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ANNALS OF HEALTH LAW
Advance Directive

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

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Beazley Institute for Health Law and Policy

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ANNALS OF HEALTH LAW
Advance Directive

Editors' Note

The *Annals of Health Law and Life Sciences* is proud to present the twenty-sixth issue of our online, student-written publication, *Advance Directive*. This Issue's articles focus on the racial, ethnic, and gender disparities that are rampant within the United States' healthcare system.

The *Spring 2021 Advance Directive* Issue will dive into a broad spectrum of topics within the current conversation taking place in the United States surrounding racial, ethnic, and gender inequalities. These issues have been brought to the forefront of healthcare discussion by recent events including the COVID-19 pandemic and racial unrest.

This Issue addresses health disparities that have an adverse impact on populations that experience systemic obstacles in accessing quality healthcare in the United States. This Issue also aims to evaluate the constitutionality of state and federal responses to current and future health crises. Additionally, this Issue proposes novel ways to fund healthcare programs using tax dollars. Further, the Issue discusses the impact of racism and discrimination in both accessing and receiving culturally competent care. Finally, this Issue draws attention to the use of current technology to reduce disparities commonly seen in the healthcare system. The range of topics covered in this Issue exemplifies the widespread failure of the United States healthcare system in addressing racial, ethnic, and gender disparities.

We would like to thank Karin Long, our Annals Editor-in-Chief, for her leadership and support. We would also like to thank and acknowledge our Annals Executive Board Members: Dan Duffy, Natasha Shukla, and Krystal Tysdal. The members of Annals deserve recognition for their hard work, dedication, and well-thought articles. Lastly, we must thank the Beazley Institute for Health Law and Policy and our faculty advisors, Professors Sawicki and Paradise and Kristin Finn for their guidance and support.

We hope you enjoy this Issue of *Advance Directive*.

Sincerely,

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Addressing Racial Disparities in the Distribution of the COVID-19 Vaccine

Matt Allinder

I. INTRODUCTION

It is well documented that systemic health and social inequalities have put many individuals belonging to racial and ethnic minority groups at increased risk of being exposed to and dying from COVID-19.[1] Social determinants of health are conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.[2] For individuals that belong to racial and ethnic minority groups, inequalities in social determinants of health are interrelated and create barriers that prevent them from having fair opportunities for economic, physical, and emotional help. COVID-19 has amplified the effect of these disparities.[3]

Now, after nearly a year of social distancing, a vaccine has been authorized and has kicked off the most urgent mass immunization campaign since polio shots were rolled out in the 1950s.[4] In the race to vaccinate Americans against COVID-19, there are growing concerns about racial and

[1] *Health Equity Considerations and Racial and Ethnic Minority Groups*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html (last updated February 12, 2021).
[2] Office of Disease Prevention & Health Promotion, *Social Determinants of Health,* HEALTHYPEOPLE.GOV, https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health (last visited April 28, 2021).
[3] *Health Equity Considerations and Racial and Ethnic Minority Groups*, *supra* note 1.
[4] Peter Loftus & Melanie Grayce West, *First Covid-19 Vaccine Given to U.S. Public,* WALL ST. J. (Dec. 14, 2020), https://www.wsj.com/articles/covid-19-vaccinations-in-the-u-s-slated-to-begin-monday-11607941806.

ethnic disparities in the distribution and administration of the vaccine.[5] Early data shows that Black and Latino Americans are receiving the COVID-19 vaccination at a significantly lower rate than white Americans, despite the fact that Black and Latino Americans are dying from COVID-19 at three times the rate of white Americans.[6]

There is a long history of racial disparities in vaccination rates, rooted in abuse and mistreatment by the healthcare system.[7] COVID-19 has exacerbated and amplified health disparities among racial and ethnic groups, and health officials must work proactively and intentionally to make the distribution of the COVID-19 vaccination as equitable as possible to combat these issues.[8]

While federal agencies have attempted to address and prevent further racial and economic disparities with vaccination distribution, there is a greater responsibility being placed on state, territorial, and local governments.[9] Because one of the primary ways to accomplish mass vaccination is a targeted approach, states are in a unique position to address vaccination disparities in the fight against COVID-19. Additionally, the federal government has left it up to the states to decide on their own plan for which groups of people will be vaccinated first.[10] For these reasons, this article will not address policies and legislation that should be implemented

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[5] Ari Shapiro, *Early Data Shows Striking Racial Disparities In Who's Getting the COVID-19 Vaccine*, NPR (Jan. 28, 2021), https://www.npr.org/sections/coronavirus-live-updates/2021/01/28/961703505/early-data-shows-striking-racial-disparities-in-whos-getting-the-covid-19-vaccin.
[6] *Id.*
[7] Samantha Artiga & Jennifer Kates, *Addressing Racial Equity in Vaccine Distribution,* KAISER FAM. FOUND. (Dec. 3, 2020), https://www.kff.org/racial-equity-and-health-policy/issue-brief/addressing-racial-equity-vaccine-distribution/.
[8] *Id.*
[9] *Id.*
[10] *Frequently Asked Questions about Vaccination,* CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html (last updated Jan. 25, 2021).

on a federal level. Instead, this article will focus on steps that states can take on a local level.

On a state and local level, vaccination disparities can be addressed by greater implementation of evidence-based interventions, including the use of reminder/recall systems, standing orders for vaccinations, regular assessments of vaccination coverage levels among provider practices, vaccination registries, and improving public and provider awareness of the importance of vaccination. Multi-sector collaborations including culturally relevant communications to reach specific target populations are important parts of reducing vaccination and health disparities, generally. While systemic health and social inequalities may seem insurmountable, there are a variety of policies and steps that can be implemented to mitigate the growing disparity in COVID-19 vaccination levels across racial and ethnic groups.

II. A HISTORY OF RACIAL DISPARITIES IN VACCINATION RATES

Disparities in vaccination levels among racial and ethnic groups are not novel.[11] In 2014, the 2012 National Health Interview Survey was analyzed to assess adult vaccination by race and ethnicity for six vaccines routinely recommended for adults.[12] Vaccination coverage was substantially lower among African Americans and Asian Americans when compared to white Americans.[13] Factors like age, education, insurance coverage, usual place of care, and number of physician visits were independently associated with the receipt of a vaccine.[14] After taking these factors into account, the study showed that racial and ethnic differences narrowed, but gaps still remained.[15]

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[11] *See generally* Peng-jun Lu et al., *Racial and Ethnic Disparities in Vaccination Coverage Among Adult Populations in the U.S.,* 49 AM. J. OF PREVENTATIVE MED., S412-25 (2015), https://www.ajpmonline.org/article/S0749-3797(15)00099-9/fulltext.
[12] *Id.*
[13] *Id.*
[14] *Id.*
[15] *Id.*

The specific factors that account for this gap are unclear, but it likely stems from systemic health and socioeconomic inequalities among racial and ethnic groups.

In addition to these inequalities, another contributing factor is difference in the level of trust placed on physicians and the healthcare system among racial and ethnic groups.[16] Trust is a key component in the physician-patient relationship.[17] In healthcare, trust in physicians is generally defined as the belief that the physician will act in your best interest and that the physician is honest and competent.[18] It is commonly believed that trust in physicians has declined over the past forty years in the United States.[19] This decline can be attributed to the growth of for-profit healthcare, prior episodes of unethical research, malpractice, and publicity surrounding medical errors.[20] This distrust has centered on the African American population because of the long history of negative treatment and abuse of African Americans dating back to slave experimentation and including the Tuskegee Syphilis Study.[21] Researchers for the American Journal for Public Health conducted a study to examine the differences in physician trust among racial groups and found distrust of physicians was higher among African Americans and Hispanics than among Whites.[22]

III. ANALYSIS

The Centers for Disease Control ("CDC") is working with state, tribal, territorial, and local jurisdictions on the development of COVID-19

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[16] Katrina Armstrong et al., *Racial/Ethnic Differences in Physician Distrust in the United States,* 97 AM. J. OF PREVENTATIVE MED. 1283-1289 (July 2007), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1913079/.
[17] *Id.*
[18] *Id.*
[19] *Id* (discussing how, in most segments of society, social and capital trust has seen a decline in the last 40 years).
[20] *Id.*
[21] Armstrong et al., *supra* note 16.
[22] *Id.*

vaccination plans for their respective areas.[23] State and local municipalities are encouraged to follow the CDC guidelines for implementation and distribution of the vaccine.[24] Within these guidelines there is a strategic framework to help state and local officials facilitate vaccination with confidence.[25] The plan focuses on building trust, empowering healthcare personnel, and engaging with communities and individuals.[26]

Public outreach campaigns can be an effective way to combat disparities in vaccination rates. In Illinois more than four million vaccinations have been administered so far.[27] In Chicago, the vaccination rate in majority-Black or Latino ZIP codes has averaged five percent while majority-White ZIP codes have averaged thirteen percent.[28] Mayor Lori Lightfoot has repeatedly acknowledged the long history of distrust of vaccines in the African American community and plans to implement an equitable inoculation campaign in the parts of the city that have been hit hardest by the virus.[29] Still, recent polls conducted in Chicago indicate that only twenty-four percent of African Americans and thirty-five percent of Hispanics plan to get the new vaccine, while fifty-three percent of white residents said they plan to get inoculated.[30] Based on this data, it is clear that public outreach campaigns

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[23] *Frequently Asked Questions about Vaccination*, *supra* note 10.
[24] *COVID-19 Vaccination Program Operational Guidance*, CTRS. FOR DISEASE CONTROL & PREVENTION, (Feb. 16, 2021), https://www.cdc.gov/vaccines/covid-19/covid19-vaccination-guidance.html.
[25] *Id.*
[26] *Id.*
[27] *Pritzker: 100,000 Vaccine Doses Given in Illinois*, MSN News (Dec. 23, 2020), https://www.msn.com/en-us/news/us/pritzker-100000-vaccine-doses-given-in-illinois/ar-BB1cbqYn.
[28] Nada Hassanein et al., *'Just Not All Equal': Vaccine Rollout in Chicago a Microcosm of Racial Disparities Nationwide,* (Feb. 12, 2021), https://www.usatoday.com/in-depth/news/health/2021/02/12/data-analysis-chicago-vaccine-rollout-reflects-us-racial-disparities/4418978001/.
[29] Christian Spencer, *Chicago Mayor Says There's Reluctance' About Vaccine in Black Community,* YAHOO (Dec. 4, 2020), https://news.yahoo.com/chicago-mayor-says-reluctance-vaccine-005104667.html.
[30] Angie Leventis Lourgos et al., *Clergy, Doctors and Activists Take on COVID-19 Vaccine Hesitancy and Access in Black and Latino Communities: 'Don't Underestimate the Fear'*,

are necessary, however there is more that needs to be done to combat vaccination disparities.

Once the vaccine is widely available to the public, vaccine providers will play a key role in insuring vaccines reach all patients who need them.[31] Local and state officials need to ensure that providers are implementing systems and programs that provide effective vaccine delivery and maintain coverage in their practices.[32] Currently the CDC is working with state and local health agencies to administer a quality improvement program to introduce and sustain new or improved immunization practices.[33] These programs are intended to motivate health professionals to try new immunization service delivery strategies and incorporate changes into their practices.[34] In order to reduce disparities in vaccine coverage, routine monitoring and reporting of vaccine coverage by race, ethnicity, and other socio-demographic factors might be needed.[35]

Combating distrust of physicians will not be an easy task, but it is crucial towards bridging the vaccination gap. There are several ways in which healthcare providers can implement patient-focused vaccination strategies within their own practices.[36] A strong recommendation by a health care provider is still one of the most powerful motivators for patients to comply with a vaccination.[37] Research has shown the way a healthcare professional approaches a vaccination recommendation makes a difference.[38] When the

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CHICAGO TRIBUNE, (Dec. 19, 2020), https://www.chicagotribune.com/coronavirus/ct-coronavirus-vaccine-black-latino-20201219-x6wlkklgqzbunovx5jub4w4dwi-story.html.

[31] *Immunization Strategies for Healthcare Practices and Providers,* CTRS. FOR DISEASE CONTROL & PREVENTION (July 2020), https://www.cdc.gov/vaccines/pubs/pinkbook/strat.html (discussing various strategies and best practices for immunizing both children and adults).

[32] *Id.*

[33] *Id.*

[34] *Id.*

[35] Lu et al., *supra* note 11.

[36] *Immunization Strategies for Healthcare Practices and Providers, supra* note 31.

[37] *Id*.

[38] *Id.*

provider uses a "presumptive approach," that assumes a patient will choose to vaccinate, the patient is more likely to accept the vaccination.[39] This approach was especially effective for first time visits.[40] Furthermore, a discussion of the benefits of vaccination has also been proven to be effective for vaccination compliance.[41] In this way, a physician or health professional is able to hear a patient's concerns and tailor their approach and reinforce the safety of the vaccine.[42] Therefore, it is critical that state and local officials work with healthcare providers to implement new and effective practices that will increase vaccination rates and combat physician distrust.

Another way to combat physician distrust is by creating a "culture of immunization" within a practice.[43] According to the CDC, one way to accomplish this goal is designate an immunization coordinator.[44] This individual would be the provider site's point person for all immunization activities including ensuring all staff know how to address questions from patients to maintain consistent messaging about vaccinations and promoting and motivating staff implementation of vaccination quality improvement strategies.[45] The immunization coordinator would also be responsible for setting up a system for vaccination reminders that help their fellow providers remember to recommend vaccinations.[46]

In the United States, the general public may begin to have access to the vaccine by as early as April 2021.[47] Most states are still prioritizing who will

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[39] *Id.*
[40] *Id.*
[41] *Id.*
[42] *Id.*
[43] *Id.*
[44] *See id.* (discussing why having an individual who is familiar with the practice's vaccination coverage and why some patients may not be up to date with vaccination coverage can help providers implement interventions to increase coverage in their practice).
[45] *Immunization Strategies for Healthcare Practices and Providers*, *supra* note 31.
[46] *Id.*
[47] Jason Hanna et al., *COVID Vaccines Could be Available to the General Public in April in the United States, Fauci Says*, CNN HEALTH (Feb. 12, 2021), https://www.cnn.com/2021/02/11/health/us-coronavirus-thursday/index.html.

receive the vaccine first, according to CDC guidelines.[48] However, each state is responsible for implementing its own distribution plan.[49] Therefore, it is crucial that state and local officials work closely with healthcare providers and professionals to address the emerging disparities in vaccination rates among racial and ethnic groups. From examining the history of disparity among vaccinations it is clear that a tailored approach and multi-sector collaborations that include culturally relevant communications to reach specific target populations is necessary. These approaches can be effective interventions that play a crucial rule in reducing vaccine disparities.

At the time of this writing, most states are still trying to get the vaccine to those in the first recommended phases of the rollout: healthcare workers, individuals over the age of seventy-five, and frontline essential workers.[50] In the coming months, state and local officials will bear much of the responsibility for distributing the vaccine.[51] Funding will be critical for vaccine storage, public education, and vaccine transportation.[52] Promoting equality in the vaccination will require investment and resources to ensure that outreach to minority groups is effective.[53]

In addition to better funding, there are additional steps that the states can take individually. It is unlikely that the federal government or the state governments will mandate vaccination.[54] So, the states may need to consider

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[48] *How Are States Prioritizing Who Will Get the COVID-19 Vaccine First?,* KAISER FAM. FOUND. (Dec. 16, 2020), https://www.kff.org/coronavirus-covid-19/press-release/how-are-states-prioritizing-who-will-get-the-covid-19-vaccine-first/.
[49] *Id.*
[50] WSJ Staff, *How to Get a COVID-19 Vaccine: A State-by-State Guide,* WALL ST. J (Mar. 11, 2021), https://www.wsj.com/articles/how-to-get-a-covid-19-vaccine-a-state-by-state-guide-11611703769.
[51] David Blumenthal et. al, *States Need Federal Help to Get COVID-19 Vaccines into Millions of Arms,* TO THE POINT (Dec. 16, 2020), https://www.commonwealthfund.org/blog/2020/states-need-federal-help-get-covid-19-vaccines-millions-arms.
[52] *Id.*
[53] *Id.*
[54] Grace Hauk, *Yes, Some Americans May be Required to Get a COVID-19 Vaccine But Not by the Federal Government,* USA TODAY (Dec. 5, 2020), https://www.usatoday.com/story/news/nation/2020/12/05/covid-vaccine-required-government-employers/3797885001/.

other alternatives, such as a requirement of vaccination prior to returning to schools and workplaces.[55] In the past, school entry has been an effective way of increasing vaccination compliance so this may be the route that many state officials choose.[56]

IV. CONCLUSION

Social determinants of health and distrust of vaccinations and physicians are significant barriers to combating vaccination disparities among racial and ethnic groups. State and local governments will have the greatest responsibility when it comes to combating these disparities. Culturally relevant communications that are designed to reach targeted groups will be an effective way to reduce vaccination disparities. In addition to these efforts, it is critical that healthcare providers and physicians are implementing best practices for vaccination, to create an "culture of immunization." Implementation of these evidence-based interventions will help spread awareness about the safety and efficacy of the COVID-19 vaccination.

[55] *Id.*
[56] *Immunization Strategies for Healthcare Practices and Providers*, *supra* note 31.

Importance of Improved Privacy and Security Regulations Regarding Telehealth in Order to Better Ensure the Safety of Information Given From Undocumented Hispanic Immigrants to Healthcare Professionals

Anne Bohnert

I. INTRODUCTION

With healthcare spending on the rise, and no obvious way to prevent it, policymakers are looking to telehealth as a way to cut back costs while also increasing access to care for many.[1] Telehealth uses technology in order to facilitate remote communication between the patient and healthcare provider.[2] The idea behind telehealth is that it will help to improve areas of medicine such as education and self-management, as well as make specialists available to those who may live in remote areas or far away from the specialist they need.[3] Not only will there be easier access to care, but the use of telehealth also enables physicians to track information about the patient such as glucose monitoring, sleep patterns, and lung function, through wearable devices.[4] The ultimate goal is for telehealth to be a convenient and cost-efficient route to receive care, especially for those from underserved communities and backgrounds.[5]

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[1] Sydne Enlund & Caroline Vesey, *Increasing Access to Health Care Through Telehealth,* NATL. CONF. OF STATE LEGIS., May 2019, at 1.
[2] *Id.*
[3] Mayo Clinic Staff, *Telehealth: Technology Meets Health Care*, MAYO CLINIC, May 15, 2020, https://www.mayoclinic.org/healthy-lifestyle/consumer-health/in-depth/telehealth/art-20044878.
[4] *Id.*
[5] Enlund & Vesey *supra* note 1, at 1.

With the recent increase in the use of telehealth due to COVID-19 and the need for social distancing, undocumented immigrants, such as Hispanic immigrants, have been put on the backburner.[6] There is now a dire need to improve telehealth in many areas, including privacy and security, internet access limitations, and the limited English proficiency of many undocumented immigrants.[7] Prior to telehealth becoming medium of healthcare, it is important that policymakers make major changes in the areas mentioned above.

This article will begin by discussing current regulations in telehealth as well as undocumented Hispanic immigrant's history navigating the health care system. This article will then provide an explanation as to why increased regulations in telehealth are needed for Hispanic immigrants. Lastly, this article will discuss and propose ways to help improve the privacy and safety surrounding telehealth for the Hispanic immigrant population.

II. CURRENT REGULATIONS REGARDING TELEHEALTH

In the early months of 2020, the healthcare industry understood the importance of utilizing telemedicine in responding to the COVID-19 public health emergency.[8] The technology to implement it has been around for a while, however, prior to COVID-19, physicians were not appropriately reimbursed for providing telemedicine.[9] For example, in order to be reimbursed by Medicare, the patient must first have an in-person visit with the physician.[10] Even after having the initial visit face-to-face, physician's

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[6] Altaf Saadi & Jorge A. Rodriguez, *Addressing Privacy Concerns Central to Success of Telehealth Use Among Undocumented Immigrants*, HEALTH AFFS. BLOG (Nov. 23, 2020), https://www.healthaffairs.org/do/10.1377/hblog20201118.621497/full/.
[7] *Id.*
[8] David Shaywitz, *Why Telehealth Champions are Worried About Health*, AM. ENTERPRISE INSTITUTE (March 23, 2020), https://www.aei.org/articles/why-telehealth-champions-are-worried-about-trust/.
[9] *Id.*
[10] *Id.*

pay is not equivalent to an in-person appointment.[11] In addition to lack of proper reimbursement, Health Insurance Portability and Accountability Act (HIPAA) regulations limit the type of devices and applications that can be used to communicate with patients due to security and privacy concerns.[12]

In the midst of the COVID-19 outbreak, the Department of Health and Human Services (HHS) put out a notice stating providers would not need to comply with HIPAA regulations.[13] This change allowed for providers to assess and/or diagnose patients over most forms of video chat to allow for social distancing.[14] As a result of the COVID-19 waivers, physicians are now able to speak with and assess their patients over applications like FaceTime, even if the medical issues being discussed have nothing to do with COVID-19.[15] These relaxed restrictions should make it much easier for physicians to reach their patients. Many in the healthcare industry believe protocols such as these relaxed HIPAA regulations will revert back to its original guidelines once the pandemic has subsided and life goes back to "normal."[16] This leads one to question whether the uptick in the use of telehealth will continue after COVID-19 has subsided, or if telehealth usage will decrease due to the countless regulations that make it a daunting but a much safer route for physicians to communicate with their patients.[17]

Even without these relaxed regulations, there are many concerns regarding the security and privacy of information being discussed during a telehealth

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[11] *Id.*
[12] *Id.*
[13] U.S. DEPT. OF HEALTH AND HUMAN SERV., NOTIFICATION OF ENFORCEMENT DISCRETION FOR TELEHEALTH REMOTE COMM. DURING THE COVID-19 NATIONWIDE PUBLIC HEALTH EMERGENCY (2021).
[14] *Id.*
[15] Weigel et al., *Opportunities and Barriers for Telemedicine in the U.S. During the COVID-19 Emergency and Beyond*, KAISER FAM. FOUND., (May 11, 2020), https://www.kff.org/womens-health-policy/issue-brief/opportunities-and-barriers-for-telemedicine-in-the-u-s-during-the-covid-19-emergency-and-beyond/.
[16] Shaywitz, *supra* note 8.
[17] *Id.*

visit with one's provider.[18] The concerns are not only coming from the providers, but from the patients as well.[19] One of the biggest fears of both patients and providers is that information shared will not stay confidential because of the types of devices and applications being used.[20] Outside of the communication aspect, there are also concerns with the privacy of medical devices being used.[21] For example, a patient who wears a device on their body in order to detect medical emergencies may not realize the potential for that device to also store other private information.[22] There is always the potential of a security breach and telehealth is a target for those trying to hack into others personal information.[23] Communications between two physicians have always been protected with data encryption measures and authentication, making them safe, however this is not true for communications between a physician and the patient.[24] Because of the lack of security regulations, hackers have an easier route to patient information.[25] In addition, providers worry that they will not be reimbursed properly for the services they provide via telecommunication.[26] Compared with in person visits, they have been getting reimbursed far less.[27] Between lack of proper reimbursement and the restriction of only being able to virtually "see" patients in states the provider is licensed in, there is not much incentive for

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[18] Joseph L. Hall & Deven McGraw, *For Telehealth to Succeed, Privacy and Security Risks Must be Identified and Addressed*, 33 HEALTH AFFS. 216, 216 (2014).
[19] Timothy M. Hale & Joseph C. Kvedar, *Privacy and Security Concerns in Telehealth*, 16 VIRTUAL MENTOR 981, 981 (2014).
[20] *Id.*
[21] Hall & McGraw, *supra* note 18, at 217.
[22] *Id.*
[23] Hale & Kvedar, *supra* note 19, at 981.
[24] Hall & McGraw, *supra* note 18, at 217 (communications between a physician and patient fall outside the realm of HIPAA regulations, leading to many security and privacy concerns).
[25] *Id.*
[26] *See* Shaywitz, *supra* note 8 (health systems expert Bob Kocher explains that in order to be reimbursed, Medicare requires an in-person visit before using telehealth, and even after the in-person visit, the reimbursement rates are still lower than they would receive from a typical appointment).
[27] *Id.*

physicians to continue pushing for the use of telehealth.[28] In order for telemedicine to find its place in healthcare and to gain trust from patients, providers must begin to express their trust and eagerness to implement it. [29]

Despite concerns regarding the security and privacy of telehealth, as well as physician reimbursement, there are still great things that can result from an increased use of telemedicine.[30] Recent data shows that hospitals are beginning to believe this as well; roughly seventy-six percent of hospitals now utilize telehealth, up from just thirty-five percent a decade ago.[31] Telehealth is a great alternative for those who, for any number of reasons, are not able to get to an actual office to see their physician. [32] There are many positives that may come of telehealth for patients, including the potential for lower costs, better insights into preventative care, as well as decreasing the spread of illnesses or contracting additional infections while receiving care.[33] Physicians, on the other hand, can see the benefits, such as increasing their income due to being able to see more patients in a day, as well as an increase in patient satisfaction because of shorter wait times and the overall convenience of not having to go into a doctor's office.[34]

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[28] *Id.*
[29] Hale & Kvedar, *supra* note 19, at 983.
[30] HARVARD HEALTH PUBL'G, *Telehealth: The Advantages and Disadvantages*, Oct. 2020, https://www.health.harvard.edu/staying-healthy/telehealth-the-advantages-and-disadvantages.
[31] *Id.* (patients living in rural areas are benefitting greatly, as they now have the ability to see a doctor without having to drive a long distance).
[32] *Id.*
[33] Zawn Villines, *Telemedicine Benefits: For Patients and Professionals*, MED. NEWS TODAY, (April 20, 2020), https://www.medicalnewstoday.com/articles/telemedicine-benefits.
[34] *Id.*

III. UNDOCUMENTED HISPANIC IMMIGRANTS HISTORY WITH HEALTH CARE SYSTEM

In March of 2010, the Affordable Care Act (ACA) was enacted in the hopes of bettering the healthcare system in the United States.[35] Although this was a great benefit for many Hispanic immigrants who were now eligible for healthcare coverage, the process of applying was complex and confusing for most due to obstacles such as language barriers.[36] Even with translation, many had never heard most of the complex words and terminologies that make up the insurance industry.[37] In addition to these barriers, immigrants in the U.S. had another major concern: deportation. [38] Authors Karen Hacker, Maria Anies and Leah Zallman compiled sixty-six published articles and concluded sixty-five percent of the articles mentioned deportation as a barrier due to the fear of authorities being notified that an undocumented immigrant was being taken care of at the hospital.[39] Still, several other barriers included an inability to find necessary transportation as well as a fear of being fired if they miss work for an appointment.[40]

All of these fears have been exacerbated by the changes being made to the public charge rule under our past administration, which makes immigrants ineligible for lawful permanent residence (LPR) status.[41] An undocumented immigrant is considered a public charge if they receive at least one public benefit for more than twelve months within a three-year period.[42] The list of

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[35] Inst. For Latino Studies Uni of Notre Dame, *Latino Immigrants and the Paradox of Health Care in America*, Latino Studies, 2013, at 2.
[36] *Id.* at 6.
[37] *Id.*
[38] Karen Hacker et al., *Barriers to Health Care for Undocumented Immigrants: A Literature Review*, 8 NCBI 175, 178 (2015).
[39] *Id.*
[40] *Id.*
[41] Saadi, *supra* note 6.
[42] DEPT. OF HOMELAND SECURITY, PUBLIC CHARGE FACT SHEET (2020), https://www.uscis.gov/news/public-charge-fact-sheet.

services offered that could make an immigrant a public charge expanded greatly.[43] Not only was this a threat to Hispanic immigrants trying to cross the border, but it has also forced many already in America to decide between their family's health or the safety of staying in America.[44]

The threat of deportation has led many immigrants to wait until they fear imminent death before they seek care.[45] Hospitals in Chicago have gone as far as to post brochures and posters stating that they are not affiliated with law enforcement in order to limit the anxiety of immigrants who fear they will be deported if healthcare workers discover they are undocumented.[46] In a Chicago Tribune article, the author tells the story of one Hispanic immigrant who waited until his toe had turned black, a sign of gangrene which is a side effect of diabetes, before he decided it was time to go to the emergency department.[47] As one could imagine, all of these fears combined have led to decreased health for Hispanic immigrants, including their mental health.[48]

IV. UNDOCUMENTED HISPANIC IMMIGRANTS NEED FOR GREATER REGULATIONS IN TELEHEALTH

As the healthcare industry increases its use of technology, Hispanic immigrants now have an additional worry to add to their plate—the fear that they could be caught by immigration enforcement officials through the use

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[43] Peniel Ibe, *U.S. Allows Trump Admin. To Move Forward With Cruel "Public Charge" Rule*, AM. FRIENDS SERV. COMMITTEE BLOG, (Feb. 24, 2020), https://www.afsc.org/blogs/news-and-commentary/what-you-need-to-know-about-trumps-cruel-public-charge-proposal.
[44] *Id.*
[45] Alexia Elejalde-Ruiz, *Fear, Anxiety, Apprehension: Immigrants Fear Doctor Visits Could Leave Them Vulnerable to Deportation*, CHI. TRIBUNE, (Feb. 22, 2018), https://www.chicagotribune.com/business/ct-biz-immigration-fears-hurt-health-care-access-0225-story.html.
[46] *Id.*
[47] *Id.*
[48] *Id.* (citing decrease in mental health stemming from families fears that they will be split apart if they go to a hospital to receive medical care).

of telehealth.[49] A study done on Hispanic immigrants showed that many had concerns that the government agencies (hospitals and law enforcement) would be able to share the information given to their physicians.[50] In addition, HIPAA regulations do not protect information shared on the device patients are using, they only protect provider-to-provider communications.[51] Along with the use of telecommunication, providers are now utilizing remote monitoring tools such as blood pressure cuffs as well.[52] These monitoring tools, although a great way to assess patients from afar, add an additional route that undocumented immigrants' information could be obtained by the wrong people.[53]

In addition to the fear of having their private information end up in the hands of the wrong person are the less obvious fears. Many fail to realize that different cultures are going to place an importance on different areas of telehealth.[54] For example, a Hispanic undocumented immigrant may place a much larger importance on the privacy of their conversations with a physician, compared to a legal citizen, who may not worry about the small likelihood of someone hacking into their medical information. Because of this, there is a great need to explore telehealth from the perspective of all cultures, including American citizens as well as undocumented immigrants.[55] Other potential stressors for undocumented immigrants include whether the process will be easy and straightforward, if they will have someone to converse with that speaks their language, as well as having access to a safe and reliable internet source.[56]

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[49] Saadi & Rodriguez, *supra* note 6.
[50] *Id.*
[51] *Id.*
[52] *Id.*
[53] *Id.*
[54] Ann Blandford et al., *Opportunities and Challenges for Telehealth Within, and Beyond, a Pandemic*, 8 LANCET 1364, 1365 (2020).
[55] *Id.*
[56] *Id.*

V. PROPOSED WAYS TO IMPROVE PRIVACY AND SECURITY REGULATIONS IN ORDER TO ENSURE SAFETY FOR UNDOCUMENTED IMMIGRANTS

An increase in the regulations will allow for many immigrants, including Hispanic immigrants, to feel a sense of safety when utilizing new technology such as telehealth. COVID-19 has brought much attention to the lack of protection guaranteed to undocumented immigrants who utilize these services.[57] Dr. John Emdur, a doctor in Colorado, began a non-profit called Clinica Colorado, to give undocumented immigrants access to volunteer doctors and medical students via telehealth.[58] This organization promises safe, free access, to bi-lingual health care providers who are HIPAA compliant.[59] This service, which will remain after the pandemic is over, gives undocumented immigrants in Colorado somewhere to turn to where they are not afraid that deportation is going to be the end result of a health scare.[60] This program has helped to prevent surges in the health care system and has been used to educate immigrants on when it is appropriate and necessary to go to the emergency room.[61]

Non-profits, such as the one mentioned above, give hope that more options like that will be made available to undocumented immigrants moving forward in other states as well. Telehealth is not just a cost-effective way to give immigrants the medical services that they need, but it can also be a great route for preventative care and education.[62] Lack of knowledge regarding proper treatment is an issue for immigrants.[63] Cultural beliefs and practices,

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[57] *Id.* at 1364.
[58] Georgia Perry, *Clinica Colorado Provides Telehealth Services to Undocumented Immigrants*, DENVER'S MILE HIGH MAGAZINE, (May 2020), https://www.5280.com/2020/05/clinica-colorado-provides-telehealth-services-to-undocumented-immigrants/.
[59] *Id.*
[60] *Id.*
[61] *Id.*
[62] Alejandro Portes et al., *The U.S Health System and Immigration: An Institutional Interpretation*, NAT'L INST. OF HEALTH, (Sept. 2009), at 8.
[63] *Id.*

such as folk healers and home remedies, may lead immigrants to prolong a trip to the doctor or emergency department.[64] Having access to a telehealth system where they can find information in their native language on preventative care, nutrition and basic hygiene could help keep them out of the hospital in the first place.[65]

One of the main areas that needs to be better regulated is privacy and security.[66] While it is important not to push back on the great advancements that have been made, healthcare providers must be able to ensure to their patients that provided medical information is and will remain confidential and protected.[67] As the pandemic subsides, and telehealth is not the only option, providers need to take a step back and make sure they have all proper security measures in place to allow for a safe space to converse with their patients.[68] The initial rush to utilize telehealth was necessary, but now the relaxed protocols should be removed, and providers need to start from the beginning to make sure they are following all HIPAA protocols.

There are many important steps to ensuring this safety. One topic discussed is the use of multi-factor authentication (MFA) when logging in to meet with a healthcare provider.[69] It has been proven that having MFA prevents 99.9% of hackers from hacking into your personal information.[70] By using MFA, instead of simply asking for a username and password to enter a telehealth appointment, the patient would need to answer an additional security question or enter a code given from the physicians'

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[64] *Id.*
[65] *Id.*
[66] *Id.*
[67] *Id.*
[68] *Id.*
[69] Jessica Davis, *Must-Have Telehealth, Remote Work Privacy and Security for COVID-19*, HEALTHITSECURITY, (March 31, 2020), https://healthitsecurity.com/news/must-have-telehealth-remote-work-privacy-and-security-for-covid-19.
[70] *Id.*

office.[71] This would help to reduce unauthorized individuals from obtaining confidential patient information.[72] Another well-liked idea is to dictate how much access clients have available to them based on what type of device they are using for the telehealth appointment.[73] For example, if using FaceTime on their phone, a patient may only be able to have the conversation, whereas if they are using a healthcare app on their laptop, they would have access to information such as their health history.[74] Another relevant factor is education for both provider and patient.[75] Providers need to make sure that all employees have a baseline understanding of how to use the applications in order to ensure that they keep patient information confidential and do not end up sharing information with the wrong person.[76] Patients also need to be educated on how they can help to make sure their information stays confidential.[77] One way they could make sure education is received on both ends would be to require all workers to receive proper education as well as requiring patients to watch an educational video prior to beginning the use to telehealth.

Not only is the lack of privacy and security a common concern for all, but it is one of the biggest worries of undocumented immigrants.[78] As mentioned throughout this article, immigrants fear that law enforcement will be able to access the information they share with providers via telehealth.[79] In order to help ease the concerns of immigrants, healthcare providers utilizing telehealth should be required to inform patients of the risks associated with

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[71] *Id.*
[72] *Id.*
[73] *Id.*
[74] *Id.*
[75] Mike Miliard, *Telehealth Privacy and Security: Investment and Education are Key, Attorney Says*, HEALTHCARE IT NEWS, (June 25, 2020), https://www.healthcareitnews.com/news/telehealth-privacy-and-security-investment-and-education-are-key-attorney-says.
[76] *Id.*
[77] *Id.*
[78] Saadi & Rodriguez, *supra* note 6.
[79] *Id.*

using telehealth to ensure they are properly informed.[80] This will help to ensure that there is a level of trust between patient and provider.[81] Groups such as undocumented immigrants, who could benefit greatly from telehealth, must be a top priority as organizations and healthcare facilities begin to figure out ways to improve the current system.[82]

VI. CONCLUSION

There are a lot of obstacles to navigate in order to be able to properly and efficiently utilize telehealth now and in the future. Undocumented Hispanic immigrants make up a large proportion of people who could greatly benefit from the usage of telehealth. From being able to speak with physicians without having to find transportation or miss work, to being able to watch videos in their native languages to educate themselves, there is a lot of great that could come from the increased use of telehealth. Before telehealth can be further implemented, there are many issues within privacy and security that need to be assessed, and it is key that groups such as immigrants are of upmost concern when discussing ways to improve the system as a whole.

[80] *Id.*
[81] *Id.*
[82] *Id.*

Equitable State Policies for Increasing Insulin Access

Scott Hulver

I. THE INSULIN PROBLEM

Diabetes is a terrible, pervasive disease in the U.S., afflicting an estimated fifteen percent of Americans,[1] and leading to a range of other health complications from kidney disease to death.[2] Although not curable, diabetes is manageable thanks to insulin.[3] For decades now, insulin has extended and saved millions of lives.[4] However, this much-needed access to insulin is being threatened by several changes in the pharmaceutical industry and with insurance. First, the price of insulin is skyrocketing. From 2012 to 2016 alone, the average national price of insulin nearly doubled, averaging $666 per prescription in 2016.[5] High costs create a large barrier to obtaining insulin; there are reports of patients rationing their insulin because they are unable to afford it.[6] Second, people are losing access to insurance, a tool that can help cover the costs of insulin.[7] Although the Affordable Care Act

[1] *Diabetes*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/nchs/fastats/diabetes.htm (last updated Jan. 25, 2021).
[2] Mayo Clinic Staff, *Diabetes*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/diabetes/symptoms-causes/syc-20371444 (last visited Jan. 22, 2021).
[3] *Id*.
[4] *The History of a Wonderful Thing We Call Insulin*, AM. DIABETES ASS'N (July 1, 2019), https://www.diabetes.org/blog/history-wonderful-thing-we-call-insulin.
[5] John Hargraves & Amanda Frost, *Price of Insulin Prescription Doubled Between 2012 and 2016*, HEALTH CARE COST INST. (Nov. 29, 2017), https://healthcostinstitute.org/diabetes-and-insulin/price-of-insulin-prescription-doubled-between-2012-and-2016.
[6] Bram Sable-Smith, *Insulin's High Cost Leads to Lethal Rationing*, NPR (Sept. 1, 2018), https://www.npr.org/sections/health-shots/2018/09/01/641615877/insulins-high-cost-leads-to-lethal-rationing.
[7] Katherine Keisler-Starkey & Lisa N. Bunch, *Health Insurance Coverage in the United States: 2019*, U.S. CENSUS BUREAU (Sept. 15, 2020), https://www.census.gov/library/publications/2020/demo/p60-271.html.

initially helped expand insurance coverage, the number of uninsured people has slowly risen since 2016.[8] This trend is likely exacerbated by COVID-19 as over six million people are thought to have lost employer-sponsored insurance since the beginning of the pandemic.[9] This poses a problem for all diabetic patients, but it is particularly harmful for BIPOC communities.[10]

Racial disparities in patients with diabetes are seen in both diagnoses and insurance coverage.[11] People of color are more likely to be diagnosed with diabetes than white people. Whereas about 7.5% of white people are diagnosed with diabetes, people of color are diagnosed at rates as high as twice that, with Native Americans diagnosed at a rate of 14.7%.[12] Black and Hispanic populations are diagnosed at rates of 11.7% and 12.5% respectively.[13] Similarly, Black people are almost twice as likely as white people to be uninsured, and Hispanic people are more than three times as likely to be uninsured.[14] These rates illustrate how not only is the need for insulin higher in communities of color because of higher rates of diagnoses, communities of color also have a more difficult time than white people accessing affordable insulin because of higher uninsurance rates.

State governments have long been both innovators and experimenters of healthcare policy, and policies around insulin access are no exception.[15]

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[8] *Id*.
[9] Josh Bivens & Ben Zipperer, *Health Insurance and the COVID-19 Shock*, ECON. POL'CY INST. (Aug. 26, 2020), https://www.epi.org/publication/health-insurance-and-the-covid-19-shock/.
[10] *See Statistics About Diabetes*, AM. DIABETES ASS'N, https://www.diabetes.org/resources/statistics/statistics-about-diabetes (last updated March 22, 2018) (explaining the higher rates of diabetes among people of color).
[11] *Id*.
[12] *Id*.
[13] *Id*.
[14] Keisler-Starkey & Bunch, *supra* note 7.
[15] *See e.g.*, The Alec Smith Insulin Affordability Act, HF No. 3100, 91st Leg., Reg. Sess. (Mn. 2020) (guaranteeing that qualified individuals can buy a 30-day supply of insulin for $35).

State policy is particularly important for drug pricing given the lack of federal action.[16] Particularly over the last decade, states have passed a slew of laws to combat rising insulin prices (and laws designed to lower drug prices more generally, including insulin).[17] All of these policies work in different ways, ranging from regulating prices to controlling distribution.[18] Although increasing insulin access for anyone is beneficial, the most needed policies are those designed to eliminate race-based gaps in insulin access. This article will preview a selection of different state approaches to reducing the cost of insulin. This article will then analyze how these different approaches either do or do not help close racial disparities in insulin access and discuss what approach legislators should take when designing insulin access policies.

II. STATE INSULIN ACCESS POLICIES

As the great laboratories of the U.S., states have taken many different approaches to increasing access to insulin.[19] Although price is not synonymous with access, it is the biggest barrier to insulin (be it through copays, out of pocket expenses, affording insurance, etc.).[20] Accordingly,

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[16] Although President Trump signed several executive orders to lower the price of pharmaceuticals, these actions are seen as severely inadequate solutions to the problem. Thomas Waldrop & Nicole Rapfogel, *Too Little, Too Late: Trump's Prescription Drug Executive Order Does Not Help Patients*, CTR. FOR AM. PROGRESS (Oct. 15, 2020), https://www.americanprogress.org/issues/healthcare/news/2020/10/15/491425/little-late-trumps-prescription-drug-executive-order-not-help-patients/.

[17] *See generally, State Legislative Action to Lower Pharmaceutical Costs*, NAT'L ACAD. FOR STATE HEALTH POL'Y, https://www.nashp.org/rx-legislative-tracker/ (last updated Jan. 26, 2021) (listing state health legislation over recent years) [hereinafter NASHP].

[18] *See State Drug Pricing Laws: 2017-2019*, NAT'L ACAD. FOR STATE HEALTH POL'Y (NASHP), https://www.nashp.org/rx-laws/ (last updated December 3, 2021) (listing different approaches states have taken to insulin pricing, and drug pricing more generally).

[19] *Id*.

[20] Samantha Willner et al., *"Life or Death": Experiences of Insulin Insecurity Among Adults with Type 1 Diabetes in the United States*, 11 SSM POPUL. HEALTH 1, 3 (June 27, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7352063/pdf/main.pdf (describing a 2017 study in which "[a]ll participants cited the high cost of health care as a primary [insulin access barrier].").

most states have attempted to increase access by tackling the financial access to insulin, broadly in one of two ways. The first is by regulating the price of insulin, where price is defined as the amount for which a drug manufacturer sells their product.[21] The second way is by regulating the cost of insulin, with cost meaning the amount that a patient ends up paying to purchase insulin.[22] Price and cost are often very different in the pharmaceutical world because there are so many middle distribution players who are offered discounts and rebates off the manufacturers' price, in turn selling insulin to patients at a cost lower than the list price; insurance also helps reduce the cost patients see. For instance, Eli Lilly may market a certain dosage of Humalog (its brand-name insulin) at a price of $530.40.[23] However, when a patient goes to fill their prescription, the insulin might end up costing the patient between $0 and $95 (with private insurance).[24]

a. Price-based regulation

Price-based regulations have both benefits and drawbacks to their use. One large benefit is that by regulating the price, patients are less likely to see companies compensate for losses by raising other prices the patient would

[21] This is commonly known as the Wholesale Acquisition Cost (WAC). Joey Mattingly, *Understanding Drug Pricing*, U.S. PHARMACIST (June 20, 2012), https://www.uspharmacist.com/article/understanding-drug-pricing.
[22] There is not a standard method to measure the cost patients pay, in part because there are so many variables including whether a patient is insured or uninsured, and differences of insurance formularies, etc. Charles Ornstein & Katie Thomas, *Prescription Drugs May Cost More with Insurance Than Without It*, N. Y. TIMES (Dec. 9, 2017), https://www.nytimes.com/2017/12/09/health/drug-prices-generics-insurance.html.
[23] *How Much Should I Expect to Pay for Humalog U-100®?*, ELI LILLY, https://www.lillypricinginfo.com/humalog (last visited March 29, 2021).
[24] The exact amount depends both on the form of the product and the type of insulin. Although Eli Lily says that most patients with private insurance would not pay more than $95 for a monthly prescription, some patients pay an average of $345 a month (depending on the formulation). *Id*.

have to pay.[25] For instance, with a cost-based regulation that caps how much an insurance company can charge for insulin medication and supplies, such an insurance company could simply increase yearly premiums, deductibles, or other aspects of a plan to compensate for a loss of revenue. But price-based regulations target the drug manufacturer; drug manufacturers do not have other charges they can shift price increases into.[26] This helps ensure that patients receive net cost savings, instead of net paying the same amount across different charges.[27]

A second benefit is that, by targeting the first seller, price-based regulation passes on savings to *all* patients, regardless of whether a patient is insured or what type of insurance they have. When a drug manufacturer has a cap on the price they can sell a drug, subsequent sales of the drug also tend to be lower.[28] Thus, it will not matter whether a patient pays out of pocket or has insurance; the entity the patient buys from will have previously bought the insulin at a lower price, and savings will be passed on to the consumer.[29] One caveat is price-regulation does not guarantee how much of the price savings will passed to patients. The other entities in the distribution chain – pharmacy benefit managers, wholesale distributors, etc. – are all vying for a

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[25] Insurance companies have many types of costs associated with coverage including monthly premiums, deductibles, and co-pays. *Your Total Costs for Health Care: Premium, Deductible & Out-of-Pocket Costs,* U.S. CTRS FOR MEDICARE & MEDICAID, https://www.healthcare.gov/choose-a-plan/your-total-costs/ (last visited 28 March 2021). If a rational insurance company did not want to lose money but the copays for insulin were capped, it could raise another charge like premiums to compensate.

[26] Technically, if only the price of insulin was regulated, drug manufacturers might respond by raising the cost of non-insulin medicines. However, this would likely depend on a host of other market factors.

[27] For example, if the state regulates insurance companies to charge $30 less for insulin copays than they otherwise would, insurance companies could increase premiums by a multiple of $30 to balance out for the lost revenue.

[28] Paul R. Zimmerman & Julie A. Carlson, *Competition and Cost Pass-Through in Differentiated Oligopolies*, FED. TRADE COMM'N (15 October 2010), https://mpra.ub.uni-muenchen.de/25931/1/MPRA_paper_25931.pdf.

[29] *Id*.

share of the profit.[30] Pharmacy benefit managers have been particularly adept at manipulating the price of insulin in subsequent sales and increasing their share of the profits.[31]

However, state regulation of price has been difficult to implement effectively.[32] First, there are legal barriers. Price is set by manufacturers, who are far upstream in the distribution chain; pharmaceuticals often are bought and sold by wholesale distributors, pharmacies, and others before the patient can buy the medicine.[33] When a drug manufacturer first sells a particular product, the sale is unlikely to occur in the regulating state (because that first sale is not to the patient), which raises dormant commerce clause considerations.[34]

In practice, Maryland passed a good example of such a price-based regulation in 2017.[35] The law restricted drug manufacturers from "price-gouging" pharmaceutical products (not limited to insulin), defined simply as an "unconscionable increase."[36] Although an "unconscionable increase" is not defined, the law requires the Maryland Attorney General to be notified when a drug's wholesale acquisition price increases more than fifty percent from the previous year, suggesting at least some of the cases the legislature

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[30] Health Strategies Consultancy, *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*, KAISER FAM. FOUND. (March 2005), https://www.kff.org/wp-content/uploads/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf.

[31] *Insulin: Examining the Factors Driving Rising Costs of a Century Old Drug*, S. FIN. COMM. REP. (2021), https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf [hereinafter Senate Insulin Report].

[32] For example, Maryland's price regulation law, H.D. 631, 2017 Leg., 437th Sess. (Md. 2017), was struck down as unconstitutional. Association for Accessible Medicines v. Frosh, 887 F.3d 664, 667 (4th Cir. 2018). Regulating how much drug manufacturers can price medicines at is difficult because of complexities of the pharmaceutical distribution chain and limitations of the dormant commerce clause.

[33] Mattingly, *supra* note 21.

[34] Frosh, 887 F.3d at 667. The dormant commerce clause, among other things, prohibits states from regulating activity that occurs outside of their borders. *Id*.

[35] H.D. 631, 2017 Leg., 437th Sess. (Md. 2017).

[36] Md. Code Ann., Health-General § 2-801(c).

had in mind when writing "unconscionable increase."[37] However, this law was struck down for violating the dormant commerce clause.[38] The Fourth Circuit held that most of the pharmaceutical manufacturers were located outside the state's borders, and most of the sales of pharmaceuticals from manufacturers to distributors also took place outside of the state.[39]

b. Cost-based regulation

Like price-based regulations, cost-based regulations have benefits and drawbacks. The biggest benefit is that this approach ensures effectiveness; cost-based regulations guarantee that patients will only be charged the regulated amount, as it fixes the amount in the sale to the patient instead of an amount higher upstream in distribution.[40]

Another advantage is this approach is well-established to be within states' powers to regulate; there is little risk that a cost-based regulation would be struck down in court. States have exercised this power over areas, such as housing.[41] The entities involved in selling insulin directly to a patient all have a presence in the state – for instance, the pharmacy and the patient's insurance company – thereby avoiding the dormant commerce clause concerns of a price-based regulation.[42]

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[37] Md. Code Ann., Health-General § 2-803(a)(1)(i). This notification requirement has several other stipulations, including when absolute price for a 30-day course of treatment is above $80. Md. Code Ann., Health-General § 2-803(1)(2).
[38] Frosh, 887 F.3d at 667.
[39] *Id*.
[40] There are many distribution entities in-between a drug manufacturer and the patient who could drive the cost of a medicine up if price was regulated. Health Strategies Consultancy, *supra* note 30.
[41] Jim Lapides et al., *Rent Control Laws by State*, NAT'L MULTIFAM. HOUS. COAL. (September 2, 2020), https://www.nmhc.org/research-insight/analysis-and-guidance/rent-control-laws-by-state/.
[42] Unlike in cases where pharmaceutical entities are located outside of the state. Frosh, 887 F.3d at 667.

