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Table of Contents

INSTITUTE OF ONEWORLD HEALTH: A NONPROFIT PHARMACEUTICAL COMPANY

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Abstract

Neglected tropical diseases are a category of diseases that affect more than one billion people worldwide. Many of these tropical diseases are infectious diseases that affect the poorest communities within developing countries. Developing countries bear 90% of the world's disease burden. However, pharmaceutical companies allocate only 3% of their research and development ("R&D") budgets toward diseases in the developing world. There is an imbalance between R&D for the developing world and its disease burden. In order to bridge the R&D gap and stimulate innovation, entrepreneurs and philanthropists have founded nonprofit organizations, like the Institute for OneWorld Health, that specifically develop drugs to target diseases in developing countries. These nonprofit initiatives operate through an innovative collaboration model in the form of public-private partnerships called product development partnerships (PDPs). This type of collaboration combines public and philanthropic funds with the scientific and technical prowess of private industry to develop drug products. PDPs are positive developments that will help alleviate the R&D imbalance for neglected diseases and bring relief to people suffering in developed worlds.

This Article argues that OneWorld Health's unique nonprofit pharmaceutical business model is advantageous in the fight against neglected diseases. However, those who are considering the use of such a business model need to be aware of the potential consequences that may result in developing countries from using such a model. There are also challenges and obstacles that such a nonprofit pharmaceutical company may face in getting neglected disease drugs into the hands of those who desperately need them. The Article will explore OneWorld Health's history, products in development and on the market, recent strategic changes to the organization, its nonprofit pharmaceutical business model, and advantages and disadvantages. The Article will also address some potential obstacles and challenges that OneWorld Health and PDPs in general may face in its drug development efforts.

I. Introduction

Neglected tropical diseases are a category of diseases that affect

more than one billion people worldwide.[1] Many of these tropical diseases are infectious diseases that affect the poorest communities within developing countries.[2] Examples of tropical infectious diseases are malaria, leishmaniasis, schistosomiasis, Chagas disease, dengue, and diarrheal diseases.[3]

There is an imbalance between R&D for the developing world and its disease burden.[4] Developing countries bear 90% of the world's disease burden.[5] However, pharmaceutical companies allocate only 3% of their R&D budgets toward diseases in the developing world.[6] Since most developing countries with neglected diseases are poor and lack purchasing power, they are not viable commercial markets for the pharmaceutical industry to target.[7] The majority of pharmaceutical drugs is covered by patents, and drug companies are able to maximize profits on patented drugs.[8] Pharmaceutical companies want to invest money in developing drugs whose sales will allow them to recoup their costs.[9] Drug companies are unable to recoup costs when developing countries account for only about 10% of global pharmaceuticals sales.[10] Instead, drug companies focus their R&D on drugs directed towards countries where companies can achieve 90-95% of their revenues, such as the United States, Europe, and Japan.[11] Therefore, there is a gap between pharmaceutical R&D in developing and

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[1] *World Health Statistics 2014*, WORLD HEALTH ORGANIZATION, (2014), http://www.who.int/gho/publications/world_health_statistics/en/.

[2] *See* William W. Fisher & Talha Syed, *Global Justice in Healthcare: Developing Drugs for the Developing World*, 40 U.C. DAVIS L.REV. 581, 583 (2007); *Tropical Diseases*, WORLD HEALTH ORGANIZATION, http://www.who.int/topics/tropical_diseases/en/ (last visited Oct. 5, 2015).

[3] *See Institute for OneWorld Health*, THE WORLD TECHNOLOGY NETWORK, http://www.wtn.net/2004/bio196.html (last visited Oct. 29, 2015); *Tropical Diseases*, *supra* note 2.

[4] *See* Helen Coster, *Can Non-Profit Drug Companies Cure Diseases of Poverty?*, FORBES, (Jan. 12, 2011, 4:46 PM), http://www.forbes.com/sites/helencoster/2011/01/12/can-non-profit-drug-companies-cure-diseases-of-poverty/.

[5] *Id.*

[6] *Id.*

[7] *See id.*; Taiwo A. Oriola, *Strong Medicine: Patents, Market, and Policy Challenges for Managing Neglected Diseases and Affordable Prescription Drugs*, 7 CAN. J. L. & TECH. 57, 101 (2009); *See* WORLD HEALTH ORGANIZATION, *Report of the Commission on Intellectual Property Rights, Innovation and Public Health, Public Health, Innovation and Intellectual Property Rights*, (Geneva: WHO Press, 2006), at 2.

[8] *See* Fisher & Syed, *supra* note 2, at 583.

[9] *See* Coster, *supra* note 4; Oriola, *supra* note 7, at 101.

[10] *See* Oriola, *supra* note 7, at 101.

[11] Fisher & Syed, *supra* note 2, at 583.

developed worlds.[12]

In order to bridge the R&D gap and stimulate innovation, the private and public sectors have implemented several unique strategies and solutions.[13] Research institutions are adopting novel licensing strategies to ensure that resulting drug products will be available to developing countries at low costs.[14] Remarkably, drug companies are agreeing to such terms.[15] For example, Yale and Bristol Myers Squibb ("BMS") had an agreement with terms where BMS agreed to not enforce Yale's stavudine patent in South Africa.[16] Another example is where the NIH Office of Technology Transfer implemented an open licensing approach to develop a rotavirus vaccine by offering partially-exclusive, regional licenses to drug companies in developing countries.[17] Such a licensing strategy offers multiple partners the opportunity to innovate and develop the vaccine, which can lower drug costs for patients.[18]

In recent years, entrepreneurs and philanthropists have founded nonprofit organizations that specifically develop drugs to target diseases in developing countries.[19] Many of them target specific diseases, such as the Medicines for Malaria Venture, Global Alliance for TB Drug Development, and the International AIDS Vaccine Initiative.[20] Other nonprofit organizations, such as the Institute for OneWorld Health ("OneWorld Health"), target a broader set of diseases.[21] These nonprofit initiatives operate through an innovative collaboration model in the form of public-private partnerships called product development partnerships (PDPs).[22] This type of collaboration combines public and philanthropic funds with the scientific and technical prowess of private industry to develop drug products.[23] PDPs

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[12] *See* Oriola, *supra* note 7, at 101.

[13] *See* Amy Kapczynski, *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1068, 1073-75 (2005).

[14] *See id.* at 1073-74.

[15] *See id.* at 1073.

[16] *See id.*

[17] *See id.* at 1074.

[18] *See id.*

[19] *See id.*

[20] *Id.*

[21] *Id.*

[22] *See Product Development Partnership Model*, MEDICINES FOR MALARIA VENTURE, http://www.mmv.org/partnering/product-development-partnership-model (last visited Oct. 29, 2015); *see also* Kapczynski, *supra* note 13, at 1073-74.

[23] *See* Kapczynski, *supra* note 13, at 1073-74; Dan Phair, *Orphan Drug Programs,*

are positive developments that will help alleviate the R&D imbalance for neglected diseases and bring relief to people suffering in developed worlds.[24]

This Article will focus primarily on OneWorld Health. This Article argues that OneWorld Health's unique nonprofit pharmaceutical business model is advantageous in the fight against neglected diseases. However, those who are considering the use of such a business model need to be aware of the potential consequences that may result in developing countries from using such a model. There are also challenges and obstacles that such a nonprofit pharmaceutical company may face in getting neglected disease drugs into the hands of those who desperately need them. Part II will explore OneWorld Health's history, products in development and on the market, and recent strategic changes to the organization. Part III will describe OneWorld Health's nonprofit pharmaceutical business model and its advantages. This part will also examine concerns such a business model and PDPs raise, and the consequences that developing countries may experience. Part IV will address some potential obstacles and challenges that OneWorld Health and PDPs in general may face in its drug development efforts. Part V will conclude.

II. Institute for OneWorld Health

A. History

In July 2000, Dr. Victoria G. Hale founded the Institute for OneWorld Health in San Francisco, California.[25] OneWorld Health became the first nonprofit pharmaceutical company in the United States.[26] Its mission is to develop "safe, effective, and affordable" new infectious disease medications for people in the developing world.[27] In order to do so, the company has relied on both public and philanthropic

Public-Private Partnerships and Current Efforts to Develop Treatments for Diseases of Poverty, 4 J. HEALTH & BIOMEDICAL L. 193, 195 (2008); *Public-Private Partnerships for Global Health: How PATH Advances Technologies Through Cross-Sector Collaboration*, PATH (March 2013), http://www.path.org/publications/files/ER_app_ppp_policy_rpt.pdf [hereinafter *Public-Private Partnerships for Global Health*].

[24] *See Institute for OneWorld Health*, *supra* note 3; *Product Development Partnership Model*, *supra* note 22.

[25] Jerald Hess, *NGO Update*, 14 NO. 1 HUM. RTS. BRIEF 49 (Fall 2006).

[26] *Id.*

[27] *Id.*

funds, along with private industry collaborations.[28] For example, the Bill and Melinda Gates Foundation has awarded millions of dollars to OneWorld Health.[29] The Gates Foundation granted $4.6 million in 2002,[30] $42.6 million in 2004,[31] $30 million in 2005,[32] and $10.7 million in 2010.[33] With these funds, OneWorld Health has been able to seek collaborations with governments, foundations, private companies, public institutions, and academia.[34]

B. Products Developed and in Development

1. Visceral Leishmaniasis: First Commercial Success

After OneWorld Health's inception, its first project was to bring the drug Paromomycin to the Indian market to treat visceral leishmaniasis.[35] Visceral leishmaniasis, also known as "black fever" or "kala azar," is a parasitic disease transmitted through sand fly bites.[36] The disease afflicts over 12 million people worldwide and kills 60,000 people each year.[37] India carries the greatest burden for black fever.[38]

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[28] *See* Kapczynski, *supra* note 13, at 1074-75.

[29] *See Bill & Melinda Gates Foundation Awards $4.6 Million to Institute for OneWorld Health for Drug Development in Fight Against Neglected Insect-Born Diseases*, GATESFOUNDATION, http://www.gatesfoundation.org/Media-Center/Press-Releases/2002/08/Institute-for-OneWorld-Health-Receives-Grant (last visited Oct. 5, 2015) [hereinafter *Gates Awards $4.6 Million*]; *Collaboration of Biotech, Academia, and Nonprofit Pharma Could Significantly Reduce Cost, Boost Supplies of Antimalarial Drug*, GATESFOUNDATION, http://www.gatesfoundation.org/Media-Center/Press-Releases/2004/12/OneWorld-Health-Receives-Grant (last visited Oct. 5, 2015) [hereinafter *Collaboration of Biotech*]; *Institute for OneWorld Health Receives $10.7 Million from Gates Foundation*, PHILANTHROPY NEWS DIGEST (July 12, 2010), http://www.philanthropynewsdigest.org/news/institute-for-oneworld-health-receives-10.7-million-from-gates-foundation [hereinafter *OneWorld Health Receives $10.7 Million*]; *Institute for OneWorld Health to Create Innovative and Sustainable Disease Control Program*, GATESFOUNDATION, http://www.gatesfoundation.org/Media-Center/Press-Releases/2005/12/Institute-for-OneWorld-Health-Receives-Multimillion-Dollar-Grant (last visited Oct. 5, 2015) [hereinafter *OneWorld Health Disease Control Program*].

[30] *See Gates Awards $4.6 Million*, *supra* note 29.

[31] *See Collaboration of Biotech*, *supra* note 29.

[32] *See OneWorld Health Disease Control Program*, *supra* note 29.

[33] *See OneWorld Health Receives $10.7 Million*, *supra* note 29.

[34] *See* Coster, *supra* note 4; *Institute for OneWorld Health*, *supra* note 3; *Collaboration of Biotech*, *supra* note 29.

[35] Stephanie Strom, *A Small Charity Takes Lead in Fighting a Disease*, N.Y. TIMES, July 31, 2006, http://www.nytimes.com/2006/07/31/health/31charity.html.

[36] *See Gates Awards $4.6 Million*, *supra* note 29.

[37] *See id.*

[38] *See id.*

Without treatment, black fever has a mortality rate near 100%.[39]

Two decades after the pharmaceutical industry identified Paromomycin as a cheap, simple, and effective treatment for black fever, Phase II clinical trials were completed.[40] However, after formal testing in the late 1980s, the industry abandoned the drug.[41] Paromomycin ended up at the World Health Organization ("WHO"), but WHO lacked the money to conduct Phase III clinical trials and bring the drug to market.[42] This is where OneWorld Health came in to the picture. With Gates Foundation grants[43], OneWorld Health became partners with WHO to finish Phase III clinical trials in India, and successfully brought the drug to the Indian market in 2006.[44] OneWorld licensed and transferred the drug to Gland Pharma, an Indian drug company.[45] The Indian company agreed to manufacture the drug and sell it at cost upon approval.[46] The agreement and lack of patents on the drug dramatically lowered the cost of Paromomycin to only $10.[47] In comparison, other treatments cost $100 to $200.[48]

To date, Paromomycin has achieved regulatory approval in India, Nepal, and Uganda.[49] In December 2012, Paromomycin completed Phase III clinical trials in Bangladesh.[50]

2. Other Parasitic Diseases

In addition to its work on black fever, OneWorld Health's projects include work on other parasitic diseases such as Chagas disease, schistosomiasis, and malaria.[51]

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[39] *See id.*

[40] *See* Strom, *supra* note 35.

[41] *See id.*

[42] *See Gates Awards $4.6 Million*, *supra* note 29; Strom, *supra* note 35.

[43] *See Gates Awards $4.6 Million*, *supra* note 29; *OneWorld Disease Control Program*, *supra* note 29.

[44] *See Gates Awards $4.6 Million*, *supra* note 29; *See* Hess, *supra* note 25.

[45] *See* Strom, *supra* note 35.

[46] *See id.*

[47] *See id.*

[48] *See id.*

[49] *Kala-azar Treatment Completes Phase 3(b) Clinical Trial in Bangladesh*, PATH (Dec. 2012), http://www.path.org/news/press-room/139/.

[50] *Id.*

[51] *See Gates Awards $4.6 Million*, *supra* note 29; *Institute for OneWorld Health*, *supra* note 3; *Institute for OneWorld Health Licenses Potent Therapy from Yale and University of Washington to Treat Chagas, One of the Largest Parasitic Diseases in the World*, YALE NEWS (July 8, 2003), http://news.yale.edu/2003/07/08/institute-oneworld-health-licenses-potent-therapy-yale-and-university-washington-treat-ch [hereinafter *OneWorld Health Licenses from*

a. Chagas Disease

A parasitic bug, commonly known as the "kissing bug," causes Chagas disease.[52] Worldwide, Chagas disease affects about six to seven million people, however occurrences are primarily in Latin America.[53] The disease is a slow killer, and patients usually die from heart failure after decades of the disease causing irreversible damage to the heart, colon, and esophagus.[54] In 2002, Celera Genomics, a biopharmaceutical company, donated a pre-clinical compound for Chagas disease to OneWorld Health.[55] In 2003, OneWorld Health received an exclusive license from Yale University and the University of Washington for a novel class of high-potency compounds to treat Chagas disease in developing countries.[56] The licensing agreement reserved rights for the universities to seek a pharmaceutical partner to develop the same compounds for fungal infections in developed countries.[57]

Since the donated compounds were still in the research and pre-clinical phases, there is no further progress to report in this area. To date, there are only two drugs on market to treat acute Chagas disease, but both medications are expensive with high side effect risks.[58] There are currently no treatments for chronic Chagas disease or vaccines available.[59]

b. Schistosomiasis

Schistosomiasis is a disease that afflicts nearly 240 million people

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Yale]; *UC Santa Barbara Donates Discovery to OneWorld Health that May Speed Disease Treatment*, BIO-MEDICINE (Feb. 24, 2004), http://news.bio-medicine.org/biology-news-2/UC-Santa-Barbara-donates-discovery-to-OneWorld-Health-that-may-speed-disease-treatment-2344-1/ [hereinafter *UC Santa Barbara*].

[52] *See Gates Awards $4.6 Million*, *supra* note 29.

[53] *Chagas Disease (American Trypanosomiasis)*, WORLD HEALTH ORGANIZATION, http://www.who.int/mediacentre/factsheets/fs340/en/ (last visited Jan. 11, 2016).

[54] *See Gates Awards $4.6 Million*, *supra* note 29.

[55] *See Gates Awards $4.6 Million*, *supra* note 29; *OneWorld Health Licenses from Yale*, *supra* note 51; *see Celera Makes Use of its Axys in Drug Donation to Nonprofit*, WASHINGTON BUSINESS JOURNAL (Feb. 25 2002), http://www.bizjournals.com/washington/stories/2002/02/25/story8.html.

[56] *See OneWorld Health Licenses from Yale*, *supra* note 51.

[57] *Id.*

[58] *See Chagas Disease*, BIO VENTURES FOR GLOBAL HEALTH, http://www.bvgh.org/Current-Programs/Neglected-Disease-Product-Pipelines/Global-Health-Primer/Diseases/cid/ViewDetails/ItemID/1.aspx (last visited Oct. 15, 2015).

[59] *Id.*

worldwide.[60] Parasitic larvae infect people who encounter infested fresh water.[61] Microscopic adult worms live in veins and lay eggs into human tissue, causing major damage.[62] In 2004, the University of California, Santa Barbara decided to donate to OneWorld Health all patent rights to a class of cardiovascular compounds for use against schistosomiasis.[63]

To date, there are no other press releases or information regarding progress with these compounds.

c. Malaria

Malaria is a parasitic disease transmitted by infected mosquitoes.[64] In 2013, an estimated 584,000 people died from malaria, mostly African children.[65] In humans, the parasites infect red blood cells and multiply in the liver.[66] Left untreated, malaria can disrupt the blood supply to vital organs and become life threatening.[67] In 2004, the Gates Foundation granted $42.6 million to OneWorld Health to fight malaria.[68]

OneWorld Health then sought partnerships with the University of California, Berkeley, Amyris, and Sanofi-Aventis to increase artemisinin supply.[69] Artemisinin is a key ingredient in first-line malaria treatments.[70] The large amount of time and labor needed to extract artemisinin from Asian wormwood plants had contributed to a shortage of artemisinin.[71] With this partnership, UC Berkeley used

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[60] *Schistosomiasis*, WORLD HEALTH ORGANIZATION, http://www.who.int/schistosomiasis/en/ (last visited Oct. 30, 2015).

