.

8. Ernst R. Berndt et. al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, 26:3 HEALTH AFFAIRS 790, 791 (2007).

9. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified in scattered sections of 21 U.S.C., 35 U.S.C., and 42 U.S.C.).

10. *Id.*

address marketing approval for generic versions of drugs that had previously been approved by the Food and Drug Administration ("FDA") within federal food and drug law.[11] The Hatch-Waxman Act provided the ability to ensure generic drug quality while concurrently eliminating excessive research costs for the generic company.[12]The reduced research time and cost greatly accelerated access to more affordable medications.[13]

Before Hatch-Waxman, independent generic manufacturers were forced to prove that a particular drug was safe and effective through a multitude of clinical tests, even though their products were chemically identical ("bioequivalent")[14] to those of name-brand pharmaceuticals.[15] Instead of this rigorous and expensive process, generic companies could instead submit an Abbreviated New Drug Application ("ANDA") to the FDA which allows an independent generic applicant to receive marketing approval by demonstrating that the proposed generic is bioequivalent to the previously approved name-brand drug, without expensive clinical trials to prove safety and efficacy.[16] Alternatively, the generic company could turn in a Section 505(b)(2) application, which is sometimes called a "paper NDA."[17] Like a New Drug Application ("NDA") that is turned in for a brand-name drug, a

11. *See* Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA: JOURNAL OF LAW AND TECHNOLOGY (1999), 389 (stating that generic drug manufacturers were required to perform the same tests as the name-brand pharmaceuticals while being aware that they would need to market their drug for a lesser price).

12. Thomas Chen, *Authorized Generics: A Prescription for Hatch-Waxman Reform*, 93 VA. L. REV. 459, 464 (2007).

13. *Id.*

14. The FDA defines bioequivalence as, "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered in the same molar dose under similar conditions in an appropriately designed study." *See* 21 C.F.R. §320.1.

15. *See, e.g.*, Justina A. Molzon, *The Generic Drug Approval Process*, 5 J. OF PHARMACY & L. 275, 276 (1996).

16. *Id.*

17. WENDY SCHACHT & JOHN THOMAS, CONG. RESEARCH SERV., R41114, THE HATCH-WAXMAN ACT: A QUARTER CENTURY LATER (2011).

Section 505(b)(2) application contains a report of all clinical investigations of safety and effectiveness of the pharmaceutical product.[18] In contrast to a name-brand NDA, Section 505(b)(2) applications normally rely upon previously published works that provide pre-clinical or clinical data.[19]

In many cases, once the ANDA or paper NDA is approved through the FDA the manufacturer can place the approved bioequivalent drug on the market as soon as any relevant patents held by the name-brand company expire.[20] In exchange for this quicker entry into the market, Congress provided patent owners with a way to extend their patent term that may have run while awaiting FDA approval.[21] The extension period is capped at five years, making the total effective patent term not more than fourteen years.[22] The rights of the patent owners during the extension period is normally limited solely to the use of the product that was approved during the original regulatory process and therefore caused the regulatory delay.[23]

A company that wishes to sell a generic drug must receive marketing approval from the FDA as well as justify any patent rights that pertain to that product.[24] Before the ANDA or Section 505(b)(2) applicant is approved,

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18. GUIDANCE FOR INDUSTRY: APPLICATIONS COVERED BY SECTION 505(B)(2), FOOD & DRUG ADMIN. (1999).

19. *Id.*

20. AUTHORIZED GENERIC PHARMACEUTICALS: EFFECTS ON INNOVATION, CONG. RESEARCH SERV. 1 (2013) [hereafter EFFECTS ON INNOVATION]; 35 U.S.C. §156(b).

21. 35 U.S.C. §156(a) ("The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section. . .").

22. 35 U.S.C §156(c)(3) ("if the period remaining in the term of a patent after the date of the approval of the approved product under the provision of law under which such regulatory review occurred when added to the regulatory review period as revised under paragraphs (1) and (2) exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years. . .").

23. 35 U.S.C. §156(a) (stating that the extension begins at the end of the original patent.); 35 U.S.C.§156(a)(5)(A) (stating that other than two exceptions, the extension is granted for "first permitted commercial marketing or ise of the product under the provision of law under which such regulatory review period occurred" meaning the indication it was first approved for is the only use they are allowed to continue receiving exclusive marketing for is the use originally approved.).

24. EFFECTS ON INNOVATION, *supra* note 20.

they must declare what Orange Book listed patent is associated with the proposed drug to be marketed.[25] Four possible relationships between the proposed generic drug and the already approved brand-name drug exist: (I) the brand-name pharmaceutical company has not filed any patent information with respect to the drug in question; (II) the patent for the brand-name drug in question has already expired; (III) the proposed generic company agrees not to market until the date the patent will expire; or (IV) the patent is invalid or will not be infringed by the generic company.[26] These are commonly referred to as Section or Paragraph I through IV certifications.[27]

An ANDA or Section 505(b)(2) application certified under parts I or II of 21 U.S.C. § 355(j)(2)(A)(vii) will be approved immediately if it meets all applicable regulatory requirements.[28] A generic company that files an ANDA or Section 505(b)(2) application that claims a paragraph III certification must, even after meeting all regulatory requirements, wait for approval until the name-brand drug's listed patent expires.[29] Finally, the filing of any application with a paragraph IV certification initiates a "somewhat artificial" patent infringement under the Hatch-Waxman Act that requires the generic applicant to notify the name-brand company of the patents that are being discussed under the paragraph IV certification.[30] The patent owner normally responds to this notification with the beginning stages of patent infringement

25. 21 U.S.C. §355(j)(2)(A)(vii). The Orange Book identifies drug products that are approved by the FDA under the Food, Drug, and Cosmetic Act (FDCA) and all related patent and exclusivity information, see APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (ORANGE BOOK), FOOD & DRUG ADMINISTRATION available at https://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm (last updated Feb. 2018).

26. 21 U.S.C. §355(b)(2)(A)(i).

27. *See generally*, EFFECTS ON INNOVATION, *supra* note 20.

28. 21 U.S.C. §355(j)(5)(B)(i); 21 U.S.C. §355(j)(5)(B)(ii); 21 U.S.C. §355(j)(2)(B)(i).

29. 21 U.S.C. §355(j)(5)(B)(iii).

30. 21 U.S.C. §355(j)(5)(B)(iv); EFFECTS ON INNOVATION, *supra* note 20, at 4. This would not be a normal patent infringement as infringement occurs after the drug is made, used, bought, sold, etc. under the patent statute and the party holding the patent is normally the one to bring the case. Whereas, in this situation the generic company is telling the name-brand company that this is what they are doing.

litigation against the applicant.[31]

The Hatch-Waxman Act encourages the filing of these paragraph IV challenges by awarding a 180-day generic drug exclusivity period to the first patent challenger.[32] During this 180-day period, the name-brand company and the first generic company are the only companies allowed to sell that medication.[33] After this 180-day exclusivity period, generic competitors may receive approval from the FDA and enter the market which normally lends itself to lower prices for generic medicines.[34] The FDA may not approve any other ANDA containing a paragraph IV certification with respect to the same name-brand drug during the 180-day period.[35] Notably, this exclusivity applies to ANDA applicants only; it does not apply to 505(b)(2) applications.[36]

Name-brand companies frequently pursue litigation when receiving the paragraph IV challenge which automatically triggers a thirty-month stop in the FDA's approval of the ANDA until one of the following dates occurs: the patent expires, the litigation is completed, or the thirty months are over.[37] Though patent litigation is extremely expensive, the first generic applicant has the potential to obtain higher profits than subsequent filers as the introduction of more generics in the market causes the price to drop considerably due to competition.[38]

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31. EFFECTS ON INNOVATION, *supra* note 20, at 5.
32. *Id.* at 5-6.
33. *Id.* at 5.
34. *Id.* at 5-6.
35. 21 U.S.C. §355(j)(5)(B)(iv); CTR. FOR DRUG EVALUATION & RESEARCH, GUIDANCE FOR INDUSTRY: LISTED DRUGS, 30-MONTH STAYS, AND APPROVAL OF ANDAS AND 505(B)(2) APPLICATIONS UNDER HATCH-WAXMAN, AS MODIFIED BY THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003 10 (2004) [hereafter LISTED DRUGS].
36. *Id.* at 11.
37. 21 U.S.C. § 355(j)(5)(B)(iii); http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1003&context=ipbrief
38. EFFECTS ON INNOVATION, *supra* note 20, at 6; Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1064 (D.C. Cir. 1998).

Paragraph IV creates a generic industry model where generic companies race to file the first Paragraph IV certification hoping to successfully challenge the name-brand drug's patent(s) and obtain the larger profits of 180-day exclusivity.[39] This process serves as a vital patent oversight instrument to expose invalid patents and quicken access to generic drugs for consumers.[40] However, this process is being thwarted by the introduction of authorized generics to the market.