However, there are drawbacks to the cost-based approach, the major one being that the system is so complex it can be difficult to regulate accurately and effectively.[43] First, not all patients have insurance.[44] Among those covered by insurance, there are many different types of plans, each with its own formulary structure.[45] There is also a large amount of variation within pharmacies (for instance, brick and mortar pharmacies versus mail order pharmacies).[46] In theory it may be simple to place cost caps on these entities, but given the relationships between each other and great deal of variance, there are likely to be unintended consequences.[47] For instance, an insurance company could simply raise premiums for consumers to replace any revenue lost with a price cap.[48] If patients end up paying the same amount between insurance charges and the insulin itself, cost-based regulation would not be effective.[49]

One example of cost-based regulation is Illinois's new insulin law, which caps the amount that a patient would have to pay for a 30-day supply of insulin at $100.[50] This is limited to patients who are covered by insurance, and for patients whose plans provide coverage for insulin.[51] Illinois's

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[43] *See* Health Strategies Consultancy, *supra* note 30 (describing the complex distribution chain).
[44] *See e.g.*, Bivens & Zipperer, *supra* note 9 (describing how the COVID-19 pandemic has reduced the number of insured people).
[45] *See generally*, Stephane A. Regnier, *How Does Drug Coverage Vary by Insurance Type? Analysis of Drug Formularies in the Unites States*, 20(4) AM. J. MANAGED CARE 322 (April 2014), https://cdn.sanity.io/files/0vv8moc6/ajmc/f968d20eab6e54e0042113693f5c9cb3a ade39b0.pdf.
[46] Gordon Hanson, *Types of Pharmacies: 7 Places People Pick Up Prescriptions*, RASMUSSEN UNIVERSITY (January 17, 2018), https://www.rasmussen.edu/degrees/health-sciences/blog/types-of-pharmacies/.
[47] *See, e.g.*, James H. Thrall, *Unintended Consequences of Health Care Legislation*, 8 J. AM. COLL. RADIOL. 687 (October 1, 2011) (describing some unintended consequences of health care legislation regulating complex areas like insurance).
[48] *Supra* notes 24–26 and accompanying text.
[49] *Supra* notes 24–26 and accompanying text.
[50] 215 ILCS 5/356z.41.
[51] *Id*.

regulation does account for inflation and future cost increases by increasing the $100 cap by the percentage that the "medical care component of the Consumer Price Index of the Bureau of Labor Statistics" increases yearly.[52]

III. A STATE LEVEL SOLUTION

Before jumping into what state legislators should do, it is worth pausing to say what legislators should not do. Most importantly, state legislators should not assume that taking either a price-based approach or cost-based approach alone will fix the problem.[53] Price-based regulations are difficult to implement because of where pharmaceutical entities are located and restrictions stemming from the dormant commerce clause.[54] Cost-based regulations, on the other hand, do not guarantee that cost savings will actually be passed on to patients, and even if savings were, people of color are disproportionately not insured and so would not equitably benefit.[55] The pharmaceutical landscape is constantly changing in the wake of scientific innovation and federal regulation,[56] so any insulin policy will likely need to be flexible to adapt and multi-pronged. It is also important to note that state policy will not be a substitute for federal action; only federal regulation has the potential to regulate the price of drugs and bring the associated costs down across the healthcare system.[57]

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[52] 215 ILCS 5/356z.41(g).
[53] Diabetes has many associated costs besides insulin that need to be addressed. *Infra* notes 67–69 and accompanying text.
[54] *Supra* notes 31–37 and accompanying text.
[55] Samantha Artiga, Kendal Orgera, & Anthony Damico, *Changes in Health Coverage by Race and Ethnicity since the ACA, 2010-2018*, KAISER FAM. FOUND. (March 5, 2020), https://www.kff.org/racial-equity-and-health-policy/issue-brief/changes-in-health-coverage-by-race-and-ethnicity-since-the-aca-2010-2018/.
[56] NASHP, *supra* note 18.
[57] Because of the dormant commerce clause, a state will be unlikely to lower the net amount of money spent on pharmaceuticals and will be limited to changing who is paying. *See generally* Association for Accessible Medicines v. Frosh, 887 F.3d 664, 667 (4th Cir. 2018).

I propose cost-based plus regulation as the basic cost-based regulation discussed above, plus additional regulations that help eliminate the drawbacks. After all, in theory, regulating the end-cost of insulin to patients guarantees a maximum amount they will pay.[58] Regulating the end cost is important to ending racial disparities in insulin access because of the disparities in insurance coverage. Insulin can be very expensive without insurance[59] and if only the price were regulated, distribution entities could still drive the price up.[60] There are still problems that come with this approach. For cost-based regulation, that problem is insurance agencies being incentivized to increase other costs like premiums to offset losses from a price cap.

There are two additional strategies states should consider: increasing insurance coverage and aggregate buying. It would be very difficult for a state to put a price cap on the different charges of an insurance plan such that an insurer would be forced to absorb some increased cost of insulin coverage; it is simply too complex.[61] But what a state can do is incentivize insurance companies to spread those cost increases out, so that individuals see cost savings. Most importantly, diabetes is a costly disease for patients not just because of insulin, but because of all the other costs and associated diseases.[62] Given that people of color are both disproportionated effected by diabetes

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[58] *Infra* note 40 and accompanying text.
[59] *See* ELI LILLY, *supra* note 23 (stating that "[i]f you do not have prescription medication insurance coverage, or if your insurance does not cover Humalog, you can expect to pay close to the list price [as high as $530.14] shown above, plus any additional pharmacy charges depending on where you purchase your medicine.").
[60] *See* Senate Insulin Report, *supra* note 31 (describing how pharmacy benefit managers have driven the price of insulin up).
[61] *See Key Facts: Cost Sharing Basic*s, CTR. ON BUDGET & POL'Y PRIORITIES, https://www.healthreformbeyondthebasics.org/cost-sharing-charges-in-marketplace-health-insurance-plans-answers-to-frequently-asked-questions/ (last updated August 2020).
[62] Anjali D Deshpande, Marcie Harris-Hayes, & Mario Schootman, *Epidemiology of Diabetes and Disease-Related Complications*, 88(11) PHYS. THER. 1254 (2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3870323.

and uninsured,[63] increasing insurance coverage would help patients afford treatments for associated diseases and so should be a top accompanying priority of states. Not only does this help create equitable care, this also means insurance companies are able to increase revenues and spread out costs among more people. If, for example, a patient saves $500 a year under a cost-based regulation, but their premiums also increase $500 a year, under a cost-based plus regulation where more people are insured, patients' premiums might rise by a smaller amount.

Aggregate buying is a different additional strategy that could help ensure cost-based regulations turn out to net zero savings for patients. Essentially, insurance companies would be less likely to increase other charges if insulin was cheaper to acquire. Although states cannot force drug manufacturers to sell insulin at a lower cost,[64] there are things that could help put pressure on manufacturers to lower prices. One such tool is allowing entities to buy insulin together. Economics suggests that increased buyer power leads to lower prices;[65] if buyers come together to negotiate and purchase insulin, they could in theory buy insulin at lower prices than if they had bought insulin separately. Another way this could be implemented is for the state to use its own buying power, through Medicaid programs. Already many states require pharmaceutical manufacturers to sign supplemental rebate agreements for the pharmaceutical company's products to be covered by Medicaid.[66] States could expand these agreements to require pharmaceutical

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[63] *Statistics About Diabetes*, AM. DIABETES ASS'N, https://www.diabetes.org/resources/statistics/statistics-about-diabetes (last updated March 22, 2018).
[64] Frosh, 887 F.3d at 667.
[65] John B. Kirkwood, *Buyer Power and Healthcare Prices*, 91 WASH. L. REV. 253, 257–258 (2015).
[66] Kathleen Gifford et al., *How State Medicaid Programs are Managing Prescription Drug Costs: Results from a State Medicaid Pharmacy Survey for State Fiscal Years 2019 and 2020*, KAISER FAM. FOUND. (April 29, 2020), https://www.kff.org/report-section/how-state-medicaid-programs-are-managing-prescription-drug-costs-payment-supplemental-rebates-and-rebate-management.

manufacturing companies to sign an additional agreement, that could be a negotiated price for the state and insurance companies.

Regulating the cost of insulin will be insufficient to completely end racial disparities in diabetes patients; lawmakers must consider the larger context in which diabetic patients buy medicines. Diabetes usually requires much more than just insulin to treat; at a minimum, patients require devices to inject the insulin, like a syringe or a pump.[67] Diabetes is also closely linked with a range of other expensive diseases to treat.[68] Ensuring insulin access alone will not help patients afford treating these closely related diseases.[69]

One way to help cover these costs is for states to help everyone gain insurance coverage. Although insurance will not pay for all of these costs, insurance will help lower the costs for patients.[70] About twelve states still have the option to make easy gains in insurance coverage by expanding Medicaid.[71] Right now, the "Medicaid gap" population (those who make too much to qualify for Medicaid but too little for ACA subsidies) lack an accessible insurance option.[72] If these states were to enroll in Medicaid, an estimated two million people would gain insurance coverage, making the costs of diabetes and related diseases more affordable.[73]

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[67] *Insulin Injection Know-How*, ASS'N OF DIABETES CARE & EDUC. SPECIALISTS, https://www.diabeteseducator.org/docs/default-source/legacy-docs/_resources/pdf/general/Insulin_Injection_How_To_AADE.pdf.
[68] *Diabetes Related Conditions*, DIABETES UK, https://www.diabetes.org.uk/diabetes-the-basics/related-conditions (last visited 2 April 2021).
[69] *See id.* (discussing which related diseases are not treatable, and which are manageable).
[70] Juliette Cubanski et al., *Insulin Costs and Coverage in Medicare Part D*, KAISER FAM. FOUND. (June 4, 2020), https://www.kff.org/medicare/issue-brief/insulin-costs-and-coverage-in-medicare-part-d/.
[71] *Status of State Medicaid Expansion Decisions: Interactive Map*, KAISER FAM. FOUND. (March 31, 2021), https://www.kff.org/medicaid/issue-brief/status-of-state-medicaid-expansion-decisions-interactive-map/.
[72] Rachel Garfield, Kendal Ogera, & Anthony Damico, *The Coverage Gap: Uninsured Poor Adults in States that Do Not Expand Medicaid*, KAISER FAM. FOUND. (January 21, 2021), https://www.kff.org/medicaid/issue-brief/the-coverage-gap-uninsured-poor-adults-in-states-that-do-not-expand-medicaid/.
[73] *Id*.

IV. CONCLUSION

The high prevalence of diabetes and exorbitant cost of treatment makes access to insulin incredibly important.[74] The problem is further exacerbated by racial disparities in both diabetes diagnoses and insurance coverage.[75] To increase access to insulin and decrease racial disparities, state legislators should regulate the cost of insulin to patients, in addition to expanding insurance coverage and promoting aggregate insulin purchasing.[76]

[74] *Supra* notes 1–10 and accompanying text.
[75] *Supra* notes 11–14 and accompanying text.
[76] *Supra* Part III: A State Level Solution.

Using mHealth to Close Racial and Ethnic Health Care Disparities: Proposals for Indiana

Leanne Jossund

I. INTRODUCTION

Mobile health technology, also known as mHealth, refers to a vast array of wireless devices and technologies, including mobile phones.[1] With smart watches and cellular devices being more widely available than before, there are additional means by which the average lay person can become actively involved in their health care.[2] Blood glucose monitors, menstrual cycle trackers, activity or sleep tracking, and heart rate monitoring are just some of the many ways anyone can track their health.[3] Many fitness trackers work alongside phone applications to monitor and report health information, but some of these phone applications can be utilized regardless of fitness tracker ownership.[4] Some phones can track your heart rate directly on the phone, utilizing the camera or another type of sensor, allowing easy fitness and heart health tracking.[5] Indiana is now positioned to employ these important and

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[1] Sarah Iribarren et al., *What is the Economic Evidence for mHealth? A Systematic Review of Economic Evaluations of mHealth Solutions*, 10 PLOS ONE 1, 2 (2017).
[2] *Demographics of Mobile Device Ownership and Adoption in the United States*, PEW RSCH. CTR. (June 12, 2019), https://www.pewresearch.org/internet/fact-sheet/mobile/.
[3] *See generally* Joseph Tran et al., *Smartphone-Based Glucose Monitors and Applications in the Management of Diabetes: An Overview of 10 Salient "Apps" and a Novel Smartphone-Connected Blood Glucose Monitor*, 30 CLINICAL DIABETES 173 (2012) (providing an overview of mobile phone glucose tracking applications); *see also* APPLE https://www.apple.com/ios/health/ (last visited Mar. 13, 2021) (providing an example of a built-in smartphone health tracking app that serves many functions including menstrual cycle tracking, exercise, and sleep tracking).
[4] *See generally* APPLE, *supra* note 3; s*ee also* Samsung, https://www.samsung.com/us/apps/samsung-health/ (last visited Feb. 8, 2021) (another example of a smartphone health tracking app that links with various devices such as smartwatches and smart TVs).
[5] *See generally* Ron Amadeo, *Google Pixel Phones Will Soon Track Heart Rate Using Only the Camera*, ARS TECHNICA (April 28, 2021) https://arstechnica.com/gadgets/2021/02/

widely available tools as a means to directly improve health outcomes for its residents.[6] The Indiana Office of Minority Health (OMH) is capable of apportioning funding to state organizations already engaged in this type of community outreach and should do so as part of its stated goal to improve health care utilization and engagement among disadvantaged populations.[7]

II. BACKGROUND

The Medicaid expansion from the ACA was an important component of beginning to improve racial equity in access to care.[8] In January 2015, then-governor Mike Pence reached an agreement with the Obama administration on a waiver allowing Indiana to try a form of Medicaid expansion called the Healthy Indiana Plan ("HIP") 2.0, an offshoot of the already existing Healthy Indiana Plan.[9] HIP is a sub-plan of multiple services offered by Indiana Medicaid.[10] An estimated six and a half million people in Indiana were covered by Medicaid as of 2019, and insured rates increased six percent in the state between 2013 and 2017.[11] In 2013, racial and ethnic minority

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google-pixel-phones-will-soon-track-heart-rate-using-only-the-camera/ (describing a new phone model tracking heart rate); *See also* Samsung, https://www.samsung.com/us/heartrate sensor/ (last visited Feb. 8, 2021) (describing how Samsung devices, both wearables and phones, can measure one's heart rate).

[6] *See ISDH: About Minority Health*, IND. DEP'T OF HEALTH, https://www.in.gov/isdh/25104.htm (last visited Apr. 14, 2021) (describing the goals and the responsibilities of the Office of Minority Health, which include reduction of minority health disparities through monitoring community-based programs).

[7] *Id*.

[8] *See* Jesse Baumgartner et al., *How the Affordable Care Act Has Narrowed Racial and Ethnic Disparities in Access to Health Care*, COMMONWEALTH FUND (January 16, 2020), https://www.commonwealthfund.org/publications/2020/jan/how-ACA-narrowed-racial-ethnic-disparities-access (discussing how the ACA tangibly increased access to health care amongst racial and ethnic minority groups).

[9] Alana Semuels, *Indiana's Medicaid Experiment May Reveal Obamacare's Future*, ATLANTIC (December 21, 2016) https://www.theatlantic.com/business/archive/2016/12/medicaid-and-mike-pence/511262/.

[10] *See Managed Care Health Plans*, INDIANA MEDICAID, https://www.in.gov/medicaid/members/170.htm (last visited Feb. 8, 2021) (discussing the different health plans offered by the state of Indiana).

[11] *Medicaid in Indiana Fact Sheet*, KAISER FAM. FOUND. (October 2019) http://files.kff.org/attachment/fact-sheet-medicaid-state-IN (last visited Feb. 8, 2021).

groups made up a significant percentage—thirty-four percent (twenty-one percent Black, ten percent Hispanic, and three percent listed as "other"—of Medicaid recipients in the state.[12] Therefore, any efforts to close the racial health disparity gap through Medicaid-specific programs could have substantial impact on low-income, marginalized communities.[13]

Indiana's OMH has acknowledged the existence of disparities in accessibility to health care and intends to tackle them through the establishment of the Minority Health Advisory Committee and the Healthy Indiana Minority Health Plan.[14] The goal of this committee is to "elimin[ate] racial and ethnic health disparities in Indiana."[15] This is coupled with legislative initiatives empowering the Office of Minority Health to take action to reduce disparities.[16] Indiana Code section 16-46-11-1 charges the Office with many specific duties, including to "[p]rovide funding, within the limits of appropriations, to support preventive health, education, and treatment programs in the minority communities that are developed, planned, and evaluated by approved organizations."[17] These powers are numerous and broad, reflecting a legislative desire to identify and tackle the issue of minority health disparities.[18]

In 2018, Indiana's OMH applied for and received separate funding from the U.S. Department of Health and Human Services' Office of Minority

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[12] *Medicaid Enrollment by Race/Ethnicity*, KAISER FAM. FOUND. (2013) https://www.kff.org/medicaid/state-indicator/medicaid-enrollment-by-raceethnicity/.
[13] *Id*.
[14] *Indiana Minority Health Plan*, INDIANA DEPARTMENT OF HEALTH, https://www.in.gov/isdh/23416.htm (last visited Feb. 8, 2021).
[15] *Id*.
[16] IND. CODE §16-46-11 (2020), http://iga.in.gov/legislative/laws/2020/ic/titles/016/#16-46-11 (while IN Code 16-19-14-5 establishes the Office, 16-19-14-5 empowers the Office to perform the legislative duties outlined in 16-46-11. These duties include conducting research establishing policy, staffing a minority health hotline, developing health promotional programs, funding minority health programs and other initiatives).
[17] *Id*.
[18] *Id*.

Health to support the Indiana Office in its efforts to close this gap.[19] One of the strategies of Indiana's OMH included creating and developing "online knowledge-based intervention activity targeting African Americans and focused on improving personal health behavior to promote healthier lifestyles."[20] The OMH has also made translation resources available on its website through partner organizations, which would work well in tandem with a mobile technology literacy program.[21] Another program, called EMPOWERED, outlines funding programs for health education-based initiatives focusing on decreasing obesity, improving access to smoking cessation opportunities, and other goals.[22] The seeds for continued efforts in this space are planted, and additional efforts to integrate mHealth into these initiatives, as well as develop mHealth-specific programs, should continue.

Engaging Medicaid recipients via mobile technology is a method that has been tried by other local and state governments using limited population groups.[23] The scope of this paper is limited to discussing the funding-based options for Indiana to develop mobile, online-based interventions. Indiana's OMH should begin targeted outreach programs to vulnerable and underserved groups of people already using Medicaid and the HIP program, utilizing mHealth as a key tool to assist in closing the health care disparity and improving outcomes. This paper theorizes that mHealth is a diverse set

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[19] *Indiana State Partnership Grant Program to Improve Minority Health*, U.S. DEP'T OF HEALTH & HUM. SERVS. (May 30, 2018) https://minorityhealth.hhs.gov/omh/content.aspx?ID=17&lvl=2&lvlid=51.

[20] *Id*.

[21] *Language, Translation, & Migrant Programs*, IND. DEP'T OF HEALTH, https://www.in.gov/isdh/25113.htm (last visited Apr. 28, 2021).

[22] *Enhancing Minority Partnership Opportunities; Working to Eliminate Racial and Ethnic Disparities*, IND. DEP'T OF HEALTH, https://www.in.gov/isdh/23434.htm (last visited Apr. 28, 2021) [hereinafter *EMPOWERED*].

[23] *See* James Bush et al., *Impact of a Mobile Health Application on User Engagement and Pregnancy Outcomes Among Wyoming Medicaid Members*, 23 TELEMEDICINE AND E-HEALTH 891 (2017) (describing mHealth outreach to pregnant women in Wyoming); *see also* Sharon Laing, *Mobile Health Technology Knowledge and Practices Among Patients of Safety-Net Health Systems in Washington State and Washington, DC*, 5 J. PATIENT-CENTERED RSCH. & REVS. 204 (2018) (discussing a study done on low-income and safety-net patients in Washington state and Washington, DC).

of tools with untapped potential, advocates for a move into the more specific approaches previously tried by different research groups across the United States, and finally, proposes an approach that the State of Indiana could take to increase health accessibility in the state.

III. PROPOSAL

Indiana's OMH has numerous means of approaching this problem using mHealth including providing financial support to organizations, engaging in direct outreach, or subsidizing mHealth devices. These programs look like direct funding or grants to local health systems and organizations, subsidies, compensation to purchase or use mHealth interventions, or engagement and training Medicaid recipients on mHealth tools. Indiana should utilize its position as a state health authority to close health care access disparities, and its smaller population makes the state an excellent test ground for implementing these types of outreach methods. One way the Office could accomplish its goals is by providing additional funding to organizations and health care providers who have promised to take similar steps, and amending existing initiatives to emphasize mHealth interventions as an important tool.[24] This approach is favorable because these hospital systems and health care providers are already established in their communities, have the existing physical and digital infrastructure to take on mHealth outreach, and see a significant volume of patients.[25] Additionally, this includes other programs already established by OMH, such as the EMPOWERED program.[26] Since this program is focused on grants to statewide partners specifically focused

[24] Press Release, Indiana University, IU establishes Pandemic Health Disparities Fund; committee work begins (June 26, 2020), https://news.iu.edu/stories/2020/06/iu/releases/26-pandemic-health-disparities-fund-established.html. (providing an example of an organization taking such steps).
[25] *Id*.
[26] *EMPOWERED*, *supra* note 22.

on outreach and education, mHealth initiatives and counseling could easily be looped in as part of the four outlined objectives.[27]

Ideally, Indiana would direct state funding through OMH to local community groups and organizations already engaging in this work, through the establishment of grant programs like EMPOWERED or similar methods of funding to the communities.[28] This approach is similar to grants given by the Department of Health and Human Services to state efforts in the accessibility sphere.[29] The three largest Indiana health systems, Community Health Network, Eskenazi Health and Indiana University Health (IU Health), all pledged in a joint statement to take action to improve the health care workplace and the communities they serve, so the providers are also willing to engage in these programs.[30]

This funding approach has several advantages. Importantly, the community infrastructure and trust is already in place.[31] These health networks have been embedded in their communities for years, and therefore are better suited to understanding the specific needs of patients.[32] Moreover, these networks have explicitly pledged to "regularly measur[e], monitor[] and improv[e] the care of underserved populations" as well as advocate for investments that "achieve improvements in access, quality and health outcomes in communities."[33] The OMH should also work with local university health programs to reach out to marginalized young adults.[34] Indiana University, which also operates IU Health, established a "Pandemic

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[27] *Id*.
[28] *Indiana State Partnership Grant Program to Improve Minority Health*, *supra* note 19.
[29] *Id*.
[30] WTHR.com staff, *3 Central Indiana Health Systems Address Racism in Health Care*, WTHR (October 22, 2020) https://www.wthr.com/article/news/health/3-central-indiana-health-systems-address-racism-in-health-care/531-8da91190-4fa3-4a17-96c9-f37532664386.
[31] Disha Kumar et al., *Mobile Phones May Not Bridge the Digital Divide: A Look at Mobile Phone Literacy in an Underserved Patient Population*, 11 CUREUS 1, 7 (2019).
[32] *Id*.
[33] WTHR.com staff, *supra* note 30.
[34] Press Release, Indiana University, *supra* note 24.

Health Disparities Fund" targeted at addressing the needs of African American or Hispanic students.[35] Indiana University is uniquely poised to conduct outreach to marginalized young people given its position as an educational institution and its existing digital and physical infrastructure.[36] The University established public health and safety measures for these specific programs, including screening and testing, mental health services and other student wellness programs targeted specifically at Black or Hispanic students.[37]

Community Healthcare System uses an application and website called MyChart, which allows patients to access and view test results, appointments, and other components of their medical records.[38] This is a secure application used by many other health networks throughout the country and combined with technology support, could assist patients of these systems in understanding their personal health information.[39] Since the application is so widely used by different health systems on the web and on mobile applications, there is the potential for a lot of feedback on the design and usability aspects of this software.[40] Outreach by Indiana state and health systems to counsel underrepresented groups in the usage and understanding of this software would significantly help community members engage more

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[35] *Id.*
[36] *See id*. (IU establishes programming committee of faculty and staff representing crucial student-focused health areas).
[37] *Id*.
[38] MYCHART, https://mychart.comhs.org/mychart/default.asp?mode=stdfile&option=faq.
[39] *See* MYCHART, https://mychart.clevelandclinic.org/ (example of a health system that uses MyChart); *see also* Google Search Returning Several Health Systems that use the MyChart Application, Google, https://www.google.com/search?client=firefox-b-1-d&q=mychart (click link and view results).
[40] *See* MYCHART, https://www.mychart.com/ (MyChart's home page, which states that over 100 million patients manage their care through the app).

with their health care providers and be active participants in the health care process.[41]

The most attractive option that exists to the state of Indiana as a Medicaid insurer is the provision of subsidies or compensation to Medicaid recipients for the purchase of mHealth devices or the usage of mHealth applications. BlueCross BlueShield provides "rewards" such as gift cards (measured through a point system) to those who engage in "healthy activities" that are tracked on the website or application.[42] Walgreens pharmacies use a program called "myWalgreens health goals" where an individual receives "Walgreens Cash" rewards for making healthy lifestyle choices and tracking them through the mobile application or website.[43] The State of Indiana as an insurance provider should look to these methods as a model for incentivizing mHealth tracking and utilization. Additionally, providing subsidies or free mobile devices is a strong selling point and helps bridge the gap between owners of mobile phones and non-owners, which is a known barrier to mHealth utilization.[44] However, these devices are not immune to damage or theft, and therefore these programs may not be wholly effective at ensuring adherence and engagement with mHealth interventions.[45]

IV. ADDITIONAL CONSIDERATIONS AND COMPLICATIONS

One drawback of using mHealth tools is a potential lack of technological literacy, especially among older adults in Indiana's population. Mobile

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[41] *See generally* Enid Montague & Jennifer Perchonok, *Health and Wellness Technology Use by Historically Underserved Health Consumers: Systematic Review*, 14 J. MED. INTERNET RESEARCH 1, 10 (2012).
[42] *See generally* ANTHEM BLUECROSS BLUESHIELD, Anthem Health Rewards https://file.anthem.com/25529ANMENABS.pdf (last visited Feb. 8. 2021) (discussing the BCBS health rewards program functionality and compensation).
[43] WALGREENS, myWalgreens health goals https://www.walgreens.com/topic/help/steps-balance-rewards.jsp (last visited Feb. 8. 2021).
[44] Charkarra Anderson-Lewis et al., *mHealth Technology Use and Implications in Historically Underserved and Minority Populations in the United States: Systematic Literature Review*, 6 JMIR MHEALTH UHEALTH 1, 5 (2018).
[45] *Id*. at 6.

phone literacy is generally defined as the ability to access, understand, and use the features of mobile phones.[46] Younger adults are more likely than older adults to use their phones to browse the Internet and use social media and other applications.[47] Therefore, any outreach by Indiana and its OMH to state Medicare and Medicaid populations will need to take age into account as a factor when assessing how much technological counseling to provide as part of the programs.[48] Because disparities exist in mobile phone usage and understanding, the utilization of mHealth should not magnify those disparities, and outreach should not be limited to mHealth interventions alone.[49]

Further, the divide between smartphone owners and non-smartphone owners is narrowing but still present.[50] For example, even something as ubiquitous-seeming as text messaging may not be something many people have access to.[51] Conventional SMS messaging is not always unlimited in modern phone plans, resulting in text notifications and updates quickly adding up to significant costs on an individual's phone bill.[52] Fortunately, after adjusting for gender, education level and race, the only predictor of lower cell phone ownership was age.[53] Taking these statistics into account, there may be less cell phone ownership hurdles to overcome when working with racial and ethnic minorities.[54] This is a positive development, as low-income and racial and ethnic minority populations are disproportionately

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[46] Kumar et al., *supra* note 31, at 2.
[47] *Id*. at 7.
[48] *Id*.
[49] *Id*.
[50] Nita Vangeepuram et al., *Smartphone Ownership and Perspectives on Health Apps Among a Vulnerable Population in East Harlem, New York,* 4 MHEALTH 1, 5-6 (2018).
[51] Kumar et al., *supra* note 31, at 7.
[52] *Id*. at 6-7.
[53] Vangeepuram et al., *supra* note 50, at 3.
[54] *Id*.

affected by chronic disease, generally have less access to quality care, and experience worse health outcomes.[55]

Another potentially significant drawback is one of adherence.[56] In a study of primary care patients in the Washington, Wyoming, Alaska, Montana and Idaho (the "WWAMI") region, many reported stopping usage of mHealth tools after a short time due to the time it took to utilize the tools.[57] This suggested a limited appeal of mHealth for patients managing long-term chronic diseases that require sustained self-management and tracking, but this could be mitigated by patient-centered design methods targeted at ease of use, convenience, and other needs identified by patients.[58] Another study working with Spanish-speaking patients with diabetes in the Oakland, California suggested that the subject population may have de-prioritized health concerns in the face of other personal issues, such as deportation, crime, and social stress.[59] Therefore, it remains important to consider the socioeconomic factors surrounding target groups, and the realistic usage patterns of mHealth technology.[60] It seems that Indiana is familiar with its Medicaid population, and already conducts comprehensive Black and Minority Health Final Reports approximately every two years.[61] This investigation into the difficulties faced by marginalized groups must continue until the racial health disparities gap has closed because it is crucial to be working with the most updated research and information available.[62]

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[55] *Id*. at 5.
[56] Amy Bauer et al., *Use of Mobile Health (mHealth) Tools by Primary Care Patients in the WWAMI Region Practice and Research Network (WPRN),* 28 J. AM. BD. OF FAM. MED. 780, 787 (2014).
[57] *Id.*
[58] *Id*.
[59] Raman Khanna et al., *An Automated Telephone Nutrition Support System for Spanish-Speaking Patients With Diabetes*, 8 J. DIABETES SCI. TECH. 1115, 1119 (2014).
[60] *Id*. at 1118.
[61] *See ISDH: Interagency Council on Black and Minority Health,* IND. DEP'T OF HEALTH, https://www.in.gov/isdh/23413.htm (last visited Apr. 14, 2021) (page discussing and hosting the previous Interagency State Council on Black & Minority Health Final Reports).
[62] *Id*.

Taking into account difficulties that target groups are facing and personalizing outreach to those groups is key to efficacy.[63] This is why studies and interventions cannot be completely translated across countries, and between racial and ethnic groups.[64] One study set in Oakland, California mimicked a similar pilot study in Mexico.[65] However, many cultural differences exist between Spanish-speakers in Mexico and Spanish-speaking immigrants in the United States.[66] In addition to the differing social stressors between individuals living in Mexico, immigrants living in Oakland may not have as much familial or community support.[67] This is especially pronounced where such interventions are depersonalized or sterile.[68]

Moreover, participants in prospective studies may unintentionally not adhere to programs due to phone numbers becoming disconnected or other issues stemming from lack of mobile phone service.[69] Sixty-five percent of participants, in the Oakland, California study did not follow up for different reasons, including a disconnected phone, not responding to messages, or not showing up to a scheduled appointment.[70] Additionally, this study of Spanish-speaking patients involved mostly automatic phone calls.[71] This suggests that preparing patients for the phone interactions may increase the effectiveness of the technological intervention, albeit at an increased cost to properly prepare a patient for a phone check-in with health professionals.[72] Therefore, when Indiana works to engage the state Medicaid population, the state must consider that preparation for phone interactions with health care

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[63] Khanna, *supra* note 59, at 1118.
[64] *Id*. at 1119.
[65] *Id*.
[66] *Id*.
[67] *Id*.
[68] *Id*.
[69] Anderson-Lewis et al., *supra* note 44, at 7.
[70] Khanna, *supra* note 59, at 1118.
[71] *Id*. at 1119.
[72] *Id*.

professionals, while potentially adding to overhead cost, would likely increase readiness to engage with the programs. This concept dovetails with avoiding depersonalizing the outreach to target individuals.[73] If Indiana wishes to maintain a high level of adherence to their programs, the above factors are crucial to consider.

Inevitable and unpredictable technological "hiccups" could also interfere with mHealth management, such as lost passwords or login information, damaged or broken devices, and server issues.[74] Server issues can arise from increased usage of any online sites.[75] Outages are inevitable under normal conditions, but with the increased load of traffic due to the recent transition to a primarily online workforce, schooling and entertainment, outages rose dramatically in March 2020.[76] Further, with many patients from across the country rushing to book vital appointments, such as COVID-19 vaccines on centralized sites like MyChart, serious outages can potentially occur.[77] Avoiding these issues is not entirely within Indiana's power, as many programs are hosted by companies in other states or locations, however, the failure of technology is a potentially mitigating factor in how accessible and helpful any mHealth tools could be.[78]

Generally, mHealth interventions and programs have significant potential to improve health outcomes in the United States.[79] mHealth applications can be adapted to meet language capacities of underserved populations, and they

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[73] *Id*.
[74] Anderson-Lewis et al., *supra* note 44, at 6.
[75] *Revealed: COVID-19's Impact on Internet Disruptions*, DATACENTERNEWS, https://datacenternews.us/story/revealed-covid-19-s-impact-on-internet-disruptions.
[76] *Id*.
[77] *See generally* Cleveland Clinic, Ohio COVID-19 Vaccine Appointments (https://my.clevelandclinic.org/landing/covid-19-vaccine/ohio) (Cleveland Clinic instructions for scheduling COVID-19 vaccines utilizing MyChart).
[78] *See* EPIC https://www.epic.com/ (last visited April 28, 2021) (Epic Systems, which runs MyChart, is in Verona, WI and Indiana likely does not have significant influence over their operations).
[79] Anderson-Lewis et al., *supra* note 44, at 8.

can be localized to a person's geographical area.[80] Because of this flexibility, mHealth applications should not be overlooked as state and local municipalities in Indiana aim to close the racial and ethnic health disparity gap.[81]

Fortunately, there is also acceptance of mHealth application use among many patients.[82] In a 2014 study, sixty-one percent of those surveyed said they would like to receive text messages from providers, and seventy percent would download and use an app to track their mental health, another seventy-three percent would access general health care information on their phones.[83] These numbers reinforce the positive influences of "acceptance facilitating interventions" that illustrate the positive correlation with individuals' opinions and attitudes toward mHealth interventions and the likelihood individuals will use these services.[84] Health care practitioners with a higher proficiency in handling technologies would likely see a significant benefit from incorporating mHealth applications into patient care, as age and familiarity with technologies impact attitudes and acceptance of applications.[85] Indiana's adoption of this technology has the potential to improve health care across the board, as providers and patients become more proficient with the technology.[86]

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[80] *Id. See also* Conference Report, Tanja Walsh & Teija Vainio, Cross-Cultural Design for mHealth Applications (Nov 28-Dec 2, 2010), https://www.researchgate.net/profile/Tanja-Walsh/publication/260568455_Cross-Cultural_Design_for_mHealth_Applications/links/02e7e5319ad7c6cf41000000/Cross-Cultural-Design-for-mHealth-Applications.pdf (discussing how cross-cultural design, localization, and internationalization can be applied to mHealth applications).
[81] *Id*.
[82] THOMAS R. INSEL ET AL., DIGITAL PHENOTYPING AND MOBILE SENSING 240 (Martin Reuter et al. eds., 2019).
[83] *Id.*
[84] *Id*.
[85] *Id*. at 239-40.
[86] Anderson-Lewis et al., *supra* note 44, at 8.

V. CONCLUSION

Mobile health technologies, also known as mHealth, are an emerging component of health care delivery and monitoring in the United States. Mobile phone usage and ownership is becoming increasingly widespread, including among lower-income communities in the United States.[87] In Indiana, a significant portion of Medicaid and HIP recipients identify as racial and ethnic minorities.[88] Therefore, Indiana's OMH should direct funding to community organizations committed to using mHealth as a tool to close the racial health care access gaps identified statewide. Additionally, Indiana in its role as a Medicaid insurer could promote the use of these technologies through financial incentives and insurance benefits. While an organization's foray into mHealth is not without obstacles; as some communities have low rates of technology literacy, mobile phone ownership, and the potential for general technology issues, mHealth remains a key tool to closing these disparities because of its high versatility and adaptability.[89] Many of these concerns can be ameliorated through sensitive design philosophies and outreach programs.[90] To increase access, Indiana could potentially develop "free phone" programs, which would be beneficial to these populations in aspects of their lives other than just the use of mHealth technology.[91] A successful mHealth program in Indiana could serve as inspiration for additional states to follow, just as other states and programs have informed these proposals. Indiana has taken the first steps to reduce health access disparities among racial and ethnic minorities by developing the state Office of Minority Health and should not overlook mHealth

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[87] *See generally* Enid Montague & Jennifer Perchonok, *Health and Wellness Technology Use by Historically Underserved Health Consumers: Systematic Review*, 14 J. MED. INTERNET RSCH. 1, 10 (2012) (discussing rates of cell phone ownership and usage among African American and Hispanic people versus their white counterparts).
[88] *Medicaid Enrollment by Race/Ethnicity*, *supra* note 12.
[89] Anderson-Lewis et al., *supra* note 44, at 6.
[90] INSEL ET AL., *supra* note 82, at 240.
[91] *Id.* at 5.

interventions as a viable option to increase access to healthcare, provide telehealth services, and allow individuals to feel empowered and educated regarding their own health.

Left to their Own Devices: Addressing Racial Biases in the FDA Approval Process for Medical Devices

Sama Kahook

I. INTRODUCTION

Unconscious bias plagues the medical field and threatens the diagnosis, treatment, and physician-patient relationship between doctors and patients of color.[1] The disparities affecting people of color in the United States include "access to health care, the quality of care received, and health outcomes."[2] Healthcare disparities are exacerbated by bias, stereotyping, and prejudice.[3] Unconscious racial bias perpetrated by healthcare professionals has been increasingly addressed through the implementation of racial bias trainings in hospitals and medical schools.[4] However, such bias training becomes ineffective when the medical benchmarks and medical devices used to test, diagnose, and treat patients are inherently biased due to the biases of the healthcare professionals, scientists, and developers bleeding into the creation

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[1] *See* Jasmine R. Marcelin et al., *The Impact of Unconscious Bias in Healthcare: How to Recognize and Mitigate It*, 220 J. OF INFECTIOUS DISEASES, S62, S73 (Aug. 20, 2019), https://academic.oup.com/jid/article/220/Supplement_2/S62/5552356.

[2] William J. Hall et al., *Implicit Racial/Ethnic Bias Among Health Care Professionals and Its Influence on Health Care Outcomes: A Systemic Review*, 105 AM J. PUBLIC HEALTH, 60, 61 (Dec. 2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4638275/.

[3] Marcelin et al., *supra* note 1, at S62.

[4] *See* Karen Nitkin, *New Anti-Bias Training at the School of Medicine*, JOHN HOPKINS MED. (Sept. 8, 2020) (Johns Hopkins Medical School adds a three-year program to address unconscious bias and structural racism), https://www.hopkinsmedicine.org/news/articles/new-bias-and-racism-training-at-the-school-of-medicine; Syma Chowdry, *Major Michigan Hospitals Support Mandated Implicit Bias Training*, WXYZ (July 9, 2020) ("the governor signed an executive order requiring all workers in the medical field to undergo implicit bias training"), https://www.wxyz.com/news/major-michigan-hospitals-support-mandated-implicit-bias-training.

of medical devices.[5] Relying on inherently biased tools results in people of color not obtaining accurate and effective healthcare.[6] When these unconscious biases are the basis for Artificial Intelligence ("AI") algorithms in medical devices, it leaves patients of color defenseless in their fight for equitable healthcare.[7]

First, this article explores the impact of medical devices in healthcare and examines the role of AI in existing and emerging technology of medical devices. Second, it analyzes the Food and Drug Adminstration's regulatory process for medical devices and its recently released Artificial Intelligence/Machine Learning Action Plan to address health inequities. Finally, recommendations are proposed to address the gaps in the regulatory process.

II. MEDICAL DEVICES AND THEIR IMPACT ON HEALTHCARE

Medical devices are employed in diverse healthcare settings ranging from hospitals to ambulances to home health.[8] Devices aim to "diagnose illness, to monitor treatments, to assist disabled people and to intervene and treat illnesses."[9] To begin to understand what counts as a medical device, 21 U.S.C. §321(h) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") defines a device as:

> An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

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[5] *See* Kat Jerich, *FDA Highlights the Need to Address Bias in AI*, HEALTHCARE IT NEWS (Oct. 22, 2020), https://www.healthcareitnews.com/news/fda-highlights-need-address-bias-ai.
[6] *Id*.
[7] *Medical Devices*, WHO, https://www.who.int/health-topics/medical-devices#tab=tab_1 (last visited Feb. 12, 2021).
[8] *Id.*
[9] *Id.*

> 1. Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
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> 2. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
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> 3. Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and
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> Which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o).[10]

The World Health Organization "estimate[s] over two million different kinds of medical devices on the world market."[11] The United States leads the world of medical devices with its $156 billion market, making up "forty percent of global market in 2017."[12] Wearable devices range from the classic fitness trackers to personal electrocardiogram ("ECG") monitor for detecting arrhythmias, for sleep tracking, and for oxygen level monitoring.[13] Wearable medical devices contribute to the growing device market as they become even more popular due to "their relative low cost, the collection of longitudinal data, and the ability to display/transmit information suggest a host of benefits if used in clinical practice and to advance remote research."[14]

Medical devices based in AI and machine learning ("ML") technologies offer a pathway for medical innovations since they collect a "vast amount of

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[10] 21 U.S.C. §321(h).
[11] *Id*.
[12] Select USA, *The Medical Technology Industry in the United States*, U.S. DEP'T OF COMMERCE, https://www.selectusa.gov/medical-technology-industry-united-states (last visited Mar. 10, 2021).
[13] PETER J. COLVONEN ET AL., *Limiting Racial Disparities and Bias for Wearable Devices in Health Science Research,* 43 SLEEP J. 1, 1 (Sept. 7, 2020), https://academic.oup.com/sleep/article/43/10/zsaa159/5902283.
[14] *Id.*

data generated during the delivery of health care every day."[15] From the generated data, device manufacturers "innovate their products to better assist health care providers and improve patient care."[16] AI is the "science and engineering of making intelligent machines, especially intelligent computer programs."[17] AI varies in its substance and implementation through an assortment of "models based on statistical analysis of data, expert systems that primarily rely on if-then statements, and machine learning."[18] ML is a popular AI technique that adapts software algorithms based on data input.[19] For example, using AI, a smart sensor device can "estimate the probability of a heart attack" and "an imaging system that uses algorithms to give diagnostic information for skin cancer in patients."[20]

The development of both wearables and non-wearable medical devices can "reinforce existing healthcare disparities" due to incomplete metrics for darker skin tones due to the lack of Black patient participation in research and medical trials, amplifying concerns as the new devices are now transitioning from consumer goods into health-related research and their internal algorithms are becoming Food and Drug Administration (FDA) approved."[21] Medical devices are the key for early detection, diagnosis, and treatment.[22] For example, measuring blood oxygen levels through pulse oximeters by clipping onto the fingertip and serves as a key indicator to

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[15] *Artificial Intelligence and Machine Learning in Software as a Medical Device*, FDA (Jan. 2021), https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device.
[16] *Id.*
[17] *Id.*
[18] *Id.*
[19] *Id.* (ML can be implemented to create "locked" algorithms, so that the algorithm does not change, or it can create "adaptive" algorithms that adjusts with new data. Numerous medical technologies have already implemented AI/ML).
[20] *Id.*
[21] COLVONEN ET AL., *supra* note 13.
[22] *Medical Devices*, *supra* note 7.

determine whether patients need immediate medical attention.[23] A study published in the New England Journal of Medicine in December 2020 showed that pulse oximeter devices are "three times more likely to give misleading readings among Black patients."[24] The implications of these misleading readings due to the "reliance on pulse oximetry to triage patients and adjust supplemental oxygen may place Black patients at increased risk for hypoxemia," which is a below-normal blood oxygen level.[25]

The underlying reason for these misleading readings is that most, if not all, wearables use photoplethysmographic ("PPG") green light signaling.[26] "Blood readily absorbs green light, where the greater the volume of blood present, the higher the green light absorption," which is then used to measure heart rate.[27] However, the level and rate of absorption of light varies based on skin tone, which interferes with the algorithm output.[28] Studies have shown that inaccurate readings occur when measuring the heart rate in darker skin types.[29] Inaccurate readings can lead to inaccurate diagnoses; creating a greater health disparity for patients of color.[30] This calls for greater concern as wearables and their algorithms are increasingly being utilized for health research and ultimately, gaining FDA approval that the device is safe and effective for use.[31][32]

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[23] Roni Caryn Rabin, *Pulse Oximeter Devices Have Higher Error Rate in Black Patients*, NY Times (Dec. 22, 2020), https://www.nytimes.com/2020/12/22/health/oximeters-covid-black-patients.html.
[24] *Id.* (citing Michael W. Sjoding, et al., *Racial Bias in Pulse Oximetry Measurement*, 383 N. ENGL. J. MED. 2477, 2478 (DEC. 17, 2020)).
[25] Sjoding, *supra* note 24; *Hypoxemia*, Mayo Clinic, https://www.mayoclinic.org/symptoms/hypoxemia/basics/definition/sym-20050930.
[26] Colvonen, *supra* note 13.
[27] *Id.*
[28] *Id.*
[29] *Id.*
[30] *Id.*
[31] *Id.*
[32] *See* 21 C.F.R. § 860.7 (d)(1) ("There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health

III. DEVICE REGULATIONS

A. FDA Regulatory Process

The FDA's authority for device regulations stems from the 1976 Medical Device Amendments to Federal Food, Drug, and Cosmetic Act ("FD&C Act").[33] Medical devices go through numerous steps before they become available on the U.S. market. In determining whether a product meets the definition provided under the FD&C Act, the FDA further explains that the applicant should define the intended use and indications for use of the product.[34] Once it is determined that the product meets the definition of a medical device, then the applicant must "determine if an appropriate product classification exists for the product."[35]

The development process for devices varies based on the device's FDA classification.[36] Before being approved for market use, the life cycle of a medical device begins at the conceptual and design phase with a market analysis.[37] Manufacturers will then conduct clinical trials for the devices, which are sometimes randomized or blinded studies.[38] These trials may also be "under strict oversight" by the FDA's Center for Devices and Radiological Health if the device is considered high-risk.[39] After the trial, the device is

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from use of the device for its indented uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks.").

[33] *A History of Medical Device Regulation & Oversight in the United States*, FDA, https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states (last visited Mar. 8, 2021).

[34] *Classify Your Medical Device*, FDA, https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device (last visited Mar. 5, 2021).

[35] *Id.*

[36] *Device Development Process*, FDA, https://www.fda.gov/patients/device-development-process/step-1-device-discovery-and-concept (last visited Mar. 8, 2021).

[37] Jill Jin, *FDA Authorization of Medical Devices*, 311 JAMA 435, 435 (Jan. 2014), https://jamanetwork.com/journals/jama/fullarticle/1817798.

[38] *Id.*

[39] *Id.*

reviewed by the FDA or "deemed exempt from review, depending on the device class and what types of similar devices are already on the market."[40]

The medical device classification system based on risk level was established by Section 513 of the Federal Food, Drug, and Cosmetic Act.[41] Each device is assigned to one of three regulatory classes: "Class I, Class II or Class III, based on the level of control necessary to provide reasonable assurance of its safety and effectiveness."[42] Class I encompasses the devices that "pose the least amount of risk to consumers," such as oxygen masks or surgical tools.[43] The devices within this classification are subject to "general controls" which ensures that the devices are safe and effective once manufactured.[44] General controls include good manufacturing practices, standards and reporting adverse events to FDA, registration, and general recordkeeping requirements.[45]

As for Class II devices, FDA classifies these devices as "posing more risk than Class I and thus, require special controls in addition to general controls," such as labeling requirements, device specific mandatory performance standards, and device specific testing requirements.[46] Computed Tomography (CT) scanners, pregnancy test kits, and powered wheelchairs are all examples of Class II devices.[47] Class II devices are likely to be exempt from review if they are extremely low risk or similar to other released devices, but they "usually undergo a 510(k) review."[48] A 510(k) review

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[40] *Id.*
[41] 21 CFR § 860.130. *See also Step 3: Pathway to Approval*, FDA, https://www.fda.gov/patients/device-development-process/step-3-pathway-approval (last visited Mar. 5, 2021).
[42] *Step 3: Pathway to Approval, supra* note 41.
[43] *Step 1: Device Discovery and Concept*, FDA, https://www.fda.gov/patients/device-development-process/step-1-device-discovery-and-concept (last visited Mar. 10, 2021).
[44] *Id.*
[45] *Id.*
[46] *Id.*
[47] Jin, *supra* note 37.; *Learn if a Medical Device Has Been Cleared by FDA for Marketing*, FDA, https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing.
[48] Jin, *supra* note 37.

"determines whether the new device is 'substantially equivalent' to an existing device."[49] For a new device to be "substantially equivalent," it has to be "as safe and effective" as the existing legally marketed device.[50]

Class III devices "support or sustain life, are implanted in the body, or have the potential for unreasonable risk of illness or injury."[51] These include "pacemakers, breast implants, and HIV diagnostic tests."[52] Class III devices require premarket approval, are subject to general controls, and the manufacturer must prove that a device is safe and effective.[53] During the review process for Class III devices, the FDA "decides whether the new device is safe and effective in treating a specific disease or condition."[54] Ultimately, the differences in the three classifications of medical devices comes down to whether the devices are for internal or external use.[55] Therefore, if a device is implanted or used to sustain life, then, it would be subject to higher regulatory controls than a device used on the outside of a patient's body like elastic bandages.[56]

B. FDA's AI/ML-Based Software as a Medical Device Action Plan

Due to the increased reliance of medical devices on AI, the FDA must adapt its regulatory process to address the potential inaccuracies of devices on patients of color before the devices hit the market and become heavily

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[49] *Id.*
[50] *Premarket Notification 510(k)*, FDA, https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k (The FDA defines a legally marketed device as a "device that was legally marketed prior to May 28, 1976 (preadmendments device), or a device which has been reclassified from Class III to Class II or I, a device which has been found substantially equivalent through the 510(k) process, or a device that was granted marketing authorization via the De Novo classification process under section 513(f)(2) of the FD&C Act that is not exempt from premarket notification requirements.").
[51] *Step 1: Device Discovery and Concept*, *supra* note 43.
[52] *Id.*
[53] *Id.*
[54] Jin, *supra* note 37.
[55] *Classify Your Medical Device*, *supra* note 34.
[56] *Id.*

relied upon by physicians and patients.[57] The FDA released its AI/ML-based Software as a Medical Device ("SaMD") plan ("Action Plan") in January 2021, aiming to "deliver safe and effective software functionality that improves the quality of care that patients receive." [58]

Through the announcement of this Action Plan, the FDA "recognizes that bias and generalizability is not an issue exclusive to AI/ML-based devices" and views that it is essential to take these biases into account in future approval procedures of medical devices.[59] The FDA recognizes that AI/ML systems derive from "data from historical datasets" that may be "vulnerable to bias – and prone to mirroring biases present in the data."[60] The Action Plan aims to ensure that medical devices are "well suited for a racially and ethnically diverse intended patient population."[61]The goal is to shift health care into a more equitable approach, which is realized by identifying and eliminating bias in the algorithms through continuous oversight and supporting research in AI/ML.[62]

The Action Plan proposes a "multi-pronged approach to advance the [FDA's] oversight of AI/ML-based medical software."[63] The first prong involves "further developing the proposed regulatory framework."[64] This includes issuing a draft guidance on a Predetermined Change Control Plan in

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[57] Abhidmanyu S. Ahuja, *The Impact of Artificial Intelligence in Medicine on the Future Role of the Physician*, 7 PEER J. 1, 19 (OCT. 4, 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6779111/.

[58] *Artificial Intelligence and Machine Learning in Software as a Medical Device*, *supra* note 15 (The FDA recognizes that its traditional regulatory process for medical devices "was not designed for adaptive artificial intelligence and machine learning technologies.").

[59] ARTIFICIAL INTELLIGENCE/MACHINE LEARNING (AI/ML)-BASED SOFTWARE AS A MEDICAL DEVICE (SAMD) ACTION PLAN, FDA, 1, 5 (Jan. 2021), https://www.fda.gov/media/145022/download [hereinafter ACTION PLAN].

[60] *Id.* at 5.

[61] *Id.*

[62] *Id.*

[63] *Id.* at 7.