[61] *Id.*

[62] *Id.*

[63] *See UC Santa Barbara*, *supra* note 51.

[64] *Malaria*, WORLD HEALTH ORGANIZATION, http://www.who.int/topics/malaria/en/ (last visited Oct. 30, 2015).

[65] *Malaria Fact Sheet*, WORLD HEALTH ORGANIZATION, http://www.who.int/mediacentre/factsheets/fs094/en/ (last visited Oct. 30, 2015).

[66] *Malaria*, *supra* note 64.

[67] *Id.*

[68] *See Collaboration of Biotech*, *supra* note 29; *Gates Foundation Gives $10.7M for Malaria Fight*, PUGET SOUND BUSINESS JOURNAL (July 8, 2010, 10:15 AM), http://www.bizjournals.com/seattle/stories/2010/07/05/daily22.html [hereinafter *Gates Gives $10.7M*].

[69] *See Collaboration of Biotech*, *supra* note 29; *Gates Gives $10.7M*, *supra* note 68; *See OneWorld Health Receives $10.7 Million*, *supra* note 29.

[70] *See OneWorld Health Receives $10.7 Million*, *supra* note 29.

[71] *See* Victoria G. Hale, Katherine Woo & Helen Levens Lipton, *Oxymoron No More: The Potential of Nonprofit Drug Companies to Deliver on the Promise of Medicines for the*

synthetic biology to produce artemisinin from *E. coli*.[72] Amyris used this technique to create a production process.[73] Together, they developed a new, low-cost technology platform to produce artemisinin.[74] OneWorld Health managed the preclinical and regulatory work to establish that the synthetic form of artemisinin is bioequivalent with its natural form.[75] OneWorld Health then sought Sanofi for large-scale production of semisynthetic artemisinin.[76] The large-scale production will increase the supply of the ingredient for artemisinin-based combination therapies.[77] Large-scale production by Sanofi began in April 2013, and a month later, WHO announced that the semisynthetic artemisinin was prequalified.[78] The prequalification decision brought the drug manufacturing to fruition as drug companies may now use Sanofi's semisynthetic artemisinin in manufacturing their finished drug product.[79] Drug product manufacturers using semisynthetic artemisinin will more easily obtain regulatory approval, which may accelerate malaria treatment availability on the market.[80]

3. Diarrheal Disease

Diarrheal disease kills over two million children worldwide every year.[81] In 2006, The Gates Foundation granted $46 million to OneWorld Health to research and develop new drugs for diarrheal disease.[82] In 2011, OneWorld Health became partners with Anacor Pharmaceuticals to jointly discover antibacterial compounds to treat shigellosis.[83] Shigellosis is a bacterial infection that causes bloody

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Developing World, 24 HEALTH AFFAIRS, no. 4, July-Aug. 2005, at 1057, 1060, *http://content.healthaffairs.org/content/24/4/1057.full.pdf+html*.

[72] *Id.* at 1060.

[73] *Id.*

[74] *See OneWorld Health Receives $10.7 Million*, *supra* note 29; *see Sanofi and PATH Announce The Launch of Large-Scale Production of Semisynthetic Artemisinin Against Malaria*, PATH (April 11, 2013), http://www.path.org/news/press-room/422/.

[75] Hale, Woo & Lipton, *supra* note 71, at 1060-61.

[76] *See OneWorld Health Receives $10.7 Million*, *supra* note 29.

[77] *Gates Gives $10.7M*, *supra* note 68.

[78] *Semisynthetic Artemisinin Achieves WHO Prequalification*, PATH (May 10, 2013), http://www.path.org/news/press-room/430/.

[79] *See id.*

[80] *Id.*

[81] Donna Gordon Blankinship, *Gates Foundation Giving $46 Million to Fight Diarrhea*, SEATTLE TIMES (Nov. 1, 2006), http://seattletimes.com/html/health/2003335466_webgatesfoundation01.html.

[82] *Id.*

[83] *Anacor Pharmaceuticals Launches Research Collaboration with the Institute for*

diarrhea.[84] The disease affects around 80 to 165 million people worldwide.[85] The United Kingdom's Department for International Development has also contributed significant funding towards this project.[86]

To date, there are no other press releases or information regarding the progress of shigellosis from the joint research agreement between Anacor and OneWorld Health.

C. Strategic Changes

Even though OneWorld Health has had success in researching and developing drugs that fulfill the need for neglected diseases, the nonprofit does encounter difficulties.[87] A big challenge is the distribution of approved drugs.[88] For example, after India approved Paromomycin, the company had to distribute the drugs to patients who lived in remote Indian villages.[89] Another challenge is working with the Indian government.[90] Without governmental support in efforts to reduce black fever, OneWorld Health faces an uphill battle in its fight against the disease.

Perhaps in an effort to address some of the challenges that OneWorld Health faces, the nonprofit became an affiliate of Program for Appropriate Technology in Health ("PATH") in December 2011.[91] PATH is an international nonprofit organization that is transforming global health through innovations in vaccines, devices, diagnostics, drugs, as well as systems and services.[92] The organization is not only an international nongovernment organization, but also a research institution and business.[93]

OneWorld Health to Develop New Treatments for Diarrheal Disease, ANACOR PHARMACEUTICALS (March 7, 2011), http://investor.anacor.com/releasedetail.cfm?releaseid=554899.

[84] *Id.*

[85] *Id.*

[86] *Id.*

[87] *See* Strom, *supra* note 35.

[88] *See id.*

[89] *See id.*

[90] *See id.*

[91] *See OneWorld Health to Become an Affiliate of PATH*, PATH (Dec. 16, 2011), http://www.path.org/news/press-room/203/ [hereinafter *Affiliate of PATH*]; *See generally The Birth of Path*, PATH, http://www.path.org/about/birth-of-path.php (last visited Oct. 30, 2015) [hereinafter *The Birth of Path*].

[92] *About PATH*, PATH, http://www.path.org/about/index.php (last visited Oct. 30, 2015).

[93] *See generally id.*; *The Birth of Path*, *supra* note 91.

OneWorld Health understands that the new affiliation is a strategic move that will bring synergies to both organizations. OneWorld Health's products fit within PATH's broad product portfolio.[94] Both organizations share the same vision and goals of developing and commercializing drugs for neglected diseases in the developing world.[95] OneWorld Health also benefits greatly from PATH's international reach and reputation, distribution channels, established network with more than 100 private-sector partners, and governmental connections.[96]

III. Advantages and Disadvantages of OneWorld Health

A. Advantages of a Nonprofit Pharmaceutical Company Business Model

The establishment of OneWorld Health has been a positive development as it fills a gap in the neglected disease space for those suffering in developing countries.[97] OneWorld Health's success comes from its business model as a nonprofit pharmaceutical company.[98] Through PDPs with private drug companies and public institutions, OneWorld Health is then able to commercialize new drugs for neglected diseases.[99]

As a nonprofit, OneWorld Health overcomes the profitability hurdle many for-profit drug companies face.[100] Drug companies spend an average of $1 billion, and about ten to fifteen years, to take a drug from R&D to commercialization.[101] Since pharmaceutical development is very expensive and time-consuming, drug companies want to recoup the cost of drug development.[102] This profitability

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[94] *Affiliate of PATH*, *supra* note 91.

[95] *See id.*

[96] *See PATH's Framework for Product Introduction*, PATH (Feb. 2007), http://www.path.org/publications/files/TS_product_intro_framework.pdf; *Public-Private Partnerships for Global Health*, *supra* note 23; *Affiliate of PATH*, *supra* note 91.

[97] *See* Hale, Woo & Lipton, *supra* note 71, at 1058.

[98] *See* Coster, *supra* note 4; *Product Development Partnership Model*, *supra* note 22; *Public-Private Partnerships for Global Health*, *supra* note 23; *See* Hale, Woo & Lipton, *supra* note 71.

[99] *See* sources cited *supra* note 98.

[100] *Institute for OneWorld Health*, *supra* note 3.

[101] Helen Liu, Note, *Adopting Solutions for Orphan Drug Shortages*, 48 UC DAVIS L. REV. 2077, 2086 (2015).

[102] *See* Coster, *supra* note 4.

hurdle prevents the best pharmaceutical and biotechnology research and drugs from ever reaching those in the developing world.[103] Instead, OneWorld Health does not have to worry about shareholders and delivering financial returns.[104] The company is able to select drug development projects that align with its mission and goals.[105] Since OneWorld Health receives substantial grants from organizations such as The Gates Foundation, the company can focus on its operations instead of worrying about recouping costs and profitability.[106] Another way OneWorld Health lowers its administrative and operational costs is that it does not possess a sales and marketing team.[107] The company does not sell drugs to doctors as a traditional pharmaceutical company would.[108]

Even though OneWorld Health is a nonprofit, it is still a pharmaceutical company.[109] Traditionally, a pharmaceutical company is a fully integrated pharmaceutical company ("FIPCO").[110] A FIPCO encompasses the full spectrum of a big pharmaceutical company that ranges from discovery, R&D, development, manufacturing, and sales and marketing.[111] Instead, OneWorld Health's collaborative approach is more similar to a partially integrated pharmaceutical company that retains some components of a FIPCO, but outsources the rest.[112] With a piecemeal approach to drug development, the company retains flexibility and uses resources and funds efficiently and appropriately.[113]

As part of its piecemeal approach and strategy, OneWorld Health has no laboratories, and does not worry about conducting its own early

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[103] *Institute for OneWorld Health*, *supra* note 3.

[104] *See* Hale, Woo & Lipton, *supra* note 71, at 1059.

[105] *See id.*

[106] *See generally id.* at 1059-60.

[107] *See id.* at 1059

[108] *See generally id.* at 1058-59.

[109] *See id.* at 1059; *Institute for OneWorld Health*, *supra* note 3.

[110] *From FIPCO to FIPNET to VIPCO — Say What?*, DISCOVERY MANAGEMENT SOLUTIONS, http://www.discoverymanagementsolutions.com/from-fipco-to-fipnet-to-vipco-–-say-what/ (last visited Oct. 30, 2015); *see* Theresa Phillips, *Biotech Business Models*, ABOUT.COM, http://biotech.about.com/od/strategy/tp/BusinessModels.htm (last visited Oct. 30, 2015).

[111] *Business Models in the Pharmaceutical Industry: The Case of Novo Nordisk*, BIOSTRATEGY ANALYTICS (May 8, 2013), http://biostrategyanalytics.wordpress.com/2013/05/08/business-models-in-the-pharmaceutical-industry-the-case-of-novo-nordisk/ [hereinafter *Business Models*]; *see* Phillips, *supra* note 110.

[112] *See* Simon P. Forster et al., *Virtual Pharmaceutical Companies: Collaborating Flexibly in Pharmaceutical Development*, 19 DRUG DISC. TODAY 201, 348-49 (March 2014; *Business Models*, *supra* note 111.

[113] *See* Hale, Woo & Lipton, *supra* note 71, at 1059.

staged research.[114] Instead, OneWorld Health provides incentives to for-profit drug companies and other organizations to be involved in R&D without shouldering the financial risks or costs.[115] OneWorld Health can then enjoy its own in-house expertise and capabilities — employing scientists, product development experts, clinical specialists to conduct clinical trials, and regulatory professionals to navigate market approval processes.[116]

OneWorld Health also depends on outside partnerships to acquire intellectual property and assets through licensing agreements and donations.[117] Donated compounds and intellectual property serve as tax deduction benefits for donors.[118] When OneWorld Health licenses compounds from drug companies or academia, it receives generous terms, such as a no or low royalty.[119] Licensed or donated compounds are generally late-stage with substantial safety and efficacy data already available.[120] This portfolio development strategy saves money and lowers the drug development cost. OneWorld Health already benefited from this strategy when it acquired an off-patent drug that already completed Phase II clinical trials.[121] With preclinical and a majority of the clinical trials out of the way, OneWorld Health only had to use its funding to conduct Phase III clinical trials.[122]

OneWorld Health also relies on partnerships for manufacturing capabilities.[123] One example is OneWorld Health's partnership with India's Gland Pharma to manufacture Paromomycin.[124] Without brick and mortar assets, such as manufacturing facilities, OneWorld Health

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[114] MICHAEL GORDON, DESIGN YOUR LIFE, CHANGE THE WORLD: YOUR PATH AS A SOCIAL ENTREPRENEUR, Ch. 6, http://www.profmichaelgordon.com/book/6.html.

[115] *See* Coster, *supra* note 4; *Public-Private Partnerships for Global Health*, *supra* note 23; *see also Product Development Partnership Model*, *supra* note 22.

[116] *See* GORDON, *supra* note 114; *Institute for OneWorld Health*, *supra* note 3; Hale, Woo & Lipton, *supra* note 71, at 1059.

[117] *See* Hale, Woo & Lipton, *supra* note 71, at 1059; *see, e.g.*, *OneWorld Health Licenses from Yale*, *supra* note 51 (illustrating an example where OneWorld Health licensed a compound); Strom, *supra* note 35 (illustrating an example where OneWorld Health acquired an off-patent drug).

[118] Hale, Woo & Lipton, *supra* note 71, at 1060.

[119] *See id.* at 1060.

[120] *See id.* at 1059; *see, e.g.*, Strom, *supra* note 35 (noting how OneWorld Health acquired a donated off-patent drug that had completed Phase II clinical trials).

[121] *See* Strom, *supra* note 35.

[122] *See id.*

[123] *See, e.g.*, *id.* (showing how Gland Pharma manufactured Indian drug for black fever).

[124] *See id.*

lowers drug development costs significantly.[125] Through these types of PDPs, especially with those in developing countries, technology transfer occurs from a developed country to a developing one.[126] Companies in developing countries will benefit from this flow of information and knowledge.[127] Taking Gland Pharma as an example, Gland capitalized on this partnership by developing a cost effective process for OneWorld Health's off-patent drug.[128]

Overall, OneWorld Health utilizes PDPs and other contributions to accelerate new drug development, decrease failure risks, and lower the cost of new drug development.[129] OneWorld Health passes along these drug development savings to the end-users: low-income patients who benefit from affordable drugs.[130] OneWorld Health's success in commercializing Paromomycin at a cost of $10 perfectly illustrates the cost savings that patients realize.[131]

B. Potential Disadvantages and Concerns

Although OneWorld Health has greatly benefited patients suffering from neglected diseases, there are also potential concerns and ramifications that may arise from its operations. These concerns may have detrimental consequences to those in the developing world. These concerns do not specifically pertain to just OneWorld Health, but to other PDPs as well. Those contemplating a similar nonprofit pharmaceutical business model should be aware of these concerns and potential consequences.

As mentioned, OneWorld Health was able to commercialize Paromomycin and license the drug to a local Indian drug company for manufacture at cost.[132] The drug is now available at a low and

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[125] *See* GORDON, *supra* note 114; Hale, Woo & Lipton, *supra* note 71, at 1062; Robin Elizabeth Margolis, *The Future of Pharmaceutical Contract Manufacturing*, THE HOUSTON CHRONICLE, http://smallbusiness.chron.com/future-pharmaceutical-contract-manufacturing-81785.html (last visited Oct. 30, 2015).

[126] *See Technology Transfer*, IFPMA, http://www.ifpma.org/global-health/access/technology-transfer.html (last visited Oct. 30, 2015).

[127] *See id.*

[128] *See generally* Nagesh Kumar, *Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries*, ECON. & POL. WEEKLY, Jan. 2003, at 209, 219-20, http://infojustice.org/download/gcongress/globalarchitectureandthedevelopmentagenda/kumar%20article.pdf.

[129] *Institute for OneWorld Health*, *supra* note 3.

[130] *See* Strom, *supra* note 35.

[131] *See id.*

[132] *See id.*

affordable price to Indian patients suffering from black fever.[133] Technology transfer of knowledge and information occurred from OneWorld Health to Gland Pharma. Gland Pharma utilized its cost-effective manufacturing process to produce the drug product, and furthered its own development and competitiveness.[134] As a domestic drug company, Gland was able to also further the development of local technological capabilities in pharmaceuticals.[135] Not only is the drug distributed to Indian end-users, but also once approved in other markets, the drug can be exported to other countries.[136] India's economy benefits from increased export activities.[137] However, Gland Pharma may be a unique example of local manufacturing and technological development that is not necessarily replicable in other developing countries.

India is a distinctive example of a developing country that has the right environment for local technological development, endogenous growth, and innovation. Today, India's pharmaceutical industry is one of the most advanced among developing countries.[138] India is able to distinguish itself from other developing countries due to its history with intellectual property rights ("IPRs").[139] Before 1970, India's patent system protected almost all inventions, creating a high barrier of entry for Indian chemical and pharmaceutical firms.[140] During 1970, India passed new laws that reduced the scope of patentability in food, chemicals, and pharmaceuticals.[141] As a result, patent protection was available for only processes and not products.[142] Indian drug companies enjoyed great growth and development with India's chemical and pharmaceutical process innovations.[143] India benefited from technology transfer that occurred when foreign investors and multi-national corporations ("MNCs") took notice of India's

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133 *See id.*

134 *See* Kumar, *supra* note 128, at 218-20.

135 *See id.*

136 *See id.* at 219.

137 *See id.*

138 *See* Sudip Chaudhuri, *Is Product Patent Protection Necessary to Spur Innovation in Developing Countries? R&D by Indian Pharmaceutical Companies After TRIPS*, *in* THE DEVELOPMENT AGENDA: GLOBAL INTELLECTUAL PROPERTY AND DEVELOPING COUNTRIES 265, 266 (Neil W. Netanel ed., 2009).

139 *See* Kumar, *supra* note 128, at 217-20.

140 *See id.* at 217.

141 *See id.* at 217-18; Chaudhuri, *supra* note 138, at 266.

142 *See* Kumar, *supra* note 128, at 218.