II. WHAT ARE AUTHORIZED GENERICS?

An "authorized generic" is a drug that is marketed by or on behalf of a name-brand pharmaceutical company while still being sold under a generic name.[41] These generics are also referred to as "branded," "flanking," or "pseudo" generics.[42] Authorized generics began to appear in the early 2000's likely because physicians, pharmacists, and patients started to switch to generic drugs as soon as they were available which would pull large amounts of profit from the name-brand company's pockets.[43] If a name-brand company decides to put this authorized generic plan to use and employ a generic company to produce a version of their patented drug before the patent term on the original drug has run there are steps it must follow.[44] Most relevant to this discussion, the name-brand company is required by Title XI of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 to notify the Federal Trade Commission (FTC) and Department of Justice (DoJ) within 10 days of any agreements involving the exclusivity

39. Chen, *supra* note 12, at 461.
40. *Id.* at 466.
41. EFFECTS ON INNOVATION, *supra* note 20, at 6.
42. *Id.* at 1.
43. Sandra Levy, *Why authorized generics are making a comeback*, DRUG TOPICS (Nov. 3, 2003) http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?id=111159.
44. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173, §§ 1111-13, 117 Stat. 2066 (2003).

period in an attempt to discourage anticompetitive settlements.[45]

III. ANTITRUST

Those familiar with the industry believe authorized generics could potentially discourage independent generic companies from challenging drug patents through Paragraph IV challenges, and from selling their own products.[46] Brand-name pharmaceutical companies are in the common practice of introducing authorized generics at the exact time that generic competition becomes a possibility.[47] This discourages independent generic companies from filing both paragraph IV challenges of the drug patents and from selling their own generic products.[48] This reduction of independent generic companies causes a decrease of the name-brand companies marketing authorized generics because of the lack of competition with independent generic companies.[49]

Paragraph IV patent litigation is a multimillion-dollar pursuit that, if successful, rewards generic company with six months of exclusivity.[50] These benefits can exceed the costs of litigation.[51] However, if there is already a generic in the market that did not have to incur this litigation cost many firms might forgo challenging patents as there would be no benefit.[52] Authorized generics may negotiate exclusive supply contracts that extend well into the 180-day exclusivity period before the ANDA IVs have even begun marketing.[53] Antitrust problems arise to the extent that authorized generics

45. *Id.*
46. EFFECTS ON INNOVATION, *supra* note 20, at 1.
47. SCHACHT, *supra* note 17, at 11.
48. EFFECTS ON INNOVATION, *supra* note 20, at 8.
49. *Id.* at 7.
50. *Id.* at 8.
51. *Id*.
52. *Id.* at 9.
53. *See* ROY LEVY, THE PHARMACEUTICAL INDUSTRY: A DISCUSSION OF COMPETITIVE AND ANTITRUST ISSUES IN AN ENVIRONMENT OF CHANGE, (1999), www.ftc.gov/reports/pharmaceutical/drugrep.pdf.

are capable of imposing *greater* competitive harm than ANDA IVs.[54] Authorized generics can exploit unique characteristics like identical chemistry make-up and identical trade dress to that of the name-brand drug, decreasing consumer confusion.[55] Such benefits are not afforded to ANDAs.[56]

Patent licensing guidelines specifically denote that anticompetitive potential arises when the licensing agreements affect parties in horizontal relationships, as this horizontal relationship can, "increase the risk of coordinated pricing, output restrictions, or the acquisition or maintenance of market power."[57] The licenses for authorized generics are horizontal.[58] They are selling the same product to the same customers and they are designed to deter the entry of ANDA competition in three ways: by increasing the risk of market power of the name-brand company, reducing the output of other generic companies, and are able to coordinate prices to ensure the name-brand company is making a worthwhile investment.[59] The market containing both the name-brand and generic drugs is a very difficult field to enter as the prices are not allowed to vary by large differentials due to a number of factors that the generic company without a name-brand backer cannot challenge.[60]

The defensive maneuvering of the name-brand companies to protect their patents is especially troublesome when considering that challengers of patents enjoy a seventy-three percent success rate.[61] This suggests that it is commonplace for pharmaceutical patents to have questionable validity.[62]

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54. Chen, *supra* note 12, at 484.
55. *Id.* at 489.
56. *Id*.
57. *Id.* at 491.
58. *Id*.
59. *Id.* at 490-91.
60. LUKE M. OLSON & BRETT W. WENDLING, THE EFFECT OF GENERIC DRUG COMPETITION ON GENERIC DRUG PRICES DURING THE HATCH-WAXMAN 180-DAY EXCLUSIVITY PERIOD 12 (2013).
61. Chen, *supra* note 12, at 492.
62. Steve Backmann and Gene Quinn, *Are More Than 90 Percent of Patents*

Furthermore, keeping Paragraph IV challenges consistent serves an important function—eliminating unwarranted monopolies.[63] The Supreme Court has also addressed the issue of name brand pharmaceutical companies reverse settling patent litigation disputes with generic companies (paying millions of dollars to the generic company to not challenge the patent that was held) and deemed it unlawful and a possible antitrust violation.[64] This decision was also reaffirmed in *In re Lipitor Antitrust Litigation* in the Third Circuit just last year.[65]

IV. PATENT LAW

There is an innate tension between antitrust law and patent law; antitrust laws allow monopoly if that power is acquired through business insight, while patent law does not.[66] This distinction is something to consider in the case of authorized generics which are used to prolong pharmaceutical monopolies through business insights.[67] As discussed above, the 180-day exclusivity is one of the main motivations for generic companies challenging patents held by brand-name firms but the introduction of an authorized generic during the exclusivity time makes any recovery of patent litigation expenses extremely difficult.[68] Thus decreasing the incentive for any patent

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Challenged at the PTAB defective?, IPWATCHDOG (2017), http://www.ipwatchdog.com/2017/06/14/90-percent-patents-challenged-ptab-defective/id=84343/.

63. Chen, *supra* note 12, at 493.

64. F.T.C. v. Actavis, Inc., 570 U.S. 136 (2013).

65. In re Lipitor Antitrust Litig., 868 F.3d 231 (3d Cir. 2017).

66. Chen, *supra* note 12, at 504-05.

67. *Id*. Business insight is defined as, "A thought, fact, combination of facts, data and/or analysis of data that includes meaning and furthers understanding of a situation or issue that has the potential of benefitting the business or re-directing the thinking about that situation or issue which then in turn has the potential of benefiting the business." Customer Feedback Analysis, *Extracting Business Insights: What is an insight?*, CX ADVANTAGE (2009), https://blog.walkerinfo.com/blog/extracting-business-insights-what-is-an-insight/.

68. Elizabeth S. Weiswasser & Scott L. Cunningham, *180-day Exclusivity is hotly contested*, NAT'L L.J. (Apr. 15, 2002), https://www.cov.com/files/Publication/6b08df3d-9273-4472-9b0f-ab58f110453f/Presentation/PublicationAttachment/93bf8bc3-5f1f-43cd-846c-ad1a24c99c2d/oid6232.pdf.

litigation to ensure the removal of no longer valid patents.[69]

If there is an authorized generic present during the exclusivity period the first-filing generic's revenues decrease by forty percent to fifty-two percent with revenues of the first-filing generic between fifty-three percent and sixty-two percent lower during the first thirty months after the 180-day period ends.[70] This means that when an authorized generic is in the market, hundreds of millions of dollars of revenue can be lost.[71] For example, in 2003, the name-brand company, GlaxoSmithKline, introduced an authorized generic version of a drug called Paxil®.[72] Apotex, the independent generic manufacturer, brought charges against GlaxoSmithKline to the FDA regarding an infringement of its 180-day exclusivity period.[73] The FDA ruled against Apotex.[74] During the exclusivity period, Apotex anticipated sales of up to $575 million but its sales were reported between $150 and $200 million—reduced to about two-thirds of the expected revenue due to the loss of this period.[75]

The competitive impact of litigation settlements depends upon a number of aspects including the relative strength of the patent and claims found within, the number of possible generic competitors, and the exact terms of the settlement agreement.[76] By settling patent litigation early or inducing the production of authorized generics, name-brand firms can better manage risk and stave off any competition or negative rulings regarding their patents.[77]

69. SCHACHT, *supra* note 17, at 11-12.
70. *Id.* at 12.
71. *Id.* at 11.
72. *Id*.
73. *Id.* at12
74. *Id*.
75. *Id.*
76. *Id.* at 14.
77. *Id*.

V. POSSIBLE SOLUTIONS

While there are some positive aspects of authorized generics, the negative effects brought about through patent and antitrust law must be addressed. In *Teva Pharmaceutical Industries v. FDA*, the Hatch-Waxman Act's exact language was reviewed and the court stated that the Hatch-Waxman Act, "clearly does not prohibit the holder of an approved NDA from marketing, during the 180-day exclusivity period, its own 'brand-generic' version of its drug," which means FDA practices concerning authorized generics were affirmed.[78] In another case, *Mylan Pharmaceuticals, Inc. v. U.S. Food & Drug Administration*, argued before the Fourth Circuit, generics were again addressed and the court concluded, "[a]lthough the introduction of an authorized generic may reduce the economic benefit of the 180 days of exclusivity awarded to the first paragraph IV ANDA applicant, Section 355(j)(5)(B)(iv) gives no legal basis for the FDA to prohibit the encroachment of authorized generics on that exclusivity."[79]

While the interpretations of the law made sense to the court, it begs the question of why the 180-day period is termed "exclusive" if other pharmaceutical companies can also sell during that time. The law should be changed to ensure that there are not underhanded dealings in regard to independent generic companies spending a large amount of money and time to develop a generic only to discover there is an authorized generic that will significantly harm their profits. Many times, the agreements made regarding authorized generics are not public and the generic has been in development for a significant amount of time before anyone is made aware of the authorized generic.