[64] *FDA Releases Artificial Intelligence/Machine Learning Action Plan*, FDA (Jan. 12, 2021), https://www.fda.gov/news-events/press-announcements/fda-releases-artificial-intelligence machine-learning-action-plan.

premarket submissions, which provides for the changes made to the software over time.[65] The guidance intends to include steps for "types of anticipated modifications and the associated methodology being used to implement those changes in a controlled manner that manages risks to patients."[66]

The second prong of the Action Plan is to "support the development of good machine learning practices to evaluate and improve machine learning algorithms."[67] The third prong fosters a patient-centered approach, including device transparency to users.[68] Fourth, the Action Plan will develop methods to evaluate and improve machine learning algorithms.[69] Finally, it aims to advance real-world performance monitoring pilots.[70]The second and fifth prong will work together to create the ability for the FDA and manufacturers to evaluate and monitor a software product from its premarket development through post-market performance.[71] Through this oversight, the FDA can provide a "reasonable assurance of safety and effectiveness while embracing the iterative improvement power of artificial intelligence and machine learning-based software as a medical device."[72]

If there is no trust between the patient and his physician recommending the device and between the patient and the device itself, then there is no true positive outcome for the medical device, making the third prong arguably the most important of the Action Plan.[73] Through the Action Plan, the FDA states it will take a patient-centered approach that accounts for usability, equity,

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[65] *Id.*
[66] ACTION PLAN, *supra* note 59, at 3.
[67] *FDA Releases Artificial Intelligence/Machine Learning Action Plan*, *supra* note 64.
[68] *Id.*
[69] *Id.*
[70] *Id.*
[71] ACTION PLAN, *supra* note 59, at 5.
[72] *Id.*
[73] *See* Enid N.H. Montague et al., *Trust in Medical Technology by Patients and Health Care Providers in Obstetric Work Systems*, 29 BEHAV. INFO. TECH. 541, 554 (Sept. 2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2927233/.

trust, and accountability, focusing on promoting transparency to users about the devices' functioning.[74]

A complication arises for manufacturers in the goal of transparency in labeling devices to describe the functioning, the algorithm, and the evidence of performance.[75] To address manufacturers' concerns and to put the patient-centered approach at the forefront of its effort, the FDA held a Patient Engagement Advisory Committee ("PEAC") meeting in October 2020.[76] During this meeting, the FDA sought insight from patients on which factors impact their trust in AI/ML medical devices.[77] The FDA stated that it continues to take steps to compile the input gathered and intends to share the information as well as elicit input from manufacturers at a later date to consider the best method to support transparency to users.[78]

IV. RECOMMENDATIONS

There are multiple ways the FDA can build upon the Action Plan to address many of the disparities in the current regulatory and approval process of devices with AI/ML algorithms. As previously discussed, a major concern of AI/ML algorithms lies in the lack of diverse data sets and the resulting inaccuracies of the devices on patients of color as well as the increased distrust and skepticism between patients and the devices.[79] The Action Plan proposes to build transparency between users and manufacturers through required labeling and continuous monitoring.[80] In addition to labeling, however, the required transparency should be between the FDA,

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[74] ACTION PLAN, *supra* note 59, at 4-5.
[75] *Id.* at 5.
[76] *Id.*
[77] *Id.*
[78] *Id.*
[79] *See* Marcelin et al., *supra* note 1.
[80] ACTION PLAN, *supra* note 59, at 5.

manufacturers, healthcare systems and physicians, so that physicians can confidently recommend the devices to *all* patients.[81]

Aiding in the mission of transparency, the data sets used to source the AI/ML algorithms need to be reported to the FDA in the manufacturer's FDA approval application and must be the basis for consideration for approval.[82] If the device fails to take into account a diverse data set, then it should not reach the market.[83] However, if the FDA continues to approve a device created from a non-diverse data set, then prospective users should be informed of the device's potential limitations.[84] By being transparent and improving the approval process, inaccurate readings with devices that use AI/ML algorithms and PPG signaling could be eliminated altogether by preventing the devices from even passing the FDA approval process unless they adhere to incorporating diverse data sets.[85]

Furthermore, this Action Plan must not only look forward, but must also be applied retroactively.[86] Over 160 AI/ML-based SaMDs have been approved by the FDA with seventy of those AI/ML-based SaMDs being approved in 2019.[87] Of the total approved AI devices, only seven disclosed "the racial makeup of the study population" and thirteen disclosed the gender

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[81] *See* Marcelin et al., *supra* note 1.
[82] *See* Elise Reuter, *FDA-Cleared AI Devices Lack Critical Information on Performance, Equity*, Med City News (Apr. 13, 2021), https://medcitynews.com/2021/04/fda-cleared-ai-devices-lack-critical-information-on-performance-equity/; ERIC WU ET AL., HOW MEDICAL AI DEVICES ARE EVALUATED; LIMITATIONS AND RECOMMENDATIONS FROM AN ANALYSIS OF FDA APPROVALS, 27 NATURE MEDICINE 582, 584 (APR. 2021).
[83] *See* Sjoding, *supra* note 24.
[84] *See* WU ET AL., *supra* note 82.
[85] *Id.*
[86] ACTION PLAN, *supra* note 59.
[87] Bethany J. Hills & Jean Nguyen, *FDA's Plan for AI/ML-Based Software as Medical Devices: Progress and Concerns*, MORRISON FOERSTER: MOFO LIFE SCIENCES (Mar. 3, 2021), https://lifesciences.mofo.com/topics/Progress-and-Concerns-of-FDAs-Plan-for-Regulatory-Oversight-of-Artificial-IntelligenceMachine-Learning-AIML-Based-Software-as-Medical-Devices-SaMDs.html.

makeup.[88] Devices currently on the market need to be reviewed to assess their accuracy on patients of color. For example, since pulse oximeter devices are used as a gateway diagnostic tool, the racial health gap is even wider than anticipated.[89] Inaccurate diagnoses could have been prevented with diverse research studies and an improved FDA approval process.[90]

V. CONCLUSION

It has never been more apparent that health care must be a united effort. From the physician-patient relationship to the tools used to diagnose, decreasing racial health disparities has to be prioritized for health care to be effective.[91] As health care becomes more dependent on AI/ML-based technology, the industry, as a whole, should use the FDA regulatory process as an opportunity to address past and present racial biases and to prevent further marginalization in the health care space to better the future health of all.

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[88] Casey Ross, *Explore STAT's Database of FDA-Cleared AI Tools*, STAT (Feb. 3, 2021), https://www.statnews.com/2021/02/03/fda-artificial-intelligence-clearance-products/.
[89] Sjoding, *supra* note 24.
[90] Amit Kaushal et al., *Health Care AI Systems Are Biased*, SCI. AM. (Nov. 17, 2020), https://www.scientificamerican.com/article/health-care-ai-systems-are-biased/.
[91] *See* Marcelin et al., *supra* note 1.

The LCME is Failing Medical Students and the Entire Medical Field

David Madrigal

I. INTRODUCTION

In the health care world today, many women feel their providers are either ignoring or dismissing their symptoms.[1] In a recent study, twenty percent of women felt dismissed by their providers, while about only fifteen percent of men felt their providers were either ignoring or dismissing their symptoms.[2] Why is it that women feel more like this? Are their feelings justified?

Maya Dusenbery, author of the book, *Doing Harm: The Truth About How Bad Medicine and Lazy Science Leave Women Dismissed, Misdiagnosed, and Sick*, believes that providers take a man's symptoms more seriously than a woman's.[3] Her belief stems from a cultural belief that women are normally allowed to show more emotion than men. Therefore, when a man shows emotion and asks for help, it is taken more seriously.[4] Maya Dusenbery concluded over her two years of research that this leads to delayed diagnoses for women, and the doctors who failed to diagnose the patient, never found out that they failed to diagnose their patient correctly.[5]

Societal norm are not the only factors that play a role when it comes to why genders are not being properly diagnosed. The term "gender bias"

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[1] Emily Paulsen, *Recognizing, Addressing Unintended Gender Bias in Patient Care,* DUKE HEALTH (Jan 14, 2020), https://physicians.dukehealth.org/articles/recognizing-addressing-unintended-gender-bias-patient-care.
[2] *Id*.
[3] Jenara Nerenberg, *How to Address Gender Inequality in Health Care*, GREATER GOOD (March 9, 2018), https://greatergood.berkeley.edu/article/item/how_to_address_gender_inequality_in_health_care.
[4] *Id*.
[5] *Id*.

generally refers to when an assumption is made that males and females are the same, and their needs are the same.[6] However, this is not the reality that we are faced with. Males and females do not react the same or have the same symptoms in a vast amount of different medical situations.[7] For example, cardiovascular disease in men causes significant pain and is very alarming to a man.[8] However, the symptoms are significantly less painful in women, which causes doctors to say the symptoms arise from less life-threatening conditions.[9]

This creates an issue that Maya Dusenbery calls the "trust gap," which results from doctors not believing that a woman's symptoms are significant enough to be life threatening.[10] Cardiovascular disease is one of many medical conditions that are under-researched.[11] Others include autoimmune disease, fibromyalgia, and many chronic pain conditions.[12] Studies are constantly being published which demonstrate that this is a common occurrence in health care. *Nature Communications* published a study they conducted looking at almost seven million cases of men and women in the Danish healthcare system.[13] Their final results showed that men were diagnosed before women in over 700 diseases.[14]

The Pan American Health Organization (PAHO) demonstrated a real-life example of what happens when men and women are treated the same in

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[6] Thomas Jefferson U. Online, *Exploring Gender Bias in Healthcare*, FIERCE HEALTHCARE (Sept. 16, 2019 9:00AM) https://www.fiercehealthcare.com/sponsored/exploring-gender-bias-healthcare.
[7] *Id*.
[8] *Id*.
[9] *Id*.
[10] Nerenberg, *supra* note 3.
[11] *Id*.
[12] *Id*.
[13] Lorena Alcalde-Rubio et al., *Gender Disparities in Clinical Practice: Are There Any Solutions? Scoping Review of Interventions to Overcome or Reduce Gender Bias in Clinical Practice*. 19 INT. J. EQUITY HEALTH (2020). https://doi.org/10.1186/s12939-020-01283-4
[14] *Id*.

health care.[15] The Mexican government was trying to reduce the amount of diabetes in the country.[16] They released a single brochure that laid out healthy living and eating tips to try to keep everyone healthier. [17] However, nothing changed and the percentage of the population with diabetes kept increasing.[18] Mexico discovered that men and women felt that their living and eating needs were not the same as one another.[19] This led to the release of two brochures, one for men and one for women, which led to a decrease in the percentage of the population with diabetes.[20]

Further, gender disparities do not stop just at the differences between men and women; these disparities extend to affect members of the LGBTQ community alike.[21] The same mechanisms that are in place that cause the disparities between men and women also cause the disparities that we see arise in the LGBTQ community.[22] Physicians often have internal or implicit biases.[23] In order to address these issues and to make patients feel safe and welcomed, the physicians have to address the disparities they have.[24] If physicians refuse to accept the bias they have or try to avoid them, nothing will change.[25] LGBTQ disparities must be addressed because their needs are different than people who are not members of the community.

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[15] PAN AMERICAN HEALTH ORGANIZATION, GENDER EQUALITY IN HEALTH: IMPROVING EQUALITY & EFFICIENCY IN ACHIEVING HEALTH FOR ALL (2010), https://www.paho.org/hq/dmdocuments/2010/Gender-equality-in-health-EN.pdf.
[16] *Id*.
[17] *Id*.
[18] *Id.*
[19] *Id*.
[20] *Id.*
[21] *How Gender Bias Undermines LGBT Equality*, CTR. FOR AM. PROGRESS (November 13, 2013) https://www.americanprogress.org/events/2013/11/07/79108/how-gender-bias-undermines-lgbt-equality/.
[22] *Id*.
[23] MICHAEL J. MCDOWELL & IMAN K. BERRAHOU, LEARNING TO ADDRESS IMPLICIT BIAS TOWARDS LGBTQ PATIENTS, 1 (Hilary Goldhammer, et al. eds., 2018) https://www.lgbtqiahealtheducation.org/wp-content/uploads/2018/10/Implicit-Bias-Guide-2018_Final.pdf.
[24] *Id*. at 2.
[25] *Id*.

It is clear that gender bias has caused gender disparities in the health care system, affecting men, women, and the LGBTQ community. This disparity has led to misunderstanding and misinformation on how to treat men, women, and the LGBTQ community differently. Many doctors only focus on the big differences. For example, the reproductive function of women.[26] Policy must be implemented to correct these mistaken beliefs and help undo the gender disparities occurring in the health care system. The best place to begin implementing these polices is in medical schools across the country. The Department of Education has given the Liaison Committee on Medical Education (LCME) power to accredit medical schools in the United States and Canada.[27] The Department of Education must enforce new policies upon the LCME to ensure medical students are being taught in ways that do not lead to gender disparities.

II. WHAT MEDICAL SCHOOLS ARE TEACHING

As it stands today, medical research into diseases and treatments have a strong bias to the number of male participants compared to female participants.[28] In a screening of over 3,802 medical studies, it was concluded that only twenty-two of the medical studies fully broke down all the differences between a man and a woman in the study.[29] This is an issue because medical students begin conducting their medical research while they are in medical school. Medical students learn habits and strategies that stick with them for the rest of their career.[30] This ultimately leads to any future

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[26] *Id*.
[27] *What is the LCME?,* AUGUSTA U., https://www.augusta.edu/mcg/coffice/evaluation-services/lcme/index.php, (last visited Feb 4, 2021).
[28] Thomas Jefferson U. Online, *supra* note 6.
[29] Alcalde-Rubio *supra* note 13.
[30] *Why Research Is Important For Medical Students*, ST. JAMES SCH. OF MED. (July 25, 2019), https://www.sjsm.org/2019/07/why-research-is-important-for-medical-students/.

research being conducted in the manner they were taught while in medical school.[31]

There have been many instances of where medical schools have proven that they lack the proper education of gender.[32] There have been instances where professors noticed the lack of acknowledgment of the difference between the sexes and tried to take steps to remedy the situation.[33] Professors have made it clear that medical schools do not focus on how various illness have different symptoms for women and men.[34] As explained above, this has led to gender bias in the medical field.[35]

Medical schools continue to fail medical students by having little to no curriculum relating to the medical needs of LGBTQ members compared to nonmembers.[36] Many medical schools across the country only include five hours of LGBTQ-related courses in their overall curriculum.[37] Due to this lack of LGBTQ-specific education, eighty percent of medical students felt they would not be competent or only somewhat competent to handle the needs of an LGBTQ patient.[38] This causes more disparities in the medical field that need to be addressed. Currently, in the United States 5.6% of the population identify themselves as LGBTQ.[39] Out of those people, 11.3%

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[31] *Id*.
[32] Amy Xiong, *Med School Faculty Revamp Curriculum with Sex Differences,* YALE DAILY NEWS (Mar 9, 2018) https://yaledailynews.com/blog/2018/03/09/med-school-faculty-revamp-curriculum-with-sex-differences/.
[33] *Id*.
[34] *Id*.
[35] Thomas Jefferson U. Online, *supra* note 6.
[36] Rachel D. Cohen, *Medical Students Push For More LGBT Health Training To Address Disparities*, NAT'L PUB. RADIO (Jan 20, 2019) https://www.npr.org/sections/health-shots/2019/01/20/683216767/medical-students-push-for-more-lgbt-health-training-to-address-disparities.
[37] *Id*.
[38] *Id*.
[39] Dan Avery, *Americans are Identifying as LGBTQ More Than Ever, Poll Finds*, (Feb 24, 2021) https://www.nbcnews.com/feature/nbc-out/americans-are-identifying-lgbtq-more-ever-poll-finds-n1258627.

identify themselves as transgender.[40] This number has gone up significantly since 2017.[41] This clearly shows that medical school education is out of date and needs to be changed.

III. THE LCME & WHY THEIR REQUIREMENTS MUST BE CHANGED

The LCME is recognized by the U.S. Congress as the authority responsible for accrediting medical schools.[42] The U.S. Department of Education renewed their federal recognition of the LCME on August 22, 2018 for the following five years.[43] The LCME is supposed to foster growth among medical schools and help improve them.[44] However, as discussed above, this "growth" has not kept up with the times.

Only medical schools that are accredited by the LCME become eligible for federal grants and programs.[45] These federal grants and programs are essential when it comes to medical schools conducting their own medical research.[46] Without these grants, many universities would lose professors who rely on these grants for research.[47] This in turn does not only hurt the universities, but this also hurts the entire health care field.[48]

Every year the LCME releases their standards that accredited schools, or schools that want to be accredited must follow.[49] Unfortunately, these standards do not do much to help the issue of gender disparities. For starters,

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[40] *Id*.
[41] *Id*.
[42] LIAISON COMM. ON MED. EDUC., https://lcme.org/ (last visited Feb. 19, 2021).
[43] *Id*.
[44] *Id*.
[45] *Id*.
[46] Alexis J. Ross & William L. Wang, *Med School Professor Worried About Federal Budget*, HARVARD CRIMSON (Mar. 9, 2017), https://www.thecrimson.com/article/2017/3/9/med-professors-fed-budget/.
[47] *Id*.
[48] *See id*. ("a majority of the medical research out there comes from medical schools. If medical schools lose funding for medical research a lot of good quality research would be lost.").
[49] What is the LCME?, *supra* note 27.

the term 'gender' is used only four times.[50] The first time it is used is to state that a medical school shall not discriminate based upon gender.[51] The most detail the LCME goes into in ensuring that medical students have the proper knowledge and practice on both genders is by stating that an adequate number of patients from both genders must be available.[52] However, it does not define adequate or give any other guidance.[53]

The World Health Organization (WHO) has stated that incorporating gender analysis should be the main concern when it comes to gender disparities.[54] This is because incorporating gender analysis from the beginning of one's education begins to form habits.[55] Currently, it is possible that many doctors do not believe that they are providing different care based on the gender of their patient.[56] Awareness is necessary to combating gender disparities; without knowing there is an issue, one will not know one needs to fix something.[57] An important first step in preventing gender disparities is to help eliminate the bias before it becomes an issue in the health care system. This first step means we must implement education in medical schools about the differences between men, women and the LGBTQ community and how they react in different medical situations.[58] This is an important first step because we need to gather research and see if this begins to help eliminate gender disparities.[59]

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[50] *Standards*, LIAISON COMMITTEE ON MEDICAL EDUCATION (2020), https://lcme.org/publications/#Standards.
[51] *Id*.
[52] *Id*.
[53] *Id*.
[54] Maria Luisa Panisello & Inma Pastor, *Health with Equality: A Proposal for the Incorporation of the Gender Perspective in Health Care Systems*, 20 CIENC. & SAUDE COLETIVA, 1555 (2015), http://www.scielo.br/pdf/csc/v20n5/1413-8123-csc-20-05-01555.pdf.
[55] *Id*.
[56] Paulsen, *supra* note 1.
[57] *Id*.
[58] Katarina Hamberg, *Gender Bias in Medicine*, 4 WOMEN'S HEALTH 237, 241 (2008) https://journals.sagepub.com/doi/pdf/10.2217/17455057.4.3.237.
[59] *Id.*

The second step is incorporating more women and LGBTQ members in medical school lectures and research, which will allow medical students to see the differences of the genders earlier in their education, allowing them to grow better habits. The rest of this article will focus specifically on the changes that must be made in medical school's research, clinical, and lecture work as well as the policies that can be implemented to ensure compliance.

IV. HOW TO FIX GENDER BIAS ARISING FROM MEDICAL SCHOOLS

The LCME needs to implement stronger standards for medical schools in teaching medical students about gender differences. This is an essential first step because this helps medical students develop habits that are essential for their careers.[60] As mentioned before, many doctors do not know they have gender bias habits, thus if medical schools can prevent the bias from forming, this is a great start.[61] Research in medical school can lead to the production of more medical research later on in that medical student's career.[62] This allows the medical student to form no gender bias, and may increase the amount of research that is going into gender disparities.[63] Lastly, studies have shown that conducting research in medical school leads to doctors providing better care for their patients.[64]

The PAHO created a template to help design programs and research to integrate gender.[65] The five steps are: identifying the health problem and separating it by sex; analyze the data with a gender perspective; create a program consistent with international standards; and select intended outputs

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[60] *Why Research Is Important for Medical Students*, ST. JAMES SCHOOL OF MEDICINE (July 25, 2019), https://www.sjsm.org/2019/07/why-research-is-important-for-medical-students/.)
[61] Paulsen, supra note 1.
[62] Standards, *supra* note 50.
[63] *Id.*
[64] *Id*.
[65] Pan American Health Organization, *supra* note 15.

to redress inequities.[66] This template is a good example of how the LCME can require medical research at a medical school to be conducted.

The PAHO also created the "gender assessment tool" (GAT) which helps to evaluate programs and ensure that the program is gender responsive. The GAT lists twenty-six questions that help determine if the program should be used.[67] Answering 'yes' to eleven questions between the questions of 1-20, the program is deemed 'gender transformative.'[68] This essentially means that the program helps take away gender bias. If the answer to two questions between the questions of 21-26 is 'yes,' the program may be considered gender blind or unequal.[69] The LCME should use the GAT when they examine schools for accreditation.

Medical schools also need to make changes to their clinical and lecture requirements. In many medical school textbooks, it is stated that men and women are basically the same and use a man as the normal reference point when discussing issues.[70] The LCME standards does not require an in depth look at the differences between men, women and member of the LGBTQ community.[71] This must become a standard in medical schools across the country. If medical students are not exposed to the differences when they go to their clinical work they will have a gender bias. To make matters worse, the LCME only requires that medical students have an "adequate" amount of experience on both genders.[72] This definition is not appropriate when it comes to the lives of millions of people. Stricter standards must be enforced and monitored. Overall, both in research and clinical training, the results

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[66] *Id*.
[67] *Id*.
[68] *Id*.
[69] *Id*.
[70] Ross & Wang. *supra* note 46.
[71] Thomas Jefferson U. Online, *supra* note 6.
[72] *Id*.

must be evaluated.[73] The results will help provide an understanding if this is helping with gender disparities, doing nothing, or making matters worse.[74]

Due to these reasons, the LCME should apply the GAT when accrediting schools. The LCME additionally needs to change their policy to clearly define what medical schools need to do in order to address the different needs of men, women, and the LGBTQ community. However, the Department of Education needs to ensure that the LCME is following through and ensuring that these policy changes are taking place. There must be repercussions in place for if/when the LCME does not follow the new standards.

V. HOW TO IMPLEMENT POLICY CHANGE

The LCME's power is given to them by the U.S. Congress, through the Department of Education.[75] Medical schools can only be accredited and receive federal funding if the LCME gives them the accreditation.[76] This gives the Department of Education the power to implement policy changes that are needed.

Policy changes can be implemented through two different avenues. First, the Department of Education has granted the LCME accreditation power until 2023.[77] When that contract expires, the Department of Education can force the LCME to enact new standards, such as including in the contract that unless they are satisfied with the new LCME standards, it can rescind its accreditation. Second, if the LCME does comply with the new policies, the medical schools must all go through the accreditation process again. LCME,

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[73] Ross & Wang, *supr*a note 46.
[74] *Id*.
[75] Thomas Jefferson U. Online, *supra* note 6.
[76] *Id.*
[77] *Id*.

as they currently do, will be able to rescind accreditation or warn schools that their accreditation will be taken if the new standards are not followed.[78]

Medical schools rely heavily on federal funding for research and other needs.[79] For example, in 2016 Harvard received about $600 million from the federal government.[80] If LCME does not accredit medical schools based off their new standards and the Department of Education begins to cut funding for those schools, many medical schools will find themselves in a lot of trouble. This will lead to a lot of schools following the new standards laid out by the LCME or losing their grants.

Changing the standards alone for the LCME is not enough to prevent gender bias from occurring. With the LGBT community growing rapidly, and existing gender bias in medical schools, the LCME needs to examine schools for accreditation more than they are currently.[81] As it stands today, the LCME does an accreditation visit to a medical school once every eight years.[82] This means that if the LCME does adopt new standards in 2023, some schools may not be visited until 2030.[83] Information concerning gender bias and how the different genders have different needs is constantly growing. Eight years is far too long of a time to ensure that all medical schools are up to date with the proper procedures. Thus, if the Department of Education decides to renew the LCME accreditation rights, the LCME should accredit schools every four years. Because the medical field is constantly evolving, eight years is far too long to not change standards.

If the LCME does implement new standards, the Department of Education needs to ensure that the LCME is actually applying the standards. Therefore,

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[78] *Id*.
[79] Ross & Wang, *supra* note 46.
[80] *Id*.
[81] Cohen, *supra* note 36.
[82] ASS'N OF AM. MED. COLLS. https://www.aamc.org/services/first-for-financial-aid-officers/lcme-accreditation.
[83] *Id*.

unlike previous contracts with the LCME, the Department of Education should only give the LCME their accreditation power for two-year increments.[84] This will allow the Department of Education to survey schools and determine if the new standards are making a difference.

VI. CONCLUSION

Medical schools help shape the type of doctors that medical students will be throughout their career. The habits medical students learn throughout medical school will be with them forever. In order to stop gender disparities and increase the amount of quality medical research, polices must be implemented to ensure the proper education of these students through the accreditation process. If medical schools do not follow the new standards to remedy the gender disparities, schools should lose their accreditation and lose federal funding. If the LCME fails to uphold the new standards, they should lose their power to accredit medical schools.

[84] LIAISON COMM. ON MED. EDUC., *supra* note 42.

Cultural Competency and the Law: Reproductive Justice for American Indians

Audrey Mallinak

I. INTRODUCTION

Reproductive justice combines reproductive rights, social justice, and culturally competent approaches to further the goal of intersectional representation.[1] Culturally competent medical treatment ensures individuals receive the best treatment possible by honoring cultural backgrounds, acknowledging racial and ethnic inequities, and providing medical autonomy.[2] While race is a social construct, there are cultural differences and environmental factors that warrant heightened attention from a medical standpoint.[3]

In this article, I will explain the timeline of the relationship between the U.S. Government and American Indians[4] as it relates to what access to reproductive healthcare is currently available. Next, I will argue that increased federal funding is central to reproductive justice for two reasons: (1) It will increase the access to healthcare facilities for American Indian

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[1] *Reproductive Justice*, SISTERSONG.NET (last visited Feb. 7, 2021), https://www.sistersong.net/reproductive-justice.
[2] *Cultural Competence in Health Care: Is it Important for People with Chronic Conditions?*, GEORGETOWN UNIVERSITY HEALTH POL'Y INST. (last visited Mar. 21, 2021), https://hpi.georgetown.edu/cultural/.
[3] Tamarra M. James-Todd et al., *Racial/Ethnic Disparities in Environmental Endocrine Disrupting Chemicals and Women's Reproductive Health Outcomes: Epidemiological Examples Across the Life Course*, 3 CURRENT EPIDEMIOLOGY REPORTS 161, 162 (2016).
[4] For the purpose of this paper, I will use the language "American Indian" when a specific tribe is not discussed. Terminology can vary per source, but American Indian is often preferred by those of that heritage/culture and is a legally recognized term. *Frequently Asked Questions*, NATIVE KNOWLEDGE 360 (last visited April 29, 2021), https://americanindian.si.edu/nk360/faq/did-you-know.

communities; (2) It will provide essential education for not only American Indian, but also the medical professionals who treat them. Lastly, I will discuss the complicated conversation regarding abortion as a reproductive healthcare necessity.

II. BACKGROUND

American Indians are often overlooked in conversations surrounding healthcare, and even more so in reproductive healthcare.[5] Rooted in a tumultuous history with the U.S. Government, American Indians have fought for access to healthcare.[6] However, little aid has been provided and what aid has been provided fails to match the need.[7] As early as the mid 1800's, the U.S. Government traded land for healthcare with American Indians tribes.[8] Yet current data shows that the healthcare facilities sustained through the Indian Health Services (IHS) are only located on tribal land despite the fact that only forty percent of American Indian peoples reside on reservations.[9]

On March 23, 2010, President Barack Obama signed the Indian Health Care Improvement Act as part of the Affordable Care Act.[10] Yet to this day, most IHS locations lack birthing centers.[11] This lack of healthcare is deeply seated in systemic racism when healthcare was purposefully withheld from American Indians in order to prevent future generations of American

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[5] *The Road to Reproductive Justice: Native Americans in New Mexico*, FORWARD TOGETHER (last visited March 14, 2021) https://forwardtogether.org/tools/the-road-to-reproductive-justice-native-americans-in-new-mexico/.
[6] Barbara Gurr, *The Failures and Possibilities of a Human Rights Approach to Secure Native American Women's Reproductive Justice*, 7 SOCIETIES WITHOUT BORDERS 1, 2 (2012).
[7] *Id.*
[8] *Id.* at 8.
[9] *Id.* at 9.
[10] *Indian Health Care Improvement Act*, INDIAN HEALTH SERVICES.GOV (last visited April 11, 2021), https://www.ihs.gov/ihcia/.
[11] Gurr, *supra* note 6, at 11.

Indians.[12] Further examples of distrust include a history of studies targeting American Indians where findings were purposefully withheld and communities were not awarded the benefits of risking their health to contribute findings for the rest of the population.[13]

Reproductive healthcare includes mental and physical wellbeing for all matters involving the reproductive system.[14] Sexual and reproductive healthcare is essential because it ensures people have healthy births and the ability to choose if and when to start and build families.[15] People of color are disproportionately provided inadequate reproductive healthcare at both the individual and social level. Some of the relevant factors include "fewer neighborhood health services, less insurance coverage, decreased access to educational and economic attainment, and even practitioner-level factors such as racial bias and stereotyping."[16]

III. ANALYSIS

Federal funding and regulations would greatly aid in providing better and easier accessible reproductive healthcare to American Indians. In regard to federal funding, specific access to culturally competent reproductive healthcare and education would not only ensure communities receive adequate care, but further provide communities with the information needed to make decisions about family planning. Moreover, funding specifically

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[12] Barbara Gurr, *Mothering in the Borderlands: Policing Native American Women's Reproductive Healthcare*, 37 INT'L J. SOCIOLOGY FAMILY 1 (2011); *1976: Government admits unauthorized sterilization of Indian Women,* NATIVE VOICES (last visited Jan 18, 2021) https://www.nlm.nih.gov/nativevoices/timeline/543.html.
[13] Elizabeth Hoover et al., *Indigenous Peoples of North America: Environmental Exposures and Reproductive Justice*, 120 ENV. HEALTH PERSPECTIVES 1645, 1647 (Dec. 2012).
[14] *Sexual & Reproductive Health*, UNITED NATIONS POPULATION FUND (last updated 2020), https://www.unfpa.org/sexual-reproductive-health.
[15] *Id*.
[16] Madeline Y. Sutton et al., *Racial and Ethnic Disparities in Reproductive Health Services and Outcomes, 2020*, OBSTETRICS & GYNECOLOGY 1 (2021) (discussing the broad scope of racial disparity issues and the multitude of factors contributing to lack of reproductive health access for women of color).

focused on cultural competency will allow for medical professionals to better navigate sensitive topics such as abortion and rebuilt decades of mistrust.

A. Access

Access to adequate reproductive healthcare in American Indian communities is a twofold problem: not only must there be greater access to medical centers, but there also must be an assurance that culturally competent care be provided at these facilities. One of the first barriers an individual experiences when attempting to receive treatment from an IHS facility is twofold: they first they must prove they are a registered American Indian, and then they have to provide proof that they are currently receiving Medicaid.[17] Both are exceptionally challenging for individuals without access to computers or internet.[18] Besides the limited, if any, birth control options available at these facilities, restrictions on access from the U.S. government exacerbate abortion and family planning options.[19] To address the issue of accessibility, an increased number of healthcare facilities and birthing centers in and near reservations would alleviate this major barrier and allow increased access to reproductive healthcare. Currently, traveling to hospitals and birthing centers can take several hours.[20] Keeping in mind the fact that many American Indians already live in poverty, sacrificing time and resources to utilize essential treatment prevents patients from even seeking aid.[21] An example of the disproportionate amount of health facilities is the

[17] Barbara Gurr & Nikki McGary, *Restricted Access: The Intersections of Reproductive Health, Rights and Policy for Minors and Native American Women*, 11 J. ASSOC. RSCH. ON MOTHERING 110-121, 115 (2009).
[18] *Id.*
[19] *Id.*
[20] Clemens Scott Kruse et al., *Telemedicine Use in Rural Native American Communities in the Era of the ACA: A Systematic Literature Review*, 40 J. MED. SYST. 5 (2016).
[21] Gurr & McGary, *supra* note 17, at 115.

Crow reservation in Montana which spans 2.2 million acres[22] and yet only hosts one IHS hospital and two health clinics on reservation land.[23]

Telemedicine may provide a partial fix for some reproductive healthcare needs. While an online doctor appointment does not replace a birthing center, telemedicine has been utilized by American Indians communities since the 1970's.[24] This practice can be helpful to encourage more culturally common birthing practices, such as midwifery, if a doctor can be on call while the mother is still able to utilize whatever method she chooses.[25] Yet an important criticism of telemedicine is that many reservations have little to no internet service.[26]

To exacerbate this issue, there is a severe sense of mistrust between communities and IHS facilities. Some women have reported that doctors force women into labor not because the woman or child is ready for childbirth, but because the woman is already at the medical center and it would be very challenging for her to return.[27] The most dark and overarching reasoning behind the mistrust stems from a history of forced sterilization of American Indian women.[28] Sterilization practices started in the 1930's, but grew with Congress's Family Planning Services Act in the 1970's.[29] One study found that from 1973-1976 in just four IHS serviced areas, there were 3,406 involuntary sterilization of American Indian women ranging in age

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[22] *Montana: Crow Reservation*, NATIVE PARTNERSHIP (last visited March 14, 2021) http://www.nativepartnership.org/site/PageServer?pagename=PWNA_Native_Reservations_Crow.
[23] Usha Ranji et al., *Beyond the Numbers: Access to Reproductive Health Care for Low-Income Women in Five Communities*, KFF (Nov. 14, 2019) https://www.kff.org/report-section/beyond-the-numbers-access-to-reproductive-health-care-for-low-income-women-in-five-communities-crow-tribal-reservation-mt/.
[24] Kruse et al., *supra* note 20, at 1.
[25] Loretta J. Ross et al., *The 'Sistersong Collective': Women of Color, Reproductive Health and Human Rights*, 17 AM. J. HEALTH STUDIES 79-88, 83 (2001).
[26] Kruse et al., *supra* note 20, at 8.
[27] Gurr, *supra* note 6, at 11.
[28] Beth Adams, *'Reproduction on the Reservation': The History of Forced Sterilization of Native American Women*, WXXI NEWS (Oct. 28, 2019), https://www.wxxinews.org/post/reproduction-reservation-history-forced-sterilization-native-american-women.
[29] *Id.*

from 15 to 44.[30] Misinformation played a central role to this, both through a lack of information or coercion to participate in certain medical procedures.[31] If federal funding can result in an increase of medical facilities and access to medical care through telemedicine, resources should also be allotted to ensuring that the trust lost is addressed through education and compassion.

B. Education

While more birthing centers and telemedicine increase the accessibility of some reproductive healthcare, it does not ensure that American Indian will be welcomed and treated by culturally competent doctors and medical professionals.[32] In general, birthing centers often are not equipped with cultural competency training.[33] This is dangerous because medical training is typically centered around white men, and thus, medical professionals are less able to treat and trust pain management in women of color.[34] Further, because traditional methods of medicine have been so ostracized and critiqued, American Indians have additionally lost trust and self-confidence to advocate for systemic change.[35] This also means that American Indians are often less educated about their own reproductive health, and doctors are not trained to teach medicine to lower educated populations and thus the majority of communities lose the ability to make educated decisions.[36]

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[30] Christina M. Pacheco et al., *Moving Forward: Breaking the Cycle of Mistrust Between American Indians and Researchers*, 103 AM J. PUB. HEALTH 2152, 2153 (Dec. 2013).
[31] *Id.*; Sandra K. Cesario, *Care of the Native American Woman: Strategies for Practice, Education, and Research*, 30 JOGNN 13, 14 (Jan./Feb. 2001).
[32] Tamarra M. James-Todd et al., *Racial/Ethnic Disparities in Environmental Endocrine Disrupting Chemicals and Women's Reproductive Health Outcomes: Epidemiological Examples Across the Life Course*, 3 CURRENT EPIDEMIOLOGY REPORTS 161, 169 (2016).
[33] Ross et al., *supra* note 25, at 81.
[34] *Id*. at 84.
[35] *Id*.
[36] *Id*.

In terms of sexual and reproductive education, multiple studies have indicated that culturally centered approaches are effective research tools.[37] American Indians have disproportionally high rates of HIV and are most likely to get STIs, pregnant, and not use condoms.[38] One method for educating safe sex and family planning is teaching the benefits of condoms.[39] Studies have indicated that young men are more likely to use condoms if they are taught at a younger age, preferably before they have had intercourse.[40] These studies were not aimed at forcing adolescents to use or not use protection, but rather equipping them with the knowledge to make their own decisions.[41] An essential factor to these teachings and studies is first acknowledging that traditional Western research did not engage with the community to design and implement projects.[42] Therefore, education must be centered around the community's culture. Funding cannot just target adolescents; it must connect with the entire community and *must* include community participation and influence.[43] An example of a cultural practice that impacts education surrounding sexual health is religious and traditional beliefs inhibiting any conversation about these topics.[44] Lastly, it is essential for education to be centered around the specific tribes and communities in which medical facilities provide care for. Overgeneralizing American Indian culture eliminates the intricacies and cultural differences between different groups and tribes, and it is important to keep in mind specialized training will

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[37] Elizabeth Rink et al., *Young Native American Men and Their Intention to Use Family Planning Services*, 64 AM. J. MEN'S HEALTH 324-330, 325 (2012).
[38] *Id*. at 324.
[39] Lauren Tingey et al., *The Impact of a Sexual and Reproductive Health Intervention for American Indian Adolescents on Predictors of Condom Use Intention*, 60 J. ADOLESCENT HEALTH 284, 289 (2017).
[40] *Id*.
[41] *Id*.
[42] Rink et al., *supra* note 37, at 325.
[43] *Id*.
[44] Ranji et al., *supra* note 23.

allow the best service to be provided for members of all tribes and communities.[45]

C. Abortion

While topics of sexual health are traditionally kept private, abortion continues to spark controversy and discord between different American Indian communities, with the U.S. Tribes around the country holding different views on abortion. To some, the trauma of forced sterilizations and abuse influence their stance as protecting any and all American Indian lives, including unborn embryos.[46] Tribes, such as the Osage, fiercely believe abortion furthers colonizers' attempts to eradicate them.[47] The Osage people, like many other tribes, interpret time and life as a circular concept and the act of birth is not a barrier to differentiate peoples who deserve protection.[48] Due to this deep-seated belief, many women report experiencing further trauma to their mental health because they are eliminating a life they hold so sacred.[49] However, not all communities and tribes share this view of abortion.[50] The Iroquois people, for example, have used naturopathic remedies as contraceptive methods for hundreds of years before modern medicine.[51] This reliance on nature as medicine coupled with matriarchal societies resulted in autonomy for women to decide what to do with her body.[52] Further, the Iroquois believe in protecting the happiness of children and fostering their

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[45] *In general, A Guide to Build Cultural Awareness*, SAMHSA (Jan. 2009), http://tribalnations.mt.gov/Portals/229/docs/SMA08-4354_mod.pdf.
[46] Shandiin Vandervere, *What does "Pro-Choice" Mean to Natives?* (May 3, 2020) https://medium.com/@svandervere/what-does-pro-choice-mean-to-natives-f571ff6a3dd.
[47] Elizabeth Terrill, *Abortion is Not a Solution for Native Women,* NAVAJO TIMES (Jan. 23, 2020) https://navajotimes.com/opinion/essay/abortion-is-not-a-solution-for-native-women/.
[48] *Id*.
[49] *Id*.
[50] Doug George-Danentio & Akwesane Mohawk, *Doug George - Kanentiio: Abortion in Native Societies is a Complex Issue*, INDIANAZ NEWS (June 3, 2019) https://www.indianz.com/News/2019/06/03/doug-georgekanentiio-abortion-in-native.asp.
[51] *Id*.
[52] *Id*.

innate purpose in life.[53] Therefore, when there is a chance of a child being born into a life or society of suffering, the option of aborting the embryo was not considered taboo or unthinkable.[54] American Indian peoples are comprised of hundreds of tribes, beliefs, and traditions, which means that conversations regarding abortion need to take into account the suffering of their past and acknowledge the harm done in order to allow access to an essential aspect of reproductive health.

While the battle for access to abortion has affected all people in the country, American Indians, like other women of color, have been disproportionally challenged. Access to abortion on a federal level typically involves the legalization of abortion, however, the funding for access is the core issue for American Indians.[55] With so few clinics and health facilities available to American Indians, many rely on the IHS who ultimately decide what services they want to provide.[56] This problem is exasperated when states pass abortion regulations that prohibit federal funding to abortions because this can create "abortion deserts."[57] These "abortion deserts" are dangerous because women must choose between risking unsafe abortion procedures, or spending time and resources to drive hours to another facility.[58] Ultimately, this lack of funding discriminates against poor women and strips them of opportunities to make safe and healthy choices.[59]

Abortion is important in reproductive health care for two reasons: it allows women to choose to abort an embryo when the pregnancy is unhealthy for the mother and child, and it allows for family planning. In the context of

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[53] *Id*.
[54] *Id*.
[55] Leslie Logan, *Abortion: Native Women Respond to Onslaught of Laws and Restrictions Across the Country*, INDIAN COUNTRY TODAY (June 3, 2019), https://indiancountry today.com/news/abortion-native-women-respond-to-onslaught-of-laws-and-restrictions-across-the-country.
[56] *Id.*; Ranji et al., *supra* note 23.
[57] *Id.*
[58] Vandervere, *supra* note 46.
[59] Logan, *supra* note 55.

family planning, instances of rape require women to make decisions they did not consent to be subjected to. Despite that compared to other women in the U.S., American Indian women are twice as likely to experience sexual assault, the IHS provides little to no support to victims if they elect to get an abortion.[60] Not only is birth control rarely available, but some IHS facilities are not equipped with rape kits.[61] When a woman does opt for an abortion, she has traumatizing and unfair barriers to overcome.[62] Increased funding to IHS facilities and heath care facilities surrounding reservations clears at least the hurdle of access. While this article does not intend to provide a moral stance on abortion, from a health care perspective, funding for any kind of reproductive health care must include funding for birth control including abortion. Additionally, the discussion around abortion perfectly highlights the importance of culturally competent medical care because medical practitioners in various areas must know how tribes and communities in their area view this health care option and why. Erasing the history and root of mistrust of health care perpetuates insensitive medical care and furthers the divide between accessible aid and patients in need.

IV. CONCLUSION

Cultural competency training and education should be federally funded, and federal funding cannot exclude cultural sensitivity and reproductive justice. Federal funding is integral because reproductive health not only affects current populations, but it determines how generations of American Indians will live. Funding should come from the U.S. Government because

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[60] Allison Herrera, *Indigenous Women Face Extra Barriers When It Comes to Reproductive Rights*, HIGH COUNTRY NEWS (Feb. 14, 2020) https://www.hcn.org/issues/52.3/indigenous-affairs-public-health-indigenous-women-face-extra-barriers-when-it-comes-to-reproductive-rights.

[61] *Id.*

[62] *Id.* (explaining the process or requiring a police report for abortion operations and the strict definition of rape).

they have already committed to providing healthcare and the current financial allotment to reproductive healthcare is inadequate and ethnocentric. It is imperative that the U.S. Government acknowledge the harm done to generations of Indian Americans and continue to take strides towards preserving American Indian culture by providing funding, education, and access to abortion.

The Effects of Racial Health Disparities on Maternal Health and Infant Birth Weight

Marco Martino

I. INTRODUCTION

Maternal morbidity and mortality, and associated low infant birth rate remain among the most notable disparities in health between White Americans and African Americans.[1] The staggering difference in maternal health and infant birth weight can be attributed to several factors, including differences in socio-economic statuses, access to prenatal healthcare services, psychosocial stress, occupation status, and increased perinatal infections amongst African American women.[2] Ultimately, economic inequalities and systemic racism that disproportionally affect African American women lead to a lack of family-supporting employment opportunities, food deserts, high crime and incarceration, and inadequate transportation and housing, all of which can adversely affect maternal health and subsequently lead to low infant birth weights.[3] Low infant birth weights occur at a remarkably high rate in African Americans compared to White Americans.[4] Complications of low infant birth weight include developmental delays and disorders, deafness, blindness, cerebral palsy, attention deficit disorder, and poor performance in school.[5] This paper will

[1] Rose Molina & Lydia Pace, *A Renewed Focus on Maternal Health in the United States*, 377 NEW ENGLAND J. OF MED. 1705, 1705 (2017).
[2] Michael C. Lu & Neal Halfon, *Racial and Ethnic Disparities in Birth Outcomes: A Life Course Perspective*, 7 MATERNAL & CHILD HEALTH J. 13, 14 (2003).
[3] *Id.*
[4] Mario Sims et al., *Race, Ethnicity, Concentrated Poverty, and Low Birth Weight Disparities*, 19 J OF NAT'L BLACK NURSES' ASS'N 12, 12 (2008).
[5] *Id.*

focus on the background of maternal mortality, followed by information on low infant birth weight, and then will conclude with a focus on policy changes in terms of public health, access to quality healthcare services, insurance coverage for pregnant women, and access to prenatal care.

II. BACKGROUND: MATERNAL MORTALITY

Maternal mortality is defined as the death of a woman during pregnancy or death directly or indirectly attributed to the pregnancy within forty-two days of delivery.[6] The United States has a low maternal mortality rate compared to low-income nations at 230 deaths per 100,000 live births, but surprisingly the United States' maternal mortality has doubled since 1990 and its rate is high compared to high-income nations.[7] What is most disturbing about the maternal mortality rate in the United States is the racial disparities seen with maternal mortality; low-income women and rural women are more likely to die during pregnancy, and even more troubling is that a non-Hispanic Black woman is three times more likely to die as a result of pregnancy than a White woman, as noted by an analysis looking at twenty-seven states and the District of Columbia.[8]

The causes of the disparities in maternal mortality are complex, but they can be tied to biases in the delivery of healthcare and social determinants of health.[9] For one, chronic diseases, including hypertension, cardiomyopathy, and thrombotic pulmonary embolism, which are associated with an increased risk for maternal mortality occur at a higher prevalence and are less controlled in African American women.[10] Another cause of adverse

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[6] Molina & Pace, *supra* note 1.
[7] *Id.*
[8] Marian F MacDorman et al*., Trends in Maternal Mortality by Sociodemographic Characteristics and Cause of Death in 27 States and the District of Columbia* 129, OBSTETRICS & GYNECOLOGY 811, 815 (2017).
[9] Molina & Pace, s*upra* note 1, at 1706.
[10] Emily E. Petersen et al., *Racial/Ethnic Disparities in Pregnancy-Related Deaths — United States, 2007–2016* 68, MORBIDITY & MORTALITY WEEKLY REPORT 762, 763 (2019).

outcomes for African American women stem from socio-economic considerations, all of which disproportionately affect African American women compared to White women.[11] Specifically, gaps in healthcare coverage, lack of preventative and coordinated healthcare services, lack of social services, inadequate housing, and an inability to secure reliable transportation to and from clinic visits.[12] Similarly, another adverse outcome for African American women stems from the quality of care African American women receive compared to White women.[13] Specifically, African American women tend to receive a lower quality of obstetric care and are more likely to experience implicit racial bias in the healthcare system, both of which can negatively affect patient-provider interactions, treatment decisions, patient adherence to recommendations, and patient health outcomes.[14] Examining further why African American women have a higher maternal mortality rate secondary to preexisting conditions, African American women suffer from pre-pregnancy obesity at a higher rate than White women, which can contribute to higher rates of maternal mortality.[15] Another contributor to maternal mortality is hypertension, as previously mentioned, which also tends to occur at a higher rate in African American women compared to White women.[16] Other preexisting conditions that negatively affect maternal mortality in African American women more prevalently than White women include cardiovascular disease, diabetes, kidney disease, asthma, and psychiatric disorders.[17]

African American women also tend to have more compromised living conditions than White women; for example, there tends to be less access to

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[11] *Id*. at 764.
[12] *Id*.
[13] *Id.*
[14] *Id.*
[15] Gopal Singh & Hyunjung Lee, *Trends and Racial/Ethnic, Socioeconomic, and Geographic Disparities in Maternal Mortality from Indirect Obstetric Causes in the United States*, 1999-2017, 10 INTERNAL J. OF MATERNAL HEALTH & AIDS 43, 49 (2021).
[16] *Id.*
[17] *Id.*

neighborhood amenities, such as public transportation, green space, public parks and playgrounds, sidewalks to walk on, and access to healthy food.[18] As it specifically relates to food access, African American households are at a higher risk of food insecurity in the United States, which is defined as the inability to acquire adequate food due to a lack of resources.[19] The disproportionately higher rates of food insecurity and food deserts in lower income neighborhoods has led to increased rates of obesity, particularly amongst women, which can contribute to maternal mortality.[20] Another consequence of food insecurity and food deserts is the lack of nutritious food, or the inability to pay higher prices for healthier foods and beverages.[21]

III. BACKGROUND: LOW INFANT BIRTH WEIGHT

Low birth weight (LBW) is defined as a weight at birth of less than 2,500 grams.[22] There is an alarming trend that shows that African American babies are approximately twice as likely to have a LBW compared to White babies.[23] Specifically, studies have shown that the rate of LBW in African American babies was seven percent, while the rate of LBW in White babies was three percent.[24] Unfortunately, LBW can lead to various complications in babies, including death; the infant mortality rate was 10.2 per 1,000 live births for black babies, compared to 5.4 per 1,000 live births for white babies.[25] Black babies were also three times as likely to die from causes linked to perinatal events, including prematurity.[26]

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[18] Singh & Lee, *supra* note 15, at 49.
[19] *Those with Inadequate Access to Food Likely to Suffer from Obesity*, University of Texas at San Antonio, SCIENCEDAILY (2019), www.sciencedaily.com/releases/2019/01/190123144522.htm.
[20] *Id.*
[21] *Id.*
[22] Sims et al, *supra* note 4, at 12.
[23] *Id*.
[24] Kenneth C. Schoendorf et al., *Mortality Among Infants of Black as Compared with White College-Educated Parents*, 326 NEW ENGLAND J. OF MED. 1522, 1524 (1992).
[25] *Id.*
[26] *Id.*

Babies who survive LBW tend to have developmental issues and consequences that extend into adulthood, such as cerebral palsy, deafness, blindness, attention deficit disorder, poor performance on developmental assessments, the need for special education, and poor performance in school requiring the child to repeat a grade.[27]

The causes of LBW are tied to protective and risk factors during pregnancy, which as mentioned, occur at higher rates amongst African American women compared to White women.[28] Risk factors during pregnancy that have a downstream effect on LBW include socioeconomic status, maternal risky behaviors, prenatal care, psychosocial stress, and perinatal infections.[29] Additionally, women who were at a low socioeconomic status at the time of pregnancy are at a higher rate of having a baby with a LBW compared to women with a high socioeconomic class, but data suggests that women who were born poor and eventually moved up in socioeconomic status at the time of pregnancy are less likely to have a baby with LBW.[30] In terms of maternal high risk behaviors, particularly smoking cigarettes, African American women are more likely to smoke compared to White women, which can contribute to LBW, regardless of whether smoking occurred prior or during the pregnancy.[31] Looking at prenatal care, despite receiving adequate care, African American women are still likely to have babies with LBW than White women because of the cumulative inadequate care they received prior to the pregnancy.[32] In terms of stress, African American women tend to have more chronic stressors compared to White women as a result of systemic racism.[33] Stress contributes to babies having LBW, even if the stress is managed during

[27] Sims et al, s*upra* note 4, at 12.
[28] Lu & Halfon, *supra* note 2, at 14.
[29] *Id.*
[30] *Id*. at 20.
[31] *Id*. at 21.
[32] *Id*.
[33] *Id*. at 22.

pregnancy because of the long-term damage the stress caused on their bodies.[34] Looking at perinatal infections, African American women tend to have higher rates of perinatal infections compared to White women, which can contribute to premature delivery and babies having a LBW, even if the infection is adequately treated during the pregnancy because of the damage the presence of prior perinatal infections had on their bodies.[35] Finally, the presence of racism in general has an adverse effect on maternal health, which can contribute to babies having LBW because of the chronic stress experienced, poor quality or quantity of healthcare services received, and scarcity of resources as a whole.[36]

IV. PUBLIC HEALTH CONSIDERATIONS

Racial disparities in maternal health and LBW are deeply rooted in structural racism, which is defined to mean racism that is not simply the "result of private prejudices by individuals as much as it is produced and perpetuated by laws, rules, and practices endorsed and implemented by various levels of government, and it is cemented in the economy, cultural practices, and societal norms."[37] One of the first steps at addressing the racial disparities that exist within the healthcare system is acknowledging that such issues exist and the effects that these racist practices have created.[38] Another step that the medical and public health community should take is to look within themselves both as individuals and as an institution to understand the effects that structural racism has had on minority populations, which should be seen on a daily basis based upon their actual healthcare practice locations and patient populations.[39]

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[34] *Id*.
[35] *Id*. at 22.
[36] *Id*. at 23.
[37] Zinzi D. Bailey et al., *How Structural Racism Works — Racist Policies as a Root Cause of U.S. Racial Health Inequities*, NEW ENGLAND J. OF MED. 1, 1 (2020).
[38] *Id.* at 4.
[39] *Id.* at 4.