143 *Id.*

capabilities.[144] With weaker IPRs, the country was able to innovate, build up its local capabilities and infrastructures, and become competitive suppliers of generic drugs.[145] When India ratified to join the World Trade Organization's ("WTO") Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS"), India agreed to provide stronger IPRs in its country.[146] India can afford to join TRIPS because the country has reached a certain threshold in its industrialization due to weaker IPRs where it can now benefit from strong IPRs.[147]

Even though India is an example of how a developing country becomes involved in the global pharmaceutical industry, the same success may be elusive for other developing countries. Other developing countries may not be at the same levels of innovation and growth as India to support pharmaceutical development. Developing countries in much of the Andean region in South America, almost all of sub-Saharan Africa, and large parts of Central and South Asia, lack significant technological advancements.[148] These are the same regions where people are suffering from neglected diseases.[149] This cannot be a coincidence. These countries do not have the resources, technical knowledge and expertise, professionals, and infrastructure as India does. The governments in developing countries are also cash-strapped and unable to provide financial assistance in science and technologies.[150] The critical elements contributing to technology immobility are the lack of governmental purchasing power and scientific capability in nongovernmental sectors of these countries.[151]

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[144] *See id.* at 220.

[145] *See id.* at 219.

[146] *See generally* Anand Nandkumar, *Was The TRIP Worthwhile?* FORBES INDIA, Oct. 18 2011, http://forbesindia.com/printcontent/29302.

[147] *See Integrating Intellectual Property Rights and Development Policy*, COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, Sept. 2002, at 22, http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf [hereinafter *Integrating IPRs*]; Linsu Kim, *Technology Transfer & Intellectual Property Rights: The Korean Experience*, June 2003, at 1, http://ictsd.net/downloads/2008/06/cs_kim.pdf; *see generally* Kumar, *supra* note 128, at 220-21.

[148] Jeffrey Sachs, *The Global Innovation Divide*, 3 NBER, Jan. 2003, at 131, 133, http://www.nber.org/chapters/c10795.pdf.

[149] *See The Neglected Tropical Diseases: A Challenge We Could Rise to – Will We?* WHO (2009), http://www.who.int/neglected_diseases/diseases/NTD_Report_APPMG.pdf [hereinafter *The Neglected Tropical Diseases*].

[150] Sachs, *supra* note 148, at 135.

[151] *Id.*

Since these areas have weak IPRs, lack technological capabilities, and little rent for foreign investors and firms to extract, these countries are unattractive investments.[152] Therefore, there may not be foreign direct investments ("FDIs") in these developing countries by MNCs and other foreign investors.[153] Without FDIs, developing countries cannot benefit from technology transfer and spillover of learning or technological innovation to generate endogenous growth.[154] It may also be hard for these developing countries to become exporters of goods to boost their economies. Instead, these countries seem destined to remain importers.[155] Thus, it is hard for developing countries to replicate India's success.

Although OneWorld Health was able to utilize India in manufacturing its Paromomycin drug, it seems unlikely that OneWorld Health can do the same with other developing countries as local partners for a domestic drug.[156] OneWorld Health's model is to collaborate with other entities.[157] However, there are not many drug companies in developing countries, other than India, with whom OneWorld Health can develop PDPs.[158] Therefore, OneWorld Health is not in the position to assist or invest in poor developing countries so that the countries may build themselves up domestically as innovators and technical experts in pharmaceutical development. Not taking into account the lack of government support, differing IPR structures, and other barriers, PDPs may not be the proper models to help developing countries generate endogenous growth. Developing countries may find themselves relying heavily on firms and organizations in developed countries for imported supplies of chemicals, pharmaceuticals, and technologies. Consequently, this dependence may be difficult to break.

IV. Potential Challenges and Barriers of PDPs

Even though there is positive and encouraging progress in the area of drug development for neglected diseases, there still remain

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[152] *See Integrating IPRs*, *supra* note 147, at 22; *See generally* Daniel J. Gervais, *TRIPS 3.0: Policy Calibration and Innovation Displacement*, *in* THE DEVELOPMENT AGENDA: GLOBAL INTELLECTUAL PROPERTY AND DEVELOPING COUNTRIES (Neil W. Netanel ed., 2009).

[153] *See* Sachs, *supra* note 148, at 133-34.

[154] *See generally* Gervais, *supra* note 152; Sachs, *supra* note 148, at 134.

[155] *See generally Integrating IPRs*, *supra* note 147, at 21, 24.

[156] *See supra* Part II.A.

[157] *See supra* Part I.

[158] *Id.*

challenges and potential barriers.[159] These challenges and barriers can hinder drug development and eventual access of drugs to the patients who need them.[160] OneWorld Health and other PDPs need to address these obstacles in order proceed ahead as successful organizations that fulfill their humanitarian goals.

A. Infrastructure and Delivery Channels

One challenge that PDPs may encounter is the lack of government infrastructure, organization, and support in developing countries. The types of government infrastructure and organization needed are systems to diagnose neglected diseases, buying and administering drugs, and targeted efforts to eliminate the spread of diseases.[161] To garner government support of drugs, PDPs need to strategically engage government players at an early stage to build endorsement and faster adoption of new products.[162]

Another crucial challenge that OneWorld Health and other PDPs face is access to distribution channels. It is not enough to just develop a drug for a neglected disease, but distribution channels are critical to reach the drug's end-users.[163] Problems associated with distribution issues do not stop with just transportation, but also include human resources, storage facilities, and storage conditions.[164] Many patients live in remote areas that are difficult to reach and make it impossible to use motorized vehicles.[165] PDPs need to work with governmental or nongovernmental organizations to find solutions to this problem. Solutions to distribution challenges have included the use of motorcycles equipped with coolers, bicycles, animals, canoes, and walking.[166] Now, private, public, and nongovernmental organizations are all recognizing the need to improve distribution channels and delivery systems. Many organizations are devoting energy, time, and

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159 *See supra* Part III.B.

160 *See supra* Part II.C.

161 *See, e.g.*, Strom, *supra* note 35 (illustrating India's governmental challenges relating to OneWorld Health's Paromomycin).

162 *See PATH's Framework for Product Introduction*, *supra* note 96.

163 *Id.*; *See generally* Calyn Shaw, *Innovation in Neglected Disease Drug Development: Innovative Distribution Channels*, SAUDER SCHOOL OF BUSINESS, July 2009, at 3, http://www.sauder.ubc.ca/Faculty/Research_Centres/ISIS/Resources/~/media/82FD7EB1585A4137A20B1DD26CDDED44.ashx.

164 *See* Shaw, *supra* note 163. at 8-9.

165 *See id.* at 8-9; Strom, *supra* note 35.

166 *See, e.g.*, Shaw, *supra* note 163, at 11-12; Strom, *supra* note 35.

resources towards solving this issue.[167] In 2007, The Gates Foundation joined forces with PATH and WHO to create Optimize, a five-year long joint effort to improve supply chain logistics and develop better technologies and delivery systems.[168]

B. Regulatory Harmonization Standards

There is currently no international harmonization of regulatory standards for testing and approving pharmaceutical drugs.[169] Even without international regulatory standards, a developed country is able to navigate the regulatory process in another developed country with considerable ease.[170] Regulatory bodies in a developed country have the luxury of experience in assessing pharmaceuticals from other developed countries.[171] Regulators from several developed countries have also banded together to create parallel systems and develop review efficiencies.[172] For example, the U.S. and E.U. have established a degree of regulatory harmonization.[173] The U.S., E.U., and Japan have also established the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use ("ICH").[174] The ICH reduces testing redundancies and data submissions during regulatory review of the same drugs seeking approval in each country.[175] It is not a surprise that these three developed countries have established the ICH, especially since drug companies mainly apply for drug approvals in these markets.[176] The U.S., E.U., and Japan markets make up 90-95% of drug companies' revenues.[177]

Historically, drug companies typically developed neglected

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[167] *See* Shaw, *supra* note 163, at 15.

[168] *See id.* at 15.

[169] *See* Phair, *supra* note 23, at 212.

[170] *See generally id.*; Susanne Hill & Kent Johnson, *Emerging Challenges and Opportunities in Drug Registration and Regulation in Developing Countries*, DFID Health Systems Resource Center, May 2004, http://heart-resources.org/wp-content/uploads/2012/10/Emerging-challenges-and-opportunities-in-Drug-registration-and-regulation.pdf.

[171] *See* sources cited, *supra* note 165.

[172] *See* Phair, *supra* note 23, at 212-13.

[173] *See id.* at 213.

[174] *See id.*

[175] *See id.*

[176] *See* Fisher & Syed, *supra* note 2, at 583.

[177] *See id.*

disease pharmaceuticals for both rich and poor markets.[178] Companies would first submit their drugs to Western regulatory authorities in developed countries, such as the United States Food and Drug Administration ("FDA") or Europe's European Medicines Agency ("EMA").[179] A developing country would then rely on Western authorities' pharmaceutical assessments as a basis for allowing a drug into its market.[180] However, there are disadvantages for developing countries in relying on Western regulatory agencies.[181] Since developing countries are waiting for developed countries to analyze and assess new drugs, there is a delay in drug approval for patients in the developing world.[182] Western authorities do not always account for the needs and safety of a developing country's patient population.[183] For example, Western authorities may omit data requirements that are vital for safe and large-scale use in developing countries.[184]

Currently, navigating a developing country's medical regulatory approval regime is a challenge that PDPs face when attempting to bring drugs to the market.[185] When PDPs emerged and increased, the traditional drug development paradigm began to shift.[186] PDPs began developing drugs specifically for the developing world that bypassed approval by Western authorities.[187] Yet, regulatory agencies in developing countries do not have the capacity to assess new drug products.[188] For example, a 2010 WHO study found that regulatory authorities in sub-Saharan Africa are inadequately prepared to carry out regulatory functions.[189]

Without international regulatory standards for developing countries' regulatory authorities to follow, there are no guarantees that new drugs will be safe and efficacious for patients to use.[190] Policymakers have developed new solutions to address these regulatory

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178 *See* Mary Moran et al., *Registering New Drugs for Low-Income Countries: The African Challenge*, 8 PLOS MED., no. 2, Feb. 2011, at 1.

179 *Id.*

180 *Id.*

181 *Id.*

182 *Id.*

183 *See* Moran et al., *supra* note 178, at 1.

184 *Id.* at 1-2.

185 *See id.* at 1; Phair, *supra* note 23, at 211-12.

186 *See* Moran et al., *supra* note 178, at 1.

187 *See id.*

188 *See id.*

189 *Id.*

190 *See id.*; Phair, *supra* note 23, at 212.

shortcomings.[191] For example, the European Commission established Article 58 in 2004 where the EMA assisted developing countries in assessing drug approvals and incorporated WHO in the review process.[192] The advantages of Article 58 lie in its stringent review standards, input from WHO disease experts, and efficiency.[193] Yet, drug companies have underutilized Article 58.[194] There have only been four drug applications submitted for approval using Article 58 since 2004.[195]

Another new regulatory solution is the WHO drug prequalification program.[196] The program began in 2001, and became a surrogate regulatory approval method for international procurement groups.[197] Mixed teams of developed and developing country experts assist in WHO prequalification efforts.[198] Although this type of regulatory process has accelerated access to many drugs, the process does not currently cover novel neglected disease drugs.[199] WHO prequalification can also be slow since this regulatory pathway is voluntary and with no fees.[200] These regulatory solutions are still not standardized and there are no guidelines to help drug companies and PDPs choose the regulatory pathway best suited for their needs.[201]

C. Cash and Funding

Philanthropic organizations have been funding PDPs' drug development efforts for the last decade.[202] The Gates Foundation has contributed up to $3 billion a year to different PDPs.[203] However, philanthropic organizations cannot continue to fund PDPs indefinitely, and PDPs cannot rely exclusive on philanthropic backers.[204] PDPs need to find other solutions to become financially sustainable and

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191 *See* Moran et al., *supra* note 178, at 2-3.
192 *Id.* at 2.
193 *Id.*
194 *Id.*
195 *Id.*
196 *See* Moran et al., *supra* note 178, at 3.
197 *Id.*
198 *Id.*
199 *Id.*
200 *Id.*
201 *See generally* Moran et al., *supra* note 178.
202 *See* sources cited *supra* note 29.
203 Coster, *supra* note 4.
204 *See id.*; Hale, Woo & Lipton, *supra* note 71, at 1062.

prove that the nonprofit business model works.[205]

PDPs have suggested a few solutions that may help them become financially self-sustaining.[206] One solution involves tiered pricing of neglected disease drugs.[207] PDPs may sell drugs at higher prices to foreign travelers — people who travel to developing countries and contract neglected diseases.[208] For patient populations with slightly higher incomes, a tiered pricing approach can allow for a small return in revenues.[209] Another solution could involve licensing drugs to for-profit drug companies in exchange for royalties.[210]

However, there is still optimism that philanthropic funders will continue their efforts to fund PDPs. In recent 2012 meetings, the U.S. pledged $785 million to support R&D work for neglected diseases.[211] In addition, the Gates Foundation pledged a five-year, $363 million commitment to support PDPs involved in neglected disease drug development.[212]

D. Donation of "Loser" Intellectual Property and Drugs

Since PDPs acquire many compounds and drugs through donations, there is a concern that these donated intellectual property and assets are "losers."[213] The concern is that these donations are not of the best compounds or drugs, but merely unwanted assets of which drug companies want to rid themselves.[214]

However, recent developments are promising that drug and compound donations can be of higher quality. In January 2012, Bill

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[205] *See* Hale, Woo & Lipton, *supra* note 71, at 1062; Coster, *supra* note 4.

[206] *See* Hale, Woo & Lipton, *supra* note 71, at 1062; *See generally* Strom, *supra* note 35.

[207] Hale, Woo & Lipton, *supra* note 71, at 1062.

[208] *See* Strom, *supra* note 35.

[209] *See generally* Hale, Woo & Lipton, *supra* note 71, at 1062.

[210] *See* Strom, *supra* note 35.

[211] *Private and Public Partners Unite to Combat 10 Neglected Tropical Diseases by 2020*, GATESFOUNDATION, http://www.gatesfoundation.org/media-center/press-releases/2012/01/private-and-public-partners-unite-to-combat-10-neglected-tropical-diseases-by-2020 (last visited April 20, 2014) [hereinafter *Private and Public Partners Unite*].

[212] *Id.*

[213] *See* Xuan-Thao Nguyen & Jeffrey A. Maine, *Giving Intellectual Property*, 39 U.C. DAVIS L. REV. 1721, 1762 (2006); Dennis Walsh, *Donation of Intellectual Property: What Does it Look Like?*, PLANNED GIVING DESIGN CTR., http://oc-cf.pgdc.com/pgdc/donation-intellectual-property-what-does-it-look (last visited Dec. 2, 2015); Weston Anson, *Valuing Intellectual Property for Charitable Donation: An Excerpt from Chapter 19 of Fundamentals of Intellectual Property Valuation*, CONSOR, http://www.consor.com/intellectual-property-advice/valuation-ip-charitable-donation.html (last visited Dec. 15, 2015).

[214] *See* Nguyen & Maine, *supra* note 213; Walsh, *supra* note 213.

Gates brought together the heads of thirteen of the world's biggest drug companies to the table.[215] Drug companies included GlaxoSmithKline, Pfizer, Abbott, and Johnson & Johnson.[216] This effort furthered collaborations and established commitments to end ten neglected diseases by 2020.[217] These drug companies pledged to extend their donation programs and open up their compound libraries for PDPs to access and test for potential drug treatments.[218] Drug companies look to donate an average of 1.4 billion treatments each year.[219]

E. Pharmaceutical Industry Participation

There is concern that for-profit drug company participation in PDPs will wane.[220] One fear is that even with PDPs assuming most of the financial risks and costs, drug companies still incur costs by contributing resources, such as R&D expertise and manufacturing capabilities. With responsibilities to shareholders to make a return on investments, perhaps these extra expenses are not worth bearing.[221] Another fear is that grey markets and parallel imports may arise from drugs with both rich and poor markets.[222] Cheap drugs from poor markets may flow into richer markets, where drug companies may already have competing products that sell at higher prices.[223] Therefore, parallel imports of cheaper drugs affect the financial returns of competing products.[224]

Nevertheless, recent meetings between philanthropic backers, big drug companies, and PDPs brings assurance that for-profit drug companies will continue their participation in PDPs.[225] Drug companies pledged to continue and expand collaborations efforts with

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[215] *See Private and Public Partners Unite*, *supra* note 211; Sarah Boseley, *Drug Companies Join Forces to Combat Deadliest Tropical Diseases*, THE GUARDIAN (Jan. 30, 2012), http://www.theguardian.com/global-development/2012/jan/30/drug-companies-join-tropical-diseases.

[216] *See* Boseley, *supra* note 215.

[217] *See id.*; *Private and Public Partners Unite*, *supra* note 211.

[218] *See* Boseley, *supra* note 215.

[219] *Private and Public Partners Unite*, *supra* note 211.

[220] *See* Hale, Woo & Lipton, *supra* note 71, at 1062.

[221] *See id.*

[222] *See* Liu, *supra* note 101, at 2095.

[223] *See id.*

[224] *See id.*

[225] *See* Boseley, *supra* note 215; *Private and Public Partners Unite*, *supra* note 211.

PDPs.[226] They agreed to continue sharing technical expertise, increase R&D efforts, and strengthen drug distribution and implementation programs.[227]

F. Biologic Drugs

Generally, PDPs develop pharmaceutical drugs, synthetic drugs composed of chemical compounds and substances.[228] If PDPs decide to develop biologic drugs in the future, or even if drug companies donate off-patent biologic drugs to PDPs, there are challenges associated with biologics development. Biologics are manufactured in living systems, and many are produced through recombinant DNA technology.[229] Biologic drugs are complex and expensive to develop, and a common saying is that the "product is the process."[230] PDPs may need to spend more money on biologics development in order to ensure that the manufacturing process is well developed.[231] PDPs may also have a more difficult time finding a partner with biologics manufacturing capabilities, regardless if the drug was a newly developed biologic or a biosimilar (generic biologic). For example, if OneWorld Health's Paromomycin drug had been a biologic, the nonprofit would not have been able to license the drug for Gland Pharma to produce.[232] Most drug companies outside of the U.S., such as those in India, deal with producing active pharmaceutical ingredients or generic drugs, which are chemical-based processes.[233] Therefore, foreign drug companies do not have the expertise to produce biologics or biosimilars.

It is only recently that the United States passed the Biologics Price Competition and Innovation Act, allowing the FDA to review and approve biosimilars.[234] For biosimilars to gain approval, the FDA

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226 *See Private and Public Partners Unite*, *supra* note 211.

227 *See id.*

228 *See generally* Oriola, *supra* note 7, at 72-73.