A change like the one mentioned above was made to patent law in the

78. Teva Pharm. Indus. v. FDA, 410 F.3d 51, 55 (D.C. Cir. 2005).
79. Mylan Pharmaceuticals, Inc. v. U.S. Food & Drug Admin., 454 F.3d 270 (4th Cir. 2006).

context of submarine patents—patents that would be developed and prosecuted without notice leaving other inventors that had been researching the same endeavor without any intellectual property rights.[80] Before 2011 the United States was a country that protected the first to invent rather than the first person to file for a patent.[81] Congress saw a chilling effect the uncertainty had on inventors as they became more cautious about inventing and investing in products they may not be granted protection over.[82] The same may be said of generic entry. Generic manufacturers might hold off filing Paragraph IV certifications if there is no guarantee that an unannounced authorized generic will not surface and enter the market directly before the 180-day exclusivity period. Congress specifically amended patent statutes to stop submarine patents and therefore it should consider doing the same for authorized generics.[83]

Congress attempted to make this change in 2011 by proposing legislation during the 112th Congress: H.R. 741 and S.373.[84] Under this proposed legislation, authorized generics were unable to be sold during the 180-day exclusivity period.[85] Effectively allowing for more market competition from the non-backed generic companies and allow for paragraph IV challenges to remain an important part of the patent legislation process for pharmaceuticals.[86] Unfortunately though, H.R. 741 and S. 373 were not

80. Matt Troyer, *17 Years After Trips, Do Submarine Patents Still Lurk in the Depths of Patent Data?*, ACCLAIM IP (2018), http://www.acclaimip.com/17-years-after-trips-do-submarine-patents-still-lurk-in-the-depths-of-patent-data/.

81. John Villasenor, *The United States Transitions to a 'First Inventor to file" Patent System*, FORBES (2013), https://www.forbes.com/sites/johnvillasenor/2013/03/11/march-16-2013-america-transitions-to-a-first-inventor-to-file-patent-system/#30e426ab3324.

82. Chen, *supra* note 12, at 507-08.

83. *Id*.

84. Kurt Karst, *Legislation to Ban Authorized Generics During 180-day Exclusivity Period Makes a Comeback in Congress,* FDA LAW BLOG (2011), http://www.fdalawblog.net/2011/02/legislation-to-ban-authorized-generics-during-180-day-exclusivity-period-makes-a-comeback-in-congres/.

85. *Id.*

86. *Id.*

enacted.[87]

Not allowing authorized generics to impede on the 180-day *exclusivity* period would have been the best for all parties involved as authorized generics can be beneficial for consumers (to drive market prices down) as well as name-brand companies (to ensure they do not lose all business to the generic manufacturers). The ability to market exclusively for the 180-day *exclusivity* period would not only make sense statutorily with the language provided, but would also ensure fair market practices and appropriate patent protections.

87. *Id.*

Health Multi-Level Marketing: Robbing People of their Money and their Health

Jessica Sweeb

As of 2018, there are roughly 1,400 multi-level marketing companies (MLMs) in the United States.[1] Generally, a multi-level marketing company may be defined as a form of direct sales in which a member of the company sells the company's product to their network of friends and coworkers.[2] These aforementioned company members also give the buyer (i.e., the friend or coworker) an opportunity to purchase the specific MLM's product in bulk in order to sell the product themselves, while the company member who recruited them will receive a percentage of the buyer/new member's commission.[3] MLMs are notorious for being unstable, and often become pyramid schemes when the MLM makes a higher profit from recruiting people to join than from selling the MLM's product.[4] MLMs particularly thrive in unregulated markets, where the potential for profit is high, and consumer protections are minimal.[5]

In the United States, the success of MLMs in unregulated markets has led to a recent wave of weight loss businesses to emerge within the health care

1 Ted Nuyten, *100 Solid Top MLM Companies for 2018*, BUS. FOR HOME (Jan. 1, 2018), https://www.businessforhome.org/2018/01/100-solid-top-mlm-companies-for-2018/.
2 Randy Duermyer, *What is Multi-Level Marketing (MLM)*, THE BALANCE, https://www.thebalance.com/mutli-level-marketing-mlm-1794427 (last updated Apr. 24, 2017).
3 *Id.*
4 Joe Nocera, *The Pyramid Scheme Problem,* N.Y. TIMES (Sept. 15, 2015), https://www.nytimes.com/2015/09/15/opinion/joe-nocera-the-pyramid-scheme-problem.html.
5 Jon M. Taylor, *The Case (For and) Against Multi-level Marketing*, FED. TRADE COMM'N (2011), https://www.ftc.gov/sites/default/files/documents/public_comments/trade-regulation-rule-disclosure-requirements-and-prohibitions-concerning-business-opportunities-ftc.r511993-00017%C2%A0/00017-57317.pdf.

sector.[6] By way of illustration, more than one-third of adults in the United States, or approximately 36.5% of the population, are considered obese.[7] Various weight loss business models and trends have emerged, causing the U.S. weight loss market to add up to a $64 billion industry in 2014.[8] Some of these businesses are organized as MLMs that specialize in health and wellness—such as Herbalife and Isagenix.[9] Further, some of the MLMs that have jumped on the health bandwagon have begun to promote products that are unregulated, adulterated, and have the potential to be harmful to consumers.

The Federal Trade Commission (FTC) has issued guidance for those who are considering joining MLMs, with the goal of protecting future members from falling prey to pyramid schemes and losing their investments due to being unable to recover their money through the sale of the product.[10] However, there has been little guidance from any government agency about the safety and efficacy of the health and wellness products that MLMs are promoting, since dietary supplements currently do not require approval by the Food and Drug Administration (FDA) before MLMs can market them.[11]

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6 *U.S. Weight Loss Market Worth $66 Billion*, CISION PR NEWSWIRE (Dec. 20, 2017), https://www.prnewswire.com/news-releases/us-weight-loss-market-worth-66-billion-300573968.html.

7 *Adult Obesity Facts*, CTRS. FOR DISEASE CONT. & PREVENTION, https://www.cdc.gov/obesity/data/adult.html (last updated Aug. 29, 2017); *Defining Adult Overweight and Obesity*, CTRS. FOR DISEASE CONT. & PREVENTION, https://www.cdc.gov/obesity/adult/defining.html (last updated Jun. 16, 2016) ("Weight that is higher than what is considered as a healthy weight for a given height is described as overweight or obese.")

8 John Kell, *Lean Times for the Diet Industry*, FORTUNE (May 22, 2015), http://fortune.com/2015/05/22/lean-times-for-the-diet-industry/.

9 Pritam Nagrale, *Top 20 MLM Companies Based on Health Products*, MONEYCONNEXION.COM (Nov. 16, 2016), http://moneyconnexion.com/health-based-mlm-companies.htm.

10 *Business Guidance Concerning Multi-Level Marketing*, FED. TRADE COMM'N (Jan. 2018), https://www.ftc.gov/tips-advice/business-center/guidance/business-guidance-concerning-multi-level-marketing.

11 *Beware of Products Promising Miracle Weight Loss*, U.S. FOOD & DRUG ADMIN, https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm246742.htm (last updated Nov. 19, 2017).

Since MLMs are distributing these products with such ease through technology and are posing huge health risks to consumers, the FDA should set up strict guidelines for what these companies can market and sell.

This Article posits that in order to effectively regulate the health MLM market and protect consumers entirely, the FTC and the FDA should combine their regulating powers and fully preserve the financial and health interests of the public. In doing so, this Article will explore the structure of health MLMs, their regulation under FTC regulations, their lack of guidance and regulation from the FDA due to the Dietary Supplement and Health Education Act (DSHEA), and the risks they bring to consumers. First, Part I will cover a brief history of MLMs and how they relate to pyramid schemes. Next, Part II will discuss the legality of pyramid schemes and MLMs. Following this, Part III will examine pyramid schemes and MLMs which relate specifically to health. Finally, Part IV will delve into how these MLMs are regulated and how they can impact health.