Analyzing how racial disparities have adversely affected maternal health and LBW here in Chicago, the COVID-19 pandemic has worsened a maternity care desert seen in the South Side of Chicago, which stems from the lack of funding for healthcare on a governmental level.[40] To compensate for the surge of COVID-19 patients being admitted into these hospitals, maternal services were either eliminated or suspended.[41] However, maternal services were already being compromised before the COVID-19 pandemic because these hospitals in the South Side were operating over budget.[42] The theme behind these adversarial trends stems from lack of funding, both from the State in terms of legislation and in terms of Medicaid reimbursement as Medicaid reimbursement rates in the State of Illinois are amongst the worst in the nation.[43] Although COVID-19 has hurt state and federal budgets all across the country, it is imperative that legislation and budgets are passed that increases funding for healthcare in Illinois.[44] The State of Illinois recently took a positive step when Governor Pritzker signed SB 2541 and SB 1864 into law, which brought in $250 million in federal money for hospitals, particularly to uninsured and underserved areas in Illinois.[45] The federal government took another positive step more recently with the passage of the American Rescue Plan Act of 2021, which gives states funding for women for up to twelve months after giving birth.[46] Women who qualify for this benefit must be on Medicaid or the Children's Health Insurance Program

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[40] Curtis Black, *South Side's Maternal Health Desert Poses Added Risks for Black Women During Pandemic*, CHICAGO REPORTER, https://www.chicagoreporter.com/south-sides-maternal-health-desert-poses-added-risks-for-black-women-during-pandemic/ (last visited March 2, 2021).
[41] *Id*.
[42] *Id.*
[43] *Id.*
[44] *Id.*
[45] *Gov. Pritzker Signs Hospital Assessment Legislation Bringing $250 Million in Additional Federal Funding for Health Care to Illinois*, STATE OF ILLINOIS, https://www2.illinois.gov/Pages/news-item.aspx?ReleaseID=21790.
[46] Mara McDermott et al., *American Rescue Plan Act Of 2021: Key Healthcare Provisions*, The National Law Review, https://www.natlawreview.com/article/american-rescue-plan-act-2021-key-healthcare-provisions.

(CHIP), and this benefit lasts for at least the next five years.[47] CHIP is an important insurance program that provides health insurance for pregnant women and their infants whose incomes are too high to qualify for Medicaid, but still cannot afford to buy private health insurance. [48]Whereas this progress has arguably been realized in the face of a pandemic, it is imperative that these provisions for maternal health services get renewed, hopefully permanently, and are at least perpetually discussed during budget proceedings.

Speaking in terms of Medicaid coverage mentioned prior, there have been legislative efforts to reduce Medicaid coverage and eligibility by reducing federal Medicaid funding by thirty-five percent by 2030.[49] This proposal could be damaging to pregnant women for numerous reasons; for one, decreasing Medicaid funding would decrease the prenatal care, care during childbirth, and postpartum care.[50] Additionally, decreasing Medicaid eligibility would cause gaps in coverage if a woman were to become pregnant because many new mothers who were eligible for Medicaid solely because they are pregnant would then lose insurance coverage for sixty days after delivery; if a woman lost her insurance coverage, any chronic diseases that she may have had would then be untreated and can have adverse effects on the fetus should she become pregnant.[51]

To address these issues, public policy should be implemented on a federal level that would require states to cover new mothers via this pathway beyond these sixty days until at least one year after giving birth, and require full Medicaid benefit coverage during this period.[52] Arguably, this policy would alleviate the aforementioned issues, such as ensuring that there is no gap in

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[47] *Id.*
[48] Jamila Taylor et al, *Eliminating Racial Disparities in Maternal and Infant Mortality: A Comprehensive Policy Blueprint*, Center for American Progress. 1, 10 (2019).
[49] Molina & Pace, *supra* note 1, at 1706.
[50] *Id.*
[51] *Id.*
[52] Taylor et al, *supra* note 48, at 9.

coverage during this critical time for the mother's and infant's health and extending their care, especially in the African American population where Medicaid is more likely to be the primary insurance provider and subsequently covers over half of all births in the United States.[53] There should also be public policy focused on expanding Medicaid coverage, particularly in the States that did not expand Medicaid coverage after the implementation of the Affordable Care Act (ACA).[54] Research has shown that infant mortality rates have declined in the states that expanded Medicaid coverage, with the greatest decline seen among African American infants.[55] This research has also shown that if Medicaid is expanded in the seventeen non-expansion states, 141 infant deaths could be averted per year.[56] This finding is especially important because the African American women who are most affected by the discontinuation or loss of insurance live in the Southern United States, which is a region where most states have chosen not to expand Medicaid coverage.[57]

The South Side of Chicago also has its share of safety-net hospitals, which is defined as hospitals that organize and deliver a significant level of health care and other health-related services to patients with no insurance or with Medicaid.[58] These hospitals are shutting down or suspending their maternal health services in the South Side of Chicago, partly due to reduced Medicaid reimbursement.[59] Due to delayed and reduced Medicaid reimbursement, these safety-net hospitals cannot recruit and retain quality physicians to give poor patients the maternal health services they desperately deserve and need.[60] SB 2541 and SB 1864 that were recently signed by Illinois Governor

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[53] *Id.*
[54] *Id*. at 9
[55] *Id.*
[56] *Id.*
[57] Taylor, *supra* note 49, at 10.
[58] *Characteristics of Safety-Net Hospitals*, 2014, Healthcare Cost & Utilization Project, https://www.ncbi.nlm.nih.gov/books/NBK401306/pdf/Bookshelf_NBK401306.pdf.
[59] Black, *supra* note 40.
[60] *Id.*

Pritzker, as mentioned prior, provide financial relief to safety-net hospitals, and thus provides increased funding and reimbursement for the Medicaid-majority patients seeking maternal care services at these safety-net hospitals to the tune of $3.9 billion.[61] Citing the American Rescue Plan Act of 2021 includes a provision that provides a five percent point increase in the Medicaid Federal Medical Assistance Percentage (FMAP) for the twelve states that currently have not expanded Medicaid coverage pursuant to the ACA.[62] Again, whereas this progress has arguably been realized in the face of a pandemic, arguably, public policy changes need to be advocated for in terms of the funding models and formulas used to calculate Medicaid reimbursement, especially for the at-risk safety-net hospitals in the South Side of Chicago.[63]

V. CONCLUSION

While the United States has a low maternal mortality rate amongst low-income nations, it is extremely troubling to note the relatively high rate of maternal mortality amongst other high-income nations. This observation is even more pronounced when compared between White Americans and African Americans. This staggering disparity in maternal health and associated maternal mortality can be attributed to several factors. Some of these causes include differences in socio-economic statuses, access to prenatal healthcare services, quality and quantity of healthcare services available, presence of chronic and preexisting diseases, psychosocial stress, food and housing considerations, lack of transportation, and increased perinatal infections amongst African American women. A general theme amongst these important issues is the presence of systemic racism that

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[61] *Gov. Pritzker Signs Hospital Assessment Legislation Bringing $250 Million in Additional Federal Funding for Health Care to Illinois*, *supra* note 45.
[62] McDermott et al., *supra* note 46.
[63] Black, *supra* note 40.

disproportionately affects African American women more than White women, as further demonstrated by a lack of economic and employment opportunities, risky behaviors, food desserts, and high crime and incarceration, all of which adversely affects maternal health and can subsequently lead to LBW in infants. There is also a marked disparity in LBW amongst African American babies compared to White American babies, which can have notable consequences, such as developmental delays and disorders, blindness, cerebral palsy, attention deficit disorder, and poor performance in school.

Public policy initiatives are imperative, such as access to quality healthcare services, insurance coverage for women regardless of pregnancy status, access to prenatal care, Medicaid coverage and qualification, and overall bridging of the gap to equilibrate the disparities seen between African American and White American mothers and infants. Progress has certainly been made with regards to access to maternal care and expansion of Medicaid funding and reimbursement, both on a state and more recently on a federal level. However, further public advocacy is needed both on a state and federal level to ensure that maternal health services are prioritized, and Medicaid funding meets the unique, ever-changing needs of the disparate population in the low-income areas of Chicago.

Addressing International Physician Credentialling in Arizona

Robert Morlock

I. INTRODUCTION

The American Association of Medical Colleges projects that the United States will face a physician shortage of between 54,100 to 139,000 physicians by 2033.[1] Despite these grim predictions, thousands of internationally trained physicians are prevented from practicing medicine in the United States due, in part, to the complex and restrictive system of state medical licensing.[2] These systems block competent physicians from practicing medicine in the United States' while the country's health care system becomes increasingly in need of their services.[3]

Recognizing the need to increase their physician workforces during the COVID-19 pandemic, multiple states made temporary changes to their requirements for licensing internationally trained physicians.[4] Arizona, however, was not one of those states.[5] Despite having a severe physician

[1] AAMC, *New AAMC Report Confirms Growing Physician Shortage*, (Jun. 26, 2020), https://www.aamc.org/news-insights/press-releases/new-aamc-report-confirms-growing-physician-shortage.
[2] Silvia Mathema, *Removing Barriers for Immigrant Medical Professionals is Critical to Help Fight the Coronavirus*, CTR. FOR AM. PROGRESS (Apr. 2, 2020), https://www.americanprogress.org/issues/immigration/news/2020/04/02/482574/removing-barriers-immigrant-medical-professionals-critical-help-fight-coronavirus/.
[3] Patrick Boyle, *U.S. Physician Shortage Growing*, AMA (Jun. 26, 2020), https://www.aamc.org/news-insights/us-physician-shortage-growing.
[4] Markina Hawryluk, *Amid Covid Health Worker Shortage Foreign-Trained Professionals Sit on Sidelines*, KAISER FAM. FOUND. (Jan. 25, 2021), https://khn.org/news/article/amid-covid-health-worker-shortage-foreign-trained-professionals-sit-on-sidelines/.
[5] Jeanne Batalova et al., *Brain Waste Among U.S Immigrants with Health Degrees,* MIGRATION POL'Y INST. 1, 11-14 (2020), https://www.migrationpolicy.org/sites/default/files/publications/MPI-HealthCare-Brainwaste-by-State-Final.pdf.

shortage, Arizona continues to prevent many internationally trained physicians from entering its workforce, employing some of the country's strictest licensing requirements.[6]

This article will discuss the physician licensing process with regards to internationally trained physicians in Arizona. Then, this article will examine state changes to licensing of internationally trained physicians during COVID-19. Finally, this article will propose a change to Arizona's licensing system that would make it easier for physicians who are licensed internationally to obtain credentials in Arizona, increasing the healthcare workforce and driving needed medical expertise to rural and tribal areas.

II. LICENSING OF INTERNATIONALLY TRAINED PHYSICIANS IN ARIZONA

Internationally trained physicians make up a significant part of the United States health care workforce.[7] However, for an internationally trained physician, the process for obtaining a license to practice medicine in the United States is a significant obstacle which can prevent him or her from continuing to practice medicine.[8] The licensing barriers imposed on an international physician vary from state to state as the United States federalism

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[6] *See* Coats et al., *Tackling the Primary Care Physician Shortage in Arizona*, ARIZ. CTR. FOR RURAL HEALTH POL'Y BRIEF, 1, 1 (2019), https://crh.arizona.edu/sites/default/files/pdf/topics/20190219_Tackling-PCP-shortage.pdf (showing Arizona's physician shortage); *see also* Siskind Susser, PC, Chart of Physician Licensing Requirements by State, 2 (Oct. 2014), http://www.visalaw.com/wp-content/uploads/2014/10/physicianchart.pdf. (showing Arizona requires three years of postgraduate training from foreign physicians, as much as any other state).

[7] Guey-Chi Chen et al., *Professional Experiences of International Medical Graduates Practicing Primary Care in the United States,* 25 J. GEN. INTERNAL MED. 947, 947 (2010) ("International medical graduates (IMGs) comprise approximately 25% of the US physician workforce, with significant representation in primary care and care of vulnerable populations.").

[8] Rabben, *Credential Recognition in the United States for Foreign Professionals*, MIGRATION POL'Y INST. 1, 4 (2013), https://www.migrationpolicy.org/pubs/UScredentialrecognition.pdf.

structure allows each state to implement its own rules for physician licensing.[9]

In Arizona, physician licensing is regulated by the Arizona Medical Board.[10] In 1971, the Arizona Medical Board established its laws for licensing graduates of international medical schools.[11] In doing so, the Board required that all international applicants complete twenty-four months of post graduate training in an approved residency program, complete medical education from a board approved institution, have a "working ability to read, write, speak, understand and be understood" in English, and be certified by the Education Council for Foreign Medical Graduates ("ECFMG").[12] Arizona has largely left it licensing requirements unchanged.[13] International physicians are still required to obtain ECFMG certification, be able to speak and write in English, and graduate from medical school.[14] Notably, Arizona has increased the length of required post graduate training for internationally trained physicians from twenty-four months to thirty-six months.[15]

Securing ECFMG certification requires an applicant to provide documentation showing they have completed their medical training at an approved international medical school.[16] Additionally, applicants must also prove their competency by passing steps one and two of the United States Medical Licensing Examinations ("USMLE").[17] Both step one and step two

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[9] See *id.* at 1 (stating "Because of the United States' decentralized federal system, no single structure governs professional certification").
[10] *Arizona Medical Board*, STATE OF ARIZ. RSCH. LIBR., (Mar. 8, 2020), https://azlibrary.gov/sla/agency_histories/arizona-medical-board.
[11] *Id.*
[12] ARIZ. REV. STAT. ANN. § 32-1424 (1971).
[13] ARIZ. REV. STAT. ANN. § 32-1423.
[14] *Id.*
[15] *Id.*
[16] *See Educational Commission for Foreign Graduates*, ECFMG CERTIFICATION FACT SHEET, 2 (2020), https://www.ecfmg.org/forms/certfact.pdf. ("The application for ECFMG Certification requires applicants to confirm their identity, contact information, and graduation from or enrollment in a medical school that is listed in the World Directory as meeting eligibility requirements for its students and graduates to apply to ECFMG for ECFMG Certification and examination.").
[17] ARIZ. REV. STAT. ANN. § 32-1425(A).

of the USMLE are medical exams which test as applicant's skills in clinical knowledge and clinical skills.[18] The exams are required for licensing of international and domestic physicians alike.[19]

Even after an international applicant provides proof of their medical education, and passes the first two steps of the USMLE, they are still not eligible to obtain a medical license in Arizona.[20] Instead, the applicant must apply for and be admitted into a board approved residency program. [21] Once in the program, the applicant must complete three years of residency training.[22] Finally, after completing the requisite years of post-graduate training and completing the third and final step of the USMLE the applicant may finally apply for an Arizona medical license.[23]

An exception to this process exists as Arizona allows physicians who were trained in Canada to obtain a medical license without additional years of residency training.[24] Arizona statutes provide for this exception by allowing its medical board to approve international medical schools as having equivalent quality as schools and programs in the United States.[25] Students who graduate from these approved schools are not required to undergo the additional residential training required from graduates of unapproved international medical schools.[26] The Arizona medical board has approved Canada's medical schools and residency programs.[27] The board's approval of the Canadian medical schools and residency programs is reasonable as the United States' and Canada's medical credentialling bodies have worked

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[18] *Educational Commission for Foreign Graduates*, ECFMG CERTIFICATION FACT SHEET, 2 (2020), https://www.ecfmg.org/forms/certfact.pdf
[19] *Id*.
[20] Susser, *supra* note 6, at 2.
[21] ARIZ. REV. STAT. ANN. § 32-1423.
[22] ARIZ. REV. STAT. ANN. § 32-1423(3).
[23] Susser, s*upra* note 6, at 2.
[24] *Id*.
[25] ARIZ. REV. STAT. ANN. § 32-1422(A)(1-2).
[26] ARIZ. REV. STAT. ANN. § 32-1422(A)(1-2).
[27] Susser, *supra* note 6, at 2.

together to establish medical credentialling standards.[28] However, it is not clear why Arizona's medical board, unlike other states, does not make similar findings for the medical schools and residency programs of other countries.[29]

III. CHANGES TO THE LICENSING OF INTERNATIONALLY TRAINED PHYSICIANS

A. States Change International Physician Licensing Requirements During COVID-19

COVID-19 imposed unprecedented strain on hospital systems, overwhelming some acute care facilities.[30] Multiple states lowered their licensing requirements for internationally trained physicians in an effort to increase their physician workforce.[31] The general structure of these changes can be split into two frameworks.[32] First, some states lowered the amount of time internationally trained physicians were required to spend in a qualified residency program.[33] Second, other states allowed physicians who had international licenses and training to practice under a temporary license, regardless of their amount of training in the United States.[34]

New York serves as an example of a state that lowered the number of years an internationally trained physician was required to spend in a qualified residency program before seeking a license.[35] In New York, the governor

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[28] *See* Barbara Sibbald, *Made-in-Canada Accreditation Coming for Medical Schools*, 186 CANADIAN MED. ASS'N J. 84, 84 (2014) (stating that the United States' Liaison Committee on Medical Education works closely with Canada's accreditation committee to set medical school accreditation standards).
[29] *See* OECD, CONTRIBUTION OF MIGRANT DOCTORS AND NURSES TO TACKLING COVID-19 CRISIS IN OECD COUNTRIES 5 (2020) (stating, "In Utah, foreign medical graduates do not have to repeat their residencies if they practiced in Australia, the United Kingdom, Switzerland, South Africa, Hong Kong, China, or Singapore.").
[30] Blumenthal et al., *Covid 10 – Implications for the Health Care System*, 383 NEW ENG. J. MED. 1483, 1483 (2020).
[31] Batalova et al., *supra* note 5, at 11-14.
[32] *Id.*
[33] *Id.*
[34] *Id.*
[35] *Id.* at 2.

issued an emergency executive order that lowered the number of required years in residency from three years to one year.[36] This change allowed internationally trained physicians to practice in a hospital under the supervision of a licensed physician.[37] The permits issued were temporary, lasting for only two years.[38]

In the second category, New Jersey is representative of states that issued temporary licenses to internationally trained physicians regardless of their post-graduate education in the United States.[39] New Jersey's governor issued an executive order authorizing internationally trained physicians to apply for a temporary license to practice in certain medical care facilities if they had a license from another country in good standing, five years of practical experience, and had practiced for at least one of the last five years.[40] However, the license only lasts until the end of either the national health emergency or state of emergency, whichever happened later.[41]

B. An Unused Workforce of International Physicians

It is notable that even before COVID-19 it was stated that there is a population of internationally trained health care workers who were either underemployed or unemployed in the United States due, in part, to licensing requirements.[42] However, the changes made by the states during the pandemic further demonstrate that there is a substantial workforce of internationally educated physicians in the United States who are able to fill

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[36] *Id.* at 14.
[37] NY Exec. Order No. 202.10 (Mar. 7, 2020).
[38] *License Requirements,* NY ST. OF EDUC. DEP'T, (last updated Nov. 30, 2020), http://www.op.nysed.gov/prof/med/medlic.html.
[39] NJ Exec. Order 112 (Feb. 3, 2020).
[40] *Id.*
[41] *Id.* at 7.
[42] *See* Shanique C. Campbell, *"What's a Sundial in the Shade?": Brain Waste Among Refugee Professionals Who Are Denied Meaningful Opportunity for Credential Recognition*, 68 EMORY L. J. 139, 145 (2018) (discussing refugee who are unable to practice in medicine "The skills and training of these refugee professionals remain mostly untapped because few can find full-time, matching employment soon after arrival in the United States").

in during workforce shortages.[43] In New Jersey alone, more than one thousand applications for licenses were submitted by internationally trained physicians after New Jersey changed its licensing requirements.[44]

IV. PROPOSAL FOR ARIZONA TO CHANGE ITS FOREIGN PHYSICIAN LICENSING REQUIREMENTS

Arizona has a severe shortage of medical providers.[45] Approximately two in five Arizonans live in a "health care shortage area."[46] The federal government gives this designation to identify areas and people with unmet health care needs.[47] Arizona ranks forty second in the number of primary care physicians per 100,000 people.[48] The current estimated shortage of primary care physicians in Arizona is 558.[49] This gap is only expected increase to 1,941 physicians by 2030.[50] Further, Arizona's physician population is aging.[51] In Arizona, the average physician is close to 50 years old.[52] Unfortunately, Arizona does not have a sufficient pipeline of graduating physicians to meet the current demands of its growing population, or provide replacements for its elderly workforce.[53]

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[43] *Id.* at 11.
[44] *Id*.
[45] Xiaoming Zhang et at., *Physician Workforce in the United States of America: Forecasting Nationwide Shortage*, 18 HUM. RESOURCES FOR HEALTH 1, 5 (2018).
[46] Jerod Macdonald-Evoy, *Almost 40% of Arizonans Live in 'Health Care Shortage' Areas* AZMIRROR (Apr. 2020), https://www.azmirror.com/2020/04/15/almost-40-of-arizonans-live-in-health-care-shortage-areas/.
[47] *See Shortage Designations,* ARIZ. DEP'T OF HEALTH SERVS. (accessed Apr. 9, 2021), https://www.azdhs.gov/prevention/health-systems-development/shortage-designation/index.php#hpsa-home. (detailing the criteria for designation as a federal health care shortage area).
[48] B. Koch et al., *Arizona Primary Care Physician Workforce Report*, U. Of Ariz. Mel & Endi Zuckerman Coll. of Pub. Health Ctr. for Rural Health 3 (2019), https://uahs.arizona.edu/sites/default/files/2019_az_primary_care_physician_workforce_report.pdf.
[49] *Id.* at 4.
[50] *Id*.
[51] *Id.* at 17-18 (detailing data on the aging population of physicians).
[52] *Id.*
[53] *Arizona's Growing Population, Lack of Medical Student Worsen Doctor Shortage*, ABC15NEWS (Nov. 13, 2019), https://www.abc15.com/news/state/arizonas-growing-population-lack-of-medical-students-worsens-doctor-shortage.

Arizona's physician shortage has a particularly harsh impact on rural and tribal communities.[54] In 2018, between seventy-six and one hundred percent of Arizonans living in border counties such as Yuma and Santa Cruz live in an area with a primary care physician shortage.[55] Notably, in a 2020 report by the Arizona Department of Public Health the top six areas of primary care need were tribal areas.[56]

As the COVID-19 pandemic illustrated, states can loosen licensing restrictions on foreign physicians as a means of addressing physician shortages.[57] Similarly, to help address its physician shortage and improve rural and tribal health, Arizona should allow international physician to apply for a medical license if (1) they have graduated from an international medical school and completed one year or more of an approved residency, (2) graduated from an international medical school and completed at least one year residency training in Australia, Hong Kong, Singapore, Ireland, Switzerland, the United Kingdom, New Zealand or South Africa, or (3) have five years of good medical standing in a foreign country and practiced medicine in one of the last five years.[58]

Lowering the required amount of approved residency training for graduates of international medical schools from three years to one would

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[54] B. Koch et al., *Tackling the Primary Care Physician Shortage in Arizona*, U. Of Ariz. Mel & Endi Zuckerman Coll. of Pub. Health Ctr. for Rural Health 1, 1 (2019), https://crh.arizona.edu/sites/default/files/pdf/topics/20190228_Tackling-PCP-shortage.pdf.
[55] *Id.*
[56] Bureau of Women's and Children's Health, *Arizona Medically Underserved Areas*, ARIZ. DEP'T OF HEALTH SERVS. 1, 3 (2020), https://www.azdhs.gov/documents/prevention/health-systems-development/data-reports-maps/reports/azmua-biennial-report.pdf.
[57] NJ Exec. Order 112 (Feb. 3, 2020); NY Exec. Order No. 202.10 (Mar. 7, 2020).
[58] *See* Kristie De Pena, *Let Foreign Physicians Help: How States Can Prepare Now For COVID-19 Peaks*, NISKANEN CTR. (Apr. 8, 2020), https://www.niskanencenter.org/let-foreign-physicians-help-how-states-can-prepare-now-for-covid-19-peaks/ (stating that by recognizing post graduate training from Australia, Hong Kong, Singapore, Ireland, Switzerland, the United Kingdom, New Zealand and South Africa, Utah acquired access to a pool of 7,500 physicians); *see also Press Release: 2017 NRMP Main Residency Match The Largest Match On Record*, NAT'L RESIDENT MATCH PROGRAM, (Mar. 17, 2017), https://www.nrmp.org/press-release-2017-nrmp-main-residency-match-the-largest-match-on-record/ (stating over 12,000 residency positions were offered to foreign trained medical students).

allow more internationally trained physicians to apply for licenses in Arizona.[59] Arizona's current requirement of three years is the strictest in the United States.[60] This requirement closes off a workforce of physicians that are considered qualified by other states.[61] Looking to New York as an example, Arizona should recognize the need to increase their physician workforce and lower the post graduate residency requirements for internationally trained physicians from three years to one year.[62]

The ability to make this change is already integrated into Arizona's statutes.[63] Under Arizona statute, any applicant with a medical education approved by the Arizona medical board only requires twelve months of approved medical residency.[64] As previously noted, Arizona already applies this standard to Canadian medical school graduates.[65] If Arizona's medical board simply used its discretion to recognize additional foreign medical schools as equivalent to the United States and Canadian schools, the graduates from these institution would only be required to complete one year of residency in the States.[66] By making this change, Arizona would bring its licensing requirements more in line with other states.[67] Further, Arizona would help address its physician shortage by allowing internationally educated physicians to apply for medical licenses twenty-four months earlier than they can presently.[68]

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[59] De Pena, *supra* note 58.
[60] Susser*, supra* note 6, at 2.
[61] *Id.*
[62] *See* NY Exec. Order No. 202.10 (Mar. 7, 2020) (stating New York was amending its licensing requirements to, "to maintain adequate staffing").
[63] ARIZ. REV. STAT. ANN. § 32-1422(A).
[64] ARIZ. REV. STAT. ANN. § 32-1422(A)(1).
[65] *See* Susser*, supra* note 6, at 2 (requiring that medical students from Canada only complete one year of residency before obtaining their license).
[66] ARIZ. REV. STAT. ANN. § 32-1422.
[67] Susser*, supra* note 6.
[68] *See* Silvia Mathema, *Immigrant Doctors Can Help Lower Physician Shortages in Rural America*, CTR. FOR AM. PROGRESS (Jul. 29, 2019), https://www.americanprogress.org/issues/immigration/reports/2019/07/29/472619/immigrant-doctors-can-help-lower-physician-shortages-rural-america/ (discussing how removing barriers including state licensing barriers will allow foreign doctors to serve rural communities).

Even if Arizona lowered the post-graduate training requirements so international medical school graduates are required to complete only one year of an approved residency program, an internationally trained physician who has years of experience would still face the burden of completing an additional twelve months of training in one of these lower paying residency programs.[69] To expedite the licensing of physicians with prior training and experience, Arizona should (1) recognize post-graduate residency programs from Australia, Hong Kong, Singapore, Ireland, Switzerland, the United Kingdom, New Zealand and South Africa[70] and (2) allow internationally trained physicians to apply for licenses if they have been in good standing in any other country for over five years and have practiced medicine within the last year.[71]

With regards to recognizing post-graduate residency training for the above-named countries, this standard has both international and domestic precedent.[72] Canada finds that internationally trained physicians who have completed a medical residency in Australia, Hong Kong, Singapore, Ireland, Switzerland, the United Kingdom, New Zealand and South Africa have met their postgraduate training requirements.[73] Domestically, Utah enacted the same standard in 2020.[74]

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[69] *See* Brendan Murphy, *6 Things Medical Students Should Know About Physician Compensation*, AMA (Nov. 12, 2018) https://www.ama-assn.org/residents-students/resident-student-finance/6-things-medical-students-should-know-about-physician (showing resident's and specialist's compensation).
[70] De Pena *supra* note 58.
[71] *See* Batalova et al., *supra* note 5, at 11 (stating that when New Jersey accepted applications from foreign trained physicians foreign trained physicians to apply for licenses with good standing in another country for over five years and have practiced medicine within the last year, New Jersey received over 1,000 applications for licenses).
[72] Campbell et al., *Foreign-Trained Medical Professionals: Wanted or Not? A Case Study of Canada*, 3 J. OF GLOBAL HEALTH 1, 4 (2013); Utah Code Ann. § 58-67-302.7 (2020).
[73] *Id.*
[74] Utah Code Ann. § 58-67-302.5 (b) (2020); *see* OECD, *supra* note 29, at 5 (stating, "In Utah, foreign medical graduates do not have to repeat their residencies if they practiced in Australia, the United Kingdom, Switzerland, South Africa, Hong Kong, China, or Singapore").

Additionally, this standard could also be easily adopted by Arizona, as the framework is already integrated into Arizona's medical licensing regulations.[75] To adopt this framework, the Arizona medical board would only need to (1) recognize that the medical schools in these countries have an equivalent quality to medical schools in the United States and (2) approve the residency programs in these countries.[76] If Arizona's medical board simply approved the residency programs of Australia, Hong Kong, Singapore, Ireland, Switzerland, the United Kingdom, New Zealand and South Africa, an additional 7,500 physicians would be able to apply for Arizona medical licenses.[77]

Recognizing the medical educations and residencies of above named countries would lessen the requirements on physicians from those countries, but Arizona would nevertheless require that experienced physicians trained in any other country complete additional residency training.[78] To prevent experienced international physicians from having undergo further post graduate training, Arizona should also adopt New Jersey's licensing standard during the COVID-19 pandemic which allowed internationally trained physicians to apply for provisional licenses if they had five years of good standing with another country's medical board and spent at least one of the last five years practicing medicine.[79] Unlike the previous recommendations, this change would require a substantive amendment to Arizona's licensing

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[75] *See* ARIZ. REV. STAT. ANN. § 32-1422(A)(1-2) (stating that an applicant must graduate from a medical school that the board deems of equivalent quality and have twelve months in an approved internship, residency, or clinical fellowship program); *see* Utah Code Ann. § 58-67-302.5 (b) (2020) (stating applicants must have "studied medicine in a medical school located outside the United States which is recognized by an organization approved by the division").
[76] *Id.*
[77] De Pena, *supra* note 58.
[78] Susser*, supra* note 6, at 2.
[79] *See* Batalova *supra* note 5, at 11 (stating that after amending its licensing requirements to allow foreign physicians with five years of good standing in a foreign country and one year of practice in the last five years to apply for a license, New Jersey received over 1,000 applications for licenses).

regulations.[80] However, by doing so, Arizona would expand the pool of physicians eligible to work in the state.[81]

As need for additional physicians is greatest in rural communities and tribal lands, Arizona should drive physicians licensed under these relaxed requirements to rural and underserved areas.[82] As seen in New York during the COVID-19 pandemic, provisional licenses can be used to restrict a licensee's ability to practice to specified facilities.[83] While New York's licenses only restrict the facilities where a licensee can practice, Arizona should go further and adopt a model similar to Canada's which can also restrict a license to a geographic location.[84] By restricting provisional licenses to designated facilities within rural and underserved areas, Arizona can increase access to care in rural and tribal areas, improving health outcomes in these populations.[85]

V. CONCLUSION

Arizona has some of the strictest rules governing the licensing of foreign physicians.[86] At the same time, Arizona faces a severe physician shortage that disparately affects residents in rural and tribal areas.[87] To help address the physician shortage and improve health outcomes Arizona should amend its licensing requirements to ease the restrictions on the licensing of international physicians. These amendments should allow graduates of

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[80] *See* ARIZ. REV. STAT. ANN. § 32-1422 (making no exception for foreign physicians with previous experience).
[81] *See* Rabben *supra* note 8, at 6 (discussing the barrier that requiring additional residency creates for foreign physicians).
[82] *See* NY Exec. Order No. 202.10. (New York restricted licenses to care hospitals to meet the workforce demands from covid hospitalizations).
[83] *Id.*
[84] Campbell et al., *supra* note 72, at 4.
[85] *See* Mackino et al., *Quantifying the Benefits of Primary Care Physician Supply in the United States*, 37 INT'L J. OF HEALTH SERVS. 111, 121 (2007) (discussing the positive relationship between health outcomes and number of primary care physicians).
[86] Susser*, supra* note 6, at 2.
[87] Koch et al., *supra* note 54, at 1.

foreign medical schools with one or more years of approved post graduate training to apply for an Arizona medical license. Further, internationally trained physicians with at least one year of post graduate training in Australia, Hong Kong, Singapore, Ireland, Switzerland, the United Kingdom, New Zealand or South Africa should be allowed to apply for an Arizona license. And, internationally trained physicians who have five years of good medical standing in a foreign country and have practiced during one of the last five years should be able to apply for an Arizona medical license. Finally, to help address disparities in rural and tribal health, Arizona should restrict the licenses granted under this proposal to facilities within rural and tribal regions.

The Intersection of Health Policy and Immigration: Consequences of Immigrants' Fear of Arrests in U.S. Hospitals.

Mambwe Mutanuka

I. INTRODUCTION

Immigrants comprise of almost fourteen percent of the total U.S. population.[1] Despite being legally eligible to apply for numerous health-related services, many immigrants do not pursue conventional health care services.[2] Language, literacy, stigma, and fear of deportation, are contributing factors that deter immigrants from enrolling in these programs.[3] Lack of access to conventional health care and fears of deportation push many immigrants to seek unregulated care or avoid seeking care entirely.[4] This not only results in increased societal costs but contributes to racial and socioeconomic disparities within health care.[5] The resulting harm also affects U.S. citizens and exacerbates inequities within already disadvantaged populations.[6] It is essential to replace anti-immigrant policies that limit access to health services with inclusionary measures that promote access to

[1] Abby Budiman, *Key findings about U.S. immigrants*, PEW RSCH. CTR. (Aug. 20, 2020), https://www.pewresearch.org/fact-tank/2020/08/20/key-findings-about-u-s-immigrants/.
[2] Karina Fortuny & Ajay Chaudry, *A Comprehensive Review of Immigrant Access to Health and Human Services*, URBAN INST. 21, June, 2011.
[3] *Id.* at 29.
[4] Jennifer Steinhauer, *For Many Immigrants, a Health Care System Underground*, N.Y. TIMES (Aug. 20, 2020), https://www.nytimes.com/2000/08/20/nyregion/for-many-immigrants-a-health-care-system-underground.html.
[5] Brittany N. Morey, *Mechanisms By Which Anti-Immigrant Stigma Exacerbates Racial/Ethnic Health Disparities*, 108 NO. 4 AM. J. PUB. HEALTH, 460, 462 (April 2018).
[6] Medha D. Makhlouf, *Laboratories of Exclusion: Medicaid, Federalism & Immigrants*, 95 N.Y.U. L. REV. 1680, 1740-41 (2020).

health care in order to prevent disparities and reduce societal costs.[7] To address immigrant health disparities, federal laws must usurp anti-immigrant policies that put immigrants in fear of arrest while seeking care at hospitals.

Implementing policies that allow immigrants to seek care without fear of arrest will not only decrease societal costs but will help reduce inequities in health care and reduce strain on hospitals.[8] This article will first provide an overview of the intersection between the U.S. immigrant household and access to health care. Next, this article will examine the current environment of immigrant arrests in hospitals and the resulting impact on immigrants, the health care industry, and the public. Finally, this article will propose that the solution to the current undesirable policy environment is to enact a federal law that prohibits arrests in hospitals.

II. IMMIGRANTS AND THE U.S. HEALTHCARE SYSTEM

Immigrant families comprise of a mix of naturalized citizens, lawful permanent residents, visa holders, refugees or asylum seekers, and undocumented immigrants.[9] Over sixteen million people live in mixed-status households consisting of some variation of U.S. and non-US citizens.[10] Moreover, an overwhelming majority of children born into immigrant families are U.S. citizens.[11] Despite the belief that immigrants abuse public benefits, poor immigrants use lower percentages of public benefits than

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[7] *Id*. at 1742.
[8] Samuel Wolbert, *Universal Healthcare and Access for Undocumented Immigrants*, 5 PITT. J. ENVTL L. & PUB. HEALTH L. 61, 67 (2011).
[9] *Children in U.S. Immigrant Families*, MIGRATION POL'Y INST. https://www.migrationpolicy.org/programs/data-hub/charts/children-immigrant-families [https://perma.cc/TJ68-F743] (last visited Mar. 22, 2021).
[10] Silva Mathema, *State-by-State Estimates of the Family Members of Unauthorized Immigrants*, CTR. FOR AM. PROGRESS (Mar. 17, 2017), https://www.americanprogress.org/issues/immigration/news/2017/03/16/427868/state-state-estimates-family-members-unauthorized-immigrants/.
[11] *Children in U.S. Immigrant Families, supra* note 9.

similarly situated U.S.-born Americans.[12] In fact, when immigrants use public benefits, they cost the government less per recipient, thereby reducing societal costs.[13] Furthermore, research shows that immigrants "contribute more to the economy in taxes than they receive in public benefits," and their per capita health expenditures are much lower than American-born citizens.[14]

In recent years, Congress introduced a significant number of immigrant-focused policies that specifically address access to health care and health benefits.[15] These policies, however, have an adverse impact on immigrants and non-immigrants alike.[16] Nativist policies, such as the Trump-era "public charge" rule,[17] add complexity to an already complex health care system.[18] Because nativist immigration policies tend to impede health outcomes,[19] such policies could further accentuate racial and ethnic disparities that overwhelmingly impact immigrant health outcomes.[20] These policies can also impact lawfully present immigrants' ability to participate in insurance programs, limiting their ability to fund such programs.[21] Even though immigrants pay more for private insurance and are "net-contributor[s] to

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[12] Morey, *supra* note 5.
[13] *Id*.
[14] Susan Okie, *Immigrants and Health Care — At the Intersection of Two Broken Systems*, VOL 357 NO. 6 NEW ENG. J. MED. 525, 526 (2007).
[15] *See* Lisa J. Hardy et al., *A Call for Further Research on the Impact of State-Level Immigration Policies on Public Health*, 102 AM. J. OF PUB. HEALTH, 1250, 1250 (2012) ("In the first half of 2011 alone, state legislators introduced an unprecedented 1592 bills and resolutions relating to immigrants and refugees…").
[16] Nicolas A Vernice et al., *The Adverse Health Effects of Punitive Immigrant Policies in the United States: A Systematic Review*, 15 PLOS ONE (Dec. 16, 2020).
[17] The "public charge" rule allows the government to treat an immigrant's past use of public benefits as a negative factor when considering the immigrant's admissibility into the U.S.
[18] *See* Wendy E. Parmet, *The Worst of Health: Law and Policy at the Intersection of Health & Immigration*, 16 IND. HEALTH L. REV. 211, 228-29 (2019).
[19] *See id*. at 212. (explaining that such policies result in immigrants being denied access to reproductive health services, and physicians report that immigrants fail to show up to appointments as a result of fear).
[20] Hardy et al., *supra* note 15.
[21] *See* Parmet, *supra* note 18, at 221 (describing how "immigration law may undermine efforts to finance [the] health care system" because even though immigrants are generally younger and healthier, policies tend to restrict their ability to participate and fund insurance programs).

Medicare's trust fund, they are less likely to carry health insurance than the American-born population."[22] Fewer eligible immigrants enroll in health care programs and, consequently, seek emergency care as a last resort, which drives up societal costs.[23] Also, "tougher" immigration policies increase deportation fears and result in immigrants forgoing doctor visits and otherwise eligible benefits.[24] These fears extend to those immigrants with lawful status.[25]

The detrimental impact of these nativist policies is apparent across the country as immigrants fail to seek care due to anxieties and perceptions associated with immigration enforcement activity.[26] For example, when Arizona passed SB 1070, a law that expanded police power to allow the detention of immigrants *suspected* to be undocumented,[27] fear spread throughout the immigrant community, affecting both documented and undocumented immigrants.[28] Pilot data from a study conducted in Arizona showed immediate changes in the behavior of immigrants seeking care, even

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[22] *Id*.
[23] Arijit Nandi et al., *Expanding the Universe of Universal Coverage: The Population Health Argument for Increasing Coverage for Immigrants,* 11 J. IMMIGRANT & MINORITY HEALTH, 433, 435 (2009).
[24] Alexia Eleljalde-Ruiz, *Fear, Anxiety, Apprehension: Immigrants Fear Doctor Visits Could Leave Them Vulnerable to Deportation*, CHI. TRIBUNE (Feb. 18, 2018), https://www.chicagotribune.com/business/ct-biz-immigration-fears-hurt-health-care-access-0225-story.html.
[25] Samantha Artiga & Petry Ubry, *Living in an Immigrant Family in America: How Fear and Toxic Stress are Affecting Daily Life, Well-Being, & Health*, KFF (Dec. 13, 2017), https://www.kff.org/racial-equity-and-health-policy/issue-brief/living-in-an-immigrant-family-in-america-how-fear-and-toxic-stress-are-affecting-daily-life-well-being-health/.
[26] Hailey Cleek, *Borders Across Bodies: Assessing the Balance of Expanding CHIP Coverage at the Expense of Advancing Fetal Personhood*, VOL 34 BERKELEY J. GENDER L. & JUST. 1, 14 (2019).
[27] *See* Hardy et al., *supra* note 15 (explaining that the law, SB 1070, "took unprecedented steps in the enforcement of immigration law by making failure to possess immigration documents a crime and expanding police power to detain persons suspected of being in the United States illegally.").
[28] *See id*. ("Although the stated target of SB 1070 was undocumented immigrants, the fallout from its passage has reverberated throughout Arizona communities, affecting not only the undocumented but also families, friends, and neighbors of all immigration statuses.").

before enforcement of the law began.[29] Accordingly, this example illustrates that nativist policies have a broad impact on immigrants, their families, and society.[30]

III. THE IMPACT OF EXCLUSIONARY IMMIGRANT HEALTH POLICIES ON HOSPITALS

Immigration policies that deter documented immigrants from seeking health coverage or access to health care have a detrimental effect on society in many ways, including straining the health care system.[31] Fear of arrest experienced by mixed-status immigrant families creates a barrier for documented individuals to access health care or to provide aid to family members in their health journey.[32]

Immigration and Customs Enforcement ("ICE") currently maintains a policy that prohibits arrests in hospitals as designated "sensitive locations," except (1) in "exigent circumstances," (2) when certain exceptions are met, or (3) "prior approval is obtained."[33] This policy, however, is discretionary, and ICE can roll it back at any time.[34] Therefore, despite pleas by officials for immigrants to seek medical treatment when needed,[35] fear of arrest

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[29] *See id.* ("Pilot data suggest that the passage of SB 1070 resulted in immediate changes in health behavior and health care use even before enforcement began.").
[30] Vernice et al., *supra* note 16.
[31] *See* Parmet, *supra* note 18, at 222 ("[…] the public health threats that arise at the intersection between immigration and health derive from policy decisions, including barriers to health coverage, stresses to the health care system, the exacerbation of negative social determinants, the perpetuation of stigma, and the displacement of evidence-based public health interventions with fear-based anti-immigrant policies.").
[32] Tony Abraham, *When ICE Comes Knocking, Healthcare Workers Want to be Prepared*, HEALTHCAREDIVE (Sept. 14, 2018), https://www.healthcaredive.com/news/when-ice-comes-knocking-healthcare-workers-want-to-be-prepared/531058/.
[33] Memorandum from John Morton, Director, Immigration and Customs Enforcement., on Enforcement Actions at or Focused on Sensitive Locations (Oct. 24, 2011).
[34] Lydia Weiant, *Immigration v. Religious Freedom in Trump's America: Offering Legal Sanctuary in Places of Worship*, 58 AM. CRIM. L. REV., 257, 265 (2021).
[35] Noah Lanard, *The Right and Wrong Lessons to Take From That Viral Photo of an ICE Arrest at a Hospital*, MOTHER JONES (Mar. 13, 2020), https://www.motherjones.com/

remains rampant, with some immigrants describing their fear of ICE as "more terrifying than illness."[36] In fact, the federal government itself has recognized that not only are such arrests counterproductive; they are "heartless."[37]

Notwithstanding the federal government's position, there is no federal law prohibiting arrests in sensitive locations, and solutions at the state level are fragmented at best. It is difficult to determine the exact number of immigrants impacted by arrests in hospitals due to the Department of Homeland Security's (DHS) lack of transparency.[38] However, "[o]n an average day in November 2017, ICE had custody of thirty-eight individuals in ten hospitals across five states."[39] There is evidence that ICE does not always follow its sensitive locations policy. Under the Trump administration, ICE agents appeared to push their discretion to the outer edges by arresting immigrants near sensitive locations.[40]

In one case, ICE arrested an immigrant at a bus stop just outside a Portland hospital after watching him leave the hospital.[41] After the hospital's lawyer

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politics/2020/03/the-right-and-wrong-lessons-to-take-from-that-viral-photo-of-an-ice-arrest-at-a-hospital.

[36] Hailey Cleek, *Sanctuary Clinics: Using the Patient-Physician Relationship to Discuss Immigration Policy as a Public Health Concern*, VOL 53 WAKE FOREST L. REV. 979, 993 (2018).

[37] The Times Editorial Board, *Editorial: Arresting Immigrants at Schools, Hospitals and Courthouses Isn't Just Cold-hearted, It's Counterproductive*, N.Y. TIMES (Mar. 16, 2017), https://www.latimes.com/opinion/editorials/la-ed-trump-ice-courts-20170316-story.html.

[38] *See* Sarah Stoughton & Kathryn Hampton, *Not in My Exam Room. How U.S. Immigrations Enforcement is Obstructing Medical* Care, PHYSICIANS FOR HUM. RIGHTS (June 10, 2019), https://phr.org/our-work/resources/not-in-my-exam-room/#_ednref31.

[39] *See id*. (citing to a footnote that states that ICE had a custody of 38 individuals in 10 hospitals across five states. These include California (nine people); Florida (five); Michigan (one); South Carolina (19); and Texas (four)).

[40] The Times Editorial Board, *supra* note 37.

[41] *See* Katie Sheppard, *ICE Arrested an Undocumented Immigrant Just Outside a Portland Hospital*, WILLAMETTE WEEK (Oct. 31, 2017), https://www.wweek.com/news/courts/2017/10/31/ice-arrested-an-undocumented-immigrant-just-outside-a-portland-hospital/ (describing how "ICE agents watched a man leave Legacy Emanuel Health Center in North Portland and arrested him at a bus stop just outside the hospital—a clear violation of the agency's own "sensitive locations" policy...").

investigated the incident and found that ICE clearly violated its sensitive locations policy, ICE defended its actions by stating the arrest occurred "near, *but not on*" the hospital's property.[42] In other instances, ICE detained immigrants visiting loved ones at hospitals.[43] Such incidents exacerbate negative health consequences as immigrants avoid seeking medical care out of fear of arrest.[44] ICE's deviation from policy undermines both documented and undocumented immigrant's accessibility to health care.[45]

Citing the increased activity by ICE at or near hospitals, organizations such as Physicians for Human Rights ("PHR") have advised hospitals to establish their facilities as "sanctuary hospitals."[46] PHR has also recommended that hospitals "educate staff on how to protect patients and providers from enforcement actions."[47] Other organizations have also pursued initiatives to create model guidelines regarding how hospitals should interact with ICE.[48]

Although some hospitals have heeded such advice,[49] establishing sanctuary hospital policies is not enough. Absent a federal law that prohibits arrests in sensitive locations, hospitals are left to navigate their way through

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[42] *Id.*
[43] *See* PHYSICIANS FOR HUM. RIGHTS, ESTABLISHING SANCTUARY HOSPITALS: PROTECTING THE RIGHT TO ACCESS TO HEALTH CARE, PHR 1, https://phr.org/wp-content/uploads/2019/09/PHR-Sanctuary-Hospitals-Fact-Sheet-FINAL.pdf (describing how "ICE & CBP have detained individuals who visited ill relatives or attempted to help loved ones seek medical attention, often leaving their loved ones to fend for themselves.") (last visited Feb. 14, 2021) [hereinafter Physicians for Human Rights].
[44] Cleek, *supra* note at 36, at 992.
[45] *Id*. at 990.
[46] Physicians for Human Rights, *supra* note 43.
[47] Stoughton & Hampton, *supra* note 38.
[48] *See* Elajalde-Ruiz, *supra* note 24. (illustrating how, "[t]o address patient fears, the Illinois Coalition on Immigrant and Refugee Rights… is crafting model guidelines on how hospitals can create a welcoming environment… [and] will educate staff on what to do if [ICE] comes looking for someone at the hospital.").
[49] *See* Jorge Rivas, *Hospitals Now Have to Train to Keep ICE Agents Out of Their Buildings*, SPLINTER (Apr. 6, 2018), https://perma.cc/E75R-6XF3 (describing how a California hospital implemented staff training on how to prevent ICE agents from physically entering its hospital facility).

undeterminable immigration laws in order to adopt policies addressing the issue.[50] This lack of clarity results in some untenable actions by hospitals, including one hospital that chartered a private jet to transport comatose patients to Mexico without consulting any governmental authorities.[51] Due to the lack of clarity from federal officials, hospital executives describe such decisions as a result of "being caught between a requirement to accept all patients and a political battle over immigration."[52]

Increased immigration enforcement in sensitive locations has created fear and mistrust within many immigrant communities.[53] Although the data surrounding fear in immigrant communities is sparse, studies show that increased fear of arrest bars access to health services.[54] For example, after the Arizona state legislature passed SB 1070, researchers found that immigrants were less likely to seek medical care."[55] When immigrants avoid preventative or ongoing care that they are eligible to obtain, they are less likely to control manageable diseases, fail to treat injuries, and stop the spread of infectious diseases.[56]

In 2017, after President Trump signed an executive order that expanded the category of individuals ICE could target for deportation beyond those

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[50] *See* Abraham, *supra* note 32 ("The American Hospital Association does not have a specific policy on the removal, detainment or apprehension of immigrant patients from medical facilities, so hospitals have largely been navigating their own way through murky immigration laws.").
[51] *Id*.
[52] AP, *Report: U.S. Hospitals Deported Hundreds of Immigrants* (Apr. 6, 2013), https://www.cbsnews.com/news/report-us-hospitals-deported-hundreds-of-immigrants/.
[53] Sarah Rogerson, *Sovereign Resistance to Federal Immigration Enforcement in State Courthouses*, 32 GEO. IMMIGR. L.J. 275, 277 (2018).
[54] Ike Swetlitz, *Immigrants, Fearing Trump's Deportation Policies, Avoid Doctor Visits*, STAT (Feb. 24, 2017), https://www.statnews.com/2017/02/24/immigrants-doctors-medical-care/.
[55] *See* Altaf Saadi et al., *Making a Case for Sanctuary Hospitals*, 318 JAMA, 2079, 2079 (2017) (finding that as a result of SB 1070, "researchers found that Latina mothers, regardless of their immigration status, were less likely to use the health care system even for primary care visits for themselves or their children.").
[56] *Id.*

convicted of crimes, a California hospital reported twice as many patients canceling their appointments immediately after the announcement of the executive order.[57] The hospital's CEO cited fear within the immigrant community as the reason behind the increased cancellations.[58] This fear also impacts some U.S. citizens.[59] In Arizona, after the passage of SB 1070, medical providers reported "a drop in health maintenance, such as regular doctor visits, diabetes education, vaccines, prenatal care, HIV education, and procurement of medications."[60] Immigrants facing these fears avoid primary care visits and instead seek care in emergency rooms when pain or illnesses become intolerable, which in turn exacerbates the financial burden on the health care system."[61]

The risk of spreading infectious diseases is of particular concern during public health crises such as the COVID-19 pandemic. COVID-19 infection rates are disproportionately higher in immigrant communities than in non-immigrant communities.[62] Early data shows that immigrants are underrepresented among the demographics of vaccinated people, thereby risking the spread of disease for fear of detention.[63] Understanding the gravity of public safety threats during the COVID-19 pandemic, ICE released a

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[57] Swetlitz, supra note 54.
[58] *Id*.
[59] *See* 2018 NATIONAL AGING AND LAW CONFERENCE. CHICAGO, AMERICAN BAR ASSOCIATION, HEINONLINE, https://heinonline-org.flagship.luc.edu/HOL/P?h=hein.aba/natlaglw0001&i=182 (describing how since the President Trump took office, "[i]mmigrant families, including those with lawful status, are experiencing high levels of fear and uncertainty…" of deportation, arrest and separation from family members) (last visited Mar. 22, 2019) [hereinafter "American Bar Association]; *see also* Swetlitz, *supra* note 54 (describing how in one case, a U.S. citizen missed his oncology appointment after his caretaker would not drive him for fear of being detained by ICE.)
[60] Hardy et al., *supra* note 15, at 1252.
[61] Saadi, *supra*, note 55, at 2079.
[62] Eva Clark et al., *Disproportionate Impact of the COVID-19 Pandemic on Immigrant Communities in the United States*, 14 PLOS NEGLECTED TROPICAL DISEASES (July 13, 2020).
[63] Jaxx Artz, *COVID-19 Vaccines: Why Hispanic Americans Are Lagging in Vaccination Rates*, GLOBAL CITIZEN (Mar. 29, 2021), https://www.globalcitizen.org/en/content/covid-19-vaccine-hispanic-communities-in-us/.

statement to encourage immigrants to seek care without fear of arrest.[64] ICE sought to remind the public of its longstanding policy that it "generally prohibits ICE officers from taking people into custody," except under "extremely rare" circumstances.[65] Regrettably, such pleas from governing authorities do not alleviate immigrant fears. Therefore, it is in the public's best interest to remove all barriers to care, beginning with codifying a national sensitive locations law that would prohibit arrests in hospitals.