229 *See* Liu, *supra* note 101, at 2085; *How Do Drugs and Biologics Differ?*, BIOTECH. INDUS. ORG. (Nov. 10, 2010), http://www.bio.org/articles/how-do-drugs-and-biologics-differ.

230 *See* Liu, *supra* note 101, at 2085.

231 *See id*. (noting how biologics manufacturing encounters higher risks since the process needs to remain the same every single time a biologic drug is made).

232 *See generally* Strom, *supra* note 35.

233 *See* Chaudhuri, *supra* 138, at 283.

234 *See* Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-48, §§ 7001–7003, 124 Stat. 119, 804-21 (2010) (codified as amended at 21 U.S.C. §§ 355(b)(5)(B), 35 U.S.C. 271(e), 42 U.S.C. 262, 262(i) (2012)).

needs to establish that they are therapeutic equivalents with the same safety and efficacious effects as the original biologic.[235] To date, the FDA has only approved one biosimilar drug in the United States.[236] Since many regulatory authorities in developing countries still rely on developed countries to assess drugs, developing countries will need to wait and see how the biosimilars story unfolds. Biosimilars and its assessment is a new territory for everyone.

V. Conclusion

OneWorld Health has positively contributed to efforts in bridging the R&D gap between developing and developed worlds.[237] Not only does the company take advantage of its half nonprofit and half pharmaceutical business model, the company also takes advantage of PDP collaboration arrangements.[238] In doing so, OneWorld Health has successfully developed a drug for black fever at significantly low costs to Indian patients.[239] The company has also successfully scaled up a large-scale production process to increase artemisinin supplies for malaria drugs.[240]

Even with such noted achievements, there are still many concerns that OneWorld Health must take into account. The company needs to be aware of potential effects and consequences that its assistance to developing countries can have on those countries. Taking India drug manufacturers out of the equation, it is difficult to develop and manufacture drugs locally in other developing countries due to lack of resources, infrastructure, and technical expertise.[241] Therefore, developing countries are unable to grow endogenously and develop local capabilities, and benefit from technology transfer and foreign investments.[242] Developing countries may remain importers and not exporters of goods. Other obstacles relate to distribution, regulatory pathways, funding, continued pharmaceutical industry participation,

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[235] *See How Do Drugs and Biologics Differ?*, *supra* note 229.

[236] *See* Deena Beasley & Ben Hirschler, *Novartis Wins Approval for First U.S. Biosimilar Drug*, REUTERS (Mar. 6, 2015), http://www.reuters.com/article/2015/03/06/us-health-biosimilars-novartis-idUSKBN0M21HI20150306.

[237] *See supra* Part II, III.A.

[238] *See supra* Part III.A.

[239] *See supra* Part II.B.1.

[240] *See supra* Part II.B.2.c.

[241] *See supra* Part III.B.

[242] *See supra* Part III.B.

and biologics drug manufacturing.[243]

A nonprofit pharmaceutical company like OneWorld Health will have to overcome many, if not all, of these hurdles to achieve future successes and a viable operation.[244] However, OneWorld Health and other PDPs need more support from others in their mission to combat neglected diseases. The international community needs to focus more attention on neglected diseases and contribute more support, resources, and funding towards this cause. Governments from developed and developing countries need to take active roles in incentivizing research and assisting drugs through the drug development and commercialization process. Governments in developed countries should create favorable tax environments for companies to develop neglected disease drugs. These governments should also provide tax incentives for local drug companies and other enticements for foreign companies and investments to enter their countries.

OneWorld Health has many challenges and obstacles to face. It is not a surprise that the company became a PATH affiliate.[245] PATH is a reputable international nongovernment organization with significant reach, research capabilities, and established networks and connections.[246] This is a smart move on OneWorld Health's behalf. The company is creating synergies and strategic additions that will continue to benefit the company and further its missions and goals.[247] Therefore, even with the challenges and concerns that OneWorld Health needs to consider and confront, the future still looks bright for OneWorld Health and other PDPs looking to embrace similar business models.

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243 *See supra* Part IV.
244 *See supra* Part III.B, IV.
245 *See supra* Part II.C.
246 *See supra* Part II.C.
247 *See supra* Part II.C.

JUSTICE FOR INJURED CHILDREN: A LOOK INTO POSSIBLE CRIMINAL LIABILITY OF PARENTS WHOSE UNVACCINATED CHILDREN INFECT OTHERS

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Introduction

Measles, a disease that was declared eradicated in 2000,[1] currently has its worst outbreak rate in 20 years.[2] The most recent measles outbreak occurred in December 2014 with effects continuing

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[1] Yamiche Alcindor, *Anti-vaccine movement is giving diseases a 2nd life*, USA TODAY (Apr. 8, 2014, 11:41 PM), http://www.usatoday.com/story/news/nation/2014/04/06/anti-vaccine-movement-is-giving-diseases-a-2nd-life/7007955/.

[2] Jennifer Shih, *Why worry about measles outbreak?*, CNN (Aug. 7, 2014 8:33 AM), http://www.cnn.com/2014/08/07/opinion/shih-measles-vaccine/.

to be seen in January 2015.[3] There were 59 confirmed cases that were linked back to Disneyland.[4] The vaccination status of 34 of the infected people was known.[5] Of the 34 people, five were fully vaccinated, one was partially vaccinated, and the remaining 28 were not vaccinated.[6] Of the 28 people without vaccinations, six of them were too young to receive vaccinations.[7]

An even more alarming situation can be seen through two personal accounts. Jeremiah Mitchell was six when he had both of his arms and legs amputated, and had parts of his eyelids, jaw, and ears removed due to meningitis.[8] Jeremiah contracted meningitis because of an outbreak at his school that caused two deaths and five infections.[9] Jeremiah was up to date on all of his vaccinations but his school did not require the meningitis vaccine at his age.[10] He contracted meningitis because someone brought the disease into his community.[11]

Brady Alcaide was only 9 weeks old when he passed away from whooping cough, also known as pertussis, which is a vaccine preventable disease.[12] His mother received the vaccination for this disease years before Brady was born, but she was not informed that she could have received a booster shot during pregnancy that most likely would have saved his life.[13] His mother was not aware that she needed to be revaccinated.[14] However, there are many people personally choosing not to vaccinate their children.[15] Their personal choices have contributed to the recent return of largely inactive diseases previously considered historical.[16]

This Note will discuss the consequences of the recent decrease in vaccination rates and explore possible criminal liability of parents

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[3] *See* Lisa Aliferis, *Disneyland Measures Outbreaks Hits 59 Cases And Counting*, NPR (Jan. 22, 2015, 12:24 PM), http://www.npr.org/blogs/health/2015/01/22/379072061/disneyland-measles-outbreak-hits-59-cases-and-counting.

[4] *Id.* This information is current as of January 22, 2015.

[5] *Id.*

[6] *Id.*

[7] *Id.*

[8] Alcindor, *supra* note 1.

[9] *Id.*

[10] *Id.*

[11] *Id.*

[12] Alcindor, *supra* note 1.

[13] *Id.*

[14] *Id.*

[15] *Id.*

[16] *Id.*

whose unvaccinated child infects other children. Section I of this Note discusses why it is necessary to receive vaccinations. Section II shows the dangers children can face if they are not vaccinated. Section III provides various reasons that explain the increasing rate of unvaccinated children. Section IV illustrates the different State allowed exemptions from school required vaccinations. Section V explains various responses to the increased refusals to vaccinations. Section VI explores possible criminal liability for parents who choose not to vaccinate their child and whose unvaccinated child infects others.

I. Why We Need Vaccinations

There were between 13,000 to 20,000 yearly cases of paralytic polio reported in the United States before the polio vaccine was available.[17] Today, there are zero cases.[18] In 1964-1965, there were 20,000 infants born in America with congenital rubella syndrome, resulting in 2,100 neonatal deaths, and 11,250 miscarriages.[19] Of the infants born, 11,600 were deaf, 3,580 were blind, and 1,800 were diagnosed with an intellectual disability.[20] After widespread vaccination, only six cases of rubella were reported in 2000.[21] Before the diphtheria vaccine became available there were 206,000 cases and 15,520 deaths in 1921; since the introduction of this vaccination only one case of diphtheria was reported in 2000.[22] There were about 48,000 annual cases of smallpox in the early 1900's and now with the vaccine it has been eradicated.[23]

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[17] *Immunizations, What If We Didn't Vaccinate? Polio, Measles, Hib*, PKIDS ONLINE, http://www.pkids.org/immunization/consequences_not_vaccinating.html (last visited Jan. 13, 2016).

[18] *Id.*; *see also Polio Elimination in the United States*, CDC, http://www.cdc.gov/polio/us/index.html (last updated Dec. 17, 2015).

[19] *Immunizations, What If We Didn't Vaccinate? Pertussis, Rubella, Chickenpox,* PKIDS ONLINE, http://www.pkids.org/immunizatioon/consequences_not_vaccinating_2.html (last visited Jan. 13, 2016).

[20] *Id.*; *see generally Intellectual Disability*, WEBMD, http://www.webmd.com/parenting/baby/intellectual-disability-mental-retardation (last visited Apr. 11, 2015).

[21] *Id.*

[22] *Immunizations, What If We Didn't Vaccinate? Hepatitis B, Diptheria*, PKIDS ONLINE, http://www.pkids.org/immunizatioon/consequences_not_vaccinating_3.html (last visited Jan. 13, 2016).

[23] Miguel A. Faria, Jr., *Vaccines (Part II): Hygiene, Sanitation, Immunization, and Pestilential Diseases*, 5 MED. SENTINEL 55, 55-61 (March-Apr. 2000), http://www.haciendapub.com/medicalsentinel/vaccines-part-ii-hygiene-sanitation-immunization-

The Centers for Disease Control and Prevention (CDC) have ranked vaccinations among "the top ten public health achievements in the twentieth century."[24] According to CDC, the recommended first vaccination should be between birth and one month old.[25] After being born, babies still have protection against diseases that they received from their mother through the placenta.[26] However, shortly after birth this natural protection goes away and something more is needed to prevent infections in children.[27] Vaccines work by exposing the body to a small amount of the virus that has been weakened, allowing the body to recognize and attack the virus if the person is later exposed to it.[28]

Vaccinations become most effective when the amount of vaccinated people in a community reaches a number required for "herd immunity."[29] The amount of people necessary to achieve herd immunity varies by disease.[30] For example, measles requires 93-95% of the population to be immunized in order to achieve herd immunity.[31] Usually, a community is able to protect the people in their population who cannot receive vaccines when the vaccination rate reaches between 85-95% depending on the disease.[32] These people, who must rely on the community rather than their own vaccinations to protect them, include individuals with low immune systems, newborns, or elders.[33] In order to prevent outbreaks of vaccine preventable diseases, herd immunity illustrates the need for communities to have a high

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and-pestilential-diseases.

[24] James G. Hodge & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives,* 90 KY. L.J. 831, 833 (2001-2002).

[25] *See Immunizations and Developmental Milestones for Your Child from Birth Through 6 Years Old*, CDC, http://www.cdc.gov/vaccines/parents/downloads/milestones-tracker.pdf (last updated Jan. 2015).

[26] *Vaccines (Immunizations) - Overview*, N.Y. TIMES, http://www.nytimes.com/health/guides/specialtopic/immunizations-general-overview/overview.html?inline=nyt-classifier (last visited Aug. 30, 2014).

[27] *Id.*

[28] *Id.*

[29] Pamela Esquivel & Sandra Poindexter, *Plunge in kindergartners' vaccination rate worries health officials*, LA TIMES (Sept. 2, 2014, 8:50 PM), http://www.latimes.com/local/education/la-me-school-vaccines-20140903-story.html#page=1.

[30] *Herd Immunity*, ASHLANDCHILD, http://www.ashlandchild.org/vaccine-basics/herd-immunity/ (last visited Jan. 13, 2016).

[31] *Id.*

[32] *Id.*

[33] Sarah Loving, *Herd Immunity*, OXFORD VACCINE GROUP, http://www.ovg.ox.ac.uk/herd-immunity (last updated Nov. 16, 2015).

immunization rate.[34] "The more people who are vaccinated, the less likely anyone in that community will be infected."[35]

As shown from the statistics above, vaccines help protect against viruses that were once very common. However, some of these diseases are becoming more prevalent today. In 1994, the creation of the Vaccines for Children program helped the number of people infected yearly by measles drop from 500,000 to 60.[36] This program contributed to the eradication of measles in 2000.[37] However, presently the rate of measles outbreaks is the worst it has been in 20 years and the number continues to grow.[38] In 2012, there were a total of 55 cases of measles in the United States.[39] That number increased to 187 in 2013 and jumped again to 667 in 2014.[40] As of January 2, 2016, there were 189 reported cases of measles in the United States.[41] Most of the cases in 2015 are linked to the measles outbreak that occurred in California in December 2014 that resulted in 40 people contracting the virus after attending or working at Disneyland.[42] This outbreak has spread to at least six other states.[43]

What could be the cause of the reemergence of measles and other vaccine preventable diseases? The answer might be that more parents are choosing not to vaccinate their children. The CDC's director of immunizations and respiratory diseases, Anne Schuchat, says that the "[r]ecent measles outbreaks in New York, California and Texas are examples of what could happen on a larger scale if vaccination rates dropped. . . ."[44] Measles was eradicated in 2000 and now the disease is estimated to infect three times the number of people it did in 2009.[45] The majority of those who have contracted measles were not

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[34] Esquivel & Poindexter, *supra* note 29.

[35] Alcindor, *supra* note 1.

[36] Shih, *supra* note 2.

[37] *Id.*

[38] *Id.*

[39] Measles Cases and Outbreaks, CDC, http://www.cdc.gov/measles/cases-outbreaks.html (last updated Jan. 12, 2016).

[40] *Id.*

[41] *Id.*

[42] Maggie Fox & Hallie Jackson, *CDC Chief to Vaccine Worriers: Ignore the Internet Myths*, NBCNEWS (Feb. 4, 2015, 3:34 PM), http://www.nbcnews.com/storyline/measles-outbreak/cdc-chief-vaccine-worriers-ignore-internet-myths-n300286; *see also Measles*, CDPH, http://www.cdph.ca.gov/HealthInfo/discond/Pages/Measles.aspx (last updated Oct. 29, 2015).

[43] *Measles*, *supra* note 42.

[44] Alcindor, *supra* note 1.

[45] *Id.*

vaccinated.[46] The CDC director, Dr. Tom Frieden, stated, "We're concerned that measles could gain a foothold in this country if we don't stop it, if we don't increase vaccination rates. . . ."[47]

II. The Dangers Unvaccinated Children Face

It is important to know the risks an unvaccinated child can face. Some vaccine preventable diseases are very contagious and an outbreak can occur at anytime.[48] "Measles is so contagious that if one person has it, 90% of the people close to that person who are not immune will also become infected."[49] Even hours after an infected person leaves the room, an unvaccinated individual can still get measles just by entering.[50] The vaccine preventable diseases can range from mild to severe and can even be life threatening.[51] There is no way of knowing the severity of the disease the child will develop until after he or she is exposed.[52]

There are risks not only to that individual child but also to the community as a whole. In order to achieve herd immunity there needs to be a high percentage of people vaccinated in the community.[53] "Widespread vaccination prevents disease outbreaks. This protects all people from getting ill."[54] It is critical because it protects babies who cannot be vaccinated yet, elderly people who have a lower immune system and immune-compromised patients who cannot be vaccinated and are always more susceptible to getting infected.[55] Parents who refuse immunization have been called "free riders."[56] This suggests that those parents "take advantage of the benefits created by the participation and assumption of immunization risk or burden by others

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[46] Shih, *supra* note 2.

[47] Fox & Jackson, *supra* note 42.

[48] *If You Choose Not To Vaccinate Your Child, Understand the Risks and Responsibilities*, CDC, http://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/not-vacc-risks-color-office.pdf (last visited Mar. 2012) (hereinafter *If You Choose Not to Vaccinate*).

[49] *Transmission of Measles*, CDC, http://www.cdc.gov/measles/about/transmission.html (last updated Mar. 31, 2015).

[50] *If You Choose Not to Vaccinate*, *supra* note 48.

[51] *Id.*

[52] *Id.*

[53] *See* Esquivel & Poindexter, *supra* note 29.

[54] Aaron Carroll, *Why you must vaccinate your kids*, CNN (July 9, 2014, 5:07 PM), http://www.cnn.com/2014/07/09/opinion/carroll-vaccinate-kids/.

[55] *Id.*

[56] Douglas S. Diekema, *Responding to Parental Refusals of Immunization of Children*, 115 PEDIATRICS 1428, 1429 (2005).

while refusing to participate in the program themselves."[57] The risk to the child who is unvaccinated is decreased because others who are vaccinated that are surrounding the child have created a herd immunity, which will keep the child safe.[58] However, if the number of "free riders" grows then this herd immunity will start to weaken and the risk to the children will increase.[59]

It is important to keep vaccinating against diseases even if there are only a few cases reported.[60] If people stop now, then the number of infections will increase and the progress made would soon be for nothing.[61] An example of this can be seen from what occurred in Japan in the 1970's.[62] Nearly 80 percent of children in Japan received the pertussis vaccination in 1974 and in that year there were only 393 cases in the entire country.[63] After this, certain people in Japan began alleging that the pertussis vaccination was no longer safe or necessary.[64] Two years later, only 10 percent of infants received this vaccination.[65] As a result, in 1979, an epidemic broke out with more than 13,000 cases of pertussis and 41 deaths.[66] When the rates of cases amongst children for vaccine preventable diseases are low, this should not prompt parents to stop vaccinating. Instead, the parents should understand these low numbers as evidence that reflects the importance of vaccinating their children in order to keep the rates low.

III. Why Some Parents Refuse to Vaccinate Their Children

Today, there has been a greater trend of parents choosing not to vaccinate their children.[67] There are many reasons why parents choose not to vaccinate. For some families it is against their religious or

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[57] *Id.*

[58] *Id.*

[59] Steve P. Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children?*, 37 U. MICH. J.L. REFORM 353, 353 (2003-04).

[60] *Immunizations If There Is No Disease, Why Are Some Vaccines Still Necessary?*, PKIDS ONLINE, http://www.pkids.org/immunizations/immunization_necessity.html (last visited Jan. 29, 2016).