I. WHAT IS A PYRAMID SCHEME AND HOW DOES IT RELATE TO MLMS? A BRIEF HISTORY

To begin, MLMs and pyramid schemes have been used to sell products in the United States since the beginning of the twentieth century.[12] Pyramid schemes profit through the growth of the pyramid and not by the sale of the products.[13] As the pyramid gets bigger, it becomes difficult for new sellers to recruit new distributors and recover their investments.[14] In the context of MLMs, an MLM is considered a legitimate business in the eyes of the law, but it transforms into a pyramid scheme once the MLM begins reaping higher

12 William W. Keep & Peter J. Vander Nat, *Multilevel Marketing and Pyramid Schemes in the United States: A Historical Analysis*, 6 J. HIST. RSCH. MARKETING (forthcoming Nov. 2014).
13 Robert A. Peterson & Gerald Albaum, *On the Ethicality of Internal Consumption in Multilevel Marketing*, 27 J. PERS. SELLING & SALES MGMT. 317, 319 (2007).
14 *Id.*

profits from recruiting new distributors than from selling their products.[15] For example, the FTC alleged that the MLM Herbalife deceived consumers about how much money they would earn if they became distributors, while in reality almost none of Herbalife's distributors made any money at all while Herbalife made significant profits from its recruiting structure.[16]

Direct selling was originally seen as a "short term approach to reduce excess inventory" by large retail companies.[17] Direct selling is a marketing method where door-to-door salesmen will sell nationally branded products ranging from groceries to vacuums.[18] This method soon became irritating for consumers, with seventeen complaints recorded by the FTC in 1920.[19] Despite the complaints, direct selling continued to grow with the urbanization of the United States.[20] In the mid-twentieth century, direct selling began to rely on what is known as the "party plan," where instead of the sellers going to the consumers, the consumers would go to a party hosted by the seller.[21] This continues to be the dominant multi-level marketing strategy seen today, with household names such as Mary Kay and Avon.[22]

One of the first modern MLMs was Nutrilite, which established a multilevel marketing plan in 1945 to conduct door-to-door sales.[23] Nutrilite is a sub-company of Amway and sells nutritional supplements such as vitamins and weight management supplements.[24] Nutrilite relied on

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15 Susan Ward, *Learn to Distinguish Between MLM and Pyramid Schemes*, THE BALANCE, https://www.thebalance.com/is-it-multilevel-marketing-or-a-pyramid-scheme-2947159 (last updated Aug. 29, 2017).
16 Jim Zarroli, *Herbalife Agrees to Pay $200 Million To Settle Complaints It Deceived Consumers*, NAT'L PUB. RADIO (July 15, 2016, 6:42 PM), https://www.npr.org/sections/thetwo-way/2016/07/15/486174340/herbalife-agrees-to-pay-200-million-to-settle-complaints-it-deceived-consumers.
17 Keep et al., *supra* note 12, at 1.
18 *Id.*
19 *Id.* at 3.
20 *Id.*
21 *Id.* at 4.
22 *Id.*
23 *Id.*
24 *About Nutrilite*, AMWAY, http://www.amway.com/nutrition/nutrilite/about-nutrilite (last

distributors to sell to friends, neighbors and relatives.[25] Despite having issues with the FTC, Nutrilite is still in business, where they continue to sell nutritional supplements.[26]

Pyramid schemes can also be very high profile. Some popular brands that are arguably pyramid schemes are Mary Kay and Herbalife.[27] Though some companies will state that anyone can make money and continue to earn money in a pyramid scheme, this is not true.[28] Most pyramid schemes fail due to market saturation, meaning that there are too many distributors in that particular area.[29] It is a mathematical certainty that pyramid schemes fail due to market saturation.[30] In response to the request of attorneys that were trying to prosecute pyramid scheme promotors, J.L. Gastwirth, a statistics professor, and P.K. Bhattacharya, a chemical engineering professor, developed two probability models.[31] The probability models were created to show the overall fraud of pyramid schemes and chain letters.[32] They highlighted the dependency that one's earnings are to when the distributor entered the market.[33] Overall, the professors discovered that as the pyramid gets bigger, it becomes more difficult for new sellers to recruit new distributors and recover their investment.[34]

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visited Mar. 26, 2018).

25 Keep et al., *supra* note 12, at 4.

26 *About Nutrilite, supra* note 24.

27 Megan Elliott, *5 Huge Companies Accused of Being Pyramid Schemes,* CHEATSHEET (December 11, 2017), https://www.cheatsheet.com/money-career/huge-companies-accused-of-being-pyramid-schemes.html/?a=viewall.

28 Bill Schuette, *Multi-Level Marketing or Illegal Pyramid Scheme?*, DEP'T ATT'Y GEN., http://www.michigan.gov/ag/0,4534,7-359-81903_20942-208400—,00.html (last visited Mar. 26, 2018).

29 *Id.*

30 Keep et al., *supra* note 12, at 12.

31 J.L. Gastwirth & P.K. Bhattacharya, *Two Probability Models of Pyramid or Chain Letter Schemes Demonstrating that Their Promotional Claims are Unreliable*, 32 OPERATIONS RES. 527, 527 (1984).

32 *Id.*

33 *Id.*

34 *Id.* at 528.

II. LEGALITY OF PYRAMID SCHEMES AND MLMS

The FTC first took action against pyramid schemes in the 1970s, when modern MLMs became a common way of purchasing goods.[35] The boom in the MLM industry gave way for pyramid schemes to rise and prosper, which led Senator Walter Mondale to sponsor a federal anti-pyramiding bill.[36] While this bill passed through the Senate twice, it ultimately failed to become law.[37] However, the FTC had two landmark cases—*In re Koscot* and *In re Amway*—in which the agency was able to define the characteristics of illegal pyramid schemes and distinguish them from a multi-level marketing company.[38] The FTC is still working to put an end to pyramid schemes by settling cases, such as the 2014 settlement with Fortune Hi-Tech Marketing[39] and the 2016 settlement with Herbalife.[40]

In *Koscot*, an Orlando-based multi-level marketing company that sold cosmetic products was found to be in violation of Section 5 of the Federal Trade Commission Act (FTC Act).[41] Section 5 of the FTC Act states that "unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful."[42] The company had developed a practice in which each person who entered the company had to bring in other distributors along with them to order to begin making money.[43] Because the company was deceptive in

35 Debra A. Valentine, *Pyramid Schemes*, FED. TRADE COMMISSION (May 13, 1998), https://www.ftc.gov/public-statements/1998/05/pyramid-schemes.
36 *Id.*
37 *Id.*
38 *Id.*
39 Aditi Jhaveri, *The Telltale Signs of a Pyramid Scheme*, FED. TRADE COMMISSION (May 13, 2014), https://www.consumer.ftc.gov/blog/2014/05/telltale-signs-pyramid-scheme.
40 Press Release, Office of Pub. Affairs Fed. Trade Comm'n, FTC Sends Checks to Nearly 350,000 Victims of Herbalife's Multi-Level Marketing Scheme (Jan. 10, 2017) (online at https://www.ftc.gov/news-events/press-releases/2017/01/ftc-sends-checks-nearly-350000-victims-herbalifes-multi-level).
41 *See generally* In re Koscot Interplanetary, Inc., 86 F.T.C. 1106 (1975).
42 Federal Trade Commission Act, 15 U.S.C. § 45 (2006).
43 In re Koscot, *supra* note 41 at 1112.

its advertising and marketing of how much money was going to be made in its business model, the FTC found these acts "to the prejudice and injury of the public and of respondents' competitors in commerce and unfair methods and deceptive acts."[44] Additionally, the company was fixing and controlling prices at which respondents' products were being resold at wholesale and at retail.[45]

In the FTC's first breakthrough ruling in *In re Amway Corp.*, Amway was an MLM that sold personal care, car care, home care products, vitamins and nutritional supplements.[46] Specifically, Amway's business model focused on having participants bring in new distributors as a way to earn money as opposed to focusing on selling the products.[47] Because of this model, Amway was found to be in violation of Section 5 of the FTC Act.[48] The FTC characterized pyramid schemes in the 1979 decision of *In re Amway* as plans in which "the payment by participants of money to the company in return for which they receive (1) the right to sell a product and (2) the right to receive in return for recruiting other participants into the program rewards which are unrelated to the sale of the product to ultimate users."[49]

The judgment in *In re Amway Corp.* placed strict parameters on what the MLM in question could do, part of which required the cessation of price fixing and the cessation of focusing on recruiting more distributors.[50] MLMs are otherwise legal, though still subject to various laws and regulations enforced by the FTC regarding their advertising, marketing, and other areas of the business.[51] Primarily, the FTC uses Section 5 to determine whether

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44 *Id.* at 1114.
45 *Id.*
46 *See generally* In re Amway Corp., Inc., 93 F.T.C. 618 (1979).
47 *Id.* at 625–628.
48 *Id.* at 629; *see generally* Federal Trade Commission Act, *supra* note 42.
49 Clinton D. Howie, *Is It A Pyramid Scheme?*, 49 LA. B.J. 288, 289 (2002).
50 *See In re Amway Corp.*, *supra* note 46.
51 *Business Guidance Concerning Multi-Level Marketing*, *supra* note 10. ("The FTC enforces a variety of laws and regulations relating to advertising, marketing, sales, billing, privacy, data security, franchises, and business opportunities, among other topics, that apply

MLMs are unlawful.[52] The commission reviews each violation case by case in order to address each harm individually without affecting the entire industry as a whole.[53] Ultimately, MLM strategies differ from pyramid schemes in that they distribute products or services, and the suppliers earn money from what they sell from the sales of their direct and indirect recruits.[54]

In addition to enforcing rules on MLMs, the FTC has other practices to keep up with the current marketing and distribution methods used by companies.[55] The commission frequently meets with representatives from affected industries, consumer groups, and shareholders to see the developing practices and arising issues in the business.[56] Additionally, the FTC issues educational materials for both consumers and businesses.[57] Finally, the commission's Bureau of Economics dedicates its knowledge and capabilities related to direct selling and multi-level marketing strategies, which in turn helps inform the FTC's investigations of MLMs.[58]

III. PYRAMID SCHEMES AND MLMS RELATED TO HEALTH

As of late, MLM companies in the health market have been more profitable than other sectors.[59] Different types of products offered by health-specific MLMs are nutritional supplements, protein powders, vitamins,

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or may apply to MLMs").