IV. SOLUTION

The U.S. lacks a coherent centralized immigration health policy.[66] Although the federal government has exclusive reign over immigration,[67] federal law provides great discretion to the states in decision-making about immigrant access to health care.[68] The decentralized model results in a "messy reality" in which both federal and state levels of government have a role in regulating the intersection between health and immigration policy.[69] Despite evidence showing that immigrant inclusive policies improve health outcomes,[70] reduce health inequities,[71] and improve economies, state policies remain stagnant.[72] To address the gap between immigration and health policy, legislators must enact a federal law that: (1) further clarifies what "at or near" a "sensitive location" means; and (2) expands the definition of "sensitive locations" to include a "more comprehensive list of locations."[73]

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[64] Lanard, *supra* note 35.
[65] *Id*.
[66] Makhlouf, *supra* note 6, at 1682.
[67] *Id*. at 1697
[68] *Id*. at 1708.
[69] *Id*. at 1697
[70] Wobert, *supra* note 8.
[71] Makhlouf, *supra* note 6, at 1727.
[72] *Id*.
[73] Fortuny, *supra* note 2.

Under the principle of federalism, states are encouraged to engage in policy experimentation and act as laboratories so that other states may replicate successful policy templates.[74] However, this experimentation does not always produce optimal results.[75] Between 2016 and 2017, at least eight states introduced bills to prohibit arrests in sensitive locations; however, none have passed into law.[76] Additionally, even if such bills were to pass, it is unlikely that DHS would honor such state policies.[77] Lacking federal and state laws that prohibit arrests in sensitive locations, some states have resorted to enacting laws and policies that deter cooperation with federal immigration agents.[78] However, despite state legislators' good intentions, such laws and policies are inadequate in mitigating the number of arrests in sensitive locations.[79] Instead, the solution is to enact a federal law that prohibits ICE from entering all sensitive locations, including hospitals, schools, and places of worship, and imposing an injunction against agents to prohibit their presence within a certain vicinity of sensitive locations.[80] Notably, legislators have made such efforts at a federal level.[81]

In 2017, in an attempt to codify hospitals as sensitive locations, Rep. Adriano Espaillat (NY-13) sought to amend the Immigration and Nationality

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[74] *See New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting), abrogation recognized by *W. Coast Hotel Co. v. Parrish*, 300 U.S. 379 (1937) ("It is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.").
[75] Makhlouf*, supra* note 6, at 1765.
[76] Rogerson, *supra* note 53, at 296.
[77] *Id*. at 297.
[78] *See id*. at 293 ("In the last six years, states have enacted a record number of pieces of legislation and administrative policies that disfavor state cooperation with immigration enforcement and/or encourage the integration of immigrants as state citizens, affording them by legislation and state administrative policies with as many rights and privileges as can be justified under state.").
[79] *Id*. at 296.
[80] *Id*.
[81] *Id*. at 291 (describing an effort by New York Congressman Adriano Espaillat to enact a "sensitive locations" policy would be more protective of immigrants than any internal DHS policy).

Act (INA) by introducing the Protecting Sensitive Locations Act.[82] The bill provided that "enforcement action may not take place at, be focused on, or occur within, 1,000 feet of, a sensitive location, except – (1) under exigent circumstances; and (2) if prior approval is obtained."[83] Exigent circumstances involve "national security, terrorism, public safety, or the imminent risk of destruction of evidence pertaining to a criminal matter."[84] Representative Jose Serrano supported the bill and explained: "ICE activities at these vital, essential locations create a disincentive for immigrants, even those who are documented, from doing things like accessing basic benefits…and ensuring their health and well-being."[85] Despite efforts to push it through to the Senate, the bill failed.[86] Representative Espaillat made another effort to amend Section 287 of the INA when he introduced H.R. 1011 in 2019.[87] The bill, however, did not make it out of committee.[88]

Under the Biden administration, ICE is preparing to issue new guidelines that narrow the arrest and deportation criteria expanded under the Trump administration.[89] However, until national legislation replaces indeterminate guidelines, societal costs will continue to rise,[90] immigrant health disparities will continue to widen,[91] and families will continue to live in fear of arrest.[92]

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[82] Protecting Sensitive Locations Act, H.R. 1815, 115th Cong. (2017).
[83] *Id.*
[84] *Id*.
[85] Press Release, Representative Jose Serrano, Reps. Espaillat, Bonamici, Serrano, Beyer Introduce the Protecting Sensitive Locations Act (Mar. 30, 2017) (on file with author).
[86] Protecting Sensitive Locations Act, H.R. 1815, 115th Cong. (2017).
[87] Protecting Sensitive Locations Act, H.R. 1011, 116th Cong. (2019-2020).
[88] *Id*.
[89] Nick Miroff & Maria Sachetti, *New Biden Rules for ICE Point to Fewer Arrests and Deportations, and a More Restrained Agency*, WASH. POST (Feb. 7, 2021), https://www.washingtonpost.com/national/new-biden-rules-for-ice-point-to-fewer-arrests-and-deportations-and-a-more-restrained-agency/2021/02/07/faccb854-68c6-11eb-bf81-c618c88ed605_story.html.
[90] *See* Makhlouf*, supra* note 6, at 1738 ("Addressing inequities in access to health coverage can be cost-effective when it shifts spending from expensive healthcare venues like the emergency room to less expensive primary and preventive care.").
[91] *Id.*
[92] Fortuny, *supra* note 2.

Because large-scale reform at the state level is unlikely,[93] it is essential to enact an inclusionary federal law that allow immigrants to seek care and to do so without fear of arrest.[94] Such a law will lead to greater health equity,[95] and increase the number of eligible immigrants enrolling public in health benefits, thereby reducing the overall cost of health care to medical providers and the government.[95]

V. CONCLUSION

A law prohibiting arrests in sensitive locations is "common sense policy."[96] The most vulnerable individuals in our communities deserve to feel secure when seeking medical care.[97] When immigrants do not feel safe seeking care and accessing benefits for which they are eligible, health disparities and societal costs increase.[98] The fear immigrants experience transcends legal status, race, and ethnicity.[99] It is therefore incumbent on the U.S. to enact national legislation that prohibits arrests in hospitals, except under exigent circumstances.[100] ICE policies that are subject to change at any time are not sufficient, and individual state laws are too fragmented to address this national issue.[101] Congress must codify ICE's sensitive locations policy by passing the Protecting Sensitive Locations Act into law, thereby transforming indeterminate guidelines into "statutory, enforceable law."[102]

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[93] Makhlouf, *supra* note 6, at 1774 (using Medicaid as an example to explain that patchwork policies of noncitizen eligibility for Medicaid are exclusionary and "federal leadership is needed in order to enact inclusive policy[…]").
[94] Rogerson, *supra* note 53, at 296.
[95] *Id.* at 1773.
[95] Nandi, *supra* note 23.
[96] American Bar Association, *supra* note 59, at H-21.
[97] Saadi et al., *supra* note 55.
[98] Morey, *supra* note 5.
[99] Hardy et al., *supra* note 15.
[100] Rogerson, *supra* note 53, at 296.
[101] Makhlouf, *supra* note 6 at 1697.
[102] *Id*. at H-25.

Black Box Software: Artificial Intelligence in Health Care

Cristal Nova

I. INTRODUCTION

The United States Food & Drug Administration ("FDA") and European Medicine Agency ("EMA") are embracing the golden era of software as medical devices ("SaMD") which operate through deep neural networks, deep learning, and machine learning—otherwise known as artificial intelligence ("AI").[1] We encounter AI when we scroll through our social media feeds and see personally attuned advertisements,[2] when our credit eligibility is calculated for major purchases,[3] and when we receive health services.[4] AI tools can quickly decipher through massive amounts of health

[1] *See* Stan Bejamens et al., *The State of Artificial Intelligence-Based FDA Approved Medical Devices and Algorithms: An Online Database*, 118, NPJ DIGIT. MED. 1,1 (2020) (citing expressions used by the FDA to describe AI technologies).
[2] *See* Stephan Winter et al., *The Effects of Trait-Based Personalization in Social Media Advertising*, 114 COMPUTERS IN HUM. BEHAV., 1, 1 (Aug. 2020) (discussing the use of digital trace data and machine learning to predict social media users' personality types and deliver tailored virtual advertisements).
[3] *See* Diederick van Thiel & W. Fred van Raaij, *Artificial Intelligence Credit Risk Prediction*: *An Empirical Study of Analytical Artificial Intelligence Tools for Credit Risk Prediction in a Digital Era*, 19 J. ACCT. & FIN. 150, 153 (Dec. 30, 2019), (observing that AI models can improve credit decisioning in asset classes like mortgage loans and credit card loans).
[4] Marc Jannes et al., *Algorithms in Digital Healthcare an Interdisciplinary Analysis*, BERTELSMANN STIFTUNG, 1, 6 (Sep. 2019); *See* Julia Goldberg & Andrew Rosenkranz, *Artificial Intelligence and Radiology: A Social Media Perspective*, 48 CURRENT PROBS. IN DIAGNOSTIC RADIOLOGY 308, 311 (July – Aug. 2019) (reporting favorable social media opinions regarding AI in radiology, noting opposition for AI replacing radiologists).

data and derive important insights which better assist health care providers in providing patient care.[5]

In 1950, English mathematician, Alan Turing, released a pivotal publication where he reasoned that machines with the capability to imitate a human should be considered intelligent.[6] Since then, the science of engineering computers to understand and simulate the complexities of human intelligence has evolved into the artificial intelligence efforts we see today.[7] Since human intelligence is difficult to squarely define, the development of AI creates automated pathways to solve commonly understood problems.[8] Human intelligence goes beyond an IQ score, its unique manifestations offer unlimited opportunities for cognitive scientists to define how our behavior constitutes intelligence.[9] Across the vast spectrum of human abilities, well understood activities are ripe for computer programs to observe, replicate, and resolve issues.[10] Rather than overtake human intelligence, AI hopes to engineer technologies that assist humans with problem-solving and ultimately further the attainment of our goals.[11]

AI-powered technology can support health care outcomes like enhancing the patient experience and mitigating the administrative burdens assumed by well-meaning clinicians.[12] As AI filters through troves of data to advance

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[5] *Artificial Intelligence and Machine Learning in Software as a Medical Device*, FDA 1,1 (Jan. 12, 2021) https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device (last visited Mar. 27, 2021).
[6] *See* Note from John McCarthy, Stanford U., to laymen answering basic questions about AI., Formal Reasoning Group, Stanford U. (Nov. 12, 2007) on file with Stanford U. and author) http://www-formal.stanford.edu/jmc/whatisai.pdf.
[7] *Id.* at 2.
[8] *Id.*
[9] *Id.* at 3.
[10] *Id.*
[11] *Id.* at 5.
[12] *See* Andrew Steger, *How AI Improves Patient Experience Outcomes*, HEALTH TECH MAG. (Jan. 21, 2020) https://healthtechmagazine.net/article/2020/01/how-ai-improves-patient-experience-outcomes (examining AI's ability to warn providers of patients' risk factors and suggest courses of treatment).

such metrics, machine learning also acquires the data's deeply embedded implicit biases thus furthering racial disparities in health care.[13] Medical algorithms are taught to process data by recognizing patterns, drawing inferences, and adjusting care pathways to support clinicians' diagnosis and treatment decisions.[14] Applying machine learning to medical diagnoses in a hyper-technical vacuum that only recognizes images and alphanumeric codes has the potential to neglect the true challenges of providing care to an increasingly demanding patient population.[15] As new medical algorithms gain the FDA's stamp of approval, calls increasingly grow for transparency, uniform bioethical guidelines and an open access network to examine the methods used by cutting-edge developers of AI. [16] This article examines recent actions taken by the FDA to encourage the prevalence of artificial intelligence in health care, ultimately concluding that regulatory oversight is currently unequipped to reduce inequity in healthcare. Thus, this article proposes solutions that prioritize transparency and bioethics to increase disclosure of data sources relied on by AI developers.

Part II of the article traces the history of AI in healthcare, describing the logic behind the technology and addressing its pain points. Part III explores the ongoing expert discussion on the scope of considering a patient's race in the delivery of health care services. In the context of AI, this part explores how intentional adjustments to machine learning tools can lead to unintended

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[13] *See* Poppy Noor, *Can We Trust AI Not to Further Embed Racial Health Inequalities*? 368 BMJ 1,1 (Feb. 12, 2020) (citing skewed detection of melanoma when algorithms are predominately trained to detect cancer moles using images of Caucasian skin).
[14] Tom Simonite, *New Algorithms Could Reduce Racial Disparities in Health Care*, WIRED, (Jan. 25, 2021) https://www.wired.com/story/new-algorithms-reduce-racial-disparities-health-care/.
[15] *See* Nadia Sawicki, *Choosing Medical Malpractice*, 93 WASH. L. REV., 891, 900–909 (2018) (discussing healthcare consumerism, where patients are actively involved in treatment decisions).
[16] *See* Bejamens, *supra* note 1, at 1; Casey Ross, *Explore STAT's Database of FDA-Cleared AI Tools*, STAT NEWS, (Feb. 3, 2021) https://www.statnews.com/2021/02/03/fda-artificial-intelligence-clearance-products/ (independently categorizing FDA-approved software devices that rely on artificial intelligence).

consequences for vulnerable patient populations. Part III also analyzes real-world examples of how these unintended consequences can arise even when algorithms are trained to analyze seemingly race-neutral data. Part IV examines an emerging hyper-productive market of AI software development and the regulatory and healthcare industry's response. The and the regulatory responses by the FDA and concludes by supporting .

II. UNDERSTANDING ARTIFICIAL INTELLIGENCE IN HEALTHCARE

In 1974, the MYCIN clinical decision support algorithm was used to diagnose blood-based bacterial infections and recommend treatment.[17] As one of healthcare's earliest expert systems, MYCIN analyzed and learned bacteria types with information gathered from medical experts and made inferences from its associated symptoms to recommend treatments.[18] Expert system algorithms are programmed to automatically analyze data and generate conclusions, without ethical sensitivities.[19] MYCIN operates through 350 rules and diagnosed bacterial infections with greater accuracy than practicing physicians at the time.[20] Yet, the algorithm was not programmed to include patient records, facility capabilities, or adjust for recovery and mortality rates—all determinative factors in successful care delivery.[21] This decision support algorithm yielded greater health outcomes than decisions made without it, adding support to the movement for AI in other clinical specialties.[22] However, AI requires reliance of massive data

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[17] *E.g.*, McCarthy, *supra* note 6, at 11; B.J. Copeland, *MYCIN*, ENCYC. BRITANNICA, (Nov. 21. 2018); *see also* William van Melle, *MYCIN: A Knowledge-Based Consultation Program for Infectious Disease Diagnosis*,10 INT. J. MAN-MACHINE STUDIES, 313, 313–322 (1978) (discussing the development and methodology associated to the MYCIN clinical support algorithm).
[18] McCarthy, *supra* note 6, at 11.
[19] *Id.* at 9–11.
[20] *Id.* at 11; *see* also van Melle, *supra* note 17, at 316.
[21] McCarthy, *supra* note 6, at 11.
[22] *See* van Melle, *supra* note 17, at 322 (discussing applications of MYCIN's knowledgebase to diagnose psychotherapy and pulmonary disease).

sets, broadening vulnerabilities to patient data,[23] potentially inviting adversarial attacks on the data used to fraudulently skew profits.[24] Furthermore, the sheer size of proprietary data used to power machine-learning tools create significant accessibility barriers for independent researchers to audit the factors which impact racial disparities in health care.[25]

III. CONTEMPLATING INEQUALITY IN ARTIFICIAL INTELLIGENCE

The ethical examination of whether to consider a patient's race when providing care and assigning a value to this variable have long been disputed in scientific research.[26] Some scholars believe that intentionally incorporating racial and ethnic factors can improve health outcomes and revolutionize the field of personalized genomic medicine.[27] Others caution that doing so accepts race as a genetic predictor, and if not analyzed properly, can reinforce harmful notions of biological bigotry.[28] Despite the friction surrounding this discussion, many diagnostic algorithms are built to modify

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[23] *See AI in Healthcare: 5 Privacy & Security Considerations When Leveraging the Latest Technology*, IMPRIVATA, (Mar. 28, 2019), https://www.fairwarning.com/insights/blog/ai-in-healthcare-5-privacy-security-considerations-when-leveraging-the-latest-technology.
[24] *See* Cade Metz & Craig Smith, *Warnings of a Dark Side to A.I. in Healthcare*, NY TIMES (Mar. 21, 2019) https://www.nytimes.com/2019/03/21/science/health-medicine-artificial-intelligence.html (discussing the rise in adversarial attacks on healthcare algorithms); *see also* Samuel Finlayson et al., *Adversarial Attacks on Medical Machine Learning*, 363 SCIENCE 1287, 1287(Mar. 22, 2019) (discussing the motivations of adversarial attacks on healthcare algorithms and possible cures).
[25] *See* Ziad Obermeyer et al., *Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations*, 366 SCIENCE 447, 447 (Oct. 25, 2019) (discussing a widely adopted risk-prediction algorithm which disproportionally limited access to healthcare services for African American patients).
[26] Jennifer Tsai, *What Role Should Race Play in Medicine?* SCI. AM. BLOG NETWORK, (Sep. 12, 2018) https://blogs.scientificamerican.com/voices/what-role-should-race-play-in-medicine/.
[27] *Id.*
[28] *Id.*

their suggestions based on a patient's race or ethnicity to establish a patient's risk assessment profile and guide clinical decisions.[29]

Maternal health outcomes are influenced by the Vaginal Birth After Cesarean ("VBAC") calculator which relies on algorithms to anticipate safety-risks for labor and delivery.[30] Black women in the United States experience a three-fold risk of pregnancy-related mortality when compared to white women.[31] This national crisis deteriorates trust between clinicians and vulnerable patients, urging the health care industry to directly confront racial disparities and implement mindful and unbiased safety protocols.[32] A vaginal birth reduces the risk of cesarean section surgical complications, lowers the risk of hemorrhaging during delivery, and reduces the likelihood of infection, effectively shortening post-partum recovery.[33] To determine eligibility for this delivery route, the National Institute of Child Health and Human Development endorses the VBAC calculator.[34] This AI-enabled calculator measures age, prior delivery history, body mass index (BMI), and race/ethnicity – all factors collected during a pre-natal visit to assign a score to guide a clinician's guidance on the safest delivery method for that patient.[35] In its analysis of race and ethnicity, the calculator automatically subtracts from the VBAC success scores for Hispanic and African American

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[29] Darshali Vyas et al., *Hidden in Plain Sight – Reconsidering the Use of Race Correction in Clinical Algorithms*, 388 NEW ENG. J. MED., 874, 874 (Aug. 27, 2020).
[30] Darshali Vyas, et al., *Challenging the Use of Race in the Vaginal Birth after Cesarean Section Calculator*, 29 WOMEN'S HEALTH ISSUES 201, 201 (Apr. 12, 2019) (discussing a widely used risk-calculating algorithm for birth).
[31] *Id.*; *see Pregnancy Mortality Surveillance System*, CTRS. FOR DISEASE CONTROL & PREVENTION., tbl. Pregnancy-Related Mortality Ratio by Race/Ethnicity: 2014 – 2017 (last reviewed Nov. 25, 2020) www.cdc.gov/reproductivehealth/maternalinfanthealth/pmss.html (capturing pregnancy-related mortality rates of Non-Hispanic White patients at 13.4% and 41.7% for Non-Hispanic Black patients).
[32] Vyas, *supra* note 30, at 201.
[33] *Id.*
[34] *Id.*
[35] *Id.*

women.[36] This means that while a Non-Hispanic white patient that is 30 years old, with a BMI of 35 and one prior cesarean section will receive a 46% VBAC success score.[37] Yet, if the same 30 year old patient, with a BMI of 35 and prior cesarean section is identified as African American or Hispanic, her odds of success are reduced to 31%.[38] Variability in success scores influences prenatal counseling and when compounded with provider's liability concerns can dissuade providers from suggesting vaginal births to African American and Hispanic patients – restricting their access to VBAC's maternal benefits, and prolonging racial disparities.[39] The race-based mechanism coded into the VBAC calculator arises from observational findings which correlated the most successful VBAC procedures with patients who were more likely to be insured, married, and Caucasian.[40] These factors likely sought to explore the relationship between labor and delivery risk status with a woman's socioeconomic status. [41] However, when building the VBAC calculator, marital status and insurance coverage were excluded from the tool while race and ethnicity was coded into the calculator's predictive model.[42] The lines of reason between a patient's age, BMI and prior history of delivery inform the biology of a successful birth delivery, but the inclusion of race and ethnicity does not offer such clinical rationales.[43] It is not uncommon for AI developers to offer either no basis or outdated observations when justifying race-based presumptions into clinical tools. [44] Making responsible claims that correlate racial data with medical outcomes

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[36] *Id.*
[37] *Id.*
[38] *Id.*
[39] *Id.*
[40] *Id.* at 202; *see also* Mark Landon et al., *The MFMY Cesarean Registry: Factors Affecting the Success of Trial of Labor after Previous Cesarean Delivery*, 193 AM. J. OBSTET. & GYNECOL. 1016, 1018 (Sept. 1, 2005).
[41] Vyas, *supra* note 30, at 202.
[42] *Id.*
[43] *Id.*
[44] Vyas et al., *supra* note 29, at 879.

is a delicate and complex task, which remains frequently debated by experts.[45] Federal guidelines require patients' identities to be classified using five racial and two ethnic categories.[46] These confined categories create confusion for clinicians assessing patients with one black and one white parent or patients who might hail from Latin America or the Caribbean and self-identify as both black and Hispanic.[47] The conundrum of circumscribing race and ethnicity[48] calls for researchers to reconsider how these variables can be attuned to the broader provision of clinical services.[49]

Even when AI tools are not trained to flag race and ethnicity, seemingly neutral presumptions baked into algorithms may still further racial disparities in access to health care services.[50] Commercial risk prediction tools are used by health insurers and hospital systems to make determinations regarding the care of over 200 million Americans annually.[51] One such tool was used to determine patient eligibility for a high-risk care management program.[52] These programs are costly to coordinate, but aim to reduce wasteful spending by streamlining coordinated care appointments for patients who stand to benefit most from such attentive care.[53] AI technology was trained to scrub medical records to distinguish patients with the highest healthcare expenditures for enrollment into a hospital's high-risk care management

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[45] *Id.*
[46] Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity, 62 Fed. Reg. 58782-01, 58782 (Oct. 30, 1997) (listing the ethnicities as Hispanic and Latino and the racial categories as: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander and White).
[47] Vyas, s*upra* note 30, at 203.
[48] Tsai, *supra* note 26, at 7 (considering how the "Native American" racial classification encompasses over 500 distinct tribes and citing other cultural considerations when identifying race).
[49] Vyas, s*upra* note 30, at 203.
[50] Obermeyer, *supra* note 25, at 447; *see also* Ibram Kendi, *There is no Such Thing as Race in Health-Care Algorithms*, LANCET DIGITAL HEALTH, 1, (Dec. 2019) e375, e375.
[51] Obermeyer, *supra* note 25, at 447.
[52] *Id.*
[53] *Id.*

program.[54] Inferring that patients with astronomical medical bills have a greater need for the harmonized services offered by high-risk coordination program enrollment seems like a sound conclusion.[55] This is a widely adopted assumption across many risk-predicting algorithms.[56] In fact, the data revealed similarities in health care costs between the average white and average black patient. [57] Still, this pure numerical inquiry disregarded how health care costs were distributed; with the average black patient more likely to be managing multiple chronic conditions like diabetes, hypertension, kidney failure, and anemia.[58] Really, the healthcare costs for managing the same amount of chronic conditions between the average black and white patient was $1,800 less.[59] This divergence in cost reflects a reduced access to health care services for black patients, attributable to systematic and interpersonal racial discrimination by health care providers.[60] The algorithm directed hospitals to devote their high-risk care management program resources to patients who generated the most clinical costs from high engagement with the system, rather than to its most vulnerable patient cohorts.[61] Thus, the commercial risk prediction tool required black patients to be sicker or absorb more healthcare costs than white patients before being considered for additional risk-management resources.[62] Since this error was revealed, researchers have collaborated with the AI tool's developer to identify the problematic variables and reduced the tool's bias by eighty-four

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[54] *Id.*
[55] *See* Heidi Ledford, *Millions of Black People Affected by Racial Bias in Health-Care Algorithms*, NATURE, (last updated Oct. 26, 2019) https://www.nature.com/articles/d41586-019-03228-6.
[56] Obermeyer, *supra* note 25, at 447.
[57] Ledford, *supra* note 55.
[58] *Id.*
[59] *Id.*
[60] *Id.*
[61] *Id.*
[62] *Id.*

percent.[63] The presence of biased outcomes through machine learning may not reflect racially motivated developers.[64] Addressing and curing racial bias in health care algorithms is more critical than ever as AI adoption intensifies in a clandestine way that influences decisions so closely intertwined with life-and-death consequences. [65]

IV. ANALYSIS

Machine learning tools that lack a methodological explanation are often referred to as "black box" software.[66] In health care, this software is shaped using a vast repository of generally accepted clinical practice guidelines. [67] Currently, this black box effect leaves purchasers, users, and regulators in the dark about the data sources used to power artificial intelligence tools.[68] Disclosure of AI improvements are further narrowed by business choices to safeguard emerging technologies.[69] This protection is generated by substantial patent investments[70] and reliance of trade secrecy protections.[71] Between 2002–2016 the U.S. Patent and Trademark Office observed an annual influx of artificial intelligence applications submitted from 30,000 to 60,000.[72] Companies that have not secured patent approval can rely on trade secrecy laws and the HIPPA privacy rule retain their data sources and

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[63] *Id.*
[64] *See* Kendi, *supra* note 50, at e375.
[65] Obermeyer, *supra* note 25, at 447.
[66] *See* Gregory Daniel et al., *Current State and Near-Term Priorities for AI-Enabled Diagnostic Support Software in Health Care* 14 (Patricia Green ed., 2019).
[67] *See* CHRISTINA SILCOX ET AL., TRUST, BUT VERIFY: INFORMATIONAL CHALLENGES SURROUNDING AI-ENABLED CLINICAL DECISION SOFTWARE 14 (Patricia Green ed., 2020).
[68] *Id.* at 8.
[69] *Id.*
[70] *Id.*
[71] *Id.*
[72] OFFICE OF THE CHIEF ECONOMIST, INVENTING AI: TRACING THE DIFFUSION OF ARTIFICIAL INTELLIGENCE WITH U.S. PATENTS, 5 IP DATA HIGHLIGHTS 2 (5th ed. 2020).

methodologies away from the consuming public and independent researchers. [73]

Advocates outside of the health care industry have made Congress well aware of AI's potential to amplify bias, foster discrimination, and exploit consumers.[74] The Algorithmic Accountability Act was introduced to grant federal authority to screen, evaluate and provide risk-mitigation guidance on AI and machine learning high-risk automated decision systems which either contribute to discrimination or influence sensitive decision-making using data collected from consumers' behavior patterns.[75] The Algorithmic Accountability Act would invite the Federal Trade Commission ("FTC") among other federal agencies to scrutinize the high-risk automated decision systems employed by corporations earning above $50 million in annual revenue, companies that receive data from at least one million people or devices and corporations that function as brokers in consumer data transactions.[76] This criteria hopes to incline technology's stakeholders to improve the algorithms used to predict consumer behavior, direct consumer's legal rights and rectify those that amass data from publicly accessible physical places.[77] For decades, the FTC has defended consumer rights against automated predictive tools that perpetuate unfair and discriminatory outcomes in financial credit underwriting.[78] Realizing the potential risks of using intelligent predictive models, the FTC is committed to holding AI

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[73] Silcox et al., *supra* note 67, at 10.
[74] Joshua New, *How to Fix the Algorithm Accountability Act of 2019*, CTR. FOR DATA INNOVATION, (Sept. 23, 2019), https://datainnovation.org/2019/09/how-to-fix-the-algorithmic-accountability-act/.
[75] H.R. 2231, Algorithmic Accountability Act of 2019. 116th Cong. (2019–2020); s*ee also* Adi Robertson, *A New Bill Would Force Companies to Check their Algorithms for Bias*, VERGE, (Apr. 10, 2019), https://www.theverge.com/2019/4/10/18304960/congress-algorithmic-accountability-act-wyden-clarke-booker-bill-introduced-house-senate.
[76] Robertson, *supra* note 75.
[77] *Id.*
[78] *See* Andrew Smith, *Using Artificial Intelligence and Algorithms*, F.T.C., (Apr. 8, 2020 9:58 AM), https://www.ftc.gov/news-events/blogs/business-blog/2020/04/using-artificial-intelligence-algorithms (discussing litigation against AI models in finance).

developers accountable for mismanaged algorithms obscurely used in health care treatment and diagnostic decisions.[79] The Algorithmic Accountability Act remains under consideration, and its approval could remarkably transform our online and real-life experiences.[80]

Having already approved many artificial intelligence/machine-learning ("AI/ML") systems for clinical use – some that are operable without physician oversight – the gatekeeper of these impressive clinical predictors is the FDA.[81] To reach clinical settings, an AI/ML software must be approved through the FDA's rigorous 510(k) clearance, premarket approval or de novo classification processes.[82] The levels of scrutiny may be relaxed when the developer proves that the innovative algorithm is substantially equivalent to another similar, legally-marketed algorithm.[83]

The global price tag for machine-based learning tools in health care is projected to exceed $28 billion.[84] The unanticipated arrival of a global pandemic only intensified the need for data tracking, with health care and life science executives calling for a more aggressive adoption of AI technology in the next two years.[85] Business leaders are prepared to embrace AI to further innovation in telemedicine, robotic tasks and the delivery of patient care.[86]

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[79] Edith Ramirez et al., BIG DATA: A TOOL FOR INCLUSION OR EXCLUSION? v (2016).
[80] Robertson, *supra* note 75.
[81] MICHAEL MATHENY, ARTIFICIAL INTELLIGENCE IN HEALTH CARE: THE HOPE, THE HYPE, THE PROMISE, THE PERIL 97 (Sonoo Thadaney Israni et al. eds, 2019).
[82] *Id.* at 183 tbl. 7-1 (describing the legal and regulatory framework for variations of AI software).
[83] Benjamens, *supra* note 1, at tbl. 1 (describing the three types of FDA approvals for AI/ML-based medical technologies).
[84] *Id.* at 6.
[85] Heather Landi, *Healthcare AI Investment Will Shift to these 5 Areas in the Next 2 Years: Survey*, FIERCE HEALTHCARE, (Mar. 9, 2021), https://www.fiercehealthcare.com/tech/healthcare-executives-want-ai-adoption-to-ramp-up-here-s-5-areas-they-plan-to-focus-future.
[86] *See* Bill Borden, *From the 'Digital Front' Door to Tracking PPE, Healthcare Finding New AI Uses*, KPMG, (Mar. 9, 2021), https://info.kpmg.us/news-perspectives/technology-innovation/thriving-in-an-ai-world/ai-adoption-healthcare.html (surveying 100 healthcare and life science respondents from companies with over $100 million in revenue).

Moreover, those at the helm of top health systems are mindful of the risks of AI poses, with two-thirds reporting that their organization has already implemented AI ethical policies to help govern the use of such tools.[87]

With major stakeholders ready to embrace innovation, FDA's Center for Devices & Radiologic Health has recently released an Action Plan responding to stakeholders' concerns regarding algorithmic bias.[88] Between 2012–2020, the FDA granted clearance to 161 AI-enabled products, with 73 publicly disclosing the amount of patient data used to validate device performance.[89] Only eleven AI developers divulged the genders included in their data sets and seven shared the race and ethnicity information controlling the mechanism's decisions.[90] The approved tools included smartwatches to detect cardiac arrythmias, and tools that flag stroke, cancer and respiratory illnesses from millions of images.[91] The regulatory framework for this large swathe of clinical AI tools lacks standardized approach to assuring safety standards and leaves wide room for doubt in predicting patient outcomes.[92] The lack of uniformity and absence of efficacy standards only arise after independent review because FDA lacks a centralized database for the public to review the logic driving these algorithms.[93] FDA's Action Plan has responded to these mounting concerns by recognizing that AI/ML systems are trained from historical data sets that might include biases, and thus are prone to preserving biases.[94] FDA's Centers for Excellence in Regulatory Science and Innovation ("CERSIs") is currently collaborating with academic

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[87] *Id.* fig. 1; *see also* SREEKAR KRISHNA ET AL., THRIVING IN AN AI WORLD 19 (2021).
[88] *Artificial Intelligence and Machine Learning in Software as a Medical Device*, *supra* note 5, at 5 (citing that bias is not an exclusive issue to AI/ML and recognizing the importance of medical devices not perpetuating discrimination in diverse patient populations).
[89] Ross, *supra* note 16, at 2.
[90] *Id.*
[91] *Id.*
[92] *Id.*
[93] *Id.* at 6.
[94] *Artificial Intelligence and Machine Learning in Software as a Medical Device*, *supra* note 5.

research institutions to expand the framework necessary to adjust these devices using real-world performance data.[95]

As the health care industry galvanizes in support of AI, hospitals are left with testing efficacy in real-time with a lack of standard evidence protocols before the software enters the market.[96] The regulatory environment currently in development by CERSIs aims to identify and reduce bias, to improve machine learning algorithms for a racially and ethnically diverse patient population.[97] By actively including the FDA Office of Minority Health and Health Equity ("OMHHE") in regulation-writing, minority's health concerns can be considered with the intention of establishing a digital space that protects underrepresented groups from aggravating health disparities.[98] Currently, OMHHE is dedicated to increasing diverse participation of ages, races, ethnicities and genders in clinical trials for medical devices before they are marketed to the general public.[99] Clinical trials testing the safety and efficacy of medical devices currently several products including: toothbrushes, 3D printers, contact lenses, surgical tools and dialysis machines.[100] Medical algorithms must surpass the hurdles created by the FDA's regulatory requirements in order to develop and bring

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[95] *Id.*; s*ee also* UCSF, *USCF-Stanford Center of Excellence in Regulatory Science and Innovation (CERSI)*, (last viewed March 27, 2021) https://pharm.ucsf.edu/cersi.
[96] Ross, *supra* note 16, at 8.
[97] *Artificial Intelligence and Machine Learning in Software as a Medical Device*, *supra* note 5.
[98] *Office of Minority Health and Health Equity,* FDA, (current as of Mar. 4, 2021), https://www.fda.gov/about-fda/office-commissioner/office-minority-health-and-health-equity.
[99] FDA, *Medical Device Clinical Trials*, YOUTUBE (Oct. 20, 2020), https://www.youtube.com/watch?v=SApXnmZlgFE.
[100] *Id.*

these innovations to market.[101] OMHHE also supports external research studies about minority health and health disparities .[102]

So, its engagement AI/ML approvals may provide pre-market entrance resources for health care AI developers mindful about race, ethnicity, and gender in their software .[103] So, its engagement AI/ML approvals may provide pre-market entrance resources for health care AI developers mindful about race, ethnicity, and gender in their software. [104]

On January 15, 2021, a Notice was published requesting additional information on permanently deregulating the FDA's 510(k) approval process for ninety-one medical device classes.[105] The Notice was estimates that deregulating these classes would allow between $9.1- $364 million in saved start-up funds for market entry to be redeployed for devices designed to mitigate the impact of the COVID-19 public health emergency.[106] An average 510(k) submission has an 10 month timeline and costs ranging from $100,000 – $4 million.[107] These expensive figures dissuade new players from entering the market.[108] The legislative intent of the Food and Drug Act is not to place undue economic hardship on the new entry of necessary medical devices. [109] The COVID-19 regulatory flexibilities aimed to improve device

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[101] Benjamens, *supra* 1, at 1.
[102] Minority Health and Equity Research Collaboration, *Extramural Research*, FDA, https://www.fda.gov/science-research/minority-health-and-health-equity-research-and-collaboration/extramural-research (last updated Nov. 02, 2020).
[103] *Id*.
[104] *Id.*
[105] Making Permanent Regulatory Flexibilities Provided During the COVID-19 Public Health Emergency by Exempting Certain Medical Devices from Premarket Notification Requirements; Request for Information, Research, Analysis, and Public Comment on Opportunities for Further Science and Evidence-Based Reform of Section 510(k) Program, 86 Fed Reg. 4088, 4098 (Jan. 15, 2021).
[106] *Id.*
[107] *See id.* at 4089; (citing "the average total cost for participants to bring a low-to-moderate-risk 510(k) product from concept to clearance was approximately $31 million, with $24 million spent on FDA dependent and/or related activities.").
[108] *Id.* at tabl. 1
[109] *Id.* at 4089 (citing Congressional intention to avoid using Food and Drug Act provisions as an economic trade barrier).

supply including: thermometers, air purifiers, hospital gowns and gloves, non-invasive patient monitoring devices and image acquisition and/or optimization guided by artificial intelligence.[110] Immediate access to innovative technology is appealing for patients and beneficial to its manufacturers; but further deregulation in this area may prove to be a perilous path. [111]

V. CONCLUSION

Artificial intelligence is here to stay – its ability to comb through patient health information, seeking patterns and providing reliable data for clinicians at the bedside is a remarkable innovation that should be celebrated and made accessible throughout nearly all healthcare facilities. However, we must be conscious of the assumptions these prototypes rely on to deliver care. Socioeconomic factors may be embedded in these algorithms to expose clinicians to areas of care they have long overlooked. A collaboration that places equitable healthcare outcomes and transparency above commercial gain and innovation is desperately needed before black box software becomes more akin to the present that seems valuable but in reality, is a curse.[112]

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[110] Ross, *supra* note 16, at 6.
[111] *Id*. at 10.
[112] ENCYC. BRITANNICA, (Editors of Encyc. eds., 2020) https://www.britannica.com/topic/Pandora-Greek-mythology.

Mitigating Disparities in Access to Healthcare Among Native American Communities Through Telehealth

Delaney Perl

I. INTRODUCTION

Marginalized communities have long suffered from various health disparities including access to healthcare.[1] Native Americans in particular suffer from a wide range of socioeconomic, physical, and mental health disparities.[2] More than twenty-five percent of Native Americans are living in poverty, and in some reservations, the rate of unemployment is up to thirty-five percent.[3] When it comes to being the victim of a violent crime, Native Americans have the highest per capita rate of any marginalized group.[4] These factors alone cause an indescribable amount of mental and physical suffering, yet Native Americans suffer significantly from health inequity.[5]

This article will discuss how telehealth can mitigate these disparities by providing greater access to care. First, the article will look at the history of

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[1] *See generally* Paula A. Braveman et al., *Health Disparities and Health Equity: The Issue Is Justice*, 101(S1) AM. J. PUB. HEALTH S149 (2011) (noting how "The first decade of the 21st century has ended with little if any evidence of progress toward eliminating health disparities by race or socioeconomic status." Thus, marginalized communities continue to suffer more disparities and inequities in health).

[2] *See generally* Michelle Sarche & Paul Spicer, *Poverty and Health Disparities for American Indian and Alaska Native Children: Current Knowledge and Future Prospects*, 1136 ANNALS OF THE N.Y. ACAD. OF SCI. 126 (2008) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2567901/ (discussing the different disparities plaguing American Indian and Native Alaskan populations).

[3] *Id.* at 127.

[4] *Id.*

[5] Mary Smith, *Native Americans: A Crisis in Health Equity*, AM. BAR ASS'N https://www.americanbar.org/groups/crsj/publications/human_rights_magazine_home/the-state-of-healthcare-in-the-united-states/native-american-crisis-in-health-equity/ (last visited Feb. 4, 2021).

healthcare among Native Americans. Second, the article will analyze the use of telehealth in Native American communities. Finally, the article will turn to whether or not telehealth has truly improved access to care, looking to any disparities that remain prevalent.

II. BACKGROUND

In July of 1955, the Indian Health Service ("IHS") was created as a part of the Department of Health and Human Services ("HHS") as a way to "provide federal health services to American Indians and Alaskan Natives."[6] This agency was created in part because of the Meriam Commission, which pressured an inspection of Office of Indian Affairs.[7] This inspection led to the Meriam Report, which exposed the health disparities suffered by American Indians in comparison to the general population, highlighting high death rates and high rates of tuberculosis and trachoma.[8] The Meriam Report called for immediate action to create public health clinics and incited a movement in the 1920's to improve overall health outcomes.[9]

This movement drew attention to the problems and inequities in Native American health care which eventually led to the transfer of Native American Health programs from the Bureau of Indian Affairs to the Public Health Service in 1954, and a year later the IHS was created.[10] IHS has been able to

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[6] *Agency Overview*, INDIAN HEALTH SERV. https://www.ihs.gov/aboutihs/overview/ (last visited Feb. 4, 2021); Everett R. Rhoades et al., *The Organization of Health Services for Indian People*, 102(4) Pub. Health Rep. 352, 354 (July 1987).

[7] David Vecchioli, *"If You Knew the Conditions…" Health Care to Native Americans*, U.S. NAT'L LIB. OF MED., https://www.nlm.nih.gov/exhibition/if_you_knew/ifyouknew_07.html (last visited Feb. 4, 2021) (discussing the Meriam Commission, a survey team made up of specialists and headed by Lewis Meriam to uncover and report about living conditions for Native Americans, particularly its findings regarding substandard health conditions).

[8] LEWIS MERIAM ET AL., THE MERIAM REPORT: THE PROBLEM OF THE INDIAN ADMINISTRATION, 3 (Johns Hopkins Press Eds. 1928).

[9] *Id.* at 53; *see also* Vecchioli, *supra* note 7 ("The Meriam Commission's findings spurred a movement during President Franklin D. Roosevelt's administration to improve health conditions for Native Americans.").

[10] *See* Vecchioli, *supra* note 7 (The Indian Health Service (IHS) began on July 1, 1955, a year after the transfer of Native American health services from the Bureau of Indian Affairs (BIA) to the Public Health Service (PHS).").

provide the delivery of federal health services to approximately 2.2 million American Indians and Alaskan Natives.[11] However, many still do not have access to proper health care.[12] In an effort to reach more American Indian and Native Alaskan individuals, who live largely in rural and isolated communities, telehealth has become an essential component of the IHS delivery system.[13]

III. ANALYSIS

Telehealth has long been used as a way to ensure that those in remote areas have access to healthcare services.[14] About fifty-four percent of American Indians and Native Alaskans live in rural areas, meaning over half of the population suffers from rural health disparities caused by "geographic isolation, lower socioeconomic status, higher rates of health risk behaviors, limited access to healthcare specialists and subspecialists, and limited job opportunities."[15] As a way to mitigate travel costs and increase access, telehealth has become a crucial part of the IHS's delivery of care.[16] This section will discuss the different efforts made to bring telehealth to Native Americans in rural areas.

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[11] *Fact Sheets, Quick Look*, INDIAN HEALTH SERV., https://www.ihs.gov/newsroom/factsheets/quicklook/ (last visited Feb. 4, 2021).
[12] Smith, *supra* note 5.
[13] Howard Hays et al., *The Success of Telehealth Care in the Indian Health Service*, 16 AM. MED. ASS'N J. OF ETHICS 986, 986 (Dec. 2014); *see also, Telehealth: Defining 21st Century Care,* ATA (2020) ("Telehealth and virtual care can increase access to care for rural communities, underserved and vulnerable patient populations, and to individuals unable to secure in-person care, ensuring that everyone has access to safe, effective, and appropriate care when and where they need it.").
[14] TRACY A. LUSTIG, THE ROLE OF TELEHEALTH IN AN EVOLVING HEALTH CARE ENVIRONMENT: WORKSHOP SUMMARY 6 (National Academic Press Eds. 2012).
[15] Rural Tribal Health, RURAL HEALTH INFO. HUB https://www.ruralhealthinfo.org/topics/rural-tribal-health (last visited Feb. 6, 2021); *Rural Health Disparities*, RURAL HEALTH INFO. HUB https://www.ruralhealthinfo.org/topics/rural-health-disparities (last visited Feb. 6, 2021).
[16] Hays et al., *supra* note 13, at 986.

A. Native American Connectivity Act

In 2004 a bill was introduced to Congress called the Native American Connectivity Act ("NACA").[17] The act was introduced as a way to provide federal grants to tribal governments so they could set up infrastructure to provide telecommunications.[18] The Committee on Indian Affairs noted that at the time only ten percent of families living on tribal lands had access to internet and only around seventy percent had telephone service.[19] Rural Native American households suffered the same deficiencies.[20] NACA was introduced as a way to provide support to these communities.[21]

One of the specific purposes of the bill was to "enhance the health of Indian tribal members through the availability and use of telemedicine and telehealth."[22] The NACA devised a block grant program that would authorize $20 million in 2005 to be appropriated to tribes and organizations whose applications met the necessary criteria."[23] Though this grant program would easily provide assistance to these communities and improve access to healthcare by making telehealth and telemedicine possible, it did not make it past the Senate.[24] It was reintroduced to the 109th Congress in 2005, but once again failed to receive the needed support.[25]

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[17] Native American Connectivity Act, S. 2382, 108th Cong. (2004).
[18] *Id*.
[19] *Id*.
[20] *Id*.
[21] *Id*.
[22] *Id*. at 4.
[23] 14877 1 (2004) To establish grant programs for development of telecommunications capacities in Indian country.
[24] Native American Connectivity Act, S. 2382, 108th Cong. (2004); *S. 2020 (108th): Freedom of Choice Act*, GOVTRACK https://www.govtrack.us/congress/bills/108/s2020 (last visited Mar. 14, 2021).
[25] Native American Connectivity Act, S. 535, 109th Cong. (2005); *S. 535 (109th): Native American Connectivity Act*, GOVTRACK https://www.govtrack.us/congress/bills/109/s535 (last visited Mar. 14, 2021).

B. Rural Health Care Support Mechanism

Though the NACA was unsuccessful, Native Americans living in rural areas could benefit from the Rural Health Care Support Mechanism.[26] The Federal Communications Commission ("FCC") selects applications for their Rural Health Care ("RHC") Pilot Program meant to create infrastructure necessary to support telehealth.[27] A significant amount of applicants to the Pilot Program (hereafter "the Program") were Native American communities.[28] The FCC recognized that tribal lands traditionally have inadequate access to care and the lowest levels of telecommunication services.[29] This made them prime candidates for the Program.

One example of the Program in action is the Health Care Research and Education Network, meant to serve a large population of Native Americans.[30] This Network plans to use its grant to facilitate health care delivery to underserved, rural Native American communities.[31] In doing so, and expanding access to care the Program could, in turn, relieve some of the health disparities that plague these communities.[32]

In 2013, the FCC reformed the Pilot into the Health Care Connect Fund.[33] The revision expanded access to broadband for health care providers.[34] Part of this involved consulting with the IHS to help incorporate broadband, specifically in the way of collection of data from providers electronically.[35] The Health Care Connect Fund goes as far as to mention that it will not preclude the IHS from receiving support because its core purpose is to reach

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[26] *Id.* (showing that NACA was unsuccessful in Congress); Rural Health Care Support Mechanism 71 Fed. Reg. 65,517 (Nov. 8, 2006).
[27] Rural Health Care Support Mechanism, 73 Fed. Reg. 8670, 8670 (Feb. 14, 2008).
[28] *Id*.
[29] *Id*.
[30] *Id*.
[31] *Id*.
[32] *Id*.
[33] Rural Health Care Support Mechanism, 47 C.F.R. Part 54 (2013).
[34] *Id*.
[35] *Id*.

underserved populations.[36] This was a meaningful step towards improving access to care for Native American communities.

C. Affordable Care Act

One of the primary goals of the Patient Protection and Affordable Care Act ("ACA") is increasing access to healthcare.[37] Consistent with this theme the ACA permanently reauthorized the Indian Health Care Improvement Act ("IHCIA").[38] The IHCIA is essentially a "statutory foundation for the provision of health care to American Indians and Alaska Natives."[39] In its reinstatement, there were certain modifications made to the IHCIA to improve access to healthcare for American Indians and Alaskan Natives.[40] As it pertains to telehealth there are two relevant sections: the Indian Health Care Improvement Fund and the Indian Youth Telemental Health Demonstration Project.[41]

The goal of the Indian Health Care Improvement Fund ("IHCIF") is to help eliminate disparities in health status and resources in American Indian and Native Alaskan communities in order to make them more equitable.[42] In the interest of meeting this goal, IHCIF authorizes the Secretary to appropriate funds to "[meet] the health needs of Indians in an efficient and

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[36] *Id*.
[37] David Blumenthal et al., *The Affordable Care Act at 10 Years: What's the Effect on Health Care Coverage and Access?*, COMMONWEALTH FUND (Feb. 26, 2020) https://www.commonwealthfund.org/publications/journal-article/2020/feb/aca-at-10-years-effect-health-care-coverage-access.
[38] Donald Warne & Linda Bane Frizzel, *American Indian Health Policy: Historical Trends and Contemporary Issues*, 104(53) Am. J. Pub. Health S263, S265 (2014).
[39] Indian Health Care Improvement Act: Basics 101, TRIBAL HEALTH REFORM RESOURCE CTR., https://www.nihb.org/tribalhealthreform/ihcia/ (last visited Feb. 5, 2021).
[40] *See generally* 25 U.S.C. §1641–47d (2010) (discussing the changes made to the IHCIA in order to improve access to care for Native Americans).
[41] 25 U.S.C. §§ 1621, 1667b (2010).
[42] ELAYNE J. HEISLER, CONG. RSCH. SERV., R41630, THE INDIAN HEALTH CARE IMPROVEMENT ACT REAUTHORIZATION AND EXTENSION AS ENACTED BY THE ACA: DETAILED SUMMARY AND TIMELINE 7 (2014).

equitable manner, including the use of telehealth and telemedicine when appropriate."[43]

The Indian Youth Telemental Demonstration Project improves access to care, specifically youths, whose mental health is suffering.[44] Young American Indians and Alaska Natives experience disproportionately high rates of mental illnesses.[45] This program provides grants to Indian Healthcare Programs with telehealth capabilities.[46] In doing so it is able to expand access to Native American and Alaska Native youths needing suicide prevention and treatment.[47]

Through these provisions, the ACA explicitly improves Native Americans' access to health care.