[61] *Id.*

[62] *Id.*

[63] *Id.*

[64] *Id.*

[65] *Id.*

[66] *Id.*

[67] Malia Jones & Alison Buttenheim, *Anti-vaccination beliefs are contagious like a disease*, WASH. POST (Sept. 22, 2014), http://www.washingtonpost.com/blogs/monkey-cage/wp/2014/09/22/anti-vaccination-beliefs-are-contagious-like-a-disease/.

philosophical beliefs to receive vaccinations.[68] Some children are physically incapable of receiving vaccinations because it would be detrimental to their health.[69] And some parents have become more concerned that vaccines are "unsafe, ineffective, or unnecessary."[70]

Parents fear that vaccinations are unsafe.[71] This reasoning can come from many different sources, but misinformation about the risk of vaccinations is one.[72] A national study showed that twenty-five percent of parents inaccurately believed that too many vaccinations would cause their child's immune system to be weakened.[73] For example, people still strongly argue that either vaccines or thimerosal, a mercury antifungal vaccine preservative, causes autism.[74] This movement started in the 1990s when an increase in autism cases occurred at the same time that the Haemophilus influenzae b (Hib) and hepatitis B vaccines were universally recommended which increased infant exposure to thimerosal.[75]

However, there are numerous scientific studies that do not support the link between autism and vaccinations.[76] One study compared children who were vaccinated with the pertussis vaccination containing thimerosal and children with the same vaccination but without thimerosal.[77] In Denmark, as of 1970 the only vaccination that still contained thimerosal was the pertussis vaccination but in March of 1992 the last of the vaccines containing thimerosal were distributed.[78] The study compared children born January 1, 1990 until December 31, 1996 by looking at information such as, vaccinations received, diagnoses of autism, and other relevant information.[79] The results of the study showed no relationship between vaccines containing

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[68] *Vaccine Laws*, NAT'L VACCINE INFO. CTR., http://www.nvic.org/vaccine-laws.aspx (last visited Jan 17, 2016).

[69] *Id.*

[70] *Id.*

[71] *Id.*

[72] *See* Diekema, *supra* note 56, at 1430.

[73] *Id.* at 1429.

[74] Donald G. McNeil, Jr.*, A Multitude of Vaccine Benefits, Yet Controversy Persists*, N.Y. TIMES (Mar. 28, 2008), http://www.nytimes.com/ref/health/healthguide/esn-vaccinations-ess.html.

[75] Greene et al., *Autism and Thimerosal-Containing Vaccines Lack of Consistent Evidence for an Association*, 25 AM. J. PREV. MED. 101, 101 (2003).

[76] *See, e.g., id.* at 106.

[77] Anders Hviid et al., *Association Between Thimerosal-Containing Vaccine and Autism*, 290 JAMA 1763, 1763 (2003).

[78] *Id.*

[79] *Id.* at 1764.

thimerosal and the development of autism.[80]

One source of the theory that vaccinations cause autism is Andrew Wakefield.[81] In the late 1990's, he conducted a study and theorized that there was a correlation between the measles, mumps, rubella (MMR) vaccine and autism.[82] In 1998, he published those studies in the *Lancet* and soon after the amount of MMR vaccination rates drastically dropped out of fear from parents of the risk of autism to their children.[83] However, soon after the Wakefield paper was published numerous epidemiological studies were conducted that refuted the link between MMR vaccines and autism.[84] The publication of these studies seriously undermined Wakefield's hypothesis.[85] Of the 12 co-authors of the study 10 retracted stating there was insufficient data when they concluded that there was a causal link between the MMR vaccine and autism.[86] In February 2010, the *Lancet* retracted the whole Wakefield paper stating that many of the elements in the paper were incorrect.[87] Wakefield and colleagues were said to have committed fraud by publishing false facts and the *British Medical Journal* published many articles exposing the fraud.[88]

Two commentators have suggested that the "Wakefield fraud is likely to go down as one of the most serious frauds in medical history."[89] Nevertheless, the Wakefield paper led many parents to choose not to vaccinate their children against serious diseases out of concerns that their child would get autism, overshadowing the legitimate safety issues for their children by not vaccinating them.[90] Despite all of the studies disputing this correlation, some people continue to believe vaccines are dangerous.[91] Some public figures

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[80] *Id.* at 1764-65.

[81] John Thomas, *Autism, Medicine, and the Poison of Enthusiasm and Superstition*, 7 J. HEALTH & BIOMEDICAL L. 449, 449-50 (2012).

[82] *Id.*

[83] T. S. Sathyanarayana Rao & Chittaranjan Andrade, *The MMR Vaccination and Autism, Sensation, Refutation, Retraction and Fraud*, 53 INDIAN J. PSYCHIATRY 95, 95 (2011), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3136032/.

[84] *Id.*

[85] *Id.*

[86] *Id.*

[87] *Id.*

[88] *Id.*

[89] *Id.*

[90] *Id.*

[91] *See* Karen D. Brown, *More parents are refusing immunizations for their children, raising fears among the medical community of disease outbreaks*, BOSTON GLOBE (Nov. 11, 2013), http://www.bostonglobe.com/lifestyle/health-wellness/2013/11/11/more-parents-are-

continue to promote the idea that autism can be caused from vaccinations.[92] The Internet makes it easy for these ideas to rapidly spread and some people choose to believe the rumors rather than scientific proof.[93] Dr. Tom Frieden, the director of CDC, is urging people to stop accepting everything on the Internet as true.[94]

Vaccine related safety concerns have been addressed through the Federal Food and Drug Administration (FDA).[95] The FDA requires manufacturers of vaccinations to thoroughly test the proposed vaccination before it is brought to the general public.[96] This process can take up to ten years.[97] Then once the vaccine is in the general use, the FDA and the CDC will monitor any side effects through the Vaccine Adverse Event Reporting System.[98] If there are side effects and safety concerns involved with the vaccination the FDA and the CDC can prohibit the use of the vaccination.[99]

Ironically, the exceptional success of vaccinations has led some parents to forget how severe the effects of vaccine preventable diseases can be.[100] Dr. Tom Frieden, director of CDC, explains that it is rare to find people who are completely opposed to vaccinations.[101] Rather, most parents who choose not to vaccinate their child do so not because they are opposed to the idea of vaccinations, but simply because they are unaware that the diseases are still around.[102] The illnesses that the mandatory vaccines prevent are no longer major killers in society, making parents focus more on the risks they believe the vaccinations present rather than the benefits.[103] "Most people cannot remember a time when polio, measles, diphtheria, and smallpox killed tens of

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refusing-immunizations-for-their-children-raising-fears-among-medical-community-disease-outbreaks/m3mGJgFhzrT7PUehai87tN/story.html.

92 Alcindor, *supra* note 1.

93 *See* Mark A. Largent, *What If Vaccines Caused Autism?*, GENOTOPIA (Aug. 29, 2013), http://genotopia.scienceblog.com/366/what-if-vaccines-caused-autism/.

94 Fox & Jackson, *supra* note 42.

95 Hodge & Gostin, *supra* note 24, at 884.

96 *Id.*

97 *Vaccine Safety*, PKIDS ONLINE, http://www.pkids.org/immunizations/vaccines_safe_choice.html (last visited Jan. 22, 2016).

98 *Id.*

99 *Id.*; Hodge & Gostin, *supra* note 24, at 884.

100 Diekema, *supra* note 56, at 1428.

101 Fox & Jackson, *supra* note 42.

102 *Id.*

103 Calandrillo, *supra* note 59, at 388-89

thousands of children each year."[104] Now that outbreaks of these diseases are becoming more common, it is time for parents to shift their focus from risks they believe vaccines can cause to risks the vaccine preventable diseases can cause to their children.

IV. State Allowed Exemptions

All states make it mandatory for children to receive certain vaccinations before entering school.[105] However, all fifty states have some form of a statutory exemption for student-required vaccinations.[106] Every state has a medical exemption.[107] All states but three, Mississippi, West Virginia, and California, have an exemption for religious beliefs.[108] Eighteen states allow a philosophical exemption for those who deem the required immunization to be against their "personal, moral, or other beliefs."[109] The standards for receiving an exemption vary between states, but statutes usually require parents to show that the vaccine would "contradict a sincere religious belief" for a religious exemption.[110] "Philosophical exemption indicates that the statutory language does not restrict the exemption to purely religious or spiritual beliefs."[111] For example, Minnesota's statute allows a philosophical exemption if the refusal is based on "conscientiously held beliefs of the parent or guardian."[112]

There is extensive debate surrounding the risks of allowing non-medical exemptions to school required vaccinations. One study gathered information on individuals who contracted measles and pertussis in Colorado between 1987 and 1998.[113] The study, which

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[104] Hodge & Gostin, *supra* note 24, at 888.

[105] *STATES WITH RELIGIOUS AND PHILOSOPHICAL EXEMPTIONS FROM SCHOOL IMMUNIZATIONS*, NAT'L CONF. OF STATE LEG. (March 3, 2015), http://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx [hereinafter *Religious and Philosophical Exemptions*].

[106] The College of Physicians of Philadelphia, *Vaccine Exemptions*, HISTORY OF VACCINES, http://www.historyofvaccines.org/content/articles/vaccination-exemptions (last updated July 31, 2014).

[107] *Id.*; *see also Religious and Philosophical Exemptions*, *supra* note 105.

[108] *State Law & Vaccine Requirements*, NAT'L VACCINE INFO. CTR, http://www.nvic.org/vaccine-laws/state-vaccine-requirements.aspx (last visited Jan. 26, 2016).

[109] *Religious and Philosophical Exemptions*, *supra* note 105.

[110] *Id.*

[111] *Id.*

[112] *Id.*

[113] Feikin DR, Lezotte DC, Hamman RF, Salmon DA, Chen RT, Hoffman RE. Individual and Community Risks of Measles and Pertussis Associated with Personal Exemptions to

compared children exempted from vaccinations to vaccinated children from ages 3 to 18, found that exempted children were 22 times more likely to get measles and 5.9 times more likely to get pertussis.[114] The study also found that in areas where the frequency of exemptions was greater, the cases of measles and pertussis were also greater.[115] The study illustrated that the geographical and social clustering of children who claim an exemption increases the community risk.[116] Children who are especially vulnerable in these communities are those who cannot receive vaccinations because of medical reasons or children "who do not develop a sufficient immunological response to the vaccine."[117]

Another concern is that non-medical exemptions are granted too easily.[118] The standards for exemptions based on a religious or personal belief vary from state to state. Some states require that a parent prove that the family belongs to a bona fide religion that objects to vaccinations.[119] For example, Iowa requires the parent to show that "immunization conflicts with a genuine and sincere religious belief and that the belief is in fact religious, and not based merely on philosophical, scientific, moral, personal, or medical opposition to immunizations."[120] However, many states only require a parent to sign a form that states the vaccination is against his or her religious beliefs.[121] For example, in Connecticut, a parent's only requirement is to file a state religious exemption form with the school nurse that states:

> I/we hereby assert that the immunization of this student would be contrary to the religious beliefs of this child. Therefore, this child shall be exempt from the required immunizations under Section 10-204a of the Connecticut General Statutes and shall be permitted

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Immunizations. *JAMA*. 2000 Dec 27: 284(24): 3145-50.

[114] *Id.*

[115] *Id.*

[116] *Id.*

[117] Daniel A. Salmon, *Mandatory Immunization Laws and the Role of Medical, Religious and Philosophical Exemptions*, at 2 (October 2003) (unpublished commentary) (on file with Institute for Vaccine Safety at St. Johns Hopkins Bloomberg School of Public Health), http://www.vaccinesafety.edu/exemptreview101503.pdf.

[118] *See* Emily Oshima Lee et al., *The Effect of Childhood Vaccine Exemptions on Disease Outbreaks*, CENTER FOR AM. PROGRESS (Nov. 14, 2015), https://cdn.americanprogress.org/wp-content/uploads/2013/10/VaccinesBrief-1.pdf.

[119] The College of Physicians of Philadelphia, *supra* note 106.

[120] *Id.*

[121] *Id.*

> to attend a licensed child care program or school except in the case of a vaccine-preventable disease outbreak.[122]

Once a parent completes this form there is no test or way to verify the information provided.[123] Dr. Sandy Carbonari, a Connecticut pediatrician, explained that once a parent refuses vaccinations for personal beliefs, the conversation stops.[124] The doctors are not responsible for following through with what happens before the students enter the school system and therefore would have no way of finding out if the parent later goes on to claim a religious exemption.[125]

New York does not require that the parent prove that the religion opposes vaccines, but only that the parent provide a "genuine and sincere" religious objection to vaccines.[126] The use of this exemption is rising.[127] In New York, the percentage of children with a religious exemption went from .23 percent in 2000 to .45 percent in 2011.[128] The state's Health Department showed that New York City schools granted 3,535 religious exemptions in the 2012-2013 academic year.[129] Although the overall city school immunization rate is still near 97 percent, this is concerning because the rates for 37 private schools were under 70 percent.[130] As explained above, this is not enough to establish a "herd immunity" and therefore the children are at serious risk.[131]

Almost all of the twenty states that allow the personal belief exemption simply require a parent to file a one-time or yearly form demonstrating a personal objection to the vaccination.[132] In states that allow medical, religious, and personal belief exemptions, the personal belief exemption is typically the one most commonly used.[133] Between 1991 and 2004 the use of the personal belief exemption, in states that

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122 Josh Kovner, *State Looks To Close Any Loopholes in Vaccine Waiver*, CTNOW (Feb. 8, 2015, 7:24 AM), http://touch.ctnow.com/#section/-1/article/p2p-82758339/.

123 *Id.*

124 *Id.*

125 *Id.*

126 Benjamin Mueller, *Judge Upholds Policy Barring Unvaccinated Students During Illnesses*, NY TIMES (June 22, 2014), http://www.nytimes.com/2014/06/23/nyregion/judge-upholds-policy-barring-unvaccinated-students-during-illnesses.html?_r=0.

127 *Id.*

128 *Id.*

129 *Id.*

130 *Id.*

131 *See id.*; *see also Herd Immunity*, *supra* note 30.

132 The College of Physicians of Philadelphia, *supra* note 106.

133 *Id.*

permit it, increased from 0.99% to 2.45%.[134] Last year, in California alone, the number of kindergarteners with personal belief exemptions totaled 14,921.[135] It is alarming to see the number of parents choosing not to vaccinate their child due to the personal belief exemption and the minimal requirements needed to receive this exemption. The recent outbreaks of measles and pertussis have been "traced to pockets of unvaccinated children in states that allow personal belief exemptions."[136] David Magnus, a professor of pediatrics and director of the Center of Biomedical Ethics at Stanford University, stated "[a]n exemption is something we can only allow under the condition where it very rarely is exercised. The fact that there has been so much misuse means it is time to tighten things."[137]

V. Responses to the Decrease in Children Vaccination Rates

States are becoming more concerned about children who are not vaccinated and have taken steps to ensure safety. For example, states have prevented children from attending school if they are unvaccinated and an outbreak occurs.[138] In New York, when an unvaccinated [home-schooled] child contracted the measles, the child's unvaccinated sibling was not allowed to attend school.[139] Several parents [impacted by similar restrictions] felt that not allowing their children to attend school violated certain constitutional rights and filed lawsuits.[140] Recently, in *Phillips v. City of New York*,[141] the court upheld the city's policy of not allowing unvaccinated children to attend school when a student contracts a vaccine preventable disease.[142] There, the plaintiff's children were exempted from receiving the school-mandated vaccinations because of their religious beliefs.[143] The plaintiffs argued

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134 *Id.*

135 Alcindor, *supra* note 1.

136 *Personal belief exemptions put people at risk. Examine the evidence for yourself,* IMMUNIZATION ACTION COALITION, (Aug. 14, 2014), http://www.immunize.org/catg.d/p2069.pdf.

137 Lisa M. Krieger & Jessica Calefati, *Two state lawmakers look to limit vaccine exemption*, TIMES STANDARD (Feb, 4, 2015, 7:32 PM), http://www.times-standard.com/general-news/20150204/two-state-lawmakers-look-to-limit-vaccine-exemptions.

138 *See* Mueller, *supra* note 126.

139 *Id.*

140 *See id.*

141 Phillips v. City of New York, 27 F. Supp. 3d 310 (E.D.N.Y. 2014).

142 *Id.* at 311-12; *see also* Mueller, *supra* note 126.

143 *Phillips*, *supra* note 141, at 311.

that it was unconstitutional to prohibit the children from going to school because of an outbreak of a vaccine preventable disease.[144] The court granted the defendant's motion to dismiss for all of the plaintiffs' claims.[145] The court explained, when dismissing the plaintiff's First Amendment claim, there is nothing in the Constitution that requires a state to provide a religious exemption to vaccinations.[146]

California legislation imposed certain requirements to make it more difficult for a parent to receive the personal belief exemption for their children.[147] After January 1, 2014, the parent or guardian has to present a signed confirmation from a practicing health care practitioner showing that the practitioner provided information about the risks and benefits of the required immunizations.[148] The parent or guardian must also write and sign a statement indicating that they received this information.[149] This must be done no more than six months prior to the required vaccination date as a condition of school.[150] The fact that the legislature acted shows its concern that more parents have chosen not to vaccinate their children. The 2014-2015 academic year was the first that was affected by the new legislation and there has been almost a twenty percent decrease in the use of the personal belief exemption.[151] The immediate decrease in exemption use as a result of the new law, which mandates a physician to discuss all the risks and benefits of the vaccine, shows that some parents are basing their decision to not vaccinate their child solely on misinformation.[152]

The most recent measles outbreak in 2015, 102 cases in 14 states,[153] has shown the dangerous consequences of not vaccinating and has resulted in legislation that changes or eliminates certain vaccine exemptions.[154] Recently, on June 30, 2015, the governor of California signed into law SB 277, which removes personal and religious belief exemptions from school required vaccines and allows only exemptions

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144 *Id.* at 313.
145 *Id.*
146 *Phillips*, *supra* note 141, at 312-13.
147 Jones & Buttenheim, *supra* note 67.
148 Cal. Health & Safety Code § 120365, *repealed by* S.B. 277 (Cal. 2015).
149 *Id.*
150 *Id.*
151 Aliferis, *supra* note 3.
152 *Id.*
153 Kovner, *supra* note 122.
154 Krieger & Calefati, *supra* note 137; *see also Religious and Philosophical Exemptions*, *supra* note 105 (listing as of July 2015 the different legislation being introduced on this topic).

for medical reasons.[155] This law will take effect July 1, 2016.[156] A parent can still file a personal belief exemption before January 1, 2016 under the requirements explained in the above paragraph.[157] If a parent files the correct paperwork prior to January 1, 2016 then the child is allowed to attend school unvaccinated until the child begins the next grade span.[158] The statute explains that "grade span" means " (A) birth to preschool, (B) kindergarten and grades 1 to 6, and (c) grades 7 to 12."[159] Governor Jerry Brown, who once advocated for parental choice, explained in his signing statement that "[t]he science is clear that vaccines dramatically protect children against a number of infectious and dangerous diseases. While it's true that no medical intervention is without risk, the evidence shows that immunizations powerfully benefits and protects the community."[160]

The President of the United States has also urged parents to vaccinate their children.[161] President Obama stated "[t]here is every reason to get vaccinated – there aren't reasons not to."[162] President Obama recognizes that people are concerned with the effects that vaccinations can have, but points out that "the science is pretty indisputable."[163]

Doctors have also become more concerned with parental refusal of vaccinations.[164] There are doctors nationwide who will refuse new patients if they know the family is not vaccinated and will continue to choose not to vaccinate.[165] A Virginia pediatrician following this practice explains, "[w]e don't want to put our patients at risk because

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[155] *Id.*

[156] *California State Vaccine Requirements,* NAT'L VACCINE INFO. CTR. (Jan. 22, 2016), http://www.nvic.org/Vaccine-Laws/state-vaccine-requirements/california.aspx.