52 *Id.*

53 *Id.*

54 Peter J. Vander Nat & William W. Keep, *Marketing Fraud: An Approach for Differentiating Multilevel Marketing from Pyramid Schemes*, 21 J. PUB. POL. & MARKETING 139, 140 (2002).

55 *Business Guidance Concerning Multi-Level Marketing*, *supra* note 10.

56 *Id.*

57 *Id.*

58 *Id.*

59 Ahmed Zayed, *Nutritional MLM Companies & Its Networking Marketing Over the World*, CONSUMERHEALTHDIGEST, https://www.consumerhealthdigest.com/health-news/best-nutritional-mlm-companies.html (last visited Mar. 26, 2018).

drinks, weight-loss plans, and more.[60] Because Americans are becoming more health-conscious in the twenty-first century, health-specific MLMs have become a multi-million dollar industry.[61] For instance, Herbalife, which sells products catering to nutrition, weight loss, fitness, and personal care, has approximately eight thousand employees[62] and annual sales that added up to approximately $4.5 billion in 2017.[63]

Moreover, the Vitamins, Minerals, and Supplements (VMS) industry is projected to reach $60 billion by 2021 according to the Nutritional Business Journal.[64] Roughly one-third of Americans take multi-vitamins; further, use increases with age, with 41% of Americans taking multi-vitamins by age 71.[65] With this growing market, MLMs and pyramid schemes relating to health will most likely not slow down any time soon, since a large portion of products sold by health MLMs involve vitamins and supplements.[66]

Furthermore, there are certain statutory inhibitors that may put consumers and distributors at risk when dealing with health-specific MLMs. The Dietary Supplement Health and Education Act of 1994 (DSHEA) defines the term dietary supplement as a "vitamin, mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination [thereof]."[67] Fundamentally, Congress's passage of

60 Pritam Nagrale, supra note 9.
61 *See* Zayed, *supra* note 59. (See chart on top Utah-based MLM companies).
62 *Multivitamin/mineral Supplements Fact Sheet for Consumers*, NAT'L INST. HEALTH, https://ods.od.nih.gov/factsheets/MVMS-Consumer/ (last updated Feb. 17, 2016).
63 *Top 50 MLM Companies by Global Revenue*, NETWORK MARKETING CENT., http://www.networkmarketingcentral.com/top-100-network-marketing-companies/ (last visited Mar. 26, 2018).
64 David Lariviere, *Nutritional Supplements Flexing Muscles as Growth Industry,* FORBES (Apr. 18, 2013, 7:09 PM), https://www.forbes.com/sites/davidlariviere/2013/04/18/nutritional-supplements-flexing-their-muscles-as-growth-industry/#5f45ca9c8845.
65 *Multivitamin/mineral Supplements Fact Sheet for Consumers*, NAT'L INST. HEALTH, https://ods.od.nih.gov/factsheets/MVMS-Consumer/ (last updated Feb. 17, 2016).
66 Zayed, *supra* note 59.
67 Dietary Supplement Health and Education Act of 1994, NAT'L INST. HEALTH,

DSHEA authorized the FDA to regulate Dietary Supplements falling within the province of the Act.[68] However, it is important to note that the FDA has other, more intense, sets of regulations for other products such as drugs under other acts of Congress and their corresponding regulations.[69]

At its core, DSHEA prohibits manufacturers and distributors of dietary supplements from marketing their products that are misbranded or adulterated.[70] The companies themselves are responsible for testing the safety of their own products to ensure they meet DSHEA and FDA standards before they are marketed and sold.[71] In effect, the FDA alone essentially monitors the marketplace: it requires pharmaceutical companies to meet certain requirements and standards in order to sell their products in the United States.[72] In addition, regulated companies must label their products appropriately and be able to demonstrate the effectiveness of their products by going through clinical trials.[73] Furthermore, it is the FDA's statutorily mandated responsibility to take action against any misbranded or contaminated dietary supplement after it is marketed.[74]

IV. REGULATION AND IMPACT ON HEALTH

Health MLMs often advertise that consuming their products will better a consumer's lifestyle and help them achieve their goal weight.[75] However,

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https://ods.od.nih.gov/About/DSHEA_Wording.aspx (last visited Apr. 3, 2018).

68 Stephen Ostroff, *Making Progress in Protecting Consumers from Unsafe Supplements*, U.S. FOOD & DRUG ADMIN. (Jan. 20, 2016), https://blogs.fda.gov/fdavoice/index.php/tag/dietary-supplement-health-and-education-act-dshea/.

69 *Development & Approval Process (Drugs)*, U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm (last updated Jan. 16, 2018).

70 *Dietary Supplements*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Food/DietarySupplements/ (last updated Nov. 29, 2017).

71 *Id.*

72 *Id.*

73 *Id.*

74 *Id.*

75 William T. Jarvis, *Buyers and Sellers Alike Need to Beware of Multilevel-Marketing*

many herbal supplements may contain harmful drugs that occur naturally or are added through adulteration.[76] Notably and of critical importance, the FDA does not regulate nutritional supplements and other MLM products under the strict guidelines that they use to regulate food and drug products.[77] Instead, these supplements are regulated under DSHEA, which places the burden of testing the safety and efficacy of supplements on the manufacturers themselves.[78] However, if a manufacturer uses a new ingredient in their formula, it must be reported to the FDA before it is marketed.[79] Once reported to the FDA, the FDA simply asks for notice to review, which is *different* than approval of safety.[80] Specifically, notice of review asks for the general public to comment and review on products that are marketed, while safety approval means that the products being marketed have been subjected to the FDA's rigorous standards. Since the FDA does not approve all dietary supplements before they are marketed and sold, they have implemented a system that allows health professionals, consumers, and members of the industry to report any harmful side effects or adverse reactions to products on the market directly to the FDA.[81] In addition, the FDA publishes a list on its website of serious reactions and illnesses so consumers can gauge whether their reaction is severe.[82]

Health Products, NAT'L COUNS. AGAINST HEALTH FRAUD (December 4, 2000), https://www.ncahf.org/articles/j-n/mlm.html.

76 *Id.*

77 *Dietary Supplements, supra* note 70.

78 Tonya Dodge, Dana Litt, & Annette Kaufman, *Influence of the Dietary Supplement Health and Education Act on Consumer Beliefs About the Safety and Effectiveness of Dietary Supplements*, 16 J. OF HEALTH COMM'N 230, 231 (2011).

79 *Dietary Supplements: What You Need to Know*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Food/DietarySupplements/UsingDietarySupplements/ucm109760.htm (last updated Nov. 29, 2017).

80 Press Release, U.S. Food & Drug Admin., FDA Updates Draft Guidance on Premarket Safety Notifications for Dietary Supplement Industry (Aug. 11, 2016) (online at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm516197.htm).

81 *Dietary Supplements—How to Report a Problem*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Food/DietarySupplements/ReportAdverseEvent/default.htm (last updated Nov. 29, 2017).

82 *Id.*

There is a clear, significant distinction between regulations imposed by the FDA and regulations imposed by DSHEA.[83] This is because DSHEA regulations are extremely lax compared to FDA regulations.[84] On the one hand, the primary regulatory standards used by the FDA to safeguard the quality of pharmaceuticals are the Current Good Manufacturing Practices (CGMPs).[85] These CGMPs involve "establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories."[86] This process ensures that the products meet certain quality standards and prevents instances such as contaminations, mix-ups, and errors.[87] On the other hand, under DSHEA regulations, manufacturers are only required to provide a simple evaluation of their product, and are permitted to label their own products on their own terms before they are marketed.[88]

As DSHEA is currently written, the FDA has an extremely limited capacity to enforce its regulations and statutory duties to protect consumers. The FDA can only step into the dietary supplement regulation process when an individual reports an adverse reaction to that supplement.[89] Further, DSHEA's regulation standards are not strict enough to govern the vast growing number of nutritional supplements being promoted by health MLMs.[90] The current industry approach of self-reporting and allowing all dietary supplements to be tested by the manufacturers creates an issue of

83 *Dietary Supplements*, *supra* note 70.
84 Ostroff, *supra* note 68.
85 *Facts about the Current Good Manufacturing Practices (CGMPs)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm (last updated Oct. 6, 2017).
86 *Id.*
87 *Id.*
88 *Id.*
89 *Dietary Supplements – How to Report a Problem*, *supra* note 81.
90 Ostroff, *supra* note 68.

bias.[91] DSHEA has effectively caused many supplements to pass undetected with self-reporting,[92] since the primary drive of the supplement manufacturers is to approve their product so it can be marketed and sold.[93] Overall, the FDA's guidelines are much stricter than DSHEA's.[94] Although the FDA does not have the authority to regulate dietary supplements under DSHEA,[95] it would be extremely beneficial if Congress amended DSHEA to authorize the FDA to regulate supplements under their strictly regimented guidelines before they are marketed.