IV. IMPACT

The aforementioned programs and Acts were created to increase access to healthcare to Native American populations, but the question remains as to whether or not these provisions truly made a real change to these underserved communities. Unfortunately, there are still remarkable gaps in healthcare for American Indians and Alaska Natives.[48] This is partially due to a lack of funding to the IHS.[49] Aside from underfunding, access to care remains a major issue in these communities who sometimes have to travel hours to

[43] 25 U.S.C. § 1621(a)(3) (2010).
[44] Heisler, *supra* note 42, at 28.
[45] *Native American Youth Depression and Suicide*, CHILD WELFARE INFO. GATEWAY https://www.childwelfare.gov/topics/systemwide/diverse-populations/american indian/mentalhealth/depression/ (last visited Feb. 5, 2021).
[46] Heisler, *supra* note 42, at 28.
[47] 25 U.S.C. § 1667b(c)(1)(B)(ii).
[48] Misha Friedman, *For Native Americans, Health Care is a Long, Hard Road Away*, NPR (Apr. 13, 2016) https://www.npr.org/sections/health-shots/2016/04/13/473848341/health-care-s-hard-realities-on-the-reservation-a-photo-essay.
[49] *Id.*

reach the necessary health care facilities.[50] That being said there have been a few successes regarding expansion of care.[51]

The Alaska Tribal Health system has long relied on telehealth.[52] One of its programs, the Alaska Federal Health Care Access Network, has 250 sites working to improve access to care for Alaska Natives.[53] Using this Network over seventy percent of ear, nose and throat consultations have been conducted via telehealth, which saved between $8 million and $10 million in travel costs for patients and greatly reduced wait times.[54] These metrics have allowed for greater in-person visits and expedited consultations which allow more timely access to care.[55]

Another success comes from teleophthalmology.[56] Diabetes is highly prevalent in American Indian and Alaska Native communities.[57] Those with diabetes are meant to get an annual exam to check for diabetic retinopathy, a condition that can lead to blindness.[58] These exams are often not completed due to problems involving access to care.[59] The IHS implemented the Joslin Vision Network ("JVN"), a Network that allows these exams to be done virtually through teleophthalmology.[60] This telehealth option has increased exam rates by nearly twenty percent and almost doubled patient compliance with the diabetic retinopathy care standards.[61]

Multiple disciplines have integrated telehealth as a way to improve access to care for American Indians and Alaska Natives.[62] By collaborating with

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[50] *Id.*
[51] Smith, *supra* note 5.
[52] Hays et al., *supra* note 13, at 987.
[53] *Id.*
[54] *Id.* at 988.
[55] *Id.* at 987.
[56] *Id.* at 990.
[57] *Id.*
[58] *Id.*
[59] *Id.*
[60] *Id.* at 991.
[61] *Id.* at 991–92.
[62] Neil Schoenbach, *Telemedicine in Native American Tribes*, GLOBALMED (Nov. 2, 2019) https://www.globalmed.com/telemedicine-in-native-american-tribes/ ("Currently IHS and

different health care facilities, telehealth programs have made life-changing strides.[63] Care Beyond Walls and Wires, a program helping Native Americans suffering from chronic diseases, remotely monitored patients' vitals.[64] In doing so the program was able to decrease hospital stays, lower hospital charges and improve overall satisfaction, all by making it easier for Native Americans living in remote areas to monitor their conditions.[65]

These are all clear benefits of telehealth, but they fail to tell the whole story. The fact is access is still a major issue in Native American communities.[66] Only about ten percent of tribal lands have proper access to broadband.[67] Cultural views towards technology must be carefully balanced with these technological improvements in order for them to be truly effective.[68] Education, both on part of these communities and those trying to promote telehealth, plays a major role in its success.[69] If the needs of these local Native American communities are properly implemented into the telehealth system it is likely that usage will expand and improve.[70]

Even with expansion and improvement of telehealth, the fact is for the 2.2 million Native Americans still living in rural areas, geography remains a major obstacle when it comes to access to care.[71] Even those who live in more

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tribal clinics use telehealth for a range of disciplines: behavioral health, dermatology, cardiology, maternal health, nephrology, rheumatology, endocrinology, infectious diseases and more.").

[63] *Id.*

[64] *Id.*

[65] *See generally* Care Beyond Walls and Wires, Using Remote Monitoring to Enhance Patient Care, QUALCOMM WIRELESS REACH (2017) https://www.qualcomm.com/media/documents/files/united-states-care-beyond-walls-and-wires.pdf (showing data regarding the benefits of telehealth).

[66] Clemens Scott Kruse et al., *Telemedicine Use in Rural Native American Communities in the Era of the ACA: A Systematic Literature Review*, 40(6) J. Med. Sys. 1, 1 (2016).

[67] *Id.* at 7.

[68] *Id.*at 7.

[69] *Id.* at 8.

[70] *Id.*

[71] Allison Barlow & Laura Hammit, *What we can Learn from the First Peoples of the United States in the era of COVID-19*, HILL (May 6, 2020) https://thehill.com/opinion/civil-rights/496470-what-we-can-learn-from-the-first-peoples-of-the-united-states-in-the-era.

urban areas struggle with access.[72] It is rare that health care providers outside the IHS see Native American patients because of barriers that make it difficult for these populations to access care in the private sector.[73] The underfunding of the IHS and the lack of federal compensation for private care need to be addressed for access problems to have a legitimate chance at improvement.[74]

Only one in three American Indians and Alaska Natives have private healthcare, meaning the remaining uninsured rely heavily upon the IHS.[75] That being said, the annual per capita spending by the IHS is less than half that of the general population and substantially lower than other federally funded programs.[76] This widening gap is just one of the underlying causes of health disparities among these communities.[77] It remains at issue because federal spending on American Indian and Alaska Native's healthcare is largely discretionary.[78]

The issue of underfunding was moderately improved by the IHCIF, however, the IHS does not receive IHCIF funding every year.[79] The last

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[72] *See* Hilary N. Weaver, *Urban and Indigenous: The Challenge of Being a Native American in the City*, 20(4) J. OF CMTY. PRAC. 470, 470 (2021) ("Urban Native Americans often experience significant social, health, and economic problems while having access to substantially fewer Native-specific resources than their reservation-based counterparts.").
[73] Eric Whitney, *Native Americans Feel Invisible in U.S. Health Care System*, NPR (Dec. 12, 2017) https://www.npr.org/sections/health-shots/2017/12/12/569910574/native-americans-feel-invisible-in-u-s-health-care-system.
[74] *Id.*
[75] JENNIE R. JOE, UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN HEALTH CARE, 529 (Brian D. Smedley, Adrienne Y. Stith & Alan R. Nelson eds., 2003).
[76] *See id.* at 530 ("The IHS annual per capita healthcare spending at $1430 is less than one-half that for the general U.S. population ($3766). This IHS per capita spending is also substantially lower than that for Medicare ($3369); Bureau of Prisons ($3489); and Veterans' Administration ($5458) (FCNL, 2000).").
[77] *Id.*
[78] *Id.* at 532 ("Because federal funding for Indian healthcare has historically been discretionary, improvement in healthcare resources for American Indians/Alaska Natives has continued to be piecemeal and void of consistent long- range planning.").
[79] Indian Health Care Improvement Act, 25 U.S.C. § 1621 (1976); *General Questions*, INDIAN HEALTH CARE IMPROVEMENT FUND https://www.ihs.gov/ihcif/ihcif-consultation/ (last visited Mar. 15, 2021).

funding was $72 million appropriated in 2018.[80] This brought third-party collections on the IHS to $1.09 billion in 2018, with an initial budget appropriation of $5.5 billion.[81] This is for 2.2 million users.[82] This notorious lack of funding leads to limited staff, limited services offered, and limited access to services.[83]

Even with the rise of telehealth making care more accessible to marginalized communities, until Congress appropriates funds to this program, American Indians and Alaska Natives will suffer the consequences.[84] The Government needs to invest in the health of these tribal communities and the first step is addressing these challenges and appropriating the funds suitable to care for the health and well-being of this population.[85]

This step could be taken in a handful of ways. One being to modify the federal spending scheme to make it possible for the IHS to receive IHCIF funding annually, which can be done by modifying the current discretionary spending scheme.[86] The President's budget outlines the amount of funding recommended for each program.[87] It is possible to propose that the current appropriations to IHS and other American Indian and Alaska Native healthcare need to be revised.[88] With the current changes in the political climate of the United States, it is more likely that these social programs will

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[80] *General Questions*, *supra* note 79.
[81] *IHS Profile*, INDIAN HEALTH SERV. https://www.ihs.gov/newsroom/factsheets/ihsprofile/ (Aug. 2020).
[82] *Fact Sheets, Quick Look*, *supra* note 11.
[83] Joe, *supra* note 75.
[84] Smith, *supra* note 5.
[85] *Id*.
[86] *See generally, Policy Basics: Introduction to the Federal Budget Process*, CTR ON BUDGET AND POL'Y PRIORITIES https://www.cbpp.org/research/introduction-to-the-federal-budget-process (Apr. 2, 2020) (discussing the different ways in which Congress makes spending decisions each year).
[87] *Id.*
[88] Niv Elis, *Biden $1.5T Budget Proposes Major Hike in Social Programs*, HILL https://thehill.com/policy/finance/547341-biden-15t-budget-proposes-major-hike-in-social-programs (Apr. 9, 2021) ("The White House pointed to significant proposed spending increases in programs it said would make the country healthier and more equal...".).

get much-needed attention.[89] Using this momentum would be an attractive opportunity to bring light to the underfunding issue and take this initial step towards mitigating the challenges and barriers the American Indian and Alaska Native communities face in regard to their health and well-being.

V. CONCLUSION

Native Americans have historically lacked proper access to health care.[90] With shorter life expectancy, and higher rates of diabetes, suicide, chronic liver disease and more, Native Americans are a highly vulnerable population.[91] Though American Indians and Alaska Natives experience poorer health outcomes than the general population, they face greater access issues.[92]

The IHS was created as a way to deliver health care services to Native Americans but it remains highly underfunded.[93] As a way to cut costs and improve access, telehealth has become a staple in these communities.[94] Over the years there have been a few interventions by the Federal Government to help provide the infrastructure to rural Native American and tribal communities to allow for telehealth.[95] These interventions have allowed for a multitude of different disciplines to improve care outcomes through telehealth.[96]

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[89] *Id.*
[90] Smith, *supra* note 5.
[91] *See* Arnav Shah et al., *The Challenge of COVID-19 and American Indian Health*, COMMONWEALTH FUND (Aug. 12, 2020) https://www.commonwealthfund.org/blog/2020/challenge-covid-19-and-american-indian-health ("American Indians die at higher rates from chronic liver disease and cirrhosis, type 2 diabetes, unintentional injuries, assault/homicide, and self-harm or suicide.").
[92] *Id.*
[93] Friedman, *supra* note 48.
[94] Hays et al., *supra* note 13 at 986.
[95] *See supra* note 66, at 7 (discussing the different interventions the Government has implemented or attempted to implement over the years).
[96] *See generally* Hays et al., *supra* note 13 (noting the different ways telehealth has been used to improve health outcomes over the years).

Even with these successes, several barriers remain.[97] Access to internet continues to be an issue.[98] Beyond access, there are cultural opinions regarding technology that bring an air of skepticism.[99] Access to care can be mitigated by telehealth but only to an extent. Without proper funding and attention to the cultural and structural barriers, access will always remain a disparity in the Native American community.

[97] *See generally,* Kaitlynn Ely, *Addressing Determinants of Health and Barriers to Care for Native Americans*, AMJC (Feb. 11, 2018) https://www.ajmc.com/view/addressing-determinants-of-health-and-barriers-to-care-for-native-americans (discussing barriers that plague Native American access to care in the United States).
[98] Kruse et al., *supra* note 67, at 7.
[99] *Id.* at 8.

Those Caught in Between: Why the Government Must Safeguard the Patients Who Rely on Independent Charity Patient Assistance Programs

Tom Saviski

I. INTRODUCTION

Independent Charity Patient Assistance Programs ("PAPs") are programs operated by charitable entities separate from pharmaceutical manufacturers which serve to provide financial assistance to patients who struggle to afford their premiums or cost-sharing obligations.[1] Since 2015, large drug manufacturers have been subject to lawsuits by the Department of Justice ("DOJ") under the Anti-Kickback Statute ("AKS"), which prohibits the knowing and willful payment of remuneration to induce the generation of business involving any item payable by the Federal health care programs.[2] These suits have come about because these manufacturers use PAPs to induce Medicare beneficiaries to use their drugs by covering the patients' cost-sharing obligations for the manufacturer's products yet providing no such coverage for low-cost generic drugs which serve an equivalent purpose.[3] These now-common lawsuits can result in multi-million dollar settlements,[4]

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[1] John C. Hood, *Are Good Deeds Being Punished?: Independent Charity Patient Assistance Programs and the Anti-Kickback Statute*, 72 FLA. L. REV. 639, 645 (2020).
[2] 42 U.S.C. § 1320a-7b(b) (2018).
[3] Press Release, Off. of Pub. Affrs., Dep't of Just., United States Files False Claims Act Complaint Against Drug Maker Teva Pharmaceuticals Alleging Illegal Kickbacks (Aug. 23, 2020), https://www.justice.gov/opa/pr/united-states-files-false-claims-act-complaint-against-drug-maker-teva-pharmaceuticals; Press Release, Off. of Pub. Affrs., Dep't of Just., Drug Maker Pfizer Agrees to Pay $23.85 Million to Resolve False Claims Act Liability for Paying Kickbacks (May 24, 2018), https://www.justice.gov/opa/pr/drug-maker-pfizer-agrees-pay-2385-million-resolve-false-claims-act-liability-paying-kickbacks.
[4] Press Release, Office of Pub. Affrs., Dep't of Just., Drug Maker United Therapeutics Agrees to Pay $210 Million to Resolve False Claims Act Liability for Paying Kickbacks

and often include Corporate Integrity Agreements ("CIAs"), which bind the offending drug manufacturer for a limited period of time to the U.S. Department of Health & Human Services Office of Inspector General's ("OIG") terms.[5]

In 2014, the OIG signaled its intent to safeguard Medicare from manufacturers who attracted Part D enrollees to their products by using Independent Charity PAPs to subsidize copays, then raising the prices of those drugs.[6] The increase in prices resulted in greater costs for low-income and uninsured patients and acted as a serious barrier to healthcare access, especially for people of color, who are over-represented in these groups.[7] While it seems just to reduce pharmaceutical companies' manipulation of prices at the expense of insurance providers, a significant portion of people who use PAPs rely on their support for vital medications.[8] As industry use of Independent Charity PAPs declines in response to prosecution,[9] the OIG must ensure that those who rely on PAPs to afford their copays are not deprived of access to their medication. To avoid or minimize such

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(Dec. 20, 2017), https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability.

[5] Kaitlyn Moseley & Jesse Witten, *HHS-OIG: Pharma Manufacturer's Proposed Copayment Assistance Program 'Highly Suspect' Under Federal Anti-Kickback Statute*, JDSUPRA (Oct. 2, 2020), https://www.jdsupra.com/legalnews/hhs-oig-pharma-manufacturer-s-proposed-99577/.

[6] Office of Inspector Gen., Dep't of Health and Hum. Servs., Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31,120, 31,120 (May 30, 2014); Tino Illiparambil, *Pharmaceutical Philanthropy or Resisting Regulations?: Why Pharmaceutical Donations Do Not Violate the Anti-Kickback Statute*, 85 BROOK. L. REV. 571, 591-92 (2020).

[7] *See generally* Gery P. Guy Jr., *The Effects of Cost Sharing on Access to Care Among Childless* Adults, 45(6 Pt 1) HEALTH SERV. RSCH. 1720, 1721-23, PMC3026955 (Dec. 2010) (higher cost sharing leads to barriers in access and higher rates of unmet medical need, particularly among low-income individuals); *see also* John Creamer, *Inequalities Persist Despite Decline in Poverty for All Major Race and Hispanic Origin Groups*, (Sept. 15, 2020), https://www.census.gov/library/stories/2020/09/poverty-rates-for-blacks-and-hispanics-reached-historic-lows-in-2019.html.

[8] Michelle Huntsman, *Kicking Costs Back to Patients: How Regulatory Scrutiny of Patient Assistance Programs Will Affect Patients' Wallets*, J. HEALTH CARE COMPLIANCE, July--Aug. 2018, at 27.

[9] Hood, *supra* note 1, at 666.

deprivations is important so pre-existing racial disparities in access to healthcare, particularly patient adherence to a medication regimen, are not exacerbated by this policy shift by leaving these patients without a means to afford their cost-sharing obligations.[10] The government must ensure that it does not exacerbate existing racial disparities by leaving behind those who depend on PAPs for copay coverage without providing a suitable replacement.

To minimize adverse effects on low-income racial minorities, the government should preserve this economic safety net as much as is reasonably possible without rendering its actions toothless. As such, the OIG should not entirely eliminate patient assistance programs, but instead should provide tighter regulations to ensure transparency in what types of treatments their programs cover and why, and to guarantee coverage of all suitable versions of a treatment with priority towards low-cost generics. The OIG may achieve this by requiring PAPs to submit to regular audits of their operations by independent review organizations to certify compliance with the AKS, similar to the provisions already in place in the CIAs applied to manufacturers in settlements.[11] This policy could greatly reduce the risk of fraud without forcing underserved communities to foot the bill and worsening racial disparities in access to medication.

While overarching legislation could remedy the loss of a safety net, this article will discuss actions that are currently within the OIG's authority. In doing so, this article will demonstrate how high out-of-pocket expenses have an outsized effect on racial minorities. Next, this article will elaborate on the OIG's duty to minimize barriers to racial minorities' healthcare access that it may cause by regulating Independent Charity PAPs. Finally, this article will

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[10] *Id.* at 645.
[11] Scott Liebman et al., *Scrutiny of Patient Assistance Program Funding is Rising*¸ LAW360 (Dec. 5, 2019), https://www.law360.com/articles/1225231/scrutiny-of-patient-assistance-program-funding-is-rising.

argue that the OIG can minimize deprivations by tightening regulations applicable to Independent Charity PAPs, requiring the charities to make public disclosures of how their funds are used, requiring them to cover low-cost generic medications, and allowing them to certify compliance with the AKS through regular audits by independent review organizations.

II. Background

An Independent Charity PAP are programs operated by 501(c)(3) organizations that provides payment assistance for the copays of patients in need.[12] These entities provide co-pay assistance to a variety of specialty drugs which can vary in size, the disease they focus on, and what other forms of aid they provide.[13] To this end, PAPs are notoriously opaque as to the dollar amounts of co-pay assistance provided to patients, the amount of patient drug use induced by these programs, and how these programs make coverage decisions upon receipt of patient applications.[14] This distinct lack of transparency has prevented researchers from fully evaluating the structure and efficacy of these programs.[15] Nonetheless, PAPs frame themselves as providing critical relief to patients "who make too much money to qualify for a free drug program," but remain unable to afford expensive copays.[16]

While there are PAPs directly affiliated with pharmaceutical manufacturers, Independent Charity PAPs are supposed to remain separate from pharmaceutical manufacturers and insulated from their influence.[17] However, Independent Charity PAPs are generally funded by contributions from pharmaceutical manufacturers, and there are reports indicating that

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[12] Hood, *supra* note 1, at 643-44
[13] *Id.* at 646-47.
[14] So-Yeon Kang et al., *Financial Eligibility Criteria and Medication Coverage for Independent Charity Patient Assistance Programs*, 322 JAMA 422, 427 (2019).
[15] *Id.*
[16] *Id.* at 645; Rebecca E. Wolitz, *A Corporate Duty to Rescue: Biopharmaceutical Companies and Access to Medications*, 94 IND. L.J. 1163, 1199 (2019).
[17] Hood, *supra* note 1, at 643.

these entities directly solicit donations from these manufacturers.[18] Manufacturers will then use these PAPs as conduits for kickbacks, encouraging narrow conditions for coverage to ensure that their products are the only ones eligible for financial assistance.[19] The result is that when freed from cost-sharing, patients will opt for their drug regardless of the price borne by insurers or the general population.[20] Despite the payments a company must make to a PAP to cover patient copays, the increased revenue from raising prices to insurers like Medicare still results in a net profit for the manufacturer.[21]

In 2015, the DOJ began scrutinizing donations from manufacturers to Independent Charity PAPs.[22] In doing so, it took the stance that pharmaceutical companies' donations to PAPs were AKS violations by acting as indirect payments of remuneration in the form of copay assistance to induce patients into purchasing their brand of drug.[23] As of September 2020, this policy has led to over a billion dollars in damages from eleven pharmaceutical companies and four Independent Charity PAPs.[24] These settlements often come with extensive Corporate Integrity Agreements ("CIAs"). In the case of Pfizer's CIA, the manufacturer was required to

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[18] *Id*. at 649-50; Scott Liebman et al., *Scrutiny of Patient Assistance Program Funding is Rising*, LAW360 (Dec. 5, 2019), https://www.law360.com/articles/1225231/scrutiny-of-patient-assistance-program-funding-is-rising.
[19] Brett Friedman et al., *Emerging Enforcement Trends for Patient Support Programs,* LAW360 (May 16, 2018), https://www.law360.com/health/articles/1042623/emerging-enforcement-trends-for-patient-support-programs; *see also* Hood, *supra* note 1, at 649.
[20] Hood, *supra* note 1, at 650.
[21] *See* David H. Howard, *Drug Companies' Patient-Assistance Programs--Helping Patients or Profits?*, 371 NEW ENG. J. MED. 97, 98 (2014) (explaining how the costs of funds that manufacturers contribute to PAPs are offset by the manufacturers' ability to raise drug prices with insurers like Medicare bearing the costs).
[22] Hood, *supra* note 1, at 652
[23] Hood, *supra* note 1, at 652-53; Illiparambil, *supra* note 6, at 591-92; Friedman et al., *supra* note 19.
[24] Hood, *supra* note 1, at 652; Press Release, Off. of Pub. Affrs., Dep't of Just. Gilead Agrees to Pay $97 Million to Resolve Allegations that it Paid Kickbacks through a Co-Pay Foundation (Sep. 23, 2020), https://www.justice.gov/usao-ma/pr/gilead-agrees-pay-97-million-resolve-allegations-it-paid-kickbacks-through-co-pay.

establish a compliance program to ensure that charitable donations were only made by authorized personnel in adherence to OIG guidance.[25]

III. THOSE CAUGHT IN BETWEEN

The ruling in *United States v. Greber* is central to the AKS, as it established the "one purpose" rule.[26] This rule states that if any purpose behind an action is to induce referrals, the whole action violates the statute.[27] While this rule enables the OIG to safeguard the Federal Healthcare system against fraud, it does not address how to handle patients who were reliant on the financial assistance provided by PAPs, and are now without their primary means of accessing healthcare.[28] Thus, the benefits in preventing manufacturer kickbacks caused by Independent Charity PAPs go primarily to insurers and do not immediately transfer to patients who have relied on the cost-sharing support provided by these PAPs as prices continue to rise.[29]

One area of concern is the risk that removing the PAPs safety net poses in light of an affordability crisis.[30] Increased healthcare costs pose a risk to low-income racial minorities who already face high barriers to medication access and adherence to medication regimens.[31] As the poverty rates for racial minorities are generally higher than non-Hispanic whites, the loss of cost-

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[25] *See Generally* DEP'T OF HEALTH AND HUM. SERVS., CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF THE INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND PFIZER INC. (effective May 23, 2018) (setting forth terms which Pfizer's compliance program must be in accordance with as of the effective date of its agreement with the OIG).
[26] United States v. Greber, 760 F.2d 68, 72 (3d Cir. 1985).
[27] *Id*.
[28] Hood *supra* note 1, at 642-43
[29] Jeff Lagasse, *Drug Prices Rose Three Times Faster Than Inflation Over the Last Decade, Even After Discounts,* HEALTHCARE FINANCE NEWS, (Mar. 4, 2020), https://www.healthcarefinancenews.com/news/drug-prices-rose-three-times-faster-inflation-over-last-decade-even-after-discounts.
[30] Illiparambil, *supra* note 6, at 591-93.
[31] JAMILA TAYLOR, THE CENTURY FOUND., RACISM, INEQUALITY, AND HEALTH CARE FOR AFRICAN AMERICANS, 1, 10-11 (Dec. 19, 2019) https://tcf.org/content/report/racism-inequality-health-care-african-americans/.

sharing support will disproportionately affect these groups.[32] In addition, low-income minorities are often forced to decide between paying for healthcare or covering expenses like groceries or rent.[33] Further, older white adults are slightly over twice as likely as older Black and Hispanic adults to have supplemental private insurance to cover out-of-pocket expenses.[34] Likewise, the average rate of medication adherence in the Hispanic and African-American populations on private insurance plans is around 4.8 to 6.5% lower than Non-Hispanic whites.[35] This issue is compounded by data indicating that nonwhite patients have higher incidences of all the major causes of death compared to white patients. These causes of death include heart disease, stroke, cancer, asthma, diabetes, and HIV/AIDS, all of which can require expensive medication as a necessary part of treatment.[36] Depriving these patients of a means to cover out-of-pocket medication

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[32] *See* Ruben Castenada, How Being Black in America is Bad for Your Health, U.S. NEWS WORLD REP., (July 26, 2018), https://health.usnews.com/wellness/articles/2018-07-26/how-being-black-in-america-is-bad-for-your-health (illustrating the disparate health outcomes that poor and working-class Black people face in the U.S. as a result of structural issues like barriers to health care); Panel on Race, Ethnicity, and Health in Later Life, Nat'l Rsch. Council of the Nat'l Acads., Understanding Racial and Ethnic Differences in Health in Late Life pages (Rodolfo A. Bulatao & Norman B. Anderson, eds. 2004), https://www.ncbi.nlm.nih.gov/books/NBK24693/ (herein "National Research Council Panel on Race"); Ben Gerber et al., *Racial Differences in Medications Adherence: A Cross-Sectional Study of Medicare Enrollees*, 8 AM. J. GERIATR PHARMACOTHER at 136 (Apr. 8, 2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3740123/pdf/nihms494261.pdf.

[33] CURRENT POPULATIONS REPORTS, INCOME AND POVERTY IN THE UNITED STATES: 2017, U.S. CENSUS BUREAU, (2018), https://www.census.gov/content/dam/Census/library/publications/2018/demo/p60-263.pdf.

[34] National Research Council Panel on Race, *supra* note 32; *see also* Castenada, *supra* note 32.

[35]Gerber et al., *supra* note 32; Zhiwen Xie et al., *Racial and Ethnic Disparities in Medication Adherence Among Privately Insured Patients in the United States*, 14 PLOS ONE 1, 5 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6375669/.

[36] *See* Sofia Carratala & Connor Maxwell, *Health Disparities by Race and Ethnicity Fact Sheet*, 1-6 (2020), (discussing health disparities by race and ethnicity); *see* Becky Briesacher et al., *Racial and Ethnic Disparities in Prescription Coverage and Medication Use*, 25 HEALTH CARE FIN. REV. 63, 63-76 (Winter 2003-04), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4194807/ (examining Black and Hispanic Medicare beneficiaries' access to prescribed drugs for chronic conditions).

expenses would worsen existing racial disparities by burdening these patients with greater barriers to accessing their prescriptions.[37]

IV. AN OBLIGATION TO PRESERVE ACCESS TO HEALTH CARE

While the OIG's scrutiny of Independent Charity PAPs and pharmaceutical manufacturers for AKS violations is within its authority,[38] it must consider how discouraging charities, fearful of expensive litigation,[39] from continuing their operation of the programs these patients rely on for financial assistance may hinder these patients' access to medication.

As they currently operate, Independent Charity PAPs raise prices to the benefit of pharmaceutical companies without considering how rising prices may affect a community's ability to access its medications.[40] Nonetheless, Independent Charity PAPs have positioned themselves as a de facto safety net for patients unable to afford their cost-sharing obligations.[41] To this end, it has been argued that the OIG's aggressive enforcement of the AKS, which cost eight drug companies over $645 million dollars combined in 2019 alone,[42] has a chilling effect on both charities and donors at the expense of vulnerable patients.[43] Thus, regulating PAPs in a manner that would strip vulnerable communities of a lifeline. However, permitting PAPs to exist as proxies for manufacturer kickbacks only worsens a primary barrier to equal healthcare access—high cost.[44] As it works to end the use of Independent

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[37] Hood, *supra* note 1, at 642.
[38] *See Generally,* Inspector General Act of 1978, 5a U.S.C. § 4; *About OIG*, HHS-OIG, https://oig.hhs.gov/about-oig/.
[39] Hood, *supra* note 1, at 641.
[40] Howard, *supra* note 21, at 98.
[41] Wolitz, *supra* note 16, at 1199.
[42] Scott Liebman et al., *Scrutiny of Patient Assistance Program Funding is Rising*¸ LAW360 (Dec. 5, 2019), https://www.law360.com/articles/1225231/scrutiny-of-patient-assistance-program-funding-is-rising.
[43] Hood, *supra* note 1, at 641.
[44] Off. of Disease Prevention & Health Promotion, *Access to Health Services*, HEALTHY PEOPLE 2020, https://www.healthypeople.gov/2020/topics-objectives/topic/Access-to-Health-Services (last visited Feb. 14, 2021).

Charity PAPs as vehicles for kickbacks, the OIG must preserve the safety net PAPs provide to ensure that it does not worsen racial disparities in medication access. To this end, the OIG should make AKS compliance terms clearer by further tightening regulations on PAPs and requiring transparency in the source and use of donations, mandating coverage of low-cost generics, and allowing certifications of compliance by third party auditors such as independent review organizations.

V. TRANSPARENCY IN DONATIONS

Information transparency is crucial for effective medical treatment, yet information surrounding Independent Charity PAPs funds and their uses remains unacceptably opaque.[45] Requiring greater transparency grants the OIG more certainty that a PAP will comply with regulations and will enable the agency to set clearer standards for what constitutes an AKS violation as greater transparency requirements allows for more to be data available as to PAPs' donation sources, patient application processes, and reasoning for their criteria for which drugs are eligible for copay-assistance.[46] These requirements may allow the OIG to better pinpoint the practices or organizational structures that allow manufacturers to use PAPs as conduits for kickbacks.[47] A key criticism of the OIG's 2014 special guidance bulletin is that it still enables PAPs to operate with little transparency as to which drugs are eligible under their program.[48]

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[45] Kang et al., *supra* note 14, at 427, SUZANNE M. KIRCHHOFF, CONG. RSCH. SERV., R44264, PRESCRIPTION DRUG DISCOUNT COUPONS & PATIENT ASSISTANCE PROGRAMS (PAPS) 1, 22 (Updated June 15, 2017).
[46] *Id*; Letter from Elizabeth Warren, U.S. Sen., and Sheldon Whitehouse, U.S. Sen., to Joanne Chiedi, Acting Insp. Gen., Dep't Health & Human Servs., 3 (Dec. 4, 2019), https://www.warren.senate.gov/imo/media/doc/2019.12.04%20Letter%20to%20HHS-OIG%20re%20patient%20assistance%20programs.pdf.
[47] Warren and Whitehouse, *supra* note 46, at 3.
[48] Kang et al., *supra* note 14, at 427.

This distinct lack of transparency makes academic research on the effects of PAPs more difficult, leaving regulators with less material available to make an informed decision on the matter.[49] A 2019 study by the Journal of the American Medical Association required a complex method of manual searching through a database of general nonprofit organizations to merely identify Independent Charity PAPs, since no central database or systematic studies exist for PAPs.[50] Likewise, information regarding which drugs a PAP covers or how much funding a PAP receives often goes undisclosed, which limits researchers' ability to analyze them empirically.[51] Inaccessibility of information contributes to the distrust that the general population, and racial minorities in particular, has in the healthcare system as a whole, often translating into less frequent healthcare use.[52] Requiring these foundations to publicly disclose the sources of funding for their PAPs and any conditions that may come with such funding may enable medical academia to properly examine the true effect these programs have on access to healthcare.

Similarly, a Congressional Research Service report found that the lack of transparency makes it difficult to determine the actual effectiveness of PAPs in aiding patients access their medications.[53] Public disclosure will make proving AKS violations significantly easier and faster, and will drastically increase the risk and cost of litigation borne by ill-intentioned manufacturers.[54] Compare similar applications of greater information transparency regarding medical malpractice through communication-and-resolution programs: swift disclosures of harm, commitment to investigating

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[49] *Id.*
[50] *Id*.
[51] *Id*.
[52] Katrina Armstrong et al., *Racial/Ethnic Differences in Physician Distrust in the United States*, 97(7) AM. J. PUB. HEALTH 1283, 1287 (Jul. 2007); Gary S. Kaplan, *Building a Culture of Transparency in Health* Care, HARVARD BUS. REV. (Nov. 2018)
[53] Kirchhoff, *supra* note 45, at 22.
[54] Warren and Whitehouse, *supra* note 46, at 3.

the root cause of harm, and compensation for violations.[55] This transparency has facilitated the early resolution of disputes.[56] Thus, requiring Independent Charity PAPs to publicly disclose what treatments they cover and to explain why other effective treatments are not covered may expose kickback schemes by preventing PAPs from hiding facts material to the OIG's determination, as had been the case with the now-rescinded Advisory Opinion No. 06-04.[57] The OIG should set standards defining sufficient justifications for not covering an FDA-approved treatment to aid well-intentioned PAPs' decision-making processes. Such disclosures would also allow pharmaceutical manufacturers to make tax-deductible charitable contributions to PAPs without fear of a lawsuit, while also preventing them from using those contributions for kickback schemes. This may serve to deter the troublesome practice of manipulating prices.

VI. INDEPENDENT CHARITY PAPS MUST PROVIDE SUPPORT FOR GENERICS

Manufacturers' main price-raising method is narrowing the criteria the PAP uses to provide cost-sharing assistance to such a degree that only patients who opt for their specific brand will receive said assistance.[58] The OIG has addressed this concern in previous bulletins, requiring that all Independent Charity PAPs: 1) refrain from narrowing the definition of widely recognized disease states; 2) refrain from maintaining any disease fund providing assistance for copays for a single drug or the drugs of a single manufacturer; and 3) refrain from limiting assistance to high-cost or specialty

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[55] Chih-Ming Liang*, Rethinking the Tort Liability System and Patient Safety: From the Conventional Wisdom to Learning from Litigation,* 12 IND. HEALTH L. REV. 327, 361-63 (2014).
[56] *Id.*
[57] Office of the Inspector Gen., U.S. Dep't of Health & Human Servs., Final Notice of Rescission of OIG Advisory Opinion No. 06-04 (Nov. 28, 2017) https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpnRescission06-04.pdf.
[58] Friedman et al., *supra* note 19; Kang et al., *supra* note 14, at 423.

products, but rather provide assistance for all products covered by Medicare or other insurers prescribed for treatment of a disease covered by the fund.[59] Despite these requirements, however, the persistence of AKS violations suggests a need for measures tightening monitoring and compliance frameworks to ensure PAPs provide patients support for generic alternatives as well as brand name products.[60]

Proponents of such measures, like Senator Warren and Senator Whitehouse, posit that the current restrictions are insufficient, and that requiring these entities to cover low-cost generics is the only way to end the price-gouging.[61] As of 2019, researchers have found that between two major operators of PAPs, only forty-one percent of the 2,828 Medicare Part D drugs listed on the Medicare Spending dashboard were covered, with drugs produced by a single manufacturer having a higher rate of coverage compared to drugs produced by multiple manufacturers.[62] The same study found that expensive drugs were far more likely to have at least one PAP providing coverage compared to relatively lower cost drugs.[63] Mandating that Independent Charity PAPs provide support for generic, low-cost medications would not only broaden the choices available to low-income patients, but also undercut manufacturers' ability to raise prices in a competitive marketplace.

Some states such as Massachusetts and California have taken steps to prohibit manufacturers from providing payment assistance for drugs with generic equivalents.[64] These statutes do not prevent PAPs from offering assistance to patients, but instead hold PAPs to the standard set out according

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[59] Supplemental Special Advisory Bulletin, *supra* note 6, at 31121.
[60] Kang et al., *supra* note 14, at 427.
[61] Warren and Whitehouse, *supra* note 46, at 3.
[62] Kang et al., *supra* note 14, at 423.
[63] *Id*.
[64] Richard P. Church et al, *Increased Scrutiny of Patient Assistance Programs: Enforcement Overview and Considerations*, K&L Gates (Mar. 20, 2018), https://www.klgates.com/Increased-Scrutiny-of-Patient-Assistance-Programs-Enforcement-Overview-and-Considerations-03-20-2018.

to OIG guidance documents where a low-cost generic option is available.[65] Likewise, the California statute permits manufacturers to offer drugs to patients for free on the condition that it is also free for the insurer.[66] To this end, the OIG should take note and consider the benefits of mandating that PAPs provide an equivalent amount of assistance for generic drugs in addition to brand name drugs.

Nonetheless, it is important to consider that if Independent Charity PAPs are stripped of their ability to allow manufacturers to skirt the AKS, these manufacturers may cease their contributions, and PAPs' abilities to assist patients might drop significantly as said contributions constitute a significant portion of their funding.[67] Existing enforcement actions have already caused a decrease in manufacturer contributions to PAPs.[68] However, this trend may indicate that Independent Charity PAPs' existence in the industry was primarily to enable kickbacks, a detriment to the U.S. healthcare system as a whole. Regardless, the OIG's obligation should not be to preserve PAPs in spite of their harm to the system, but to ensure that any deprivation of racial minorities' access to healthcare that results from its regulatory actions is kept to a minimum.[69]

VII. THE OIG MUST ALLOW REGULAR ASSURANCES OF COMPLIANCE

The lawsuits and hefty settlements following the 2014 bulletin have not gone unnoticed by the industry, prompting many pharmaceutical companies

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[65] *Id*.; 114 Cal Health & Saf. Code § 132008.
[66] Church, *supra* note 64; 114 Cal Health & Saf. Code § 132006
[67] Hood, *supra* note 1, at 644.
[68] Jonathan Rockoff, *U.S. Probe Sheds Light On Charities Role In Boosting Drug Sales*, WALL STREET J. (Jun. 11, 2017), https://www.wsj.com/articles/u-s-probe-sheds-light-on-charities-role-in-boosting-drug-sales-1497000601.
[69] *See* Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70623-24 (Nov. 22, 2005), (Explaining that the OIG is mindful of the importance of ensuring financially needy beneficiaries receive their prescriptions and supportive of efforts to assist these beneficiaries as long as the assistance is compliant with the AKS).

to considerably slow down their contributions to PAPs out of fear of facing a lawsuit of their own.[70] Such a chilling effect may prevent a legitimate support network of Independent Charity PAPs from filling the void created in wake of the 2014 bulletin.[71] Previously, the OIG recognized the need to assure Independent Charity PAPs of their compliance through advisory opinions,[72] but to preserve the safety net these entities provide, the OIG must adopt a method to release these assurances regularly and vigorously. To assist in this process, the OIG should allow audits by independent review organizations to certify compliance with the AKS to remove any uncertainty that may discourage the operation of Independent Charity PAPs in their entirety. Such a requirement is a hallmark of the CIAs put in place by the OIG in settlements with companies like Pfizer, which involve Independent Charity PAP abuse.[73]

While charitable foundations and manufacturers alike will undoubtedly be displeased to undertake frequent audits, they are bound to be less expensive and time consuming than expensive settlements, which are likely to require such audits in the resulting CIAs anyway.[74] These audits should be performed with the end goal of determining the best means for PAPs to adhere to OIG guidelines. To this end, a study investigating desired improvements to PAPs in clinical staff found eighty-four percent pointing towards a need for greater standardization for the patient application process and eligibility.[75]

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[70] Hood, *supra* note 1, at 641.
[71] *Id.*
[72] Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70628 (Nov. 22, 2005), https://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/2005PAPSpecialAdvisoryBulletin.pdf.
[73] Corporate Integrity Agreement, *supra* note 25.
[74] Thomas Sullivan, *Amgen and Astellas Pay $125.75 Million to Settle Allegations of Providing Illegal Kickbacks Through Patient Assistance Programs*, POL'Y & MED. (last updated Apr. 30, 2019), https://www.policymed.com/2019/05/amgen-and-astellas-pay-125-75-million-to-settle-allegations-of-providing-illegal-kickbacks-through-patient-assistance-programs.html.
[75] *See* Yelba M. Castellon et al., *The Impact of Patient Assistance Programs and the 340B Drug Pricing Program on Medication Cost*, 20 AM. J. MANAGED CARE 146, 148 (Feb. 20,

Mandating regular reviews of whether these programs are in compliance should be used to promote such standardization. Further, such audits could be used to determine if foundations are not properly disclosing how funds earmarked for PAPs are being used.[76] Taken another way, these audits can allow the OIG to be proactive in enforcing the requirements as laid out in the 2005 and 2014 special advisory bulletins as opposed to bringing forth a lawsuit for every single infraction.

It is important for the OIG not to make it profitable to violate the AKS, but it also should not make it too risky in terms of cost for PAPs to operate in general. To this end, a regular audit provides both charities and manufacturers a relative certainty as to cost, compared to the variable cost of litigation.[77] While manufacturers are reasonably concerned about the increasing costs of healthcare compliance, the penalties of violations are not to be ignored.[78] Therefore, for the OIG to certify that an Independent Charity PAP is compliant with the 2005 and 2014 Special Advisory Bulletins may quell fears from the charities and the manufacturer's that their actions will prompt a billion-dollar lawsuit.

In recognition of this point, the OIG notes that compliance with the requirements set out in its guidance will keep the PAP in the OIG's good graces.[79] Despite this, manufacturers and PAPs may be unwilling to pay the extra cost of compliance, which may even deter even well-intentioned charitable efforts.[80] To require that the OIG verify every individual PAP that

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2014) (citing to KS Duke et al., *Patient-Assistance Programs: Assessment of and Use by Safety-Net Clinics*, 62 AM. J. HEALTH SYST. PHARM., 726-731, (2005).

[76] *See Health Care Auditing and Monitoring Tools for an Effective Compliance Program*, STRATEGIC MANAGEMENT SERVS. (Dec. 2018), https://www.compliance.com/resources/health-care-auditing-and-monitoring-tools-for-an-effective-compliance-program/ (Explaining that external audits are formal reviews which in part validate information).

[77] Jennifer Zaino, *Compliance Costs Can Be Managed*, HEALTHCARE FINANCE NEWS (Nov. 4, 2014), https://www.healthcarefinancenews.com/news/compliance-costs-can-be-managed.

[78] *Id.*

[79] Supplemental Special Advisory Bulletin, *supra* note 6, at 31121.

[80] Illiparambil, *supra* note 6, at 591-92; Hood, *supra* note 1, at 641.

a single charitable foundation may operate may prove burdensome for both sides of the equation. Nonetheless, if the OIG wishes to enforce the AKS while avoiding deprivations of healthcare, it must give charities a stable arena in which they can operate instead of relying purely on the threat of litigation.

VIII. CONCLUSION

Overall, Independent Charity PAPs have undoubtedly served as a conduit for kickbacks from pharmaceutical manufacturers to patients who, in the face of rising costs, have become reliant on the financial aid PAPs provide.[81] The OIG is well within its authority to regulate PAPs so no violation of the AKS goes unpunished, but in doing so it should consider those caught in between: low-income patients, an outsized portion of whom are racial minorities.[82] In light of well documented disparities in access to medication in minority populations, it is especially important that the OIG does not exacerbate these disparities in its attempts to safeguard the federal healthcare system.

For the OIG to best preserve the safety net Independent Charity PAPs provide, the OIG must hold PAPs to a higher regulatory standard: mandating greater transparency in donations, mandating PAPs cover generic alternatives, and requiring regular certifications that the PAPs are compliant with OIG guidelines. To this end, transparency will allow for both the OIG and academia alike to better scrutinize PAPs for possible AKS violation while mandatory support for generics may serve to eliminate the main method manufacturers use to steer patients to their products. In turn, the OIG should require the PAPs undergo regular audits so it may certify that PAPs are compliant with their guidelines, granting manufacturers and charities alike a degree of certainty their actions will not result in costly litigation. While the application of these recommendations will undoubtedly come with

[81] Hood, *supra* note 1, at 647-49.
[82] Castenada, *supra* note 32.

a cost to both the OIG and the industry, maintaining access to healthcare among vulnerable populations such as racial minorities is of far greater value. In any case, the OIG must never fail to consider those caught in between.

Addressing Racial Disparities in Treatment for Opioid Use Disorder on Chicago's West Side

Rory Svoboda

I. INTRODUCTION

The opioid epidemic began in the 1990s and has since persisted with ferocity, wreaking havoc across the nation.[1] Opioids are a class of drugs used to treat pain and can come in the form of prescription opioids, fentanyl, or heroin.[2] Millions of Americans have felt the devastating effects of addiction to these drugs with white people, specifically white men, experiencing the highest rates of misuse.[3] Unsurprisingly, given that racial disparities pervade virtually every level of the U.S. healthcare system, minorities do not have the same access to opioid treatment as their white counterparts, however, minorities are experiencing opioid overdose.[4] Drugs like methadone, buprenorphine, and naltrexone have been proven to reduce opioid use by

[1] *Understanding the Epidemic*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/epidemic/index.html (last updated Mar. 19, 2020).
[2] *Opioid Basics*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/opioids/index.html (last updated Mar. 19, 2020) (Common types of prescription opioids are oxycodone, hydrocodone, morphine, and methadone. Fentanyl is a synthetic opioid pain reliever and is approved to treat severe pain, however, there is also illegally made and distributed fentanyl. Heroin is an illegal opioid).
[3] Kumiko M. Lippold et al., *Racial/Ethnic and Age Group Differences in Opioid and Synthetic Opioid-Involved Overdose Deaths Among Adults Aged ≥ 18 Years in Metropolitan Areas — United States, 2015-2017*, 68 MORBIDITY & MORTALITY WKLY. REP. 967, 967 (2019) https://www.cdc.gov/mmwr/volumes/68/wr/mm6843a3.htm ("Nearly all racial/ethnic groups and age groups experienced increases in opioid-involved and synthetic opioid–involved overdose death rates, particularly blacks aged 45–54 years (from 19.3 to 41.9 per 100,000) and 55–64 years (from 21.8 to 42.7) in large central metro areas and non-Hispanic whites (whites) aged 25–34 years (from 36.9 to 58.3) in large fringe metro areas").
[4] Kristen Schorsch, *The Opioid Treatment Gap*, CRAIN'S CHICAGO BUS. (May 28, 2018), https://www.chicagobusiness.com/static/section/opioids-data.html.

mitigating the painful symptoms of withdrawal,[5] but accessibility issues relating to insurance, clinic locations, and other socio-economic factors pose serious barriers to opioid treatment for minorities. These barriers to treatment need to be taken as seriously as the opioid epidemic itself. In order to address the disparate treatment of opioid abuse among minorities, a wide array of solutions will have to be considered and implemented.

First, this article will discuss the history of the opioid epidemic. Then it will cover the toll the epidemic has taken on society and briefly present the treatment options available to those with opioid addictions. Finally, this article will analyze the racial disparities in access to effective opioid addiction treatment and propose solutions to this problem of inequity.

II. BACKGROUND

A. The History of the Opioid Epidemic

A number of factors contributed to making the opioid epidemic what it is today, however, the general consensus is that pharmaceutical companies can take the lion's share of the blame.[6] In the second half of the twentieth century, there were growing concerns within the medical community of the under-treatment of pain.[7] The World Health Organization responded to the issue of under-treatment, specifically of cancer patient pain, with the Cancer Pain Monograph in 1986.[8] Soon after, in 1990, Ronald Melzack published an article in *Scientific American* questioning why opioids were not being used regularly to treat other chronic pain states.[9] This sentiment grew and by 1990

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[5] *Heroin Research Report: What Are the Treatments for Heroin Use Disorder?*, NAT'L INST. ON DRUG ABUSE, https://www.drugabuse.gov/publications/research-reports/heroin/what-are-treatments-heroin-use-disorder (last visited Feb. 11, 2021).
[6] Mark R. Jones et al., *A Brief History of the Opioid Epidemic and Strategies for Pain Medicine*, 7 PAIN & THERAPY 13, 16 (2018).
[7] *See generally id.* at 15.
[8] *Id.*
[9] *Id.*

opioids became the primary modality for chronic pain treatment.[10] Riding the momentum of campaigns addressing under-treatment,[11] pharmaceutical companies, like Purdue Pharma, began to aggressively push the use of opioids.[12]

Over the course of just five years from 1996 to 2001, Purdue held more than forty national pain-management and speaker training conferences where upwards of 5,000 physicians, pharmacists and nurses attended.[13] The key element of Purdue's marketing plan was the use of personalized data about individual physicians' prescribing patterns and using that data to target specific physicians' prescribing of opioids.[14] Dr. Art Van Zee, who focuses on issues surrounding the promotion and marketing of controlled drugs, explained, "one of the critical foundations of Purdue's marketing plan for OxyContin was to target the physicians who were the highest prescribers for opioids across the country."[15]

Additionally, a "lucrative bonus system encouraged sales representatives to increase sales of OxyContin in their territories."[16] "Purdue used a patient starter coupon program for OxyContin that provided patients with a free limited-time prescription for a seven- to thirty-day supply" to help sales.[17] The coupon program ended in 2001, but the damage had already been done

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[10] *Id.*
[11] *Id.* at 15-16 ("The American Pain Society launched their influential ''pain as the fifth vital sign'' campaign in 1995…The Veteran's Health Administration lent support to the campaign with their 1999 adoption of pain as the fifth vital sign initiative…the Joint Commission (TJC) published standards for pain management in 2000…The Federation of State Medical Boards and the Drug Enforcement Agency also issued statements promising less regulatory scrutiny over opioid prescribers.").
[12] Art Van Zee, *The Promotion and Marketing of Oxycontin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEATH 221, 221 (2009).
[13] *Id.*
[14] *Id*. at 222. ("Drug companies compile prescriber profiles on individual physicians—detailing the prescribing patterns of physicians nationwide—in an effort to influence doctors' prescribing habits. Through these profiles, a drug company can identify the highest and lowest prescribers of particular drugs in a single zip code, county, state, or the entire country.").
[15] *Id.*
[16] *Id*.
[17] *Id.*

with approximately 34,000 coupons redeemed nationally.[18] A consistent feature of Purdue's marketing plan was minimizing the risk of addiction and this misrepresentation contributed to rampant addiction and abuse.[19] Purdue is just one example of several drug companies that used similar and arguably insidious strategies to grow profits under the guise of the under-treatment of chronic pain.[20]

B. The Toll of Addiction and Treatment Options

Opioids are highly addictive because they have the ability to provide intense feelings of pleasure.[21] These feelings of pleasure can only be replicated by increasing dosages as tolerance to the medication builds thereby creating an inescapable dependence.[22] This dependence often results in drug seeking behaviors and a number of other undesirable side effects.[23] Opioid addiction takes a personal, societal, and economic toll on those affected. One study found that patients with opioid use disorder had worse physical and mental quality of life compared to the general population.[24] Another study comparing family burdens determined that opioid use disorder does indeed

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[18] *Id.*
[19] *Id.* at 223 ("The lifetime prevalence of addictive disorders has been estimated at 3% to 16% of the general population…In much of its promotional campaign…Purdue claimed that the risk of addiction from OxyContin was extremely small… Purdue trained its sales representatives to carry the message that the risk of addiction was ''less than one percent").
[20] Joel Achenbach et al., *Johnson & Johnson, Three Other Companies Close in on $26 Billion Deal on Opioid Litigation*, WASH. POST (Nov. 5, 2020, 10:31 PM) https://www.washingtonpost.com/health/opioid-settlement-drug-distributors/2020/11/05/6a8da214-1fc7-11eb-b532-05c751cd5dc2_story.html.
[21] Thomas R. Kosten & Tony P. George, *The Neurobiology of Opioid Dependence: Implications for Treatment*, 1 SCI. PRAC. PERSPS. 13, 14 (2002).
[22] *Id.* at 15.
[23] *Opioid Misuse and Addiction*, MEDLINEPLUS, https://medlineplus.gov/opioidmisuseandaddiction.html (last updated Dec. 28, 2020).
[24] Nicholas E. Hagemeier, *Introduction to the Opioid Epidemic: The Economic Burden on the Healthcare System and Impact on Quality of Life*, 24 AM. J. MANAGED CARE S200, S204 (2018); *see generally*, *Rx Awareness, Real Stories*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/rxawareness/stories/index.html (last updated Dec. 3, 2020) (discussing true stories of how opioid addiction has affected individuals and their families).

diminish the quality of life for people close to the individual user, like family and friends.[25] The societal and economic toll of opioid use disorder is nothing to scoff at. The Council of Economic Advisers stated past estimates had been grossly underestimated and that the more accurate estimate of the economic burden of prescription opioid overdose, abuse, and dependence in 2015 was $504 billion.[26]

Dr. Thomas Kosten and Dr. Tony George, physicians from Yale School of Medicine and Connecticut Mental Health Center, respectively, explained that, "from a clinical standpoint, opioid withdrawal is one of the most powerful factors driving opioid dependence and addictive behaviors."[27] Luckily, there are treatment options that involve lessening the painful side effects of withdrawal and have proven to be effective.[28] The medications most commonly used to treat opioid abuse are methadone, LAAM, naltrexone, and buprenorphine.[29] Which of these drugs is best to treat opioid use disorders varies by patient needs and circumstances.[30] Dr. Kosten and Dr. George further explain that, "the patient taking methadone must either visit the medical office daily (not feasible in most cases) or be responsible for taking daily doses at home, as scheduled."[31] Alternatively, for a patient who is unable to take the medication as instructed, buprenorphine (which has less

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[25] *Id.* at S204 - S205.
[26] *Id.* at S205.
[27] Kosten & George, *supra* note 21.
[28] *Id.* at 18.
[29] *Id.*
[30] *Id.* ("Methadone has effects that last for days. Methadone causes dependence, but—because of its steadier influence on the mu opioid receptors—it produces minimal tolerance and alleviates craving and compulsive drug use… A longer acting derivative of methadone, LAAM can be given three times per week… Buprenorphine offers a safety advantage over methadone and LAAM, since high doses precipitate withdrawal rather than the suppression of consciousness and respiration seen in overdoses of methadone, LAAM, and the addictive opioids. Buprenorphine can be given three times per week. Because of its safety and convenient dosing, it may be useful for treating opioid addiction in primary care settings, which is especially helpful since most opioid addicts have significant medical problems.").
[31] *Id.* at 19.

overdose potential) in three doses weekly would be a safer choice than methadone.[32]

III. ANALYSIS

A. The Problem — Inequitable Access to Treatment on the West Side

The opioid epidemic has largely been focused on white suburban and rural communities.[33] Yet, Black/African American drug overdose deaths increased by forty percent between 2015 to 2016 compared to a twenty-one percent increase for the general population.[34] The west side of Chicago, comprised of predominantly black neighborhoods,[35] is an area that has been hit particularly hard by the opioid epidemic.[36] Black people make up about thirty-two percent of the Chicago population but account for forty-eight percent of all opioid deaths in the city.[37]

A number of factors have contributed to this result, but the problem is certainly exacerbated by unequitable access to treatment. As Bechteler and Kane-Willis of the Chicago Urban League explain, "most large cities do not have the capacity to treat all of those who need treatment."[38] Considering that

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[32] *Id.*
[33] *See generally*, Julie Netherland, & Helena B. Hansen, *The War on Drugs That Wasn't: Wasted Whiteness, "Dirty Doctors," and Race in Media Coverage of Prescription Opioid Misuse*, 40 CULTURE, MED. & PSYCHIATRY 664 (2016) ("In this paper, we contrast media coverage of white non-medical opioid users with that of black and brown heroin users to show how divergent representations lead to different public and policy responses").
[34] SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., THE OPIOID CRISIS AND THE BLACK/AFRICAN AMERICAN POPULATION: AN URGENT ISSUE 3 (2020).
[35] *Race and Ethnicity in Near West Side, Chicago, Illinois*, STATISTICAL ATLAS, https://statisticalatlas.com/neighborhood/Illinois/Chicago/Near-West-Side/Race-and-Ethnicity (last visited Feb. 12, 2020) (Black people make up 45.5% of the neighborhood population compared to 37.6% white and 6.6% Hispanic).
[36] *See* Schorsch, *supra* note 4 (providing an interactive map that indicates which areas in the Chicagoland area have been hit hardest by opioids. "In 2017, there were more than 1,000 opioid related deaths in Cook County." The "zip code 60624 on the West Side, which includes [parts] of West Garfield Park, had the highest number of [opioid related] deaths.").
[37] STEPHANIE SCHMITZ BECHTELER & KATHLEEN KANE-WILLIS, CHI. URB. LEAGUE, WHITEWASHED: THE AFRICAN AMERICAN OPIOID EPIDEMIC 2 (2017).
[38] *Id.* at 6.

access to treatment is linked to insurance, it is no coincidence that the capacity available is filled primarily with those who have more wealth and/or private insurance. Those living in poorer neighborhoods where people are more likely to be uninsured or underinsured, like the West Side, are largely left out of the treatment equation.[39]

Thomas Britton, the CEO of the Gateway Foundation, which has a treatment center on the West Side, said in an interview with Crain's that the waiting list for residential care of Medicaid recipients can reach 1,000 people whereas those with private insurance can usually get in the same day.[40] This is the result of low state reimbursement rates that simply cannot compete with the three to four times higher reimbursement rates that private insurance will pay.[41] In addition, federal rules cap the number of patients that doctors may prescribe treatment drugs like buprenorphine to. "In Illinois, seventy-seven percent of providers are limited to thirty patients."[42] The maximum amount of patients a doctor can be treating with buprenorphine at a time is 275.[43] While there certainly needs to be measures taken to address opioid addiction in these communities before it begins, — like investment in underprivileged schools, childcare, and jobs programs — the solutions presented in this article will focus on access to treatment after addiction to opioids has already occurred.