[157] *Id.*

[158] *Id.*

[159] Cal. Health & Safety Code § 120335(g)(2); *see also id.*

[160] Signing Comment from Governor Edmund G. Brown to the Members of the California State Senate, Office of the Governor (June 30, 2015), http://gov.ca.gov/docs/SB_277_Signing_Message.pdf.; *see also* Krieger & Calefati, *supra* note 137.

[161] Abby Phillip, *Obama to parents doubting 'indisputable' science: 'Get your kids vaccinated'*, WASH. POST (Feb. 2, 2015), http://www.washingtonpost.com/news/morning-mix/wp/2015/02/02/get-your-kids-vaccinated-obama-tells-parents-doubting-indisputable-science/.

[162] *Id.*

[163] *Id.*

[164] *See* Brittny Mejia, *Doctors turning away unvaccinated children*, LA TIMES (Feb. 10, 2015) http://www.latimes.com/science/la-me-vaccination-policy-20150210-story.html#page=1.

[165] *Id.*

people for their own personal reasons don't want to vaccinate. We are doing our due diligence to protect our children who wait in our waiting room."[166]

VI. Liability of Parents

A parent can face criminal repercussions for physically harming a child.[167] But what if that could be extended to decisions parents make about their own child that physically harms another child? Suppose the state chose to prosecute parents of an unvaccinated child who caused another child to become ill because either the child was too young to be vaccinated, could not receive vaccinations due to a medical condition, or took the precautions by receiving vaccinations but still contracted the disease. Parents whose child is too young or physically cannot receive vaccinations would not be held liable if that child caused another child to contract the disease since it is physically impossible for the parent to vaccinate their child. This section will analyze various criminal statutes to see if a parent could be found guilty for choosing not to vaccinate his or her child and whose unvaccinated child infects someone else.

A. Reckless Endangerment

Under Connecticut General Statute § 53a-64 a person can be guilty of reckless endangerment in the second degree if "he recklessly engages in conduct which creates a risk of physical injury to another person."[168] Under the Connecticut General Statute a person acts recklessly when "he is aware of and consciously disregards a substantial and unjustifiable risk that such result will occur or that such circumstance exists."[169] The statute further explains "the risk must be of such nature and degree that disregarding it constitutes a gross deviation from the standard of conduct that a reasonable person would observe in the situation."[170] Physical injury is defined as an "impairment of physical condition or pain."[171] The refusal to vaccinate could be prosecuted under this statutory authority if as a result a child

166 Alcindor, *supra* note 1.
167 Conn. Gen. Stat. Ann. §53-21 (West 2013).
168 Conn. Gen. Stat. Ann. § 53a-64 (West 1971).
169 Conn. Gen. Stat. Ann. § 53a-3(13) (West 2013).
170 *Id.*
171 *Id.* at (3).

contracted a vaccine preventable disease. The physical injury to the child would be the contracted vaccine preventable disease and the injury would be caused by the reckless conduct of the defendant parent. The reckless conduct would be choosing not to vaccinate when the parent knew of and consciously disregarded the substantial risk that another child could become ill. The state would then have to prove that disregarding that substantial risk was a gross deviation from conduct that a reasonable person would exercise.

The state would [most likely] be able to prove that physical injury was caused to the child because contracting the disease would be impairment of physical condition or pain since possible side effects range from rashes, muscle pain, seizure, to brain damage depending on the disease.[172] As illustrated above, Jeramiah Mitchell has severe permanent injuries with all of his extremities amputated because he contracted a vaccine-preventable disease.[173] The state would then have to prove that the parent knew the risks of the vaccine preventable diseases. The American Academy of Pediatrics conducted a survey on immunization-administration practices, which found that, almost all the pediatricians educated the parents on the benefits and importance of vaccinations.[174] This shows that parents are most likely going to be informed of the risks the diseases can cause when choosing not to vaccinate. The most challenging part of this charge would be proving that the choice to not vaccinate the defendant's child amounts to a gross deviation from the standard of conduct of a reasonable person. This would depend on the circumstances of the case. For instance, if the defendant parent did not receive an exemption for a required vaccination and still chose not to vaccinate their child then this could be a gross deviation from conduct that a reasonable person would observe in this situation. As explained, pediatricians often inform parents of the vaccinations that the child needs.[175] By receiving the information on the required vaccinations and the risks of the diseases the vaccines prevent, the parent would inevitably be made aware of the risk. By choosing to not vaccinate the child, the parent would be consciously disregarding that risk. Since all states require a parent to

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[172] *Vaccine Information Statements*, CNTR. FOR DISEASE CONTROL & PREVENTION (Apr. 20, 2012), http://www.cdc.gov/vaccines/hcp/vis/vis-statements/mmr.html.

[173] *See* Alcindor, *supra* note 1.

[174] Diekema, *supra* note 56, at 1428.

[175] *See* Mejia, *supra* note 164.

obtain some form of an exemption in order to not have their child receive a school-required vaccination,[176] the parent's behavior of not vaccinating the child and not receiving an exemption could be a gross deviation from the standard of conduct that a reasonable person would observe.

Another situation could arise if the defendant parent receives a religious or personal belief exemption, but the parent cannot provide evidence and support for the exemption. As explained above, many states only require a parent to sign a form that declares the vaccinations are against their religious or personal belief.[177] In Connecticut, a parent is required only to sign a statement that says the vaccination is against the child's religious belief.[178] If the parents are charged, and they cannot prove that their religion actually prohibits vaccinations this could be reckless endangerment. If the parents were informed by the pediatrician of the risk of not vaccinating their child and the risks associated with the disease then this would show that the parents knew of the risks. To then retrieve an exemption with no facts to support it would constitute a gross deviation from the standard of conduct that a reasonable person would observe in this situation. Connecticut cases have shown that reckless conduct can be "inferred from [the] person's words and conduct when viewed in the light of the surrounding circumstances."[179] In view of the recent outbreaks of vaccine preventable diseases and the known risks involved with not vaccinating a child, a parent knowing the risks and unable to provide proof that the vaccine is against their religious or personal belief could be considered reckless conduct.

B. Criminally Negligent Homicide

Under Connecticut General Statute section 53a-58, a person is guilty of negligent homicide when acting "with criminal negligence he causes the death of another."[180] This crime is classified as a misdemeanor.[181] Criminal negligence is defined as, a failure "to

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[176] The College of Physicians of Philadelphia, *supra* note 106.

[177] *Id.*

[178] *See* Conn. Gen. Stat. Ann. § 10-204a (a)(3) (West 2011).

[179] State v. Davila, 75 Conn. App. 432, 439 (Conn. App. Ct. 2003) (quoting State v. Ghiloni, 35 Conn. Supp. 570, 573 (1978)).

[180] Conn. Gen. Stat. Ann. § 53a-58 (West 1971).

[181] *Id.*

perceive a substantial and unjustifiable risk that such result will occur or that such circumstance exists."[182] The statute further describes that "the risk must be of such nature and degree that the failure to perceive it constitutes a gross deviation from the standard of care that a reasonable person would observe in the situation."[183]

Under this statute, even if the parent did not actually know of the risk, the parent could still be prosecuted if he or she reasonably should have known the risks of vaccine preventable diseases. The state could charge a parent with this crime if a child has died from a vaccine preventable disease that he or she contracted from an unvaccinated child. The defendant parent would be guilty of negligent homicide if the parent failed to perceive the substantial and unjustifiable risk that death of another child could occur by not vaccinating his or her own child and that death did in fact occur. One side effect of measles is death.[184] The state would have to prove that the parent failed to perceive the risk that not vaccinating their child could cause death to another child. If a parent should be aware that the vaccine preventable disease can cause death and still chooses not to vaccinate then this could be a gross deviation from the standard of care of a reasonable person. With the most recent outbreaks it might be easier to prove that most parents would perceive the risk that death could occur from the vaccine preventable disease.

Parents could be held responsible, not only for harm to other children, but also for harm to their own child. Another scenario where parents could be guilty of this crime is if their own child dies from a vaccine preventable disease that the parents chose not to vaccinate the child from. The analysis would be the same as stated above except the state would prosecute because of the death of the defendant's own child. The state would have to provide evidence to show that failing to perceive the risk that their child could die if not vaccinated constitutes a gross deviation from the standard of care of a reasonable person. The state could do this by showing the recent outbreaks and deaths that have occurred from vaccine preventable diseases.

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182 Conn. Gen. Stat. Ann. § 53a-3(14) (West 2013).

183 *Id.*

184 *Vaccine Information Statements*, *supra* note 172.

C. Manslaughter in the Second Degree

Under Connecticut Penal Code section 53a-6, a person is guilty of manslaughter in the second degree when "[h]e recklessly causes the death of another person; or he intentionally causes or aids another person, other than by force, duress or deception, to commit suicide."[185] This statute could be used when a child dies from a vaccine preventable disease that he or she contracted from an unvaccinated child. The relevant part of the statute is "recklessly causes the death of another person."[186] The state would have to prove that a defendant's choice to not vaccinate their child was reckless and that it caused the death of another child. The state would also have to show that the parents were "aware of and consciously disregard[ed] a substantial and unjustifiable risk"[187] that death of another child could occur by not vaccinating their own child.

The state would have to show that the pediatrician discussed death as a risk of the disease. The doctor might also explain that the vaccine would help prevent this disease from spreading to other children in the community who cannot receive vaccinations for age or medical reasons. This could show that the parent was aware of the substantial and unjustifiable risk that another child could contract and die from this dangerous disease and that the parent disregarded it by choosing not to vaccinate his or her child. Documentation from an exemption in states that now require a signed confirmation from a health care provider that he or she discussed the benefits and risks of vaccines would provide clear evidence. The state could show that the risk of death from not vaccinating a child would "be of such nature and degree that disregarding it constitutes a gross deviation from the standard of conduct that a reasonable person would observe in the situation."[188]

VI. Proposed Policies

With the growing number of outbreaks of vaccine-preventable diseases, states could take the initiative to create legislation to help with this problem. States could mandate that if a child does not receive the required vaccinations and the child did not receive an exemption

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185 Conn. Gen. Stat. Ann. § 53a-56 (West 1971).
186 *Id.*
187 Conn. Gen. Stat. Ann. § 53a-3(13) (West 2013).
188 *Id.*

then the parents could be fined. In an older United States Supreme Court case, *Jacobsen v. Commonwealth of Massachusetts*, the plaintiff argued that a state compulsory vaccination statute violated his constitutional rights.[189] Rev. Laws, c. 75, §135 stated:

> The board of health of a city or town, if, in its opinion, it is necessary for the public health or safety, shall require and enforce the vaccination and revaccination of all the inhabitants thereof, and shall provide them with the means of free vaccination. Whoever, being over twenty-one years of age and not under guardianship, refuses or neglects to comply with such requirement shall forfeit $5.[190]

The plaintiff argued that his liberty interest was invaded when he was forced to receive a vaccination or else he would be subject to a fine or imprisonment.[191] The Supreme Court disagreed with the plaintiff and found the statute constitutional.[192] The Court explained that liberty is not an absolute right since every person is subject to the common good because without that an organized society could not provide safety for its members.[193] "Persons and property are subjected to all kinds of restraints and burdens in order to secure the general comfort, health, and prosperity of the state."[194] "A community has the right to protect itself against an epidemic of disease which threatens the safety of its members."[195]

The proposed statute would not be the same as the one discussed in that case. In *Jacobson,* the statute compelled adults to receive vaccination themselves, but here, the statute would be compelling parents to have their children receive vaccinations. Another significant distinction is the proposed statute would fine the parents if their child does not receive the state-mandatory vaccinations without an exemption but the statute in *Jacobson* only mandated adults to receive a vaccination when there was an epidemic or enough cases to have public concern. This difference could pose a challenge because the Supreme Court decision rested in part on the fact that the statute would

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189 Jacobsen v. Commonwealth of Massachusetts, 197 U.S. 11, 22 (1905).
190 *Id.* (quoting Rev. Laws, c. 75, §135).
191 *Id.* at 26.
192 *Id.*
193 *Id.*
194 *Id.* (quoting Hannibal & St. J.R. Co. v. Husen 95 U.S 465, 471 (1877)).
195 *Id.* at 27.

only be used in emergency situations.[196] There can be an argument that the proposed statute is in response to an emergency situation due to the recent decrease in vaccination rates that are leading to increase outbreaks in certain areas.

There also should be set guidelines for pediatricians when they are dealing with a family who is refusing vaccinations. The *Official Journal of the American Academy of Pediatrics* made recommendations that the pediatricians should follow in these circumstances.[197] It might be beneficial to make these recommendations requirements for pediatricians. First, the pediatrician needs to listen carefully to the parents' concerns with the vaccinations.[198] The pediatrician must provide the parents with everything that is known about the risks and benefits of each vaccine to resolve any misconceptions.[199] One useful suggestion is to have the doctor remind the parents that the risks of the vaccination need to be weighed against the risks to the child that is left unimmunized.[200] The pediatrician should explain the risk and benefits of each vaccination separately because a parent who is reluctant to accept one vaccination might be willing to allow others.[201] The pediatrician should also recognize the reason the parents are choosing not to vaccinate and if it is for financial reasons then the doctor needs to work with the parent.[202]

The doctor should also inform the family of the Vaccines for Children Program (VFC**),** which helps with financial difficulties.[203] VFC allows all vaccines to be free if the family cannot afford them.[204] The parents do not need to provide proof that the child would be eligible for free vaccinations.[205] However the doctor is required to inquire and to record if the child is on Medicaid, if the child has any insurance and if so if it would cover vaccinations, and if the child is

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196 *Id.*

197 Diekema, *supra* note 56, at 1430.

198 *Id.*

199 *Id.*

200 *Id.*

201 *Id.*

202 *Id.*

203 *Vaccine for Children Program Answers to Parent's Questions*, CDC, http://www.cdc.gov/vaccines/programs/vfc/providers/questions/qa-parents.html#fee (last updated Aug. 31, 2012).

204 *Id.*

205 *Id.*

Native American or Alaskan Native.[206] This program, however, does not cover the cost of the doctor's visit.[207] If the parents do not have Medicaid then they are responsible for this payment or the pediatrician can work with the family.[208]

Since most parents do not remember the serious effects of vaccine-preventable diseases, it should be mandatory for doctors to go over all of the risks to soon-to-be parents instead of waiting until after the baby is born. This is also highly important because the mother needs to have some vaccines, like pertussis, in order to prevent infection in the baby.[209] The risks of vaccine preventable diseases can then be restated once the child reaches the age that a vaccine is recommended. The more information on the danger of these diseases that is explained to parents the better.

Until the rate of non-medical exemptions decreases, reform needs to be achieved within States. States can add more requirements when receiving an exemption. States can also take away certain exemptions. As stated above, California recently signed SB 277 into law that will take effect July 1, 2016, which removes the religious and personal belief exemption.[210] Two other states, Mississippi and West Virginia, similarly only allow exemptions for medical reasons.[211]

VII. Conclusion

Vaccines work. The Centers for Disease Control and Prevention estimates that in the last 20 years, vaccinations prevented 322 million illnesses and 732,000 deaths.[212] However, some parents have forgotten the dangerous effects of the vaccine preventable diseases and consequently the trend to not vaccinate children is growing. This is putting surrounding children at risk and there should be an affirmative action by states to help reverse this trend. Parents of children who become ill because of an unvaccinated child should have some sort of recourse. Whether this starts with a state becoming more proactive

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206 *Id.*

207 *Id.*

208 *Id.*

209 Alcindor, *supra* note 1.

210 *California State Vaccine Requirements,* NAT'L VACCINE INFO. CTR. (Jan. 22, 2016), http://www.nvic.org/Vaccine-Laws/state-vaccine-requirements/california.aspx.

211 *State Law & Vaccine Requirements*, Nat'l Vaccine Info. Ctr, http://www.nvic.org/vaccine-laws/state-vaccine-requirements.aspx (last visited Feb. 26, 2016).

212 McNeil, *supra* note 74.

with their vaccine legislation or allowing criminal charges to be brought against parents, something needs to be done. "There's an old saying that your right to swing your fist ends at my nose, [a]nd if the choices you make for your family end up putting my children at risk or other children in our community at risk, then that's really something that community, that school board, that state need to look at really closely."[213]

[213] Fox & Jackson, *supra* note 42 (CDC director Dr. Tom Frieden expressing his view that the right not to vaccinate a child can only go so far).

"HERE'S LOOKING AT YOU, KID":* THE NEED FOR DISCRETIONARY TRANSFER PROCEDURES FOR ALL JUVENILE OFFENDERS IN CONNECTICUT

Jennifer R. Flynn†

Despite the drastic differences between a child and an adult offender, Connecticut's transfer provisions automatically subject a juvenile offender to punishment in the adult criminal system for certain offenses. The statute ignores the importance of youth and stands contrary to recent judicial decisions, research-based trends, and rehabilitative aims. Failing to provide a child with special consideration before treating him or her as an adult causes harm and fuels the criminal cycle in Connecticut. Only by determining whether each youth is appropriate to remain in the juvenile system prior to transfer will the state ensure he or she receives necessary treatment and rehabilitation services. Discretionary transfer procedures ensure each juvenile offender is provided a chance for maturity, rehabilitation, and treatment. Connecticut should eliminate automatic transfer provisions and grant judges the discretion to consider youth and its attendant circumstances in order to decide whether a transfer would be appropriate.