In addition to potentially having harmful ingredients and causing adverse reactions, dietary supplements sold by MLMs often promise results that are too good to be true.[96] For example, the MLM AdvoCare offers a variety of different cleanses, including the 10-day herbal cleanse.[97] The cleanse calls for an extremely restricted diet and requires the consumer to take three dietary supplements along with the diet, namely (1) a fiber supplement, (2) a probiotic, and (3) an herbal supplement with digestive enzymes.[98] According to AdvoCare's advertisements, this cleanse system "supports improved digestion and internal cleansing and helps rid your body of waste and absorb nutrients with its unique blend of herbal ingredients."[99] Importantly, the FDA has *not* approved the supplements that AdvoCare offers, and is not permitted to under the current DSHEA framework.[100] Additionally, the aforementioned

91 Michael McCann, *Dietary Supplement Labeling: Cognitive Biases, Market Manipulation & Consumer Choice*, 31 AM. J. L. & MED. 215, 247 (2005).
92 *Dietary Supplements – How to Report a Problem*, *supra* note 81.
93 McCann, *supra* note 91.
94 *Development & Approval Process (Drugs), supra* note 69.
95 Stephen Ostroff, *supra* note 68.
96 *Pyramid Schemes are a Health Industry Pox*, REVISIONIST HEALTH (Nov. 29, 2016), https://www.revisionisthealth.com/blog/2016/11/28/pyramid-schemes-are-a-health-industry-pox.
97 *Herbal Cleanse System*, ADVOCARE, https://www.advocare.com/store/product/w3203-herbal-cleanse-system (last visited Mar. 26, 2018).
98 *Id.*
99 *Id.*
100 *Id.* (*"*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.").

restrictive long-term diet is questionable: it calls for the consumer to abstain completely from red meat, alcohol, sugar, wheat, dairy, caffeine, and high-sugar fruits like bananas and pineapple.[101] The promotion of a long-term diet like the one suggested may lead to life-threatening health consequences, such as malnutrition and heart failure.[102]

Another example of a health-specific MLM is Isagenix. Isagenix sells its product through distributors, who buy into the company at a large price and are assured that they can recover their money by selling the product to friends and family.[103] One of the plans that Isagenix currently promotes is the "30 Day System," which asks consumers to replace two meals a day with their 240-calorie shakes, and to have a 400-600 calorie meal for their third and final meal.[104] The plan specifically targets both men and women, and adds up to an average of less than 1000 calories a day.[105]

Clearly, there are multiple problems with this Isagenix 30 Day System: the fourteen products that come with the purchase,[106] the laundry list of complex ingredients in each product,[100] and the amount of daily calories that are being promoted.[107] Isagenix has stated themselves that their products are not FDA approved.[108] Furthermore, the amount of calories a woman should eat to

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101 *AdvoCare 10 Day Cleanse Diet*, ADVOCARE, http://www.advochallengetips.com/advocare-10-day-cleanse-diet/ (last visited Mar. 26, 2018).

102 K. Aleisha Fetters, *What Happens to your Body When You Go On An Extreme Diet*, U.S. NEWS (June 19, 2015 10:36 AM), https://health.usnews.com/health-news/health-wellness/articles/2015/06/19/what-happens-to-your-body-when-you-go-on-an-extreme-diet.

103 *Pyramid Schemes are a Health Industry Pox*, *supra* note 96.

104 *30 Day System*, ISAGENIX, https://www.isagenix.com/en-us/products/pak/30-day-system (last visited Mar. 26, 2018).

105 *Id.*

106 *Id.*

100 *IsaLean Shake Creamy French Vanilla*, ISAGENIX, https://www.isagenix.com/-/media/product/catalog/individual-items/isalean-shake/isalean-shake-fact-panels/us-en-fact-panel-isalean-shake-can-creamy-french-vanilla.ashx (last visited Mar. 26, 2018).

107 *IsaLean Shake Creamy French Vanilla*, ISAGENIX, https://www.isagenix.com/-/media/product/catalog/individual-items/isalean-shake/isalean-shake-fact-panels/us-en-fact-panel-isalean-shake-can-creamy-french-vanilla.ashx (last visited Mar. 26, 2018).

108 *30 Day System*, *supra* note 104.

maintain her weight is roughly 2000 calories and generally 1500 calories if she wants to lose one pound of weight per week.[109] A man should eat roughly 2500 if he wants to maintain his weight and around 2000 calories if he wants to lose around one pound of weight per week.[110] On the 1000-calorie a day Isagenix 30 Day System, the consumer could be at risk of malnutrition, hypoglycemia, anemia, or even renal failure.[111]

In cases like Isagenix's 30 Day System, DSHEA should authorize the FDA to regulate these dietary supplements in order to protect the public's health through stricter regulations. Allowing MLMs to promote products that have questionable ingredients whilst simultaneously endorsing an unsustainable and unhealthy diet is unacceptable from a health standpoint. In addition, it is critical that DSHEA should also authorize the FDA to recommend an amount of the particular supplement at issue that should be taken, and that aligns with a healthy lifestyle.

V. WHAT DOES THIS MEAN FOR CONSUMERS AND DISTRIBUTORS?

The legal landscape of MLMs is constantly changing. The FTC recently settled a case in 2016 with Herbalife, where Herbalife agreed to pay $200 million to overhaul the reward program for their distributors.[112] Effectively, this new adjustment compensates distributors for actually selling products rather than simply recruiting more distributors.[113] MLMs and pyramid schemes are not set up to be effective in the long run—people buy into the

109 Kris Gunnars, *How Many Calories Should You Eat Per Day to Lose Weight?*, HEALTHLINE (May 30, 2017), https://www.healthline.com/nutrition/how-many-calories-per-day.
110 *Id.*
111 Stephen Harding, *The Effects of Consuming Fewer Than 1000 Calories Daily*, LIVESTRONG, (October 3, 2017), https://www.livestrong.com/article/70221-effects-consuming-fewer-calories-daily/.
112 Harris Meyer, *Blog: Herbalife settlement with FTC may prompt changes in firms selling health supplements*, MOD. HEALTHCARE (July 16, 2016), http://www.modernhealthcare.com/article/20160716/BLOG/160719907.
113 *Id.*

company, often for a large sum, with the false assurance that they will make their money back if they sell the product.[114] However, statistical studies indicate that the more people that buy into an MLM, the less likely the person will make their return back; this leaves the company with a large profit and distributors who are stuck with thousands of dollars' worth of products with no market to sell to.[115] Essentially, MLMs offer few opportunities to make a profit and are more likely to cause a person to lose money.

Furthermore, with this Herbalife settlement, the FTC has provided MLMs with standards to know what is expected of them.[116] The day that the HerbaLife settlement was announced, FTC Chairwoman Edith Ramirez stated that the commission would be issuing "guidance" for the rest of the MLM industry.[117] This guidance was issued in January 2018, describing what MLMs are, how they can violate Section 5 of the FTC Act, and how the FTC decides whether an MLM structure is unfair or deceptive.[118] With this information, MLMs are encouraged, but not required, to structure their companies to avoid any violations of Section 5 of the FTC Act.

VI. CONCLUSION

The FTC has given strict regulations on how MLMs should conduct their business practices. However, it is abundantly clear that dietary supplements do not have strict regulations. In fact, the only regulation offered by DSHEA is for manufacturers to test their own products for safety and efficacy before they are marketed. The FDA only interferes if consumers report any adverse effects are experienced.

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114 Daryl Koehn, *Ethical Issues Connected with Multi-Level Marketing Schemes*, 29 J. BUS. ETHICS 153, 154 (2001).
115 *Id.*
116 Roger Parloff, *Herbalife Deal Poses Challenges for the Industry*, FORTUNE (July 19, 2016), http://fortune.com/2016/07/19/herbalife-deal-challenges-industry/.
117 *Id.*
118 *See generally Business Guidance Concerning Multi-Level Marketing, supra* note 10.

This lack of strict regulation has had an extremely harmful impact on the general public. A study conducted by the federal government found that in 2015 alone, over 20,000 emergency room visits in the United States were caused by adverse effects to dietary supplements.[119] Most of these adverse effects were cardiovascular problems in young adults who were taking weight loss and energy enhancement supplements.[120] This is a strong illustration of why dietary supplements need stricter regulations. Dietary supplements can be extremely dangerous. If these products are being sold through MLMs, they need to be regulated more stringently. DSHEA should work through the FDA to provide tougher regulations for dietary supplements and then collaborate with the FTC to provide strict guidelines on the safety of dietary supplements being sold through MLMs.