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[39] Schorsch, *supra* note 4 ("Those who can afford private insurance jump to the front of the line. But in a community like, say, West Garfield Park, where roughly 52 percent of residents made less than $25,000 in 2015, and 55 percent weren't looking for a job, private insurance is tough to come by.").
[40] *Id.*
[41] *Id.*
[42] *Id.*
[43] *Id.*

B. Potential Solutions

Illinois is notorious for its unbalanced budget and fiscal woes.[44] This fact often means that calls for increased spending, especially for something like drug addiction, fall on deaf ears. However, law makers ought to look at the bigger picture. One where spending now saves costs later. For example, the State of Virginia, started the Addiction and Recovery Treatment Services (ARTS) program in 2017 to radically raise reimbursement rates for opioid use treatment covered by Medicaid.[45] Following the implementation of this initiative, in the first nine months, the number of Medicaid recipients on opioids who received treatment increased by twenty-nine percent, while opioid use disorder related ER trips declined thirty-one percent.[46] Additionally, treatment providers grew to 2,544, about three times the pre-program mount.[47]

Recently, Illinois proposed an amendment to its Medicaid State plan that was approved to increase rates of reimbursement for certain mental health and substance use disorder services by just two percent, effective July 1, 2020.[48] To understand the effectiveness, or lack thereof, compare this approved increase with the recent Virginia's ARTS reimbursement rate increases. For example, the old rate for substance abuse intensive outpatient treatment was a few dollars/hour. Under the new program, the rate is several hundred dollars per day.[49] In order to see similar decreases in opioid

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[44] *See generally* Ted Dabrowski & John Klingner, *The History of Illinois' Fiscal Crisis*, ILL. POL'Y (June 28, 2017), https://www.illinoispolicy.org/reports/the-history-of-illinois-fiscal-crisis/.
[45] German Lopez, *We Really Do Have a Solution to the Opioid Epidemic — and One State Is Showing It Works*, VOX (May 10, 2018, 6:00 AM), https://www.vox.com/policy-and-politics/2018/5/10/17256572/opioid-epidemic-virginia-medicaid-expansion-arts.
[46] *Id.*
[47] Schorsch, *supra* note 4.
[48] Letter from Todd McMillion, Dir., Div. Reimbursement Rev., to Theresa Eagleson, Dir., Ill. Dep't Healthcare & Fam. Servs. (Sept. 29, 2020) (on file with author).
[49] *See* DEP'T MED. ASSISTANCE SERVS., BENEFIT AND REIMBURSEMENT STRUCTURE BEFORE AND AFTER ARTS (2017) https://cdn.vox-cdn.com/

overdoses and related ER visits, Illinois needs to radically increase Medicaid reimbursement rates in the way Virginia has. It will ultimately create more equitable access to treatment for those on the West Side and have the added bonus of being a cost saving measure in the long run.[50]

For those in poverty, like many on the West Side, transportation and childcare are additional barriers to access medication assisted treatment for opioid addiction.[51] Ideally, Illinois would see a similar increase in the number of providers that Virginia saw thereby increasing access and reducing treatment wait times. An expansion in providers can help integrate healthcare into the West Side community with the increased locations helping to mitigate transportation issues. Childcare concerns could be addressed with individualized treatment plans that allow for less frequent in-person visits. With the rise of telehealth,[52] state and federal laws should adjust to allow providers to determine more flexible treatment plans that enable patients to visit with physicians either from a computer or by cell phones, which are more commonly available.

Additionally, the city should incentivize physicians, particularly those serving the West Side, to get certified in buprenorphine administration. The treatment of opioid use disorder with medication is governed by federal law—specifically, Title 42, Section 8 of the Code of Federal Regulations.[53]

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uploads/chorus_asset/file/10767475/Medicaid_ARTS_Rates__Before_and_After.0.pdf (providing tables of pre-ARTS rates versus new ARTS rates).

[50] *Crain's: What it Costs Hospitals to Reverse an Opioid Overdose*, MERCYHEALTH (Feb. 16, 2018, 6:00 AM) https://mercyhealthsystem.org/crains-costs-hospitals-reverse-opioid-overdose/ ("In 2017, the Cook County Health & Hospitals System, which includes flagship Stroger Hospital on the Near West Side, treated 4,000 to 5,000 patients whose chief complaint was related to opioids, up from about 1,000 people in 2006. In 2017, opioid-related cases cost about $25 million. Each case on average cost just over $6,000, including overdose revivals in the ER and hospitalizations.").

[51] Bechteler & Kane-Willis, *supra* note 37.

[52] Lisa M. Koonin et al., *Trends in the Use of Telehealth During the Emergence of COVID-19 Pandemic — United States, January–March 2020*, MORBIDITY & MORTALITY WKLY. REP. 1595, 1595 (2020).

[53] *19-444-26-1693-01 Access to Medication Assisted Treatment (MAT) Pilot Grant*, ILL. DEP'T OF HUM. SERVS. (Apr. 30, 2018), https://www.dhs.state.il.us/page.aspx?item=105474.

Physicians looking to begin Opioid Treatment Programs (OTPs) must complete a Substance Abuse and Mental Health Services Administration (SAMHSA) approved accredited training to become certified treaters.[54] Then the Illinois Department of Health Services must license the treatment program under this federal regulatory process.[55] This process is lengthy, which creates a barrier to increasing the number of providers.[56] However, the Drug Abuse Treatment Act of 2000 made it so that doctors could prescribe buprenorphine in settings outside of OTPs if they apply for and receive a waiver to do so.[57] "To receive a practitioner waiver to administer, dispense, and prescribe buprenorphine practitioners must notify SAMHSA's Center for Substance Abuse Treatment (CSAT), Division of Pharmacologic Therapies (DPT) of their intent to practice this form of medication-assisted treatment (MAT)."[58] This waiver process requires practitioners to complete an eight-hour SAMHSA-approved training.[59] Once qualified, practitioners can treat up to 100 patients using buprenorphine in the first year and then after one year at the 100-patient limit, qualifying practitioners can apply to increase their patient limit to 275.[60]

Surveys of doctors with and without waivers to prescribe buprenorphine showed that *not knowing how to get the waiver* was cited as one of the primary reasons why they did not seek a waiver.[61] First, the City of Chicago should invest in an information campaign that informs physicians that have

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[54] *Id.*
[55] *Id.*
[56] *Id.*
[57] *Id.*
[58] *Become a Buprenorphine Waivered Practitioner*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner. (last updated Jan. 27, 2021).
[59] *Id.* (The practitioner buprenorphine waiver training is 8 hours for physicians, 24 hours for nurses, and 24 hours for physician assistants).
[60] *Id*.
[61] Andrew S. Huhn & Kelly E. Dunn, *Why Aren't Physicians Prescribing More Buprenorphine?*, 78 J. SUBSTANCE ABUSE TREATMENT 1, 5 (2017) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5524453/.

capacity about how to earn their certification. For those that earn the certification the city may provide monetary or tax incentives. The city creates tax incentives for a variety of initiatives from housing to commercial development to small businesses in low-income communities.[62] In this same fashion, the city should create a tax incentive for healthcare providers that complete buprenorphine waivers and provide care to those in disadvantaged communities like the West Side.

IV. CONCLUSION

The opioid epidemic is not going anywhere and for communities like the West Side, it will only get worse as they are left out of the treatment equation. In order to address the disparate treatment of opioid use among minorities on the West Side, a wide array of solutions must be considered and implemented. However, the state should start by drastically increasing Medicaid reimbursement rates for treatment. The City of Chicago can further help by incentivizing physicians with patient capacity to get certified in the prescribing of buprenorphine. Now is the time for local and state officials to act.

[62] *Tax Credits - Location Based*, CITY OF CHI., https://www.chicago.gov/city/en/depts/bacp/sbc/tax_credits_-_location-based.html (last visited Mar. 20, 2021).

The Hyde Amendment's Unconstitutional Commodification of the Right to Choose

Josh Wiedner

I. INTRODUCTION

The 1973 case *Roe v. Wade* established that United States citizens have a constitutionally protected right to obtain a safe abortion without excessive government restriction.[1] This right to abortion was vested in the right to privacy, be it from the Fourteenth Amendment or Ninth Amendment.[2] However, this right is not absolute, as states maintain the right to regulate and ensure the safeguarding of their citizen's health and to protect potential life.[3]

Immediately following *Roe v. Wade*, several states passed individual restrictions to attack abortion through funding, waiting periods, and any other requirements.[4] These states are very clear about the intent behind their restrictions, as they also have laws declaring the state's intent to ban abortion to the full extent permitted by the United States Constitution.[5]

One of the most consequential challenges to *Roe* came not from the states but from the federal government in the form of the Hyde Amendment in 1979.[6] This Amendment was created to limit federal funding, namely Medicaid funds, from paying for any non-emergency abortion.[7] In the years

[1] Roe v. Wade, 410 U.S. 113, 153 (1973).
[2] *Id.*
[3] *Id.* at 154.
[4] *Abortion Policy in the Absence of Roe*, GUTTMACHER INST. (Feb. 1, 2021), https://www.guttmacher.org/state-policy/explore/abortion-policy-absence-roe.
[5] *Id.*
[6] Julie Rovner, *Abortion Funding Ban Has Evolved Over the Years*, NPR (Dec. 14, 2009), https://www.npr.org/templates/story/story.php?storyId=121402281?storyId=121402281.
[7] *Id.*

between 1973 to 1980, before the Hyde amendment took place, nearly 300,000 abortions were paid for by Medicaid.[8] In 1980, the Hyde Amendment's constitutionality was challenged in *Harris v. McRae*, where the Supreme Court, in a 5-4 decision, held that while the state could not excessively restrict someone from seeking an abortion, as it was under no obligation to remove obstacles such as financial burden.[9] The dissenting opinion indicated that the Hyde Amendment effectively allows states to ban the right to abortion for low-income individuals who heavily rely on Medicaid to pay for all their medical care.[10] The result of the holding of this case not only perpetuates the cycle of poverty; it also continues to disproportionately impact women of color.[11]

As of 2015, approximately 12.9 million women in the United States rely on Medicaid, including twenty percent women of reproductive age (women aged 15–44).[12] This rate is even higher for black and Hispanic American women.[13] Encouraging women to rely on Medicaid for necessary coverage while allowing states to restrict the ability of Medicaid to pay for abortive care essentially creates a two-tier system of rights where only those with the ability to afford abortion truly have the right to it.[14] One in every three low-

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[8] *Id.*
[9] Harris v. McRae, 448 U.S. 297, 316–317 (1980).
[10] *Id.* at 333 (Brennan, J., dissenting).
[11] *Strategic Initiative: Overturning Harris v. McRae*, IF/WHEN/HOW (Feb. 7, 2021), https://www.ifwhenhow.org/get-involved/strategic-initiatives-2/overturning-harris-v-mcrae-hyde-amendment/.
[12] *Uninsured Rate Among Women of Reproductive Age Has Fallen More Than One-Third Under the Affordable Care Act*, GUTTMACHER INST. (Nov. 17, 2016), https://www.guttmacher.org/article/2016/11/uninsured-rate-among-women-reproductive-age-has-fallen-more-one-third-under. (The study by the U.S. Census Bureau's American Community Survey defined "woman" based on self-identification. These figures fail to account for people with the ability to become pregnant who do not identify as "women" such as trans men and gender non-conforming individuals who were assigned female at birth).
[13] *Id.*
[14] Jessica Arons & Jill E. Adams, *Abortion Law: Roe was Right, but McRae was Wrong,* MS. MAG. (Jan. 22, 2015), https://msmagazine.com/2015/01/22/abortion-law-roe-was-right-but-mcrae-was-wrong/.

income pregnant people who seeks an abortion will carry the pregnancy to term because they cannot afford it.[15] A pregnant person denied abortion is three times more likely to fall below the federal poverty line within two years as government aid quickly disappears.[16] Many states have imposed welfare family caps, meaning many low-income women are forced to face the additional costs of raising a child without assistance.[17]

While Medicaid is the largest public funder of healthcare, many military personnel, federal employees, immigrants, or anyone relying on government healthcare are equally limited by the Hyde Amendment from using their healthcare to get an abortion.[18] Over the past few years, there has been a shift in public opinion towards general support for more government involvement in healthcare.[19] As more people transition to government managed healthcare, more are subject to the limitations of the Hyde Amendment.[20] This article will analyze the unconstitutional conditions doctrine through the lens of anti-commodification theory, and will reveal ways in which the Hyde Amendment unconstitutionally coerces and corrupts the right to choose to get an abortion to the point where the right is illusory. First, the article will explain and discuss the unconstitutional conditions doctrine and the many ways it has been applied by the court since its initial recognition. Second, the article will seek to explain anti-commodification, the danger of treating rights

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[15] *Id.*
[16] *Id.*
[17] *Strategic Initiative: Eliminating Welfare Family Caps*, IF/WHEN/HOW (Feb. 7, 2021), https://www.ifwhenhow.org/get-involved/strategic-initiatives-2/eliminating-welfare-family-caps/.
[18] Arons & Adams, *supra* note 14.
[19] Bradley Jones, *Increasing Share of Americans Favor a Single Government Program to Provide Health Care Coverage*, PEW RES. CTR. (Sep. 29, 2020), https://www.pew research.org/fact-tank/2020/09/29/increasing-share-of-americans-favor-a-single-government-program-to-provide-health-care-coverage/. (Evidence of increased ACA support, support for a public option, support for a single payer Medicare for all system within the recent years).
[20] *See generally* Rovner, *supra* note 6 (The Hyde amendment affects all of those with federally funded healthcare).

as publicly tradable goods as well as how failing to adhere to the doctrine can lead to both coercion of individuals due to dire economic circumstances and corruption of the public good of a right. Finally, these arguments will be applied to abortion and the Hyde Amendment to demonstrate how the Government's decision to fund childbirth but not abortion is both coercive and corrupting of the supposedly constitutionally guaranteed right to choose to get an abortion.

II. ARGUMENT

A. Unconstitutional Conditions Doctrine

The Spending Clause grants Congress almost limitless power in how it chooses to distribute resources.[21] However, there is one caveat; the government may not deny a discretionary benefit such as cash to a person on any basis that infringes upon their constitutional protected rights, specifically that of freedom of speech.[22] This principal, known as the unconstitutional conditions doctrine, was established by the Supreme Court in 1926 in *Frost & Frost Trucking Company v. Railroad Commission of California*.[23] Nearly 100 years later, the seemingly inconsequential doctrine has been interpreted and applied by the Court in many ways,[24] creating notoriously complicated,

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[21] Stephen Miller & Dylan Alper, *Re-examining funding and the Unconstitutional Conditions Doctrine*, LEGAL INTELLIGENCE (Mar. 14, 2013), https://www.cozen.com/news-resources/publications/2013/re-examining-funding-and-the-unconstitutional-conditions-doctrine.

[22] *See id.* (citing to Rumsfeld v. F. for Acad. and Institutional Rts, 547 U.S. 47, 59 (2006).).

[23] Frost et al., v. R.R. Comm'n of Cal., 271 U.S. 583, 593–95 (1926).

[24] *Compare* Rust v. Sullivan, 500 U.S. 173, 192 (1991) (Upholding funding conditions forbidding family planning organizations from discussing abortion as a family planning option because the speech restrictions were within the scope of the funding program), *with* Legal Servs. Corp. v. Velazquez, 531 U.S. 533, 549 (2001) (Rejecting funding conditions forbidding civil legal aid organizations from voicing challenges on the constitutionality of current welfare laws despite being within the scope of the program).

convoluted, and inconsistent rules.[25] However, as constitutional scholars have noted, this ambiguity is no reason to avoid the doctrine, as it plays a vital role as a sort of constitutional "glue."[26] Disregarding it would empower the government to act both coercively toward the individual and in a way that corrupts the public good of some rights,[27] specifically the right to choose to get an abortion.[28]

B. Anti-Commodification

A vital part of having rights is the ability to exercise exclusive jurisdiction over when to exercise those rights.[29] While this autonomy is a core constitutional value, constitutional rights exist to do more than simply maximize autonomy.[30] Consider, for example, the right to vote. Most of society would agree that allowing people to sell their right to vote to the government would be damaging despite it being a restriction of autonomy.[31] The anti-commodification doctrine seeks to explain and prevent potential issues that can arise when rights are treated as transferable commodities.[32] Anti-Commodification arguments generally fall into one of two categories: coercion or corruption.[33]

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[25] *See* Philip Hamburger*, Unconstitutional Conditions: The Irrelevance of Consent*, 98 VA. L. REV. 479, 480 (2012). ("This enigma is notoriously complex, and unconstitutional conditions therefore are considered a sort of Gordian knot.").
[26] Louis W. Fisher*, Contracting Around the Constitution: An Anticommodificationist Perspective on Unconstitutional Conditions*, 21 U. PA. J. CONST. L. 1167, 1170 (2019).
[27] *Id.* at 1170-71 (Noting that the government could use contracts to bypass the constitution and its protections without the unconstitutional conditions doctrine).
[28] *Id.* at 1217-18.
[29] Kathleen M. Sullivan, *Unconstitutional Conditions,* 102 HARV. L. REV. 1413, 1419 (1989) at 1486–87.
[30] Fisher, *supra* note 26, at 1214.
[31] *Id.* at 1198-99.
[32] Sullivan, *supra* note 29, at 1477.
[33] Fisher, *supra* note 26, at 1184.

i. Coercion

Much of the debate around anti-commodification is focused on coercion and consent.[34] The main worry is that conditions of extreme inequality might create a situation of desperate economic necessity in which people have fundamentally no choice but to waive their rights.[35] Not only can socioeconomic realities coerce people into waiving their rights, but due to the way inequality is structured in the United States, it can create a future in which the rightsholders are divided into classes based their socioeconomic status.[36]

Although the Court has struggled with inconsistent application and contradictions over time,[37] the unconstitutional conditions doctrine's modern interpretation of coercion has been used to prevent the federal government from overly conditioning funding based on principals of federalism[38] and free speech.[39] Regarding the topic of Medicaid expansion in *NFIB v. Sebelius*, the Court struck down the requirement that states expand Medicaid duties to cover all people under the age of 65 with incomes at or below 133% of the federal poverty line.[40] The court reasoned that threatening states with a "loss of over 10 percent" of their budget was coercive and violated the unconstitutional conditions doctrine because it left them with "no real option but to acquiesce."[41]

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[34] *Id.*
[35] Glenn Cohen, *Regulating the Organ Market: Normative Foundations for Market Regulation*, 77 L. & CONTEMP. PROBS. 71, 75 (2014).
[36] Fisher, *supra* note 26, at 1187.
[37] *Compare* South Dakota v Dole, 483 U.S. 203 (1987) (Upholding massive federal highway funding to states that choose to set minimum drinking age of 21), *with* NFIB v. Sebelius, 567 U.S. 519 (2012) (Rejecting federal funding condition requiring states to expand Medicaid as overly coercive).
[38] *Id.*
[39] AID v. Alliance for Open Society Intern., Inc., 570 U.S. 205, 214 (2013).
[40] NFIB v. Sebelius, 567 U.S. 519, 576 (2012).
[41] *Id.* at 582.

Although *NFIB* was the first instance of the federal government striking down a spending condition as unconstitutionally coercive of the state,[42] this same principal has also been applied in recent years to sanctuary cities.[43] President Trump signed an executive order in early 2017 that would withhold federal funds from cities unless the local leadership agreed to assist the federal government and ICE in detaining and deporting undocumented immigrants.[44] The enforcement of this executive order was enjoined in November of 2017 as a violation of the unconstitutional conditions doctrine, citing *NFIB's* holding regarding conditions so coercive that they rise to the level of compulsion. [45]

The Court in *McRae* attempts to explain that the Hyde Amendment is still constitutional because it does not condition all Medicaid benefits on the surrender of a constitutional right; it simply is choosing not to fund a protected activity, not imposing a penalty.[46] However, the dissent correctly points out that the Court misses a critical coercive element in its oversimplification.[47] By paying the costs of one outcome of a constitutionally protected decision, the government penalizes the choice of the non-funded option.[48]

Forcing pregnant people to choose between free childbirth and out-of-pocket abortion is forcing them to incur a loss to exercise the right of choice.[49] This is illustrated by Justice Brennan's hypothetical in the dissent of *McRae*, proposing transportation to voters based on political affiliation.[50]

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[42] Id. at 625 (Ginsburg, J., concurring in part, concurring in the judgment, and dissenting in part).
[43] Cty. of Santa Clara v. Trump, 275 F. Supp. 3d 1196 (N.D. Cal. 2017).
[44] *See generally* Exec. Order. No. 13768 § 9(a), 82 FR 8799, 8801 (labeling "sanctuary jurisdictions" and making them ineligible for federal grants).
[45] Cty. of Santa Clara v. Trump, 275 F. Supp. 3d 1196, 1202 (N.D. Cal. 2017).
[46] Harris v. McRae, 448 U.S. at 317 n.19.
[47] *Id.* at 336 n.6 (Brennan, J., dissenting).
[48] *Id.*
[49] *Id.*
[50] *Id.*

If the government were to provide free transportation to the polls for a Democratic voter but not a Republican, it would be interpreted as punitive on the non-receiving group.[51] Technically the choice "represents simply a refusal to subsize certain protected conduct," and leaves Republican voters in the same position had no funds been distributed.[52] Voters who do as the government wants relinquish their right to choose a candidate and are compensated with financial coverage for transportation.[53] Voters who act against the government's wishes and vote for the Republican candidate are punished.[54]

This voting hypothetical is analogous to the right to choose an abortion with one major twist. The cost incurred by voters to transport themselves to the polls is not nearly as significant as the burdens that low-income pregnant people faces as they scavenge, scrimp, save, sell, and sacrifice to pay for unsubsidized medical care.[55] For most indigent pregnant people, the offer of funded childbirth versus out-of-pocket abortion is so coercive that they are left with no real option but to acquiesce to the government's preferred choice.[56]

ii. Corruption

Unfortunately, much of previous scholarship has ignored the corruption argument under the unconstitutional doctrine analysis and focused solely on coercion.[57] Regardless of systemic inequality and the ability to coerce, the

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[51] *Id.*
[52] *Id.*
[53] *Id.*
[54] *Id.*
[55] *See* CTR. FOR REPROD. RIGHTS, WHOSE CHOICE? HOW THE HYDE AMENDMENT HURTS POOR WOMEN 28 (1st. ed. 2010) (low-income women are forced to go without necessities such as utilities, food and clothing to be able to afford an abortion).
[56] Jill E. Adams & Jessica Arons, *A Travesty of Justice: Revisiting Harris v. McRae*, 21 WM. & MARY J. RACE, GENDER, SOC. JUST. 5, 26 (2014).
[57] Fisher, *supra* note 26, at 1187.

anti-commodification corruption theory argues that certain moral and civic goods such as constitutional rights can be corrupted by the mere ability to be commodified and exchanged.[58] These arguments generally state that there is a unique aspect of fundamental rights like freedom of speech that ties them to human dignity.[59] To allow people to exchange their rights for money would be to allow them to exchange an intrinsic good to an extrinsic, lower good.[60] Every transfer of commodities is an expression of "value equilibrium" and to allow freedom of speech to be sold for money is denigrating to the value of the right.[61] Not only does commodification corrupt an individual's dignity, but it corrupts the public and civic good of a right.[62]

The true nature and importance of the corruption doctrine can be seen in the 2013 case *AID v. Alliance for Open Society International, Inc.* in which the Court struck down the government's restriction of funding to U.S-based NGO's who refuse to adopt policy "explicitly opposing prostitution and sex trafficking"[63] The Court ruled the policy requirement placed an unconstitutional condition on the NGO's ability to exercise their First Amendment rights.[64] In the context of abortion, *AID* is vital as it highlights the Court's modern, consistent, approach to unconstitutional conditions questions regarding the first amendment.[65]

While the majority in *AID* claims to apply a "scope of the program test,"[66] upon closer inspection, the line the Court attempts to draw is incredibly

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[58] Cohen, *supra* note 35, at 73.
[59] Fisher, *supra* note 26, at 1190.
[60] *Id.*
[61] Glenn Cohen, *The Price of Everything, the Value of Nothing: Reframing the Commodification Debate*, 117 HARV. L. REV. 689, 706 (2003).
[62] MICHAEL J. SANDEL, WHAT MONEY CAN'T BUY: THE MORAL LIMITS OF MARKETS, 61 (Farrar, Straus and Giroux eds., 2012).
[63] AID v. Alliance for Open Society Intern., Inc., 570 U.S. 205, 205 (2013).
[64] *Id.* at 221.
[65] *Id.* at 215 *see also* AID v. Alliance for Open Society, 140 S. Ct. 2082 (2020) (Where the Supreme court upheld the *AID*'s reasoning and found that it did not apply to organizations outside the United States without First Amendment rights).
[66] *Id.* at 216.

unclear and vulnerable to manipulation by the government.[67] The distinction made between conditions that define the federal program and conditions that are outside of its scope are not always conspicuous.[68] It also cannot be that *AID* was decided based solely on coercion.[69] There is no question that limiting funding would impact a NGO's ability to provide aid to people in need, but there is also no evidence that NGO's truly relied on this specific funding to provide aid.[70] It would have no doubt helped them achieve their mission, but it was not their primary sole source of funding.[71] The NGO's were not placed in an different or worse position regarding the ability to distribute aid than before additional funding under the leadership act was enacted.[72] Scholars in recent years have argued that *AID* and other first amendment unconstitutional conditions cases, can instead best be understood through the framework of corruption.[73]

The Government in *AID* is essentially attempting to commodify and purchase the constitutional right to free speech as applied to prostitution.[74] This attempt corrupts NGO's guaranteed right to freedom of expression.[75] Philosophers and constitutional scholars alike have long since argued that freedom of expression as a right is so liked to human dignity and autonomy that to allow people to sell it would harm the individual's personal dignity.[76]

Furthermore, fundamental rights like the freedom of speech exist not only to affirm and protect personal dignity, but function as societal "civic goods."[77] Allowing these types of goods to be bought and sold for money

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[67] *Id.*at 215.
[68] *Id.*
[69] *Id.* at 226 (Scalia, J., dissenting).
[70] *Id*. at 225-26.
[71] *Id.*
[72] *Id.*
[73] Fisher, *supra* note 26, at 1196-97.
[74] *Id.*
[75] *Id.*
[76] *Id.*
[77] Cohen, *supra* note 61, at 697.

corrupts their ability to function as "civic goods."[78] The right to vote is perhaps the most classic and easily understood example of this. Not only does allowing the right to vote to be sold pose issues where lower-income citizens are coerced into selling their rights, it also denigrates the value of the right for those who have not sold it.[79] Similarly, the sale of free speech rights also would produce adverse effects on the citizenry at large.[80] This reasoning is further supported by the Courts revisiting of *AID* in 2020 as applied to non-citizen NGO's, where it was held that foreign citizens do not have First Amendment rights and therefore the rights cannot be coerced or corrupted.[81]

The holding of *McRae* stated that Medicaid did not create an obligation for the government to cover any healthcare benefits.[82] The government instead could choose to exclude certain benefits as part of Medicaid or structure conditions for receiving certain benefits.[83] This essentially is a rephrasing of the scope of the program test later rejected by *AID*, as it allows the government excessive control and power in deciding what conditions restricting Medicaid funding are allowed or commodifiable.[84] The restriction of funding abortion while funding childbirth costs essentially translates into a governmental purchase of the right to choose an abortion.[85]

Not only does this raise issues with coercion of low-income pregnant people based on their socioeconomic status, but it corrupts the right of the individual people to autonomously choose to get an abortion and structure their life the way they choose.[86] In addition to this loss of individual dignity,

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[78] *Id.*
[79] Sandel, *supra* note 62, at 118.
[80] William T. Mayton, *"Buying-Up Speech": Active Government and the Terms of the First and Fourteenth Amendments*, 3 WM. & MARY BILL RTS. J. 373, 376-77 (1994).
[81] Jason Mazzone*, The Waiver Paradox*, 97 NW. U. L. REV. 801, 866 (2003).
[82] Harris v. McRae, 448 U.S. 297, 309 (1980).
[83] *Id.* at 334 (Brennan, J., dissenting).
[84] Fisher, *supra* note 26, at 1196.
[85] *Id.* at 1211.
[86] *Id.* at 1211-12.

McRae also empowers the government to corrupt the very character of the civic good of the First Amendment by encouraging transactions that exchange rights like freedom of speech for money as though they have equivalent value as goods.[87] The structural, relational, and public purpose of constitutional rights is entirely undermined by allowing the government to essentially purchase individuals' rights.[88]

While this paper proposes a drastic change to the doctrinal understanding of *McRae*, a federal challenge to the Hyde amendment is only one possible solution to this problem. Several states courts have ruled that bans on state Medicaid funding for abortion violate the state constitution.[89] Massachusetts, Alaska, California, Connecticut, Minnesota, New Jersey, New Mexico, and West Virginia have all used framework under the neutrality principal to argue that a government's decision to fund one option of a protected choice while failing to fund the other is unconstitutional.[90]

III. CONCLUSION

As more is put under the shadow of its influence, the common law jurisprudence of the Hyde Amendment deserves a contextual reproach. The Hyde Amendment claims to be a constitutional way for the government to subsidize certain constitutionally protected conduct while refusing to subsize others. This decision is counterintuitive to the unconstitutional conditions doctrine because it forces pregnant people to sacrifice their right to choose to get an abortion to not incur a structural deficit. To continue to allow the Hyde Amendment to prevent Medicaid from funding abortion while allowing it to fund child rearing is to coerce a pregnant person to give up their first

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[87] Harris v. McRae, 448 U.S. 297, 334 (1980) (Brennan, J., dissenting).
[88] Fisher, *supra* note 26, at 1172.
[89] Adams & Arons, *supra* note 56.
[90] *Id.*

amendment right to choose and corrupts the very social good of the right. Still, it can be daunting to challenge decades of common law restricting abortion rights in the United States. By attacking the Hyde Amendment on both a federal front and through state constitutions, the overly burdensome restrictions of the Hyde amendment can take their rightful place as archaic artifacts of the past that can no longer damage the lives of low-income pregnant people.

Billions Unrealized: Modifying Tax Expenditures on Employer-Sponsored Insurance Plans

Christopher Wiltowski

I. INTRODUCTION

Amidst the constant political bickering concerning America's national debt,[1] many fail to consider that tax expenditures on employer-sponsored insurance plans lose the American government upwards of a trillion dollars every year in unrealized federal tax revenue.[2] Employer-sponsored insurance ("ESI") plans are group health care plans provided by employers that offer coverage to employees and usually include the employees dependents and spouses.[3] Of the nearly $1.3 trillion deducted in tax revenue in 2019,[4] $234 billion of potential federal tax revenue came from costs relating to health care.[5] Exclusion of employer-contributions for medical insurance premiums and medical care was by far the most costly, costing an estimated $227 billion in potential tax revenue in 2021.[6] For contextual purposes, consider that the expected next most-costly tax expenditure in 2021 will likely be preferential rate structure for capital gains and dividends, which is estimated to cost the

[1] McBride et al., *The National Debt Dilemma*, COUNCIL ON FOREIGN RELS (Sept. 9, 2020, 8:00 AM), https://www.cfr.org/backgrounder/national-debt-dilemma (last visited Mar. 2, 2021).
[2] *Policy Basics: Federal Tax Expenditures*, CTR. ON BUDGET AND POL'Y PRIORITIES (Dec. 8, 2020), https://www.cbpp.org/sites/default/files/atoms/files/policybasics-taxexpenditures.pdf.
[3] *Employer-Sponsored Health Plans*, HEALTHINSURANCE.ORG (2021), https://www.healthinsurance.org/glossary/employer-sponsored-health-plans/.
[4] *Policy Basics*, *supra* note 2.
[5] *Which Tax Provisions Subsidize the Cost of Health Care?*, TAX POL'Y CTR. (2020), https://www.taxpolicycenter.org/briefing-book/which-tax-provisions-subsidize-cost-health-care.
[6] *What are the Largest Tax Expenditures?*, TAX POL'Y CTR. (2020), https://www.taxpolicycenter.org/briefing-book/what-are-largest-tax-expenditures.

government about $136.2 billion in potential federal tax revenue – barely over *half* of the potential tax revenue lost from the exclusion of taxing ESI.[7] The massive amount of money that the American government loses in unrealized federal tax revenue disproportionately affects racially-disparaged Americans, and enforcing a limit on tax expenditures for employer-sponsored insurance plans would reduce medical costs nation-wide, assisting both the insured and the uninsured. Section I of this article includes a brief perspective on the lost potential in unrealized federal tax revenue that comes from not taxing ESI plans, while section II offers background on tax expenditures for ESI plans. Section III discusses previous failures to overhaul tax expenditures for ESI plans, and section IV offers a reasonable model for tax expenditures on ESI plans, including several sub-sections explaining the benefits of this proposed model.

II. BACKGROUND ON ESI TAX EXPENDITURES

Tax expenditures are losses in potential tax revenue for the federal government due to special exclusions which result in either a tax exemption or a deferral of tax liability.[8] Tax expenditures first became intertwined with employer-sponsored insurance plans in the Revenue Act of 1918, specifically section 215 article 294, which declared "[p]remiums paid by a partnership for accident and health insurance policies covering the lives of the individual partners are not deductible from gross income of the partnership."[9] This expenditure did not initially benefit many Americans according to Melissa Thomasson, an economist at Miami University.[10] Thomasson writes that prior to 1930, most patients were simply treated by their family members as

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[7] *Id.*
[8] *Tax Expenditures*, U.S. DEP'T OF TREASURY (2020), https://home.treasury.gov/policy-issues/tax-policy/tax-expenditures.
[9] Treas. Reg. § 215-294 (1918).
[10] Melissa A. Thomasson, *The Importance of Group Coverage: How Tax Policy Shaped U.S. Health Insurance*, NAT'L BUREAU OF ECON. RSCH. 1, 3 (2000), https://www.nber.org/system/files/working_papers/w7543/w7543.pdf.

opposed to physicians prior to 1920, meaning that the main cost associated with sickness were simply lost wages.[11] The Revenue Act of 1918 section 215 article 294 meant that if an employee signed onto an ESI plan, the money spent by their employer on their health coverage would be excluded from their taxable income.[12]

The true value of ESIs came about in the WWII-era, where a labor shortage meant that businesses had to appeal to workers while being unable to raise wages, and one benefit that businesses started offering its employees was health insurance coverage.[13] By 1960, 122 million Americans received healthcare insurance from their employers, and as of 2021, nearly half the total American population is enrolled in ESI plans.[14] ESI plans today are more popular than ever, partially influenced by the fact that the Affordable Care Act requires most businesses with more than fifty employees to offer some sort of health insurance for its employees or be fined a hefty fee.[15]

III. PREVIOUS ATTEMPTS TO MODIFY TAX EXPENDITURES ON ESI PLANS

There have been numerous attempts in the past to either abolish or limit the amount of tax benefits ESI plans receive.[16] For example, the Reagan administration proposed taxing ESIs in 1983, which at the time, was expected to raise $2.7 billion a year.[17] The issue with President Reagan's plan lies in

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[11] *Id.* at 4.
[12] Treas. Reg., s*upra* note 9.
[13] Bruce Bartlett, *The Question of Taxing Employer-Provided Health Insurance*, ECONOMIX (July 30, 2013, 12:01 AM), https://economix.blogs.nytimes.com/2013/07/30/the-question-of-taxing-employer-provided-health-insurance/ (last visited Apr. 18, 2021).
[14] *Id.*; *Health Insurance Coverage of the Total Population*, KAISER FAM. FOUND. (2019), https://www.kff.org/other/state-indicator/total-population/?currentTimeframe.
[15] *How the Affordable Care Act Affects Small Businesses*, Healthcare.gov, https://www.healthcare.gov/small-businesses/learn-more/how-aca-affects-businesses/; Sachi Barreiro, *Is My Employer Required to Provide Health Care Coverage?*, NOLO, https://www.nolo.com/legal-encyclopedia/is-my-employer-required-to-provide-health-care.html.
[16] Robert Pear, *Reagan's Budget Will Seek to Tax Health Premiums*, N.Y. TIMES (Jan. 27, 1983), https://www.nytimes.com/1983/01/27/us/reagan-s-budget-will-seek-to-tax-health-premiums.html (last visited Apr. 18, 2021).
[17] *Id.*

the stress placed on employees by forcing the employee to pay taxes on their ESI plans exceeding $2,100 for families or $840 for individuals yearly.[18] The plan lacked congressional support and was not implemented.[19] Nearly twenty years later, Senator John McCain also proposed a unique plan to abolish tax expenditures on ESI plans that would have re-invested the money received from taxing ESIs to provide refundable tax credits of $2,500 to individuals and $5,000 to families, which he argued would increase competition in the healthcare market, lowering costs for all Americans.[20] Republicans silently abandoned the plan due to lack of support, however, with no mention of it since McCain announced the plan in 2008.[21]

The most recently proposed large-scale reform for tax expenditures on ESI plans was the Cadillac Tax, an attachment to President Obama's Affordable Care Act that proposed taxing insurers on ESI premiums above a certain threshold.[22] The proposed threshold was more than $8,500 for an individual or $23,000 for a family.[23] The Cadillac Tax was initially meant to be enacted in 2018, but in 2015, President Obama delayed the law to January 2020, and President Trump repealed it entirely in 2019.[24] President Biden briefly

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[18] *Id.*
[19] Yevgeniy Feyman & Charles Blahous, *Replacing the Cadillac Tax: Options and Considerations*, MERCATUS CTR. GEO. MASON UNIV. 1, 11 (2017), https://www.mercatus.org/system/files/feyman-cadillac-tax-mercatus-research-v1.pdf.
[20] Kevin Sack & Michael Cooper, *McCain Health Plan Could Mean Higher Tax*, N.Y. TIMES (May 1, 2008), https://www.nytimes.com/2008/05/01/us/politics/01mccain.html (last visited Apr. 18, 2021).
[21] Emmarie Huetteman, *McCain's Complicated Health Care Legacy: He Hated the ACA. He Also Saved It.,* KAISER HEALTH NEWS (Aug. 25, 2018), https://khn.org/news/mccains-complicated-health-care-legacy-he-hated-the-aca-he-also-saved-it/ (last visited Apr. 18, 2021).
[22] *Cadillac Tax Fact Sheet*, CIGNA (2018), https://www.cigna.com/static/www-cigna-com/docs/employers-brokers/insights/informed-on-reform/cadillac-tax/cadillac-tax-fact-sheet.pdf.
[23] *Id.*
[24] Lisa Klinger, *Cadillac Tax Delayed to 2020*, LEAVITT GRP. (Dec. 21, 2015, 9:36 AM), https://news.leavitt.com/employee-benefits-compliance/cadillac-tax-delayed-to-2020/; Ryan Golden, *Trump Signs Bill Repealing ACA Cadillac Tax, Granting 'Relief' for Employers*, HR DIVE (Dec. 23, 2019), https://www.hrdive.com/news/trump-signs-bill-repealing-aca-cadillac-tax-granting-relief-for-employer/569551/.

mentioned the Cadillac Tax in late 2019 during his presidential campaign, stating that the Cadillac Tax would likely be repealed due to a lack of support because "Republicans want to do away with the Affordable Care Act altogether."[25]

McCain's suggested plan to abolish tax expenditures from ESI plans was the most reasonable of these proposals, though one must be wary of the potential massive loss of insurance coverage that would come from abolishing tax expenditures on ESI plans all at once. Consider that, in 2019, an astounding 49.6% of Americans received their healthcare through ESI plans.[26] Completely abolishing tax expenditures for ESIs would likely result in many employers refusing to offer ESI plans, potentially leaving tens of millions of Americans suddenly without insurance.[27] While it is true that many of these employees would quickly be able to find and enroll in another insurance plan, especially with the tax credits proposed by McCain, expecting tens of millions of Americans to immediately find an insurance plan that is risky.

IV. A REASONABLE MODEL FOR TAX EXPENDITURES ON ESI PLANS

A reasonable approach to tax expenditures on ESIs would be to limit tax expenditures on ESI plans above certain thresholds – for example, using the Cadillac Tax's threshold of $8,500 for individuals and $23,00 for families.[28]

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[25] Megan Messerly, *Biden Predicts Cadillac Tax Repeal, Promises Culinary Members Can Keep Their Union Health Plan If He's Elected President*, NEV. INDEP. (Dec. 11, 2019, 2:59 PM), https://thenevadaindependent.com/article/biden-predicts-cadillac-tax-repeal-promises-culinary-members-can-keep-their-union-health-plans-if-hes-elected-president (last visited Apr. 18, 2021).
[26] *Health Insurance Coverage of the Total Population*, KAISER FAM. FOUND. (2019), https://www.kff.org/other/state-indicator/total-population/?currentTimeframe.
[27] *See How Might the Tax Exclusion for Employer-Sponsored Insurance (ESI) be Reformed?*, TAX POL'Y CTR. (2020), https://www.taxpolicycenter.org/briefing-book/how-might-tax-exclusion-employer-sponsored-health-insurance-esi-be-reformed-0 (stating that repealing tax expenditures for ESI plans completely would "eliminate a strong incentive for employers to offer ESI").
[28] CIGNA, *supra* note 22.