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* Julius Epstein, Phillip Epstein, & Howard Koch, *Casablanca*.

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I. Introduction

In Connecticut, a child as young as fifteen who is charged with certain offenses is automatically transferred to adult court.[1] Under Connecticut General Statute § 46b-127, a child can be transferred to the adult criminal court without consideration of his or her age, its attendant circumstances, and potential for rehabilitation in the juvenile justice system.

The United States Supreme Court has recognized the marked differences between a juvenile and an adult offender.[2] In particular, the

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[1] CONN. GEN. STAT. §46b-127 (2015); *see* CHRISTOPHER REINHART, OFFICE LEG. RESEARCH, AUTOMATIC TRANSFERS OF JUVENILES FROM JUVENILE CRIMINAL COURT, 2014-R-0094, at 1-2 (2014), http://www.cga.ct.gov/2014/rpt/pdf/2014-R-0094.pdf.

[2] *See* Haley v. Ohio, 332 U.S. 596, 599 (1948); Lockett v. Ohio, 438 U.S. 586, 608 (1978) (plurality opinion); Eddings v. Oklahoma, 455 U.S. 104, 115-16 (1982); Johnson v. Texas, 509 U.S. 350, 364-71 (1993); Roper v. Simmons, 543 U.S. 551, 569-71 (2005); Graham v. Florida, 560 U.S. 48, 68-9 (2010); Miller v. Alabama, 132 S. Ct. 2455, 2463-69 (2012); Montgomery v. Louisiana, 136 S. Ct. 718 (2016).

Court has stressed the significance of a juvenile's lessened culpability, developmental limitations, and ability to be rehabilitated.[3] Among other things, the decisions require that courts consider mitigating factors of youth when sentencing a juvenile to harsh penalties in the adult criminal court.[4] These individualized factors of youth clearly establish the critical distinctions between a juvenile and an adult offender and illuminate a youth's treatment needs and potential for rehabilitation.[5] Fundamental mitigating factors of youth identified by the Court include: family history, mental health, decreased culpability, and underdeveloped levels of maturity.[6]

However, recent juvenile cases decided by the U.S. Supreme Court and Connecticut Supreme Court do not go far enough to ensure justice and protection for justice-involved youth in Connecticut. For a child charged with a harsh crime, the remarkable juvenile-adult distinction and progressive ideology falters post-sentencing as the significance of youth disintegrates once he or she is confined in an adult facility.[7] Far before sentencing occurs, age and its mitigating characteristics should be weighed on a case-by-case basis to determine the appropriateness of transferring a juvenile to the adult criminal system, his or her capacity for rehabilitation, and treatment needs.[8]

As research about adolescent development advances, understanding of the mental health and rehabilitation needs of justice-involved youth is increasing.[9] The unique mental health needs of a juvenile are not adequately met when he or she is incarcerated as an adult. The adult criminal system does not have the capacity to provide appropriate mental health treatment or rehabilitation services to a transferred juvenile.[10] Sadly, confinement with adults results in

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[3] *Graham*, 560 U.S. at 68, 74; *Miller*, 132 S. Ct. at 2475.

[4] *See*, *e.g.*, *Miller*, 132 S. Ct. at 2475.

[5] *See id*. at 2467-69.

[6] *See id.*

[7] *See* JAMES AUSTIN, ET AL, U.S. DEP'T OF JUST., BUREAU OF JUST. ASSISTANCE, JUVENILES IN ADULT PRISONS AND JAILS: A NATIONAL ASSESSMENT 43 (2000), https://www.ncjrs.gov/pdffiles1/bja/182503.pdf.

[8] *See Miller*, 132 S. Ct. at 2474.

[9] *See* Delia Fuhrmann, Lisa Knoll, & Sarah-Jayne Blakemore, *Adolescence as a Sensitive Period of Brain Development*, 19 TRENDS IN COGNITIVE SCI. 558, 558-66 (2015); Joseph Cocozza & Kathleen Skowyra, *Youth with Mental Health Disorders: Issues and Emerging Responses*, 7 JUV. JUST. 3, 3-11 (2000), https://www.ncjrs.gov/pdffiles1/ojjdp/178256.pdf.

[10] Roslyn Satchel, *Lost Opportunities: Our Children Are Not Rehabilitated When They Are Treated And Incarcerated As Adults*, CAMPAIGN FOR JUV. JUST. 2 (2002), http://www.prisonpolicy.org/scans/lost_opportunities.pdf.

physical and psychological harm to an already susceptible juvenile.[11] Even where a juvenile sentenced as an adult is segregated due to his or her age, the harms of incarceration are undeniable.[12] A young offender should be afforded the opportunity for change, maturation, and rehabilitation. However, a child subject to an automatic transfer will not be given such a chance, let alone provided with the means to grow and become a productive member of society.

Nationally, states are reforming the ways that youth are treated in the justice system.[13] Many states have imposed protections that shield youth from the harms of incarceration in adult facilities.[14] Instead of punishment, the focus is on understanding and treating the mental health and trauma-related challenges of a justice-involved youth.[15] States are shifting programming away from the once popular practice of detaining juveniles and moving towards community-based efforts that benefit public safety.[16] State reform efforts are centered around ensuring that this vulnerable population receives rehabilitation, treatment for their underlying mental health issues, and hope for a better life.[17] The ultimate goal of the youth justice reform is to tackle the underlying causes of and to prevent juvenile delinquency.[18] Doing so requires embracing the significance of youth, including: evaluating the treatment needs of a child; considering his or her capacity for rehabilitation; and providing him or her with appropriate services and

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[11] Andrea Wood, *Cruel and Unusual Punishment: Confining Juveniles with Adults After Graham and Miller*, 61 EMORY L.J. 1445, 1447-48, 1461-62 (2012), http://law.emory.edu/elj/_documents/volumes/61/6/comments/wood.pdf.

[12] *See* Brad Plumer, *Throwing children in prison turns out to be a really bad idea*, WASH. POST (Jun. 15, 2013), https://www.washingtonpost.com/news/wonk/wp/2013/06/15/throwing-children-in-prison-turns-out-to-be-a-really-bad-idea/.

[13] *See, e.g., State Trends, Legislative Victories from 2011-2013: Removing Youth from the Adult System*, CAMPAIGN FOR YOUTH JUST. 1 (2013), http://www.campaignforyouthjustice.org/documents/ST2013.pdf [hereinafter *State Trends*].

[14] *See id.*

[15] *See generally id.*

[16] *Education and Public Safety*, JUST. POL'Y INST. 1, 14 (2007), http://www.justicepolicy.org/images/upload/07-08_rep_educationandpublicsafety_ps-ac.pdf.

[17] *See Better Solutions for Youth with Mental Health Needs in the Juvenile Justice System*, NAT'L CTR. FOR MENTAL HEALTH & JUV. JUST. 3 (2014), http://cfc.ncmhjj.com/wp-content/uploads/2014/01/Whitepaper-Mental-Health-FINAL.pdf [hereinafter *Better Solutions for Youth*].

[18] *See* Alina Saminsky, *Preventing Juvenile Delinquency: Early Intervention and Comprehensiveness as Critical Factors*, 20 STUDENT PULSE 1, 1-2 (2010), http://www.studentpulse.com/articles/165/2/preventing-juvenile-delinquency-early-intervention-and-comprehensiveness-as-critical-factors.

the opportunity to mature.[19]

Considering the rehabilitative potential and treatment needs of a child before subjecting him or her to the adult criminal system is imperative. A young offender who is deemed capable of rehabilitation or in need of treatment should not be transferred to the adult system. Rather, he or she should be provided with appropriate juvenile-based services in the juvenile justice system. Treatment and services in the juvenile justice system are focused on rehabilitation, community integration, and prevention.[20] The juvenile justice system in Connecticut is tailored to play exactly this role,[21] and continually aims to meet the unique needs of a justice-involved youth in accordance with emerging trends in law, science, and social science.[22]

Connecticut should replace automatic juvenile transfer provisions with discretionary procedures that allow judges to consider a child's youth-related factors, unresolved treatment needs, and the appropriateness of a transfer to the adult system before exposing the child to the harmful adult criminal system. The importance of the juvenile-adult distinction and the attendant characteristics of youth does not start and end with sentencing. Rather, children facing punishment in the adult criminal system must have their youth, individual circumstances, and treatment needs given the appropriate weight at all stages of their justice system involvement. Accordingly, courts must be granted the discretion to determine the appropriateness of transfer on an individualized basis to ensure only a youth deemed inappropriate for the juvenile justice system will enter the adult criminal system.

Connecticut's current transfer provisions are contrary to research

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[19] *See, e.g.,* Nancy Gertner, *Miller v Alabama: What It Is, What It May Be, and What Its Not*, 78 MO. L. REV. 1041 *passim* (2014), http://scholarship.law.missouri.edu/cgi/viewcontent.cgi?article=4059&context=mlr; John F. Stinneford, *Youth Matters: Miller v. Alabama and the Future of Juvenile Sentencing*, 11 OHIO ST. J. CRIM. L. 1 *passim* (2013), http://scholarship.law.ufl.edu/facultypub/423.

[20] *See* Richard Mendel, *Juvenile Justice Reform in Connecticut: How Collaboration and Commitment improved outcomes for youth*, JUST. POL'Y INST. (Feb. 27, 2013), http://www.justicepolicy.org/uploads/justicepolicy/documents/jpi_shortreport_web.pdf; *see generally Juvenile Justice*, SENT'G PROJECT, http://www.sentencingproject.org/template/page.cfm?id=184 (last visited Mar. 3, 2016).

[21] *See Juvenile Justice and Youth Development*, CONN. OFFICE OF POL'Y AND MGMT, ,http://www.ct.gov/opm/cwp/view.asp?Q=383628 (last updated Jul. 28, 2012).

[22] Mendel, *supra* note 20; *see*, *e.g.,* Mary O'Leary, *Malloy aims to extend Connecticut justice reforms to offenders through age 20, revise bail system*, NEW HAVEN REGISTER (Feb. 16, 2016, 7:59 PM), http://www.nhregister.com/general-news/20160220/malloy-aims-to-extend-connecticut-justice-reforms-to-offenders-through-age-20-revise-bail-system.

and science on adolescent development, evidence-based practices, and sound public policy. A judge should determine whether a transfer is appropriate a juvenile by weighing the legally supported and scientifically validated factors that distinguish a juvenile from an adult.[23] Examining a justice-involved youth's unique case prior to transferring him or her to the adult criminal system will ensure that he or she will remain within the juvenile justice system when it is appropriate. Until Connecticut eliminates automatic juvenile transfers, the State will continue to fuel the criminal cycle and fail to intervene and save its most vulnerable population.

Section II of this Note examines Connecticut's juvenile transfer statute, how it currently works, and recent changes to the law. Section III discusses the differences between a juvenile and an adult, including advancing science and recent juvenile sentencing decisions by the U.S. Supreme Court and the Connecticut Supreme Court, which have established promising principles for the treatment of a juvenile in the adult criminal system. Section IV discusses: the harm in sentencing a juvenile as an adult; reclaiming rehabilitative aims for juvenile offenders; the shift away from incarcerating a juvenile offender with adults; and the juvenile justice system. In Part V, I argue that Connecticut should follow the research, recent judicial progress, and positive reform trends, and eliminate automatic juvenile transfers. Section VI concludes.

II. Juveniles Charged as Adults in Connecticut

Prior to 2007, Connecticut was among a select minority of jurisdictions that automatically prosecuted youth offenders ages 16 and 17 as adults. Motivated by public safety interests, recidivism studies, juvenile protection, and the known harms of adult incarceration, the state took action with "Raise the Age" legislation in 2007, which raised Connecticut's juvenile jurisdiction age to 18 and ended the automatic treatment of 16 and 17-year-old offenders as adults.[24] Further, as of the 2016 legislative session, Connecticut Governor Dannel Malloy has proposed to raise the juvenile jurisdiction to 20-years-old to fully recognize the significance of youth in the justice system and provide

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[23] *See Miller*, 132 S. Ct. at 2467-69.

[24] *Raised the Age Connecticut*, RAISE THE AGE CT, http://www.raisetheagect.org (last visited Mar. 8, 2016). The legislative action was fully implemented in 2012 after a five-year planning and implementation period.

appropriate protections to young offenders.[25]

Despite the positive impacts of raising the age of Connecticut's juvenile jurisdiction, not every justice-involved youth is protected from automatic treatment in the adult criminal system. The age of the juvenile jurisdiction establishes the maximum age at which an offender may be treated under the juvenile jurisdiction and in the juvenile justice system. However, with Connecticut's automatic transfer statute, the age of the juvenile jurisdiction is essentially irrelevant. Instead, the terms of the statute control. Pursuant to Connecticut General Statute section 46b-127, a child aged 15-17 charged with commission of certain offenses will be automatically transferred to adult court.[26]

Despite the general recognition that a children differ from adults and the existence of a tailored juvenile justice system, many youth continue to be subjected to harsh sanctions and adult-oriented consequences.[27] In fact, in almost every state, procedural routes remain that may subject a youth to being tried and sentenced as an adult.[28] Commonly, the underlying rationale for transferring a youth's case to the adult criminal court is the severity of the offense and the child's delinquent history.[29]

Pursuant to § 46b-127, a youthful offender in Connecticut can be transferred to the adult criminal system through mandatory or discretionary procedures, depending on the offense.[30] Despite the harms that can result from transferring a child to the adult system, in 2014, 192 juveniles aged 14-17 were transferred to the adult criminal court in Connecticut.[31] Connecticut's discretionary provisions provide a child with a chance to have his or her individual case considered to

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[25] Jacqueline Rabe Thomas & Mark Pazniokas, *Malloy: Raise the Age for Juvenile Justice System to 20,* CT MIRROR (Nov. 6, 2015), http://ctmirror.org/2015/11/06/malloy-raise-the-age-for-juvenile-justice-system-to-20/.

[26] *See* CONN. GEN. STAT. § 46b-127 (2015).

[27] *Children in Prison*, EQUAL JUSTICE INITIATIVE, http://www.eji.org/childrenprison (last visited Mar. 3, 2016).

[28] Kathleen Michon, *When Juveniles are Tried in Adult Criminal Court*, NOLO, http://www.nolo.com/legal-encyclopedia/juveniles-youth-adult-criminal-court-32226.html (last visited Mar. 9, 2016); *see* CAMPAIGN FOR YOUTH JUST., JAILING JUVENILES: THE DANGERS OF INCARCERATING YOUTH IN ADULT JAILS IN AMERICA 4, 6 (2007), http://www.campaignforyouthjustice.org/Downloads/NationalReportsArticles/CFYJ-Jailing_Juveniles_Report_2007-11-15.pdf.

[29] Michon, *supra* note 28.

[30] *See* CONN. GEN. STAT. § 46b-127 (2015).

[31] OFFICE OF POLICY AND MANAGEMENT: FACTS AND FIGURES ON CONNECTICUT'S JUVENILE JUSTICE SYSTEM, http://www.ct.gov/opm/cwp/view.asp?a=2974&q=471562 (last visited Jan. 16, 2016).

determine the appropriateness of a transfer out of the juvenile justice system.[32] This Note focuses on the automatic provisions of § 46b-127, which preclude a judge or prosecutor from exercising discretion prior to transfer.[33]

A youth as young as 15 years old is automatically transferred to the adult criminal court when he or she is charged with murder with special circumstances, arson murder, a class A felony, or certain class B felonies:

> The court shall automatically transfer from the docket for juvenile matters to the regular criminal docket of the Superior Court the case of any child charged with the commission of a capital felony under the provisions of section 53a-54b in effect prior to April 25, 2012, a class A felony, or a class B felony, except as provided in subdivision (3) of this subsection, or a violation of section 53a-54d, provided such offense was committed after such child attained the age of fifteen years. . ..[34]

A capital felony pursuant to § 53a-54b is classified as murder with special circumstances.[35] The term "murder" within § 53a-54b refers only to intentional murder.[36] There are eight ways for a murder to be classified as a murder with special circumstances.[37] A violation of § 53a-54d constitutes arson murder, wherein an individual is guilty of a murder that occurs in the course of arson.[38] Class A felonies for which a young offender is automatically transferred include, but are not limited to murder, kidnapping in the first degree, and arson in the first degree.[39] Class B felonies include assault in the first degree.[40]

Albeit serious offenses, it is critical to note that even a youth who

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[32] *See* CONN. GEN. STAT. § 46b-127 (2015).

[33] *Id.* Prosecutors have discretion with Class B felony cases to transfer the cases back to juvenile court. However, there is no discretion to transfer A felony cases back.

[34] CONN. GEN. STAT. § 46b-127(a)(1) (2015).

[35] CONN. GEN. STAT. § 53a-54b (2015).

[36] *See* State v. Johnson, 241 Conn. 702, 711 (1997).

[37] CONN. GEN. STAT. § 53a-54b (2015). Generally, the eight qualifications are the killing of a member of the police and several other similarly situated members; murder for hire; murder committed an individual who has previously been convicted of intentional murder or felony murder; murder committed by an individual while serving a life sentence; murder in the course of kidnapping; murder committed in the course of committing first degree sexual assault; murder of two or more individuals at once or in the same transaction; more persons at the same time or in the course of a single transaction; or murder of a person under sixteen years of age.

[38] CONN. GEN. STAT. § 53a-54d (2015).

[39] CONN. GEN. STAT. § 53a-35a (2013).

[40] CONN. GEN. STAT. § 53a-59 (2013).

has committed a serious or violent crime can be rehabilitated.[41] Significantly, the characteristics of youth that differentiate a child from an adult offender include: lessened culpability, susceptibility to negative influences, and an under-developed sense of responsibility.[42] These inherent factors shed light on justice-involved youth.[43] However, a child charged with the statutorily designated offenses is automatically transferred to the adult system and may never have youth given any special consideration.[44] Moreover, eliminating automatic transfers would not preclude a judge from exercising discretion and determining that a youth is not appropriate for the juvenile justice system and transferring him or her to the adult criminal system.