119 Anahad O'Connor, *Dietary Supplements Lead to 20,000 E.R. Visits Yearly, Study Finds*, THE N.Y. TIMES (October 14, 2015), https://well.blogs.nytimes.com/2015/10/14/dietary-supplements-lead-to-20000-e-r-visits-yearly-study-finds/.
120 *Id.*

An Analysis of the "Patient Hotel" Concept

Justin Taylor

Scandinavian medical systems have created an alternative housing system for rehabilitating hospital patients that has been investigated and implemented since the 1980s.[1] The most recent addition is the patient hotel in Denmark's Rigshopitalet.[2] The patient hotel is a secondary medical facility complete with premium accommodations aimed at patients that have travelled far distances to receive medical treatment and patients undergoing long-term medical care.[3] The staff of the patient hotel is composed of nurses and nutritionists. The facility is also wired for easy communication between patients and medical staff.[4] The majority of Denmark's patient hospital visitors do not pay for their stay because of the country's health care policy and family members are allowed to stay as well, for an additional fee.[5]

The existence of such a facility answers a question that faced Denmark, and now faces American healthcare systems: how can hospitals hold significant numbers of patients without delivering insufficient care or enduring financial difficulty? According to hospital officials, the cost to provide private rooms in the patient hotel is one-third the cost of a hospital bed.[6]

American hospitals and healthcare providers face increased pressure from

1. Anne Quinto, *In Scandinavia, "patient hotels" provide an alternative to hospitals*, QUARTZ (Nov. 12, 2015) https://qz.com/545967/in-scandinavia-patient-hotels-provide-an-alternative-to-hospitals/.
2. *Id*.
3. *Id*.
4. *Id*.
5. Caitlin Bird, *Checking into Hotel Hospital*, B.U. RESEARCH (Aug. 2, 2016) https://www.bu.edu/research/articles/luxury-hospital-rooms/.
6. Quinto, *supra* note 1.

the requirements involved in caring for the recovery of patients, patients that need long term care, as well as the influx of emergency patients. These pressures are not the only factors. International travel continues to grow, and with it the rise of medical tourism (domestic and international travel seeking medical attention).[7] Medical tourism and domestic need for lodging for patients travelling long distances has resulted in the medical tourism trend.[8]

Addressing increased need for availability not only for ER patients, and for rehabilitating and medium-term care patients would likely come from increasing hospital bed usage.[9] However, an increase to the already 2.5 million hospital beds in use would exacerbate hospital resources due to the costs related to adherence with federal medical device requirements for hospital bed approval.[10] Hospitals require sufficient ability to cater to the number of patients entering at any given time, as well as provide care that will contribute to holistic patient rehabilitation. The patient hotel concept could potentially alleviate pressure on American hospitals without being subject to legal issues related to patient care, hospital building design, and real estate restrictions. The following provides a broad analysis of the applicability of patient hotels and their potential benefits within the framework of relevant U.S. laws.

I. THE PATIENT HOTEL ADVANTAGE

"Patient hotels" exist at hospitals in parts of the U.K. and Scandinavia.[11] The patient hotels concept focuses on alleviating overcrowding of the hospital by providing a secondary facility that combines the care involved in

7. Hessup Han et al., *Medical hotels in the growing healthcare business industry: Impact of international travelers perceived outcomes*, 68 J. BUS. RES. 1869, 1869 (2015).

8. Ian Harvey et al., *Enhancing Appropriateness of Acute Bed Use: Role of the Patient Hotel*, 47 J. EPIDEMIOLOGY & CMTY. HEALTH 368, 372 (1993).

9. U.S. Food & Drug Admin., *Practice Hospital Bed Safety* (Feb. 11, 2013), https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm164366.htm.

10. *Id*.

11. Quinto, *supra* note 1.

patient recovery with hotel-style accommodations.[12] Reports from European hospitals engaged in providing patient hotels point toward a decrease in costs for hospitals regarding hospital bed maintenance and alleviation of hospital overcrowding.[13]

As the patient hotel concept continues to materialize, public interest in medical hotels and patient-oriented hotels has skyrocketed.[14] The concept has not yet gained traction in the United States; however, a recent Boston University study suggests that U.S. patients would be inclined to engage in hotel-like hospitality during hospital stays.[15] Studies in consumer interest in premium hospital accommodations point toward a desire for a hotel-like atmosphere.[16] Researchers from Boston University's School of Hospitality Administration concluded that on average, patients would be willing to spend thirty-eight percent more for a hospital room if it "has the right kind of hotel-like quality upgrades."[17] The Boston University study also concluded that patients found that a hospitable environment that included patient family members was associated with perceived positive impact on physical, mental, psychological, and social well-being.[18] Consumer interest for out-of-pocket payment for hotel-like rooms may likely be satisfied by the Scandinavian concept.[19]

The investment in the concept may result in a significant contribution to the idea of holistic, patient-focused care, such that any potential risks are worth the potential benefit for the health of visiting patients. The use of patient hotels as a cost-saving measure would ease the stress of hospital bed regulation and usage from main facilities and allow for emergency room

12. *Id*.
13. *Id*.
14. Han et al., *supra* note 7.
15. Bird, *supra* note 5.
16. *Id*.
17. *Id*.
18. *Id*.
19. Quinto, *supra* note 1.

decongestion.[20] Patients that are deemed able to be discharged from a hospital bed yet are not quite deemed ready for hospital discharge altogether could be housed in the patient hotel, providing more timely discharge arrangements and greater hospital bed availability.[21]

Further, research into the potential eligibility for patients to move from hospital beds to a proposed patient hotel may shed light on the potential market for one's construction.[22] Initial studies have been carried out by U.K. Audit Commission, resulting in estimates that in the private sector, 5-15% of patients on hospitable beds would be suitable for transfer to patient hotels.[23] These small population sample studies set up sufficient statistical projections for wider investment in building new, or converting existing, structures into patient hotels.[24]

II. ADOPTION OF THE PATIENT HOTELS CONCEPT INTO THE U.S. FRAMEWORK

The patient hotel concept would successfully be adopted in the United States with proper application of the customs within the healthcare framework. Adopting the patient hotels concept into the U.S. hospital system would involve an in-depth assessment into the feasibility and necessity for extra patient accommodations, as well an analysis of relevant contract and real estate law on a case-by-case basis. While no one has evaluated the potential of adopting patient hotels, similar theories of an alternative form of patient housing have been discussed in limited scope.[25] Two "medical hotels" were proposed in 1986 by the Temple Medical Center and Yale-New Haven

20. Harvey, *supra* note 8.
21. *Id*.
22. *Id.* at 372.
23. *Id*.
24. *Id*. (stating that patients were generally happy with their stay in a patient hotel).
25. Sharon L. Bass, *Approval Sought for Medical Hotels*, N.Y. TIMES (Feb. 9, 1986) http://www.nytimes.com/1986/02/09/nyregion/approval-sought-for-medical-hotels.html.

Hospital.[26] These proposals were aimed at providing hotel accommodations for the families and care-givers of hospital patients.[27] However, at the time of these proposals, uncertainty surrounding reimbursement damaged the prospects of the medical hotel's ability to be instituted.[28] Even if the American prototypes of the concept were failures, modern patient hotels would still be capable of being framed in a similar way to the existing European versions.

Assuming reimbursement were not an issue, patients could obtain either basic hotel or luxury hospitality accommodations—with patients paying-out-of-pocket likely being able to pay for luxury accommodations.[29] Implementing administrative systems to carry out the processes of various levels of luxury accommodations would likely require an established and stable hospital system. Large hospital systems are prime candidates to adopt this model, based on their campus sizes and ability to transition their existing accommodations.[30] However, the level of luxury may be stifled by the necessity of the patient hotel to be a medical facility rather than a public resort.[31] Patient hotels would likely break new ground in terms of facility status and designation under Medicare and Medicaid.[32] Depending on the particular services provided in the facility, the facility could be designated an out-patient rehabilitation facility, an outright home health provider, or anything in between.[33] Alternatively, the hospital could adopt a committed

26. *Id*.
27. *Id*.
28. *Id*.
29. *Id*.
30. Makarand Mody & Courtney Suess, *Hospitality Healthscapes: A Conjoint Analysis Approach to Understanding Patient Responses to Hotel-Like Hospital Rooms*, 61 INT'L J. HOSPITALITY MGMT. 59, 61 (2017) (stating Mayo Clinic offers a "suite" product).
31. Harvey et al., *supra* note 8, at 371.
32. *Id*.
33. Ctrs. for Medicaid & Medicare Servs, *Outpatient Rehabilitation Providers*, https://www.cms.gov/ Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/OutpatientRehab.html (last visited, Feb. 17, 2018) [hereinafter *Outpatient Rehabilitation Providers*].

hospitality wing for patients. This could very well lead to increased financial flexibility to affect the treatment of all the hospital's patients.[34] Patient hotels may also increase a hospital's ability to accommodate patients that are not financially secure enough to be moved to a patient hotel but may benefit from increased hospital space.[35] One example of this potential may be found in the recent approval of a hospital to offer free lodging and meals for financially needy patients.[36]

III. LEGAL RISKS ASSOCIATED WITH IMPLEMENTATION OF PATIENT HOTELS

Introducing patient hotels into the American medical system incurs a few potential legal hurdles, however, proper planning at the early stages of design would likely overcome any potential issues. First, the construction of patient hotels requires abiding by the relevant real estate and building regulations. Second, if patient hotels treat Medicare and Medicaid patients, there may be legal pitfalls related to Stark and Anti-Kickback liability. Furthermore, efforts to provide hotel-like accommodations could subject hospitals to hospitality laws.

Hospitals would be able to rely on new or currently owned real estate to add a patient hotel as a new building or a wing. For some hospitals a patient hotel can be included within large, multi-building medical campuses.[37] By contrast, others will require additional land and new construction. Hospital officials may need to engage third party real estate firms or handle the transaction themselves.[38] Regardless, real estate transactions, particularly

34. James Swann, *Hospital Can Give Needy Patients Free Meals, Lodging*, 25 BNA HEALTH CARE POL'Y REP. 434 (Mar. 20, 2017).