This is not a drastic notion, as most other tax expenditures are limited in some capacity.[29] For example, the eleventh-largest tax expenditure, a twenty-percent deduction for qualified business income of individual taxpayers (estimated to cost $54.7 billion in 2021), only applies to high-income individuals.[30] Limiting tax expenditures on ESI plans would ensure that lower-income families can keep their ESI benefits if needed while encouraging higher-income Americans to shop around for non-ESI healthcare, further incentivizing health insurance companies to be more competitive in their offerings.[31] This would also allow the tax revenue received from ESIs to be put back into society by offering a tax credit for employees who decide not to opt-in to their ESI plan.[32]

Capping tax expenditures at the median level would raise an estimated $47 billion if the cap were applied to both income and payroll taxes.[33] While this revenue would result in only eighteen percent of the potential tax revenue that the American government would receive if they instead completely repealed all tax expenditures for ESI plans, "only 6% of revenues from capping are raised from the lower half of the income distribution."[34] Because the entire purpose of limiting tax expenditures on ESI plans would be to provide more assistance to lower-income families, this would be a reasonable solution that would not disrupt lower-income families while still driving down their medical costs.[35] Limiting tax expenditures on ESI plans would benefit Americans in three major ways: by encouraging proper healthcare

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[29] TAX POL'Y CTR, *supra* note 6.
[30] *Id.*
[31] Alain C. Enthoven, *Don't Repeal the "Cadillac Tax" on High Cost Health Plans*, HEALTH AFFAIRS BLOG (August 5, 2015), https://www.healthaffairs.org/do/10.1377/hblog20150805.049797/full (last visited Apr. 18, 2021).
[32] *Id.*
[33] Jonathan Gruber, *The Tax Exclusion for Employer-Sponsored Health Insurance*, NAT'L BUREAU OF ECON. RSCH. 1, 20 (Feb, 2010), https://www.nber.org/system/files/working_papers/w15766/w15766.pdf.
[34] *Id.* at 21.
[35] CONG. BUDGET OFF., *Options for Reducing the Deficit: 2017 to 2026* 1, 274 (2016), https://www.cbo.gov/system/files/2018-09/52142-budgetoptions2.pdf.

competition, by promoting a job market that promotes racial equity, and by lessening the effect that "job lock" (a phenomenon that influences employees to continue working in jobs they would otherwise leave) has on many Americans.[36]

A. Encouraging Proper Healthcare Competition

Limiting tax expenditures on ESIs and using the revenue to provide a tax credit to Americans who do not opt-in to their employer's ESI would encourage proper competition in the American healthcare industry, which would result in lower prices and benefit most Americans.[37] Many economists consider the cause of America's high healthcare costs to be a lack of proper competition in the industry.[38] Currently, high-income healthcare consumers who benefit from tax expenditures on ESI plans have no reason to shop around for their healthcare, meaning that healthcare companies have no reason to act competitively, which results in high healthcare costs.[39] Economist Bruce Bartlett succinctly summarized this phenomenon stating; "overbuying health insurance fueled medical cost inflation, which raised health insurance premiums, which drove up the cost of employee compensation while pushing down cash wages."[40] This phenomenon was caused by the fact that employees with ESI plans had no reason to be concerned with rising healthcare costs as those employees were already covered through their plans.[41] Subsequently, the cost of healthcare skyrocketed for those that either had their own health insurance plans or who

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[36] U.S. GOV'T ACCOUNTABILITY OFF., GAO-12-166R, JOB LOCK AND PPACA, 3 (2011).
[37] CONG. BUDGET OFF., *supra* note 35.
[38] Gaynor et al., *Making Health Care Markets Work: Competition Policy for Health Care*, BROOKINGS CTR. FOR HEALTH POL'Y 1, 1 (Apr. 2017). https://www.brookings.edu/wp-content/uploads/2017/04/gaynor-et-al-final-report-v11.pdf.
[39] Sherry A. Glied & Stuart H. Altman, *Boosting Competition Among Hospitals, Health Systems Will Improve Health Care*, STAT (Sept. 20, 2017), https://www.statnews.com/2017/09/20/hospitals-competition-health-care/ (last visited Apr. 18, 2021).
[40] Bartlett, *supra* note 13.
[41] *Id.*

were entirely uninsured and had to pay for immediate healthcare crises out-of-pocket.[42]

To put the amount of people who do not receive the benefits of ESI plans into perspective, remember that 49.6% of the American population receive healthcare insurance through their employer.[43] The 5.9% of Americans who pay out of pocket for their own insurance are forced to pay large amounts of money to account for the medical inflation caused by tax subsidies for ESI plans, and the 9.2% of Americans who are wholly uninsured are forced to bear the brunt of medical inflation by paying these inflated costs completely out-of-pocket every time they visit a healthcare provider.[44] This rising medical inflation can be tracked throughout the years – in 1960, the average healthcare cost in America for one person was $146 per year, but by 2018, that number had skyrocketed to $11,172 per year.[45] This drastic change cannot be attributed to inflation alone – the average percentage of inflation in buying power from 1960 to 2018 was 3.76%.[46] $146 in 1960 was worth about $1,239.17 in 2018, which was slightly over 1/10th of the *actual* average cost of healthcare in 2018.[47] Because ESI coverage has encouraged high-income employees to flood the healthcare market, employees with ESI plans must now accept lower take-home wages since their ESI plans are so expensive, and the uninsured suffer financially in a medically-inflated economy.[48] The inflated prices of healthcare plans also disproportionately

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[42] *Id.*
[43] *See* KAISER FAM. FOUND., *supra* note 26 (showing that 49.6% of Americans receive insurance through their employer, 19.8% receive insurance through Medicaid, 14.2% receive insurance through Medicaid, 5.9% have private insurance paid for out-of-pocket, 1.4% have military insurance, and 9.2% are uninsured).
[44] *Id.*
[45] Kimberly Amadeo, *The Rising Costs of Health Care by Year and Its Causes*, BALANCE (Oct. 17, 2020), https://www.thebalance.com/causes-of-rising-healthcare-costs-406487 (last visited Mar. 2, 2021).
[46] Ian Webster, *$146 in 1960 → 2018 | Inflation Calculator*, OFF. DATA FOUND., https://www.in2013dollars.com/us/inflation/1960?endYear=2018&amount=146 (last accessed Mar. 13, 2021).
[47] *Id.*
[48] Bartlett, s*upra* note 13.

affects employees with families—in 2019, 15% of family coverage ESI plans expected the beneficiary to pay over 50% the cost of their premiums, while only 2% of single coverage ESI plans expected the beneficiary to pay over 50% the cost of their premiums.[49]

Because few employees would voluntarily choose the most comprehensive (and most expensive) health care plan if they paid for their own plan out-of-pocket, the average citizen would need to inform themselves on the actual value of their health insurance companies.[50] This, combined with the tax credits that would be distributed to citizens if ESI plans were taxed above a certain threshold, would incentivize insurance companies to offer more affordable plans for their customers, resulting in affordable healthcare costs not only for employees, but also for the uninsured.[51]

B. Promoting a Job Market that Fights Racial Disparagement

While tax expenditures for ESI plans negatively affect employees with ESI plans and individuals who opt to pay for their own healthcare by inflating healthcare costs, these subsidies have the most disparate impact on the uninsured.[52] This is because tax expenditures on ESI plans are poorly targeted by being "large for high-income filers, who need little help affording health insurance, and small or nonexistent for people with low incomes, for whom

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[49] *Employer Health Benefits 2019 Summary of Findings*, KAISER FAM. FOUND. 1, 4 (2019), http://files.kff.org/attachment/Summary-of-Findings-Employer-Health-Benefits-2019.
[50] *See How Much Will It Cost? How Americans Use Prices in Health Care*, PUB. AGENDA (March 2015), https://www.publicagenda.org/reports/how-much-will-it-cost-how-americans-use-prices-in-health-care/ (study showing that 56% of Americans have tried comparing prices to determine what their out-of-pocket medical costs would be).
[51] *Id.*; *see The Effect of Shopping and Premium Tax Credits on the Affordability of Marketplace Coverage*, U.S. DEP'T OF HEALTH & HUMAN SERVS. 1, 2 (August 2016), https://aspe.hhs.gov/system/files/pdf/206741/APTCMarketplace.pdf (presenting HHS brief which states that the majority of citizens receiving a tax credit shop around for their healthcare on the ACA marketplace).
[52] USING TAXES TO REFORM HEALTH INSURANCE: PITFALLS AND PROMISES 3 (Henry Aaron & Leonard E. Burman eds., 2008).

health insurance is unaffordable… And the exclusion does not apply to nonworkers, regardless of income."[53]

The uninsured population in America is disproportionately non-white.[54] In 2019, 9.8% of the Caucasian population was uninsured, while 13.6% of the Black population was uninsured, 7.4% of the Asian population was uninsured, and 27.2% of the Hispanic population (of any race) was uninsured.[55] In addition to the fact that Black and Hispanic Americans are disproportionately uninsured, a disproportionate amount of Caucasian Americans also benefit from receiving any form of ESI when compared to Black and Hispanic Americans.[56] In 2018, 66% of Caucasian Americans were covered by ESI plans while only 46% and 41% of Black and Hispanic Americans, respectively, were covered by ESI plans.[57]

Tax expenditures on ESI plans exclusively help employees with jobs that offer health insurance, and those jobs tend to be full-time positions.[58] Because of this, American employees that either have part-time jobs or have jobs that do not offer ESI plans are disproportionately affected by tax expenditures on ESIs.[59] In addition to this, about 44% of employees paid no

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[53] *Id.*
[54] John Elflein, *Percentage of People Without Health Insurance in the United States from 2010 to June 2019, by Ethnicity*, STATISTA (Nov. 17, 2020), https://www.statista.com/statistics/200970/percentage-of-americans-without-health-insurance-by-race-ethnicity/.
[55] *Id.*
[56] Bobbi M. Bittker, *Racial and Ethnic Disparities in Employer-Sponsored Health Coverage*, AM. BAR ASS'N (Sept. 8, 2020), https://www.americanbar.org/groups/crsj/publications/human_rights_magazine_home/health-matters-in-elections/racial-and-ethnic-disparities-in-employer-sponsored-health-coverage/ (last visited Mar. 2, 2021).
[57] *Id.*
[58] *See* William A. Carroll & G. Edward Miller, *Differences in Health Insurance Coverage Between Part-Time and Full-Time Private-Sector Workers, 2005 and 2015*, AGENCY FOR HEALTHCARE RES. & QUALITY (April 2018), https://meps.ahrq.gov/data_files/publications/st511/stat511.shtml (finding that, in 2015, 81.4% of full-time jobs offered ESI plans while only 54% of part-time jobs offered ESI plans).
[59] Ed Dolan, *What's Wrong with Employer Sponsored Health Insurance*, NISKANEN CTR. (Nov. 6, 2018), https://www.niskanencenter.org/whats-wrong-with-employer-sponsored-health-insurance/ (last visited Mar. 2, 2021).

income tax in 2016.[60] While these employees may initially think that employer-sponsored health insurance may benefit them, they fail to realize that tax expenditures on their ESI plans actually hurt them financially as these plans have actually inflated medical costs, ultimately costing them more of their potential take-home wages.[61] Generally, ESI plans are not offered to part-time workers, meaning that these workers are forced to pay higher costs for medical care for tax expenditures that they do not receive.[62] Limiting tax expenditures on ESI plans and using the revenue to provide tax benefits to employees who do not receive ESI plans would help lower the inequity that part-time employees and employees who pay no income tax are forced to deal with.[63]

C. Job Lock

In addition to promoting a job market that fights racial disparities and encouraging competition in the healthcare industry, limiting tax expenditures on ESI plans would also free employees from "job lock."[64] Job lock is a phenomenon that occurs when an employee stays in a job they would otherwise leave due to certain benefits (in this situation, health insurance benefits) that their employer offers them.[65] Offering more affordable and competitive insurance options for all employees would allow employees to take insurance matters into their own hands, increasing job mobility and motivating employers to provide other benefits to attract potential employees.[66] Limiting tax expenditures for ESI plans would also help smaller

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[60] *T16-0121 - Tax Units with Zero or Negative Income Tax Under Current Law, 2011-2026*, TAX POL'Y CTR. (July 11, 2016), https://www.taxpolicycenter.org/model-estimates/tax-units-zero-or-negative-income-tax-july-2016/t16-0121-tax-units-zero-or-negative.
[61] Barlett, *supra* note 13.
[62] Dolan, *supra* note 59.
[63] *Id.*
[64] U.S. GOV'T ACCOUNTABILITY OFF, s*upra* note 36.
[65] *Id.* at 1.
[66] *Id.* at 3.

businesses that are unable to afford health insurance for their employees, as an ESI healthcare plan would no longer be a dealbreaker for many Americans.[67]

V. CONCLUSION

Whether tax expenditures on ESI plans will be capped remains to be seen. President Biden has not yet made an official statement on this issue since taking office, but as he was President Obama's Vice President when the Affordable Care Act was passed, and because the Affordable Care Act was intertwined with the Cadillac Tax, Biden could have an interest in the matter.[68] President Biden could very well abandon any plan to limit tax expenditures on ESI plans due to the Cadillac Tax's unpopularity with American voters.[69] This unpopularity is understandable – if you ask any American what they would think of eliminating tax expenditures on ESI plans, most would likely oppose the idea. Without an in-depth explanation of the benefits of limiting tax expenditures on ESIs, most Americans do not realize limiting tax expenditures and using the funds to give tax credits to Americans would result in proper competition in the American health care

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[67] *See* Glassdoor Team, *INFOGRAPHIC: The Age of Social Recruiting*, GLASSDOOR (March 1, 2013), https://www.glassdoor.com/employers/blog/infographic-the-age-of-social-recruiting/#prettyPhoto (Glassdoor 2013 survey finding that 43% of employees are more incentivized to take a job if an employer offers health benefits; this proved to be more popular than if an employer offers a flexible work schedule (37% of respondents), if an employer offers work-from-home options (23% of respondents), and if an employer offers stock options (15% of respondents)).

[68] *See Healthcare*, BIDEN FOR PRESIDENT (2021), https://joebiden.com/healthcare/ (stating that President Biden plans to "build on the Affordable Care Act by giving Americans more choice, reducing health care costs, and making our health care system less complex to navigate", meaning that Biden plans to keep some elements of the Affordable Care Act. Whether the Cadillac tax will be one of the elements of the Affordable Care Act that President Biden plans to build off remains to be seen).

[69] *See* Sarah Kliff, *One Poll That Explains Why Obamacare's Cadillac Tax is Doomed*, VOX (Sept 30, 2015, 12:00 PM), https://www.vox.com/2015/9/30/9423335/cadillac-tax-poll (providing a graph that shows 60% of Americans opposed the Cadillac Tax, while 28% favored it, and 12% had no answer) (last visited Mar. 2, 2021).

market, promote a job market that would promote racial equity, and reduce "job-lock" caused by employer ESI plans.

Financing Federalized Medicaid

James Wu

I. INTRODUCTION

Federalism is especially pronounced in Medicaid due to the program's joint federal-state structure predicated on cooperation that gives states wide latitude in tailoring both the implementation of covered benefits and the eligibility for coverage.[1] This has led to fragmentation and exclusion since the program's inception.[2] The dynamic has been accentuated by the Patient Protection and Affordable Care Act's ("ACA") efforts to encourage the expansion of Medicaid through enhanced federal matching funds, an incentive that did not entirely succeed—owing in large part to the Supreme Court's decision in *National Federation of Independent Business ("NFIB") v. Sebelius*.[3]

In *NFIB v. Sebelius*, the Court concluded that mandatory Medicaid expansion would be coercive because a state's refusal of the ACA's financial inducement entailed the loss of all of that state's pre-ACA Medicaid funding.[4] As a result, the Court rendered Medicaid expansion

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[1] Abbe Gluck & Nicole Huberfeld, *The New Health Care Federalism on the Ground,* 15 INDIANA HEALTH L. REV. 1, 3 (2018); Medha D. Makhlouf, *Laboratories of Exclusion: Medicaid, Federalism & Immigrants*, 95 N.Y.U, L. REV. 1680, 1700 (2020).

[2] Nicole Huberfeld, *The Universality of Medicaid at Fifty*, 15 YALE J. HEALTH POL'Y L. & ETHICS 67, 67-70 (2015) (stating that "[f]ragmentation has aptly described the United States' historically decentralized, disjointed, and disintegrated approach to health care" and "[t]he harmful effects of exclusion have been well studied and documented, but exclusion has remained an entrenched feature of American health care"); JAMILA MICHENER, FRAGMENTED DEMOCRACY: MEDICAID, FEDERALISM, AND UNEQUAL POLITICS 39 (2018) (underscoring that "failures [of proposals for national health insurance] served to orient health care policy toward a model of federalist fragmentation").

[3] Gluck & Huberfeld, *supra* note 1, at 5; National Federation of Independent Business v. Sebelius, 567 U.S. 519 (2012).

[4] *Id*. at 581.

optional.[5] One consequence of this decision has been to sustain and even heighten the unequal administration of Medicaid, leading to greater fragmentation in access to health care.[6]

This paper considers whether fully federalizing Medicaid could be a feasible solution to these issues. The first part of this paper addresses the purpose of health care federalism—whether it is an end it itself or a means to better outcomes—by examining emerging evidence of better health outcomes across an array of measures for patients in states that have chosen to expand Medicaid. The second part of this paper focuses on a proposal to finance federalized Medicaid using certain ACA taxes or creating other substantially similar ones. The notion may be appealing because it could be a way to advance the goal of uniformity in Medicaid coverage, but it also raises difficult questions concerning opinions of Medicaid in general. The prospect of financing federalized Medicaid as a solution necessitates confronting problems of fragmentation and exclusion in health care.

II. BACKGROUND

As enacted, the ACA included a provision to expand Medicaid eligibility up to 138% of the federal poverty level ("FPL") for all adults up to age 64.[7]

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[5] *Id*. at 588. *See also* Louise Norris, *What is the Medicaid 'Coverage Gap' and Who Does it Affect?*, HEALTHINSURANCE.ORG (Mar. 30, 2021), https://www.healthinsurance.org/faqs/what-is-the-medicaid-coverage-gap-and-who-does-it-affect/ (noting that the Supreme Court's 2012 decision regarding the ACA made Medicaid expansion optional).

[6] Michener, *supra* note 2, at 54-55 (stating that "by dint of federalism, Medicaid policy produces *unequal politics* and deepens already yawning racial, class, and geographic disparities in the United States" and underscoring that "among the states that were unwilling to implement Medicaid expansion were eight of the top eleven states with the largest share of the nation's African-American population…and eight of top eleven states with the highest poverty rates").

[7] *See*, *e.g*., *Medicaid expansion*, HEALTHINSURANCE.ORG, https://www.healthinsurance.org/glossary/medicaid-expansion/ (last visited Apr. 10, 2021) (stating the ACA's provision to allow all adults up to age 64 with income up to 133 percent FPL, plus a 5 percent income disregard for these purposes, to be eligible for Medicaid); *see generally*, *Financing*, MEDICAID.GOV, https://www.medicaid.gov/chip/financing/index.html (describing the manner in which the Affordable Care Act extended and enhanced financing for the Children's Health Insurance Program (CHIP) in order to incentivize states to expand coverage for children) (last visited Apr 10, 2021).

Medicaid expansion has improved a wide range of health outcomes, including racial and ethnic disparities in maternal health, infant mortality,[8] birth outcomes such as preterm births and low birth weights,[9] access to medicine,[10] and even beginning timely cancer treatments.[11] The expansion of Medicaid has also improved health outcomes for certain cancers and types of heart attacks, and has shown promise in reducing racial and ethnic disparities in access to care.[12] As of June 2019, fifteen million people were enrolled in the ACA Medicaid expansion group, resulting in twelve million individuals newly eligible.[13] The ACA modified the purpose of Medicaid by increasing coverage for low-income individuals regardless of whether they were deemed 'deserving' of public assistance.[14] In practical terms,

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[8] ADAM SEARING & DONNA COHEN ROSS, MEDICAID EXPANSION FILLS GAPS IN MATERNAL HEALTH COVERAGE LEADING TO HEALTHIER MOTHERS AND BABIES, Georgetown University Health Policy Institute: Center for Children and Families (2019).

[9] Howard Bauchner & Karen Joynt Maddox, *Medicaid Expansion and Birth Outcomes*, 321 JAMA 1609, 1609 (2019); Clare C. Brown et al., *Association of State Medicaid Expansion Status With Low Birth Weight and Preterm Birth*, 321 JAMA 1598, 1607 (2019).

[10] Benjamin Sommers et al., *Changes in Self-reported Insurance Coverage, Access to Care, and Health Under the Affordable Care Act*, 314 JAMA 366, 370 (2015).

[11] Laurie McGinley, *ACA Linked to Reduced Racial Disparities, Earlier Diagnosis and Treatment in Cancer Care*, WASH. POST (June 2, 2019), https://www.washingtonpost.com/health/2019/06/02/aca-linked-reduced-racial-disparities-earlier-diagnosis-treatment-cancer-care/ (explaining that prior to expansion, African Americans were 4.8% less likely to start treatment for advanced cancer and today African American Adults are almost caught up with white patients in receiving timely treatment).

[12] Cheryl Clark et al., *Income Inequities and Medicaid Expansion are Related to Racial and Ethnic Disparities in Delayed or Forgone Care Due to Cost*, 54 MEDICAL CARE 555, 560 (2016); Erica Valdovinos et al., *Effects of Medicaid Expansion on Access, Treatment and Outcomes for Patients with Acute Myocardial Infarction,* 15 PLoS ONE 1, 7-8 (2020).

[13] Rachel Garfield & Robin Rudowitz, *Eliminating the ACA: What Could It Mean for Medicaid Expansion,* KFF (Oct. 1, 2020), https://www.kff.org/policy-watch/eliminating-the-aca-what-could-it-mean-for-medicaid-expansion/. *But cf. Status of State Medicaid Expansion Decisions: Interactive Map*, KFF (Mar. 31, 2021), https://www.kff.org/medicaid/issue-brief/status-of-state-medicaid-expansion-decisions-interactive-map/ (specifying the conditions and limitations certain states have imposed on Medicaid eligibility upon adopting expansion, such that implementation of expansion varies state by state, even among states that are considered Medicaid expansion states for the purposes of comparative analyses of expansion versus non-expansion).

[14] David Orentlicher, *Medicaid at 50: No longer Limited to the "Deserving" Poor?,* SCHOLARLY WORKS 185, 185-6 (2015) (examining the effect of the ACA's provision to expand Medicaid eligibility based on income relative to the federal poverty level and not further limited by "categories of the poor that were viewed as especially deserving of assistance"); Gluck & Huberfeld, *supra* note 1, at 3.

expanded eligibility has resulted in individuals and families qualifying for coverage up to higher levels of income.[15] For example, in expansion states, the eligibility level for a family of three that includes a child under age 19 is approximately $29,000 (138% FPL), whereas the same family in a non-expansion state would be eligible only up to about $8,500 (40% FPL).[16] Expansion substantially improved coverage and access to care, with the largest such improvement observed in racial and ethnic minorities.[17]

Still, some states have refused to expand Medicaid, citing concerns regarding the immediate or eventual impact on state budgets, even when the ACA's Enhanced Matching Rates for newly eligible populations paid up to 100% of the cost of expansion.[18] States' fiscal concerns are justified by the projected impact of Medicaid spending in later years post-expansion when the federal government would provide less than 100% of the funding required to sustain the expanded eligibility, because Medicaid spending is the largest single category of all state spending.[19] Any increase in Medicaid spending would have to be paid for with new revenue, likely in the form of new state taxes or higher rates of existing state taxes, or alternatively, would be offset by cuts elsewhere in state budgets.[20]

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[15] Searing & Cohen Ross, *supra* note 8, at 2.
[16] *Id*. at 1;7-8.
[17] Laurent G. Glance et al., *Impact of Medicaid Expansion on Disparities in Revascularization in Patients Hospitalized with Acute Myocardial Infarction*, 15 PLoS ONE 1, 9 (2020); Sommers et al., *supra* note 10, at 370.
[18] *See*, *e.g*., Bram Sable-Smith, *In Republican States Like Missouri, Medicaid Expansion Still Faces Stiff Opposition*, ST. LOUIS PUBLIC RADIO (Apr. 5, 2017), https://news.stlpublic radio.org/2017-04-05/in-republican-states-like-missouri-medicaid-expansion-still-faces-stiff-opposition (last visited Mar. 14, 2021); Laura Snyder & Robin Rudowitz, *Medicaid Financing: How Does it Work and What are the Implications?,* KFF (May 20, 2015), https://www.kff.org/medicaid/issue-brief/medicaid-financing-how-does-it-work-and-what-are-the-implications/; *see generally* Norris, *supra* note 5 (underscoring that the ACA has not been implemented entirely as enacted).
[19] 2020 STATE EXPENDITURE REPORT: FISCAL YEARS 2018-2020, NAT'L ASS'N OF STATE BUDGET OFFICERS 1, 52 (2020).
[20] Bram Sable-Smith*, supra* note 18; TAX POLICY CTR., BRIEFING BOOK: A CITIZEN'S GUIDE TO THE FASCINATING (THOUGH OFTEN COMPLEX) ELEMENTS OF THE FEDERAL TAX SYSTEM 1, 70 (2020).

The enduring reluctance of some states to expand Medicaid, no matter the federal incentive, suggests that no proportion of federal matching funds will result in Medicaid expansion across the nation, especially when the reason for certain states' refusal is at least somewhat partisan in nature.[21] The dual state and federal organization of Medicaid gives individual states the means of withholding programmatic cooperation in Medicaid despite the demonstrated benefits of increased coverage and improved health outcomes.[22] In that sense, the ACA's implementation of Medicaid expansion is rooted in federalism.[23] Thus, so long as Medicaid retains this state and federal character, health care legislation enacted by Congress will likely face a hurdle to implementation whenever any state determines that working with the federal government is in itself a political liability.[24] This might be the case even if cooperation would lead to improved outcomes for the people of that state—including reduced racial, ethnic, and gender disparities in health care.[25]

III. REDUCED RACIAL, ETHNIC, AND GENDER DISPARITIES

By a number of measures, Medicaid expansion has resulted in improvements in racial, ethnic, and gender disparities and better health outcomes.[26] States that have expanded Medicaid as the ACA provides have seen significant reductions in racial disparities in maternal health and infant health, with lower maternal mortality rates and lower infant mortality rates.[27] Medicaid expansion has given women of childbearing age greater

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[21] Nicole Huberfeld, *Federalizing Medicaid*, 14 U. PA. J. CONST. L. 431, 435 (2011).
[22] Gluck & Huberfeld, *supra* note 1, at 3-4.
[23] *Id*.
[24] *Id.* at 2; Huberfeld, *supra* note 21, at 483.
[25] Gluck & Huberfeld, *supra* note 1, at 2; Ian Millhiser, *Federalism in a Time of Autocracy*, 35 YALE L. & POLICY REV. 521, 536 (2017).
[26] *See supra* notes 8-12; 15-17 and accompanying text. *See infra* pp. 5-8.
[27] Searing & Cohen Ross, *supra* note 8, at 1-3;7 (noting that states that have expanded Medicaid as the ACA provided have seen a 50 percent greater reduction in rates of infant

access to health insurance that increases their access to primary and preventative care, which not only improves their own health, but also leads to better health outcomes for their infants.[28] It has also led to greater utilization of services that are considered essential benefits of covered care, including maternal depression screening and treatment and tobacco use cessation programs, which have positive health impacts seen across two generations.[29] Likewise, these services provide Medicaid patients the means to seek counseling for perinatal depression and "dyadic treatment" for mother and child during well-child visits.[30] Moreover, Medicaid-covered comprehensive tobacco cessation programs afford expectant mothers and new mothers treatment that addresses smoking habits, which are associated with women's risks for a host of chronic illnesses, including cardiovascular and respiratory diseases, cancer, risks of pregnancy-related complications, and risks their children face from exposure to second-hand smoke.[31]

Further, where Medicaid expansion has been examined in the more specific context of low birth weight and preterm birth outcomes, states that expanded the program realized improvements in racial disparities for Black infants as compared to benchmark rates for white infants.[32] Non-Hispanic Black infants are twice as likely to be born at low birth weight and 1.5 times as likely to be born prematurely.[33] In Medicaid expansion states, Black infants benefitted from significant reductions in disparities in preterm birth, very preterm birth, low birth weight, and very low birth rates.[34] This result is especially important because infants born very preterm often face

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mortality as compared to non-expansion states and lower rates of maternal mortality—"1.6 fewer maternal deaths per 100,000 women").
[28] *Id*. at 1.
[29] *Id*. at 3.
[30] *Id*.
[31] *Id.*
[32] Brown et al., *supra* note 9.
[33] *Id*. at 1599.
[34] *Id*.

enduring challenges related to brain development that affect anxiety and depression as well as memory and other cognitive tasks.[35]

Medicaid expansion has been tethered to better access to care, as the ACA aimed to improve access through greater health insurance coverage by increasing Medicaid payments to primary care physicians.[36] The ACA increased payments by requiring Medicaid reimbursement rates to match Medicare reimbursement rates.[37] As implemented initially, evidence emerged that higher Medicaid reimbursement rates showed promise in improving access to primary care, where the greater the Medicaid "fee bump" to providers, the greater the increase in primary care appointment availability.[38] The ACA also directed funding to advance the "health home" concept for Medicaid patients.[39] The goal of the health home provision is to use enhanced reimbursement of designated primary care sites as an incentive for states to implement pilot programs adapting the medical home concept to Medicaid patient populations.[40] Such patient-centered medical homes prioritize quality measurement and have demonstrated improved quality.[41] Thus, better access to care has meant better quality of primary care.[42]

Additionally, Medicaid expansion has led to a number of improved health outcomes in specialized care for especially vulnerable populations. A particular study showed that previously uninsured Hispanic and Black

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[35] *The Long-Lasting Effects of Preterm Birth*, NIH (Jan. 25, 2012), https://www.nichd.nih.gov/newsroom/resources/spotlight/012612-effects-preterm-birth.
[36] Nicole Huberfeld, *Rural Health, Universality, and Legislative Targeting*, HARVARD L. & POL'Y REV. 241, 257 (2018).
[37] Kathleen Klink, *Incentives for Physicians to Pursue Primary Care in the ACA Era*, 17 AM. MED. ASS'N J. OF ETHICS 637, 638 (2015).
[38] STEPHEN ZUCKERMAN ET AL., URBAN INST., MEDICAID PHYSICIAN FEES AFTER THE ACA PRIMARY CARE FEE BUMP 1-2 (2017).
[39] MELINDA ABRAMS ET AL., THE COMMONWEALTH FUND, REALIZING HEALTH REFORM'S POTENTIAL: HOW THE AFFORDABLE CARE ACT WILL STRENGTHEN PRIMARY CARE AND BENEFIT PATIENTS, PROVIDERS, AND PAYERS 8 (2011).
[40] *Id.* at 8-10.
[41] *Id.*
[42] *See also* Valdovinos et al., s*upra* note 12, at 2.

patients who suffered acute myocardial infarction ("AMI"), a type of heart attack, had better outcomes including higher quality of surgical care, better outcomes in heart surgery, and decreases in cardiovascular mortality.[43] One measure of improved health outcomes after AMI is a decrease in readmission rates within 30 days of treatment, and Medicaid expansion was associated with a 9.5% decrease in that measure as compared to pre-expansion.[44]

Similarly, earlier treatment following a cancer diagnosis is a measure of improved access to care that is tethered to better outcomes.[45] By that measure, Medicaid expansion also shows promise in reducing racial, ethnic, and gender disparities.[46] For instance, African Americans in states that have expanded Medicaid under the ACA have nearly closed the gap in starting early treatment for advanced cancer.[47] Another study showed that women with certain gynecologic cancers were able to receive an earlier diagnosis in states that implemented the law as intended, which meant a greater likelihood of better treatment outcomes.[48] Adjusting for race, this particular study showed that the ACA's provision to increase access to insurance for women aged 21 to 26 years led to earlier-stage diagnoses.[49] As a result, treatment of patients in this age group with gynecologic cancers, such as

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[43] *Id*.; Erica Valdovinos et al., *The Association of Medicaid Expansion and Racial/Ethnic Inequities in Access, Treatment, and Outcomes for Patients with Acute Myocardial Infarction,* 15 PLoS ONE 1, 11-12 (2020).
[44] Valdovinos et al., s*upra* note 12, at 7-8.
[45] *See* Laurie McGinley, *supra* note 11 (reporting that cancer researchers conclude that "speedier diagnoses and treatment were likely to have increased patients' chances of survival").
[46] *See id*. (noting that "…before the ACA went into effect, African Americans with advanced cancer were 4.8 percentage points less likely to start treatment for their disease within 30 days of being given a diagnosis. But today, [B]lack adults in states that expanded Medicaid…have almost entirely caught up with white patients in getting timely treatment, researchers said.").
[47] *Id.*
[48] *See id*. (stating, "[A]nother study showed that after implementation of the law, ovarian cancer was diagnosed at earlier stages and that more women began treatment within a month.").
[49] Anna Jo Bodurtha Smith & Amanda N. Fader, *Effects of the Affordable Care Act on Young Women With Gynecologic Cancers*, 131 GYNECOLOGIC ONCOLOGY 966, 975.

endometrial, ovarian, and cervical cancers, had greater potential to be more effective, including fertility-sparing outcomes.[50]

In total, these results suggest that the states that have implemented the ACA's provisions to expand coverage have realized reduced racial, ethnic, and gender disparities as well as better health outcomes in their patient populations. This raises pointed questions about why some states have chosen not to expand Medicaid.[51] Evidence suggests that opposition is at least partly ideological or partisan: for instance, the Maine legislature passed bills to implement expansion five times only to have them vetoed each time by Governor LePage, a staunch opponent of the ACA.[52] Even after a referendum passed with 59% of Maine voters supporting expansion, Governor LePage stated that he would rather "go to jail" than expand the program, out of ardent concern for the effects of expansion on the state budget.[53] Likewise, when the ACA was debated in 2010, a Texas congressman characterized Medicaid expansion as an "unprecedented loss

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[50] *Id*.

[51] *See* Ian Millhiser, *supra* note 25, at 536 (stating that "[u]nder our current system, programs like Medicaid can be disrupted either by federal officials or by state governments that refuse to cooperate—just ask the millions of Americans denied health insurance because their state governments would not participate in the Affordable Care Act's Medicaid expansion"); *see* David Orentlicher, *supra* note 14, at 186-87 (posing the questions, "Does the ACA signal a more generous view of the deserving poor, or even an abandonment of the distinction between the poor and the 'deserving' poor? Or does the ACA tell us more about the nature of health care than about societal views of the poor? And what do the answers to these questions tell us about the durability of the Medicaid expansion?").

[52] *See*, *e.g*., Sarah Kliff, *How Progressives Flipped the Script on Medicaid Expansion*, N.Y. TIMES (Aug. 4, 2020), https://www.nytimes.com/2020/08/04/upshot/missouri-election-medicaid-expansion.html; *see*, *e.g*., Michael Shepherd, *LePage Joins New Lawsuit Designed to Overturn Obamacare*, BANGOR DAILY NEWS (Feb. 27, 2018), https://bangordaily news.com/2018/02/27/news/lepage-joins-new-lawsuit-designed-to-overturn-obamacare/ (noting the action of the "Republican governor [LePage] and 19 Republican-led states" took to try to overturn the ACA).

[53] AP, *LePage Says He'd Risk Jail Before Medicaid Puts Maine in Red*, AP (Jul. 12, 2018), https://apnews.com/article/b4ccacffb7e445c08f31c4fc444c2d85. *But cf*. Robin Rudowitz & Larisa Antonisse*, Implications of the ACA Medicaid Expansion: A Look at the Data and Evidence*, KFF (May 23, 2018), https://www.kff.org/medicaid/issue-brief/implications-of-the-aca-medicaid-expansion-a-look-at-the-data-and-evidence/ (emphasizing that even after the federal government's share of financing for new Medicaid eligibility decreases from the 100 percent match, some studies "project net fiscal benefit even when states begin to pay for a share of the costs…net fiscal benefit due to cost savings and increased revenue that hold even after the state share of expansion costs increases to 10 percent in 2020").

of freedom." [54] Such rhetoric suggests that opposition to Medicaid expansion is not strictly based on policy.

Indeed, in the study showing better health outcomes after heart attacks for patients in a Medicaid expansion state, the control state was Florida, whose governors since the passage of the ACA have been stalwart in refusing its incentives to expand the program.[55] Consequently, Florida has denied about 1,362,000 Floridians coverage under Medicaid, of whom an estimated 384,000 have no realistic alternative route to health insurance coverage, reflecting a coverage gap.[56] As a result, Florida has in effect also turned away $65.2 billion over the next decade in additional federal funding.[57] A similar situation in Texas has resulted in about 1,685,000 Texans who would have been covered if the state implemented the ACA as provided, with Texas turning away in effect some $114.2 billion over the next decade.[58] The refusal to accept federal funding for Medicaid expansion reflects the continuing ideological and partisan contentiousness of Medicaid expansion.[59] These stalemates suggest that some states may view the

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[54] *See* 156 Cong. Rec. H2859-01, 2010 WL 1655658 (Statement of Rep. Burgess) (characterizing the ACA's provision for Medicaid expansion as "a much more startling recession or receding of freedom than we have seen in this country. Really, it would be unprecedented the loss of freedom that will accompany this bill.").

[55] *See* Erica Valdovinos et al., s*upra* note 12, at 3 (noting that "we chose to examine California, which expanded Medicaid through the ACA, as the 'intervention' state and Florida, which did not expand Medicaid, as the 'control' state…[Florida] is home to the second highest number of adults (after Texas) who would stand to gain insurance if the state expanded Medicaid").

[56] Louise Norris, *Florida and the ACA's Medicaid Expansion*, HEALTHINSURANCE.ORG (Sept. 8, 2020), https://www.healthinsurance.org/florida-medicaid/. *See also* Rachel Garfield et al., *The Coverage Gap: Uninsured Poor Adults in States that Do Not Expand Medicaid*, KFF (Jan. 21, 2021), https://www.kff.org/uninsured/issue-brief/the-coverage-gap-uninsured-poor-adults-in-states-that-do-not-expand-medicaid/ (defining the coverage gap as the range of low to moderate incomes wherein adults are not eligible for Medicaid because their income is too high but also not eligible for tax credits to offset the price of private health insurance premiums).

[57] Norris, *supra* note 56 (stating that the money the state [of Florida] is leaving on the table over the next decade by not expanding Medicaid amounts to some $65.2 billion).

[58] Louise Norris, *Texas and the ACA's Medicaid Expansion,* HEALTHINSURANCE.ORG (Sept. 8, 2020), https://www.healthinsurance.org/texas-medicaid/.

[59] *See*, *e.g*., *Medicaid expansion*, HEALTHINSURANCE.ORG, https://www.healthinsurance.org/glossary/medicaid-expansion/ (last visited Apr. 10, 2021) (characterizing Medicaid

decision to expand Medicaid neither in terms of better health outcomes nor in terms of greater fiscal support from the federal government.

IV. FEDERALIZING AND FINANCING MEDICAID

Transforming Medicaid into a program run by the federal government could be a solution to both the problem of fragmented implementation and the uncertainty of budgetary impacts on states.[60] Medicaid reimagined as a fully federal program could relieve states of the burden of budgeting for Medicaid spending altogether and thereby remove the political pressure on governors and state legislatures in non-expansion states to modify the aims of Medicaid in order to uphold disparate ideological or partisan commitments.[61]

To be sure, successful ballot initiatives have highlighted the mismatch between voters' support for Medicaid expansion within non-expansion states and the refusal of their governors and/or state legislatures to implement the provision as enacted by the ACA.[62] But the analysis here essentially brackets issues of whether federalizing Medicaid would face legislative and political challenges and other potential issues that would arise from the precise form of such legislation. Thus, rather than grappling with the notion that health care federalism might be constitutionally

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expansion as "still a contentious issue" in states where "the legislature and/or governor are still strongly opposed to accepting federal funding to expand Medicaid").

[60] Huberfeld, *supra* note 21, at 473. *See*, *e.g.*, Makhlouf, *supra* note 1, at 1760 (noting that state constitutional balanced budget mandates "[mean] that during economic recessions, states must find ways to cut spending…[which] disproportionately affect countercyclical spending programs such as Medicaid…there is pressure for the state to restrict eligibility criteria and services in order to limit spending").

[61] Huberfeld, *supra* note 21, at 473; Millhiser, *supra* note 25, at 537; *see*, *e.g.*, Sarah Kliff, *supra* note 52 (discussing the strategy of using a ballot initiative in 2017 to pass a referendum on Medicaid expansion in Maine, which led to similar campaigns in Nebraska, Utah, Idaho, and Missouri—all states whose governor and/or state legislatures opposed expansion).

[62] *See id*. (noting that, following multiple vetoes by then-Governor LePage, in 2017 Maine was the first state where a referendum on Medicaid expansion succeeded—with 59 percent of voters supporting it).

protected or otherwise guaranteed, this approach tables those issues in favor of proceeding with an analysis that looks at funding as the central issue of feasibility.[63]

Medicaid, which accounts for about one out of every six dollars spent on health care in the United States, is largely financed through "appropriated mandatory" or "appropriated entitlement" spending at the federal and state levels.[64] As it exists today, Medicaid is the third largest domestic component in the federal budget.[65] In fiscal year 2020, federal financing accounted for 62.7% of total spending on Medicaid, with state financing accounting for the remainder.[66] The average state share for Medicaid expenditures (excluding administrative costs) was approximately 28.6% of overall state expenditures, the largest component of state budgets.[67] States have financed Medicaid expansion in a variety of ways: drawing more from their general funds, creating or increasing provider taxes, identifying cost savings, and imposing new or higher taxes on cigarettes or tobacco—a patchwork of financing sources.[68]

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[63] *See*, *e.g.*, Makhlouf, *supra* note 1, at 1698 (emphasizing that "[a]lthough the traditional presumption of state primacy in matters relating to health retains some influence in healthcare policy and constitutional jurisprudence, federal authority to regulate health insurance is undisputed. Debates over the preservation of states' roles are not based on considerations about the primary function of each level of government with respect to health insurance regulation and finance…rather, they are mainly about policy disagreements.").
[64] Snyder & Rudowitz, *supra* note 18. *See*, *e.g.*, C. STEPHEN REDHEAD ET AL. AFFORDABLE CARE ACT (ACA) AND THE APPROPRIATIONS PROCESS: FAQS REGARDING POTENTIAL LEGISLATIVE CHANGES AND EFFECTS OF A GOVERNMENT SHUTDOWN, CONGRESSIONAL RESEARCH SERVICE 3 (2013) (stating that the costs of Medicaid expansion for which the federal government would be responsible are paid through direct or mandatory spending in annual appropriations acts). *See* Huberfeld, *supra* note 21, at 447-48; 475 (noting that, through federal matching for various state administrative expenses related to Medicaid—such as training, translation, immigration verification, and fraud prevention—the federal government already pays for more than 50 percent of state administrative costs of Medicaid, which creates a "double executive structure that is inherently inefficient").
[65] Snyder & Rudowitz, *supra* note 18 (noting that the only domestic programs that account for larger portions of the federal budget are Medicare and Social Security).
[66] 2020 STATE EXPENDITURE REPORT, supra note 19, at 52.
[67] *Id*.
[68] *See* Robin Rudowitz et al. *Medicaid Enrollment & Spending Growth: FY 2019 & 2020*, KFF (Oct. 18, 2019), https://www.kff.org/medicaid/issue-brief/medicaid-enrollment-spending-growth-fy-2019-2020/.

Accordingly, one reason for federalizing Medicaid would be to streamline and make more efficient the program's financing, and another would be to help state finances.[69] The additional costs of a fully federal Medicaid program would have to be paid for with revenue from somewhere, and the lessons of the ACA might indicate precisely where such financing is feasible, if national legislation were to be paid for in the same way the ACA was meant to be.[70] The ACA created or increased the rates of some 20 taxes.[71] These sources of financing were intended to pay for the ACA's estimated 10-year price of about one trillion dollars.[72] That price accounted for reforms such as eliminating co-pays for preventive care, vaccinations, and a wide array of health screenings, as well as closing the Medicare Part D "donut hole" to offset more of the cost of prescription drugs, establishing premium tax credits to offset some or all of the cost of buying private health insurance, standardizing essential health benefits, and implementing consumer protections—such as prohibitions against the denial of coverage for preexisting conditions and prohibitions against rescission.[73]

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[69] *See* Robin Rudowitz & Larisa Antonisse*, Implications of the ACA Medicaid Expansion: A Look at the Data and Evidence*, KFF (May 23, 2018), https://www.kff.org/medicaid/issue-brief/implications-of-the-aca-medicaid-expansion-a-look-at-the-data-and-evidence/ ("State budget effects: Data supports a net fiscal benefit for states from Medicaid expansion. National research found that there were no significant increases in spending from state funds as a result of Medicaid expansion and no significant reductions in state spending on education, transportation, or other state programs as a result of expansion during FYs 2010-2015.").

[70] Julie Rovner, *The Case of The ACA's Disappearing Taxes*, KHN (Nov. 20, 2019), https://khn.org/news/healthbent-paying-for-aca-disappearing-tax-measures/.

[71] Ryan Ellis & John Kartch, *Full List of Obamacare Hikes,* AMERICANS FOR TAX REFORM (June 28, 2012), https://www.atr.org/full-list-obamacare-tax-hikes-a6996.

[72] Rovner, *supra* note 70.

[73] *See*, *e.g.*, Diane Omdahl, *The Medicare Part D Drug Plan Donut Hole Is Closed. What Does That Mean?*, FORBES.COM (Jan. 21, 2020), https://www.forbes.com/sites/dianeomdahl/2020/01/21/the-medicare-part-d-drug-plan-donut-hole-is-closed-what-does-that-mean/?sh=a68fe85288d2 (describing how the ACA closed the Part D "donut hole" by providing discounts to beneficiaries whose applicable expenses previously were not covered at all); *Chart Book: Accomplishments of the Affordable Care Act*, CTR. ON BUDGET & POL'Y PRIORITIES, (Mar. 19, 2019), https://www.cbpp.org/research/health/chart-book-accomplishments-of-affordable-care-act.

In the first four years of the ACA, several of the law's taxes were repealed—critically undermining the claim that the law was 'paid for'—but two taxes that yet remain account for most of the revenue for the law: the Net Investment Income Tax ("NIIT"), as codified in Section 1411 of the Internal Revenue Code ("IRC"), and the Additional Medicare Tax, as promulgated in 26 CFR Parts 1 and 31.[74]

The durability of these two taxes may be explained in part by the fact that relatively high-income taxpayers are the ones affected by them.[75] The NIIT applies—at a rate of 3.8%—only when individuals have a modified adjusted gross income ("MAGI") over thresholds of $250,000 for married filing jointly, or $200,000 for single filers; and when estates and trusts have adjusted gross income over the given dollar amount that defines the highest tax bracket for an estate or trust and have undistributed net investment income.[76] Further, the NIIT does not apply to any amount of gain that is excluded from gross income, which means qualified gain from the sale of a personal residence under IRC section 121 does not figure into the NIIT.[77] Moreover, the amount subject to the NIIT is the lesser of the excess of MAGI over the threshold or Net Investment Income.[78] Net Investment Income typically includes income from dividends, capital gains, and interest less certain exclusions and deductions that may be properly allocated to Gross Investment Income, such as expenses related to rental income, investment interest expenses, certain advisory and brokerage fees,

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[74] IRS, *Questions and Answers on the Net Investment Income Tax*, IRS.GOV, https://www.irs.gov/newsroom/questions-and-answers-on-the-net-investment-income-tax (last visited Mar. 14, 2021); IRS, *Affordable Care Act Tax Provisions,* IRS.GOV, https://www.irs.gov/affordable-care-act/affordable-care-act-tax-provisions, (last visited Mar. 14, 2021).
[75] Rovner, *supra* note 70.
[76] IRS, *Questions and Answers on the Net Investment Income Tax, supra* note 74.
[77] *Id*.
[78] *Id*.

tax preparation fees, fiduciary expenses for an estate or trust, as well as state and local taxes.[79]

Similarly, the Additional Medicare Tax applies and is subject to withholding—at a rate of 0.9%—only when wages, self-employment income, and certain other compensation exceed threshold amounts of $250,000 for taxpayers married filing jointly, or $200,000 for single filers.[80] The structure of the Additional Medicare Tax is sympathetic with how Medicare was funded prior to the ACA, in that 2.9% of qualified earnings are withheld and contributed to the Social Security Administration through the Federal Insurance Contributions Act ("FICA"), with employers footing half and employees the other half, and self-employed individuals responsible for the entire 2.9%.[81] Enacted as part of the ACA in 2013, the Additional Medicare Tax imposes these rates on the amounts over the thresholds mentioned above.[82] Taxpayers whose earnings are below those thresholds do not pay any Additional Medicare Taxes.[83] Moreover, taxpayers with earnings exceeding those thresholds may reduce the amount subject to the Additional Medicare Tax by moving money into flexible spending accounts, health savings accounts, or certain retirement accounts.[84]

The way these provisions are written means that they affect relatively high-income taxpayers more or less exclusively, which explains in part why these taxes have survived otherwise successful efforts to defund the ACA.[85] Accordingly, the fact that these sources of financing for national healthcare legislation remain suggests that federalizing Medicaid might be funded the

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[79] *Id*.
[80] IRS, *What is the Additional Medicare Tax?* IRS.GOV, https://www.irs.gov/newsroom/what-is-the-additional-medicare-tax, (last visited Mar. 14, 2021).
[81] S. Behring, *What is the Additional Medicare Tax?* HEALTHLINE.COM (June 29, 2020), https://www.healthline.com/health/medicare/additional-medicare-tax.
[82] *Id*.
[83] IRS, *supra* note 80.
[84] *Id*.
[85] Rovner, *supra* note 70.

same way, because these particular tax provisions have managed to withstand tremendous pressure to be eliminated.[86] Indeed, efforts to repeal the ACA in 2020 drew considerable attention to the ranges of income that stood to gain the greatest tax relief.[87] Estimates reflected the fact that the ACA's tax structure was highly disproportionate: the highest-income 0.1% of taxpayers (with average incomes of over $3 million) and the next 0.9% would have received, respectively, 42% and 25% of the share of the tax cut from jettisoning the ACA's sources of financing, whereas the second, third, fourth, and fifth quintiles each would have received a share equal to about 3 or 4%.[88] Thus, with the top 1% of the income distribution contributing nearly two-thirds of the total value of ACA taxes that remained by 2019, these sources of financing were drawn from the highest incomes almost exclusively.[89]

However, the forces that favor these ACA taxes may well vanish when applied in support of Medicaid, precisely because of the populations that Medicaid benefits.[90] The durability of the ACA taxes that have managed to survive might suggest some notion that Medicare is in principle a more 'worthy' program because Medicare beneficiaries themselves contribute to that program through federal payroll taxes.[91] Moreover, contrasting views

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[86] *Id*.
[87] *See, e.g.,* Howard Gleckman, *By Overturning the ACA, The Supreme Court Would Cut Taxes Substantially For High-Income Households*, TAX POL'Y CTR. (May 12, 2020), https://www.taxpolicycenter.org/taxvox/overturning-aca-supreme-court-would-cut-taxes-substantially-high-income-households; *see also* Aviva Aron-Dine et al., *ACA Repeal Lawsuit Would Cut Taxes for Top 0.1 Percent by an Average of $198,000*, CTR. ON BUDGET & POL'Y PRIORITIES (June 24, 2020), https://www.cbpp.org/research/health/aca-repeal-lawsuit-would-cut-taxes-for-top-01-percent-by-an-average-of-198000 (characterizing the tax cuts that would have resulted from repeal of the ACA as "a massive transfer of resources from low- and moderate-income people to those at the top of the income scale…[that] would also widen racial gaps, with Black and Hispanic people disproportionately likely to lose health coverage and the overwhelming share of the tax cuts flowing to white people").
[88] *Id*.
[89] *Id*.
[90] *See* Huberfeld, *supra* note 21, at 438-39.
[91] *Id*. at 438-440 (noting that, through federal payroll taxes, "the public feels a sense of stewardship about [Medicare]" that may not exist for Medicaid).

of these two programs trace back to their enactment in the Social Security Act Amendments of 1965.[92] The higher approval of Medicare reflects different historical contexts, as the idea of a health insurance program for everyone who reaches age sixty-five proved to be more politically popular than one for the poor.[93] Medicare's origins consisted of successful lobbying efforts pointedly rejecting any structure that would have resulted in variations by state.[94] In contradistinction, Medicaid has its origins in predecessor 'welfare medicine' programs such as Kerr-Mills, which vested in individual states discretionary control over the federal funding provided for the medical care of their indigent populations.[95] Ultimately, the analysis here sets aside such thornier concerns of whether people with low incomes might be seen as undeserving of the coverage Medicaid would provide.[96] If so, the sources of financing discussed in this paper might not be able to fund federalizing Medicaid after all, because no source of financing would

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[92] *See id.; see* Makhlouf, *supra* note 1, at 1700 (discussing the differential reception of Medicare as compared to Medicaid: "While Medicare has always enjoyed popular approval, Medicaid has long been 'burdened by the stigma of public assistance.'").

[93] Huberfeld, *supra* note 2, at 70-71 (stating, "Medicaid was created at the same time as Medicare, but the political capital was invested in creating social insurance for the elderly, who successfully lobbied for a national, universal health insurance program in Medicare. The safety net for the remainder of the poor was an afterthought…Medicaid was a continuation of the Kerr-Mills program, which provided federal funding to the states to continue their medical assistance to the poor. The Medicaid Act created a stronger federal framework…But, even with strengthened federal rules, many decisions were left in the hands of the states, continuing fragmentation through patient exclusion and disunified administration that existed in health care long before Medicaid was enacted.").

[94] Huberfeld, *supra* note 21, at 449.

[95] *Id*. at 443-45 (discussing how Medicaid incorporated features of Kerr-Mills and stating, "Medicaid contained many of the features of prior federal funding for medical care for the poor, including a sense that welfare was 'gratuitous.'"). *See* Michener, *supra* note 2, at 40-43 (discussing the historical context of Kerr-Mills and the influence of that legislation on the development of Medicaid).

[96] Huberfeld, *supra* note 21, at 438-40; s*ee*, *e.g*., Ann Marie Marciarille, *Let Fifty Flowers Bloom: Health Care Federalism After National Federation of Independent Business v. Sebelius*, 81 UNIV. OF MO. L. REV. 313, 321 (2012) (stating that "Medicaid is the disfavored step-child of the government-funded health insurance family. Medicaid's disfavored status may be as much a function of who it serves as of how it serves them.").

be deemed fairly allocated for that purpose unless the program itself were fundamentally transformed.[97]

If that turned out to be the case, then this proposed solution to federalizing Medicaid is ultimately bound to the perception of Medicaid as an equitable health insurance program.[98] This is a question not of whether the program reliably improves health outcomes.[99] Medicaid expansion provides coverage to people who otherwise could not obtain any health insurance, and it demonstrably reduces racial, ethnic, and gender disparities through increased access to care.[100] Nor is this necessarily about the feasibility of federalizing Medicaid and funding it.[101] The question, then, is not whether Medicaid can accomplish these goals.[102] From the perspective of those who would oppose any extension of the program, the question seems to be whether it should.

V. CONCLUSION

Following the Supreme Court's decision in *NFIB v. Sebelius*, the ACA's provision for Medicaid expansion preserved, and arguably enhanced, health care federalism. The current impasse in Medicaid expansion reflects certain states' fundamental disagreements over the purpose of the program and raises questions about the purpose of health care federalism in the

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[97] *See*, *e.g.*, Doug Badger, *Medicaid Work Requirements Could Help the Poor*, NAT'L REV. (Jan. 8, 2019), https://www.nationalreview.com/2019/01/medicaid-work-requirements-way-out-of-poverty/ (framing work requirements in terms of Medicaid recipients' self-interest, in that Medicaid coverage otherwise creates "perverse incentives…Work requirements help break this dynamic, discouraging long-term dependency.").
[98] Huberfeld, *supra* note 21, at 435.
[99] *See supra* notes 8-13 and accompanying text; s*ee* discussion *supra* Sections II, III.
[100] Garfield & Rudowitz, *supra* note 13. Moreover, access to Medicaid is increasingly bound up with the aim of advancing quality measurement. *See*, *e.g.*, *Quality of Care Performance Measurement*, Medicaid.gov, https://www.medicaid.gov/medicaid/quality-of-care/quality-of-care-performance-measurement/index.html (last visited Apr. 10, 2021) (stating that, "[t]he use of quality measurement helps strengthen accountability and support performance improvement initiatives at numerous levels" and listing seven areas of focus that suggest that higher quality care and better outcomes are major goals of access to care through Medicaid).
[101] *See generally* Huberfeld, *supra* note 21.
[102] *Id*.

abstract—whether it is an end in itself or a means to better health outcomes. Emerging evidence demonstrates that Medicaid expansion results in increased access to care and better health outcomes across several measures, from maternal and infant health to more timely primary care, more effective cardiac care, and earlier cancer treatment, with significant reductions in racial, ethnic, and gender disparities.

Federalizing Medicaid may be a solution for two enduring problems. First, it would mitigate fragmentation and inefficiency in the way Medicaid, as it currently exists, is implemented and administered. Second, it would prevent use of the dual federal and state structure of Medicaid as a mechanism to withhold programmatic cooperation for partisan purposes. The survival of the ACA to date suggests that financing such a solution may be politically realistic as well as scalable. Still, the appeal of fully federalizing Medicaid likely cannot be separated from difficult, perhaps intractable, issues concerning attitudes toward the people Medicaid helps and toward the role of government generally—whether state, federal, or something else.