35. *Id*.

36. *Id*.

37. NORTHWESTERN MEDICINE, *Guide to the Downtown Medical Campus*, https://www.nm.org/-/media/Northwestern/ Resources/locations/northwestern-memorial-hospital/northwestern-medicine-nmh-medical-campus-map-en.pdf?la=en.

38. John Claybrook & Deeni Taylor, *The $36M Mistake: Why Hospitals and Health*

those involving medical professionals, poses increasing risks for hospitals and health systems.[39] Depending on the complexity of medical care that hospitals intend to provide in a particular patient hotel, there could be instances where leasing the patient hotel to a medical professional to manage separately could be a cost-effective business transaction. However, hospitals should be wary of establishing patient hotels in such a manner, due to fraud and abuse implications.[40]

Regarding the design of the patient hotel, building design guidelines for hospitals and health care facilities have already predicted the lean toward patient-centered treatment environments.[41] The current design building guide emphasizes cost-effective building styles with therapeutic environments.[42] In addition, patient hotels are being designed as "all inclusive 'wellness centers'", the building construction would require adherence to various building codes and standards which include the International Building Code, Joint Commission, Americans with Disabilities Act, ABA accessibility standards, the standards of the Occupational Safety and Health Administration.[43] Furthermore, construction of the beds of patient hotels would need careful tailoring to toe the line between a hospitality bed and a hospital bed subject to federal regulation.[44] Currently, at least six different hospital bed types are regulated under chapter 21 of the Code of Federal Regulations.[45] Considering that these factors may prove discouraging for

Systems Need to be Aware of Real Estate Risks, BECKER'S HOSP. REV. (Feb. 8, 2013), https://www.beckershospitalreview.com (follow "legal & regulatory" hyperlink; or enter article name into site-wide search).

39. *Id*.

40. Andrew Dick & Kevin Howard, *A Review of the Stark and Anti-Kickback Statute as Applied to Real Estate Transactions*, AM. HEALTH LAW. ASS'N (Mar. 16, 2012) https://www.healthlawyers.org/Events/Webinars/RoundtableDiscussions/2012/Documents/roundtable_discussion_slides_120316.pdf.

41. Robert F. Carr, *Hospital*, WHOLE BUILDING DESIGN GUIDE (Apr. 6, 2017) https://www.wbdg.org/building-types/health-care-facilities/hospital.

42. *Id*.

43. *Id*.

44. U.S. Food & Drug Admin., *supra* note 9.

45. *Id*. (assessing the medical devices found through the FDA).

smaller hospitals, there is nothing that points out that the patient hotel concept cannot be adapted by existing structures that already meet building guidelines.

The Stark law and the Anti-Kickback Statute are implicated whenever a "healthcare provider sells or leases real estate to any third party."[46] The Stark law specifically prohibits physicians that have a financial relationship with a healthcare provider from making referrals to that provider where reimbursement is provided through Medicare or Medicaid.[47] Stark does have exceptions that allow for referral for physicians in the same practice group.[48] Thus, it would be in the best interest of a hospital investing in a patient hotel to consider staffing the facility with doctors that are affiliated with practice groups in the hospital rather than creating new financial relationships. All aspects of the patient hotel should fall within the guidelines of Stark to prevent potentially disastrous consequences.[49] Despite the potential danger presented by Stark law, the patient hotel concept could easily be established without the use of physicians on staff in the facility. Doing so would substantially decrease a risk of violating the law.

The Anti-Kickback Statute provides a similar roadblock for patient hotels. The statute provides that:

> anyone who knowingly and willfully receives or pays anything of value 'in return for referring an individual to a person for furnishing or arrangement for the furnishing of any item or service for which payment may be made

46. Alice C. Katayama & Lisa A. Lyons, *A Tale of Two Anti-Kickback Cases: Recommendations and Certifications are the New "Referrals"*, 11 ABA HEALTH ESOURCE (2014-2015) https://www.americanbar.org/groups/health_law/publications/aba_health_esource/2014-2015/april/a_tale.html.

47. Dick & Howard, *supra* note 40; 42 U.S.C. §1395(a)(1)(A).

48. 42 U.S.C. 1395(b)(2)(A)(i).

49. Dep't of Justice, *California Hospital to Pay More Than $3.2 Million to Settle Allegations That It Violated the Physician Self-Referral Law* (Jan. 15 2016) https://www.justice.gov/opa/pr/california-hospital-pay-more-32-million-settle-allegations-it-violated-physician-self-0.

> in whole or in part under a Federal health care program' can be held accountable for a felony.[50]

Broad interpretations of the Anti-Kickback statute as recently as 2015 have resulted in the extension of the statute to include even physician speeches as potential criminal activity.[51] Significant enforcement actions have created strong incentives for hospitals to ensure they satisfy one of the laws safe harbors.[52] Patient hotels would likely qualify under a safe harbor for personal service and management contracts with any physicians that could potentially practice in the facility.[53] The particular risks from Stark and AKS arise from the inclusion of physician services associated with medical services and real estate leasing of facilities.[54] However, the ideal patient hotel concept could rely on limited medical services carried out by nurses and nutritionists within the center in an effort to minimize the opportunities for violations to occur.[55]

The patient hotel concept may also be subject to hospitality regulations, given the nature of services provided. Hotel-like services that hospitals could potentially provide would likely fall under the relevant state hospitality laws.[56] These laws would require hospitals to determine the type of staff managing a patient hotel and determine the various contracts of employment for the staff. Should a patient hotel be deemed one of the various CMS designations for a medical facility, there may be staffing requirements that include minimums on the number of trained medical staff available

50. Katayama & Lyons, *supra* note 46; 42 U.S.C. §1320a-7b (2017).
51. Katayama & Lyons, *supra* note 46.
52. *Id*.
53. *Id*.
54. *Id*.
55. Quinto, *supra* note 1.
56. Jeffrey Miller, *Hospitality Law*, GPSOLO (May 2010) https://www.americanbar.org/newsletter/publications/gp_solo_magazine_home/gp_solo_magazine_index/miller.html.

throughout the day in a facility.[57] Patient hotels would also need to adhere to the relevant state laws regarding contracting with visitors.[58] Similar to basic hotels, the patient hotels would likely require contracts with visitors regarding booking.[59] State-based innkeeper and guest rights would regulate the potential liability for patient hotels for injury to their occupants on top of the potential liability brought on by injuries in medical facilities.[60] Consumer protection statutes would also be involved in protecting guests from non-disclosure of taxes and fees involved with booking a room, although the upfront payment style that could be adopted from the Scandinavian model would likely remedy this particular issue.[61]

Risks for a potential patient hotel may also include security breaches from third parties. Cyberattacks aimed at hotels have increased to such a degree that hotel business guidance from lawyers with expertise in the field has been implemented to ensure the protection of guest information.[62] Patient hotels provide a higher degree of risk from cyberattack, considering guests would both have financial and medical information on file in the hotel system. General business practices regarding cyber protection may prove useful for patient hotel operators, however, legal risks may arise for poor security practices and failure to properly respond in the event that cyberattacks do occur.[63] This is illuminated by numerous settlements with the Federal Trade Commission over violations of the FTC act, including a settlement with Wyndham Hotels and Resorts.[64] In that case, the FTC alleged that Wyndham

57. *Outpatient Rehabilitation Providers*, *supra* note 33.
58. *Id*.
59. *Id*.
60. *Id*.
61. *Id*.
62. Jim Butler, *Cyberattacks on Hotels—What Should Hotel Owners and Operators Do?*, HOTEL BUS. R., https://cybersecurity.jmbm.com/2018/01/12/cyberattacks-hotels-hotel-owners-operators/ (last visited Feb 16, 2018).
63. Quinto, s*upra* note 1.
64. Press Release, Jessica Rich, Director of the Fed. Trade Comm'n Bureau of Consumer Prot., Wyndham Settles FTC Charges It Unfairly Placed Consumers' Payment Card Information at Risk (Dec. 9, 2015) (online at https://www.ftc.gov/news-events/press-

had engaged in unfair and deceptive acts related to their data security when they exposed payment card information of consumers.[65]

Despite the various risks involved with the patient hotel concept, hospitals should be capable of implementing the concept with guidance from legal professionals in real estate and business transactions.[66]

IV. CONCLUSION

Although there exist legal and logistical obstacles to the implementation of patient hotels in the U.S. hospital infrastructure, their addition could provide significant contributions to the overall care for patients. Patient hotels have the potential to alleviate the pressure of crowded hospitals and provide significantly better accommodations for patients. Further engagement in the concept by hospital systems and a closer analysis of the concept success abroad may be necessary to determine whether the concept can truly flourish in the United States, but interest may push major hospital systems to consider adding a hotel wing to their hospital campus. With careful implementation of the concept, American hospitals will be capable of alleviating crowding while ensuring compliance and avoiding penalties or enforcement actions.

releases/2015/12/wyndham-settles-ftc-charges-it-unfairly-placed-consumers-payment).

65. *Id*.

66. Dick & Howard, *supra* note 40.