In 2015, the minimum age that a youth could be automatically transferred to the adult system in Connecticut was raised from 14 to 15-years-old.[45] In addition to raising the minimum age, lawmakers also provided that many class B felonies will not trigger an automatic transfer.[46] Rather, a child charged with the commission of these reclassified class B felonies is provided with a more age-appropriate discretionary proceeding upon prosecutorial motion to transfer.[47] Prior to transfer for such offenses as well as lesser felonies, the Superior Court for juvenile matters, holds a discretionary hearing which requires:

> The court shall not order that the [juvenile] case be transferred. . .unless the court finds that (A) such offense was committed after such child attained the age of fifteen years, (B) there is probable cause to believe the child has committed the act for which the child is charged, and (C) the best interests of the child and the public will not be served by maintaining the case in the superior court for juvenile matters. In making such findings,

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[41] *See generally* CHARLES M. BORDUIN ET AL., EVIDENCE-BASED INTERVENTIONS FOR SERIOUS AND VIOLENT JUVENILE OFFENDERS, IN WHAT WORKS IN OFFENDER REHABILITATION: AN EVIDENCE-BASED APPROACH TO ASSESSMENT AND TREATMENT (Leam A. Craig et al., eds., 2013).

[42] *See, e.g.*, *Roper*, 534 U.S. at 569-71.

[43] *See* CONN. GEN. STAT. § 46b-127(a)(1) (2015).

[44] *See id. But cf. Riley*, 315 Conn. at 660-61 (mandating mitigating factors of youth to be considered when a juvenile faces life without parole).

[45] *See* An Act Concerning the Juvenile Justice System, Pub. Act No. 15-183 (Conn. 2015), https://www.cga.ct.gov/2015/act/pa/2015PA-00183-R00HB-07050-PA.htm.

[46] *Id.*; *see* CONN. GEN. STAT. § 46b-127 (2015).

[47] CONN. GEN. STAT. § 46b-127. Additionally, a juvenile charged with either a Class C felony, D felony, or with an unclassified felony, may be transferred to the adult criminal court upon a motion by the juvenile prosecutor and order of a Juvenile Matters Judge.

> the court shall consider (i) any prior criminal or juvenile offenses committed by the child, (ii) the seriousness of such offenses, (iii) any evidence that the child has intellectual disability or mental illness, and (iv) the availability of services in the docket for juvenile matters that can serve the child's needs.[48]

These critical factors mandated by the legislature for the transfer of a "child" are ideal examples of what should be considered to determine the appropriateness of transferring each and every juvenile to be subjected to punishment in Connecticut's adult criminal system.[49] Unfortunately, the recent changes did not reach far enough. By continuing to permit the automatic transfer of 15 to 17-year-olds, many youth remain susceptible to transfer into the adult criminal system without any consideration of the appropriateness of a transfer, their age, or its mitigating factors. Connecticut's automatic juvenile transfer scheme is flawed. It is an undeniable fact that children are different from adults.[50] The increasing importance of this distinction has been reinforced by science, the United States Supreme Court, the Connecticut Supreme Court, and national consensus.[51] Judges need discretion to consider a child's age and his or her factors of youth to determine whether a transfer to the adult court is appropriate in each case.

III. Children are Different From Adults

A. The Advancement of Science and Adolescent Understanding

Adolescence is a period of development between puberty and adulthood that typically begins around age 10 and can continue through the early 20s.[52] This developmental stage is characterized by changes

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[48] CONN. GEN. STAT. § 46b-127(a)(3); § 46b-127(b)(1). Further, a juvenile transferred under the discretionary scheme for certain offenses can be returned to the juvenile jurisdiction by order of a judge in the adult court. There is no comparable provision to return juveniles that have been automatically transferred to the adult system back to the jurisdiction of the juvenile system. *See* §46b-127(b)(2).

[49] CONN. GEN. STAT. § 46b-127(a)(3); § 46b-127(b)(1).

[50] *See infra* Section III Children Are Different From Adults.

[51] *See infra* Section III Children Are Different From Adults; Section IV Children Sentenced and Incarcerated as Adults.

[52] *See Stages of Adolescence,* HEALTHYCHILDREN.ORG, https://www.healthychildren.org/English/ages-stages/teen/Pages/Stages-of-Adolescence.aspx (last updated Nov. 21, 2015); *The Teen Brain Still Under Construction,* NIMH, http://www.nimh.nih.gov/health/publications/the-teen-brain-still-under-construction/teen-brain_141903.pdf (last visited Apr. 8, 2016).

in a youth's brain structure and function, particularly in regions responsible for higher-level cognitive processes.[53] Adolescent development is complex, involving many interconnected and simultaneously occurring processes that include: behavioral, biological, psychological, and social components.[54] Pioneering advances in in developmental cognitive, affective, and social neuroscience over the past 15 years have resulted in an improved understanding of the period of adolescence.[55] Significantly, with this comprehensive understanding has come with the recognition that adolescence is a crucially important time.[56] "[A]dolescence as a period of vulnerabilities and opportunities relevant to a wide range of outcomes—in ways that have lifelong impact on physical and mental health, education, well-being, and social as well as economic success."[57]

Adolescence has been recently identified as a potential second "window of opportunity" for brain development.[58] A youth's brain undergoes changes, both structurally and functionally.[59] An adolescent does not possess the same kind of self-regulation as an adult.[60] Rather, this function of self control develops over the course of adolescence and into early adulthood. A youth has heightened responses to awards, especially when peer-influenced, that lead to impulsive and risky behaviors.[61] Susceptibility to peer influence is related to the inability of a youth's brain to regulate emotional arousal and rational decisionmaking.[62] Unlike adults, a youth's strong emotions are not managed by the involvement of other neurological processes that are responsible for cognitive functions in decisionmaking such as planning ahead, impulse control, and long-term cost-benefit analysis.[63] Further, a child possesses an unformed sense of self marked by changing

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[53] Fuhrmann et al., *supra* note 9, at 558.

[54] Ronald Dahl, *The Developmental Neuroscience of Adolescence: Revisiting, Refining, and Extending Seminal Models*, 17 DEV. COG. NEUROSCI. 101, 101 (2016), http://www.sciencedirect.com/science/article/pii/S1878929315001334/pdfft?md5=7c1abc3af47b6878e859521ca44d175d&pid=1-s2.0-S1878929315001334-main.pdf.

[55] *Id.*

[56] *Id.*

[57] *Id.*

[58] Fuhrmann et al., *supra* note 9, at 558.

[59] *See* Laurence Steinberg, *Should the Science of Adolescent Brain Development Inform Public Policy?* ISSUES IN SCI. & TECH. (Spring 2012), http://issues.org/28-3/steinberg/.

[60] *Id.*

[61] *See id.*

[62] *See id.*

[63] *See id.*

values, attitudes, and beliefs, through the process of adolescence self-exploration.[64] Moreover, although there is no hard and fast answer as to when an adolescent brain is fully developed into an adult brain—it is certainly well beyond a youth's early teenage years.[65]

Despite recent and rapidly advancing science, the dynamic nature of adolescence still demands further research and development to fully understand this period of brain and behavioral development.[66] This relatively newfound understanding of youth and should inform the way they are treated in society and within the justice system. It has been suggested that brain science is relevant to informing policy discussions, though perhaps not exclusively.[67] In considering the need for discretionary juvenile transfers, adolescent brain science plays a critical role. In fact, recent juvenile-focused decisions by the U.S. Supreme Court and the Connecticut Supreme Court relied on this science in advancing protections for youth charged with serious adult offenses.[68]

B. The Supreme Court's Progressive Juvenile-Adult Distinction

In addition to scientific advances, since 2005 the United States Supreme Court has decided several juvenile sentencing cases that have contributed to the juvenile justice reform momentum.[69] The Supreme Court cases pertain to the sentencing of a youth who is charged with a serious crime and facing a lengthy adult sentence.[70] However, the reasoning and principles adopted by the Supreme Court have broader utility as the juvenile-adult distinction that the cases rely upon pertains to all juvenile offenders. As the Court has recognized, juveniles are in fact cognitively, neurologically, emotionally, and psychosocially

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[64] Hilary Hodgdon, Adaptation, Elizabeth Scott & Laurence Steinberg, *Adolescent Development and the Regulation of Youth Crime*, 18 FUTURE CHILD.: JUV. JUST. 15 *passim* (2008), http://www.futureofchildren.org/futureofchildren/publications/highlights/18_02_Highlights_01.pdf.

[65] *See* Steinberg, *supra* note 59; *see also* Lucy Wallis, *Is 25 the new cut-off point for adulthood?* BBC MAGAZINE, (Sept. 23, 2013), http://www.bbc.com/news/magazine-24173194 (suggesting that brain development does not end until the mid-20s and possibly into the 30s).

[66] *See* Dahl, *supra* note 54, at 101-02.

[67] *See* Steinberg, *supra* note 59.

[68] *See infra* Section III Children Are Different From Adults; Section IV IV. Children Sentenced and Incarcerated as Adults.

[69] *See generally United States Supreme Court Juvenile Justice Jurisprudence*, NAT'L. JUV. DEFENDER CTR., http://njdc.info/practice-policy-resources/united-states-supreme-court-juvenile-justice-jurisprudence/ (last visited Mar. 19, 2016).

[70] *See generally id.*; *see*, *e.g.*, *Miller*, 132 S. Ct. 2455 (2012).

different from adults.[71]

From as early as 1947, The U.S. Supreme Court has acknowledged that the characteristics of youth impact a juvenile's culpability and require consideration.[72]

> And when, as here, a mere child—an easy victim of the law—is before us, special care in scrutinizing the record must be used. Age 15 is a tender and difficult age for a boy of any race. He cannot be judged by the more exacting standards of maturity. That which would leave a man cold and unimpressed can overawe and overwhelm a lad in his early teens. This is the period of great instability which the crisis of adolescence produces.[73]

For years, the Court has built upon the significance of a juvenile's age and emphasized the need to protect a juvenile within the adult criminal system.[74] Since 2005, a series of juvenile sentencing decisions have created substantial support for juvenile justice reforms: *Roper v. Simmons*,[75] *Graham v. Florida*,[76] *Miller v. Alabama*,[77] and *Montgomery v. Louisiana.*[78]

Roper, decided in 2005, held that sentencing an individual who committed a crime when under the age of 18 to death violated the Eighth Amendment.[79] At the time, the United States was the only country in the world that had "continue[d] to give official sanction to the juvenile death penalty."[80] Citing scientific and sociological studies as support, the Court identified three particular characteristics that distinguished a juvenile from an adult: immaturity and rudimentary levels of responsibility; an increased susceptibility to external pressure and negative influences; and the "transient, less fixed" character of

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71 *See infra* Section III Children Are Different From Adults.

72 Haley v. Ohio, 332 U.S. 596, 597 (1948) (disallowing a 15-year-old's confession on due process grounds).

73 *Id.* at 599.

74 *See, e.g.*, Eddings v. Oklahoma, 455 U.S. 104, 115-16 (1982) (reversing a death sentence imposed on a 16-year-old because relevant mitigating factors were not considered during sentencing including family history, emotional and mental development); Thompson v. Oklahoma, 487 U.S. 815 (1988) (noting that juveniles have lessened culpability and greater susceptibility to emotion and peer pressure).

75 *Roper*, 543 U.S. 551 (2005).

76 *Graham*, 560 U.S. 48 (2010).

77 *Miller*, 132 S. Ct. 2455 (2012).

78 *Montgomery*, 136 S. Ct. 718 (2016).

79 *Roper*, 543 U.S. at 568.

80 *Id.* at 575.

youth.[81] Due to a juvenile's lessened culpability, the Court concluded that juveniles are not among the worst offenders that deserve the most severe penalty.[82]

Roper rejected the argument that simply telling juries to consider a juvenile's age suffices; rather the Court emphasized the importance of considering each juvenile's individual mitigating factors during sentencing.[83] *Roper* reflected the Supreme Court's willingness to acknowledge differences between an adult and a juvenile offender that extended beyond common sense judgments. Significantly, the case also recognized that juveniles possess a marked ability to change, and a unique capacity for reform.[84]

Five years later, in *Graham*, the Court expanded the special consideration required for a juvenile offender in the adult criminal system, and banned life-without-parole sentences for juveniles convicted of non-homicide offenses.[85] The Court determined that when a state imposes a life sentence on a juvenile offender, the state must provide "some meaningful opportunity to obtain release based on demonstrated maturity and rehabilitation" by the end of the term.[86] Juvenile life-without-parole sentences inherently eliminate any chance a juvenile has at rehabilitation, which is a central aim of addressing juvenile crime.[87] Again, the Court emphasized the capacity for change and for development among juveniles. Justice Kennedy, for the majority, wrote: "Life in prison without the possibility of parole gives no chance for fulfillment . . . no chance for reconciliation with society, no hope. Maturity can lead to that considered reflection which is the foundation for remorse, renewal, and rehabilitation.[88]

By presenting specific background information about Graham at

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[81] *Roper*, 543 U.S. at 569-70; *see Eddings*, 455 U.S. at 115-16; *see also* Jeffrey Arnett, *Reckless Behavior in Adolescence: A Developmental Perspective*, 12 DEVELOP. REV. 339, 339 (1992), http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.470.7498&rep=rep1&type=pdf.

[82] *Roper*, 543 U.S. at 569-70.

[83] *Id.* at 572-73. Juvenile incarceration with adults may bring rise to constitutional issues under the Eighth Amendment, but that matter is outside of the scope of this paper. *See* Wood, *supra* note 11.

[84] *Id.* at 570.

[85] *Graham*, 560 U.S. at 74. The Court utilized reasoning from *Roper* in support of considering the known factors of youth and compared the severity of juvenile life without parole to capital punishment.

[86] *Id.* at 75.

[87] *Id.* at 74.

[88] *Id*. at 79.

the forefront of the decision, the Court makes clear the importance of individualized consideration of a juvenile's factors of youth and life circumstances.[89] The information serves as more than just an illumination of Graham's struggles or an attempt to garner sympathy. "The differences between juvenile and adult offenders are too marked and well understood to risk allowing a youthful person to receive a sentence of life without parole for a non-homicide crime despite insufficient culpability."[90]

The *Roper* and *Graham* decisions paved the way for *Miller* in 2012, in which the Court held that regardless of the offense, mandatory life-without-parole sentences for a juvenile are unconstitutional.[91] The Court reemphasized that a juvenile's youth and amenability to rehabilitation must be considered as mitigating factors.[92] Beyond this, the Court subtly exposed the underlying role of mental health and trauma commonly experienced by a juvenile offender.[93] The Court expanded the required individualized consideration during sentencing from factors inherent in youth, such as immaturity and responsibility, to those related to a juvenile's mental health and emotional well-being.[94] By highlighting the importance of considering mental health and emotional well-being, the Court illustrated the significant influence that psychological and cognitive challenges have on a juvenile offender's behavior and decisionmaking.[95]

In *Montgomery v. Louisiana*, the Court held that *Miller's* ban on mandatory juvenile-life without-parole sentences was a new substantive rule of constitutional law, and therefore *Miller's* application is retroactive.[96] Justice Kennedy for the majority reasoned that:

> Because *Miller* determined that sentencing a child to life without parole is excessive for all but the rare juvenile offender whose crime reflects irreparable corruption, it rendered life without

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[89] *Id.* at 53 ("Graham's parents were addicted to crack cocaine, and their drug use persisted in his early years. Graham was diagnosed with attention deficit hyperactivity disorder in elementary school. He began drinking alcohol and using tobacco at age 9 and smoked marijuana at age 13.").

[90] *Id.* at 78; *see also Roper*, 543 U.S. at 572-73.

[91] *Miller*, 132 S. Ct. at 2464-69.

[92] *Id.* at 2467.

[93] *Id.*

[94] *Id.*

[95] *Id.* at 2467-69.

[96] *Montgomery,* 136 S. Ct. at 736.

> parole an unconstitutional penalty for a class of defendants because of their status—that is, juvenile offenders whose crimes reflect the transient immaturity of youth.[97]

The Court highlighted that *Miller* did more than establish the requirement of considering mitigating factors of youth, "it established that the penological justifications for life without parole collapse in light of the distinctive attributes of youth."[98]

The *Roper*, *Graham*, *Miller*, and *Montgomery* decisions solidify the significance of the juvenile-adult distinction and adolescent development. But however significant youth has become in the eyes of the Court, it has yet to push the mandates of these decisions past the realm of sentencing. The Court's reliance on advancing scientific research, including adolescent neuroscience and cognitive development, adds depth and validity to the significance of youth.[99] Furthermore, the decisions illuminate that youth have specific behavioral and mental health characteristics, unique opportunities for treatment, and a marked capacity for rehabilitation. However, responsibility rested with individual states to adopt the precise application to their juvenile sentencing practices.[100]

C. The Connecticut Supreme Court's Juvenile Decisions

The U.S. Supreme Court decisions created waves in regards to juvenile sentencing and the significance of recognizing youth. In 2015, the Connecticut Supreme Court decided how the U.S. Supreme Court's juvenile sentencing decisions would be interpreted and applied in Connecticut.[101]

In *State v. Riley*,[102] the Connecticut Supreme Court adopted the U.S. Supreme Court's premise that juveniles cannot be treated the same as adults when facing harsh sentences due to the fundamental

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[97] *Id.* at 734.

[98] *Id.*

[99] *See* Erika N. Marzorati, *Children are Different . . . Sometimes: Science, the Supreme Court, and the Juvenile Brain*, KINGS SCHOLARS PROGRAM: MICH. ST. U. C. L. (Spring 2013), http://www.law.msu.edu/king/2012-2013/Marzorati.pdf.

[100] This Note was first drafted prior to the *Montgomery* decision on January 25, 2016 when interpretations were largely divided regarding the retroactivity of *Miller*. *See* Gary Gately, *Supreme Court to Weigh Retroactivity of Mandatory JLWOP, Juv. Just. Info. Exchange* (Apr. 5, 2015), http://jjie.org/supreme-court-to-weigh-retroactivity-of-mandatory-jlwop/108536/.

[101] *See* State v. Riley, 315 Conn. 637, (2015); Casiano v. Comm'r of Corr., 317 Conn. 52 (2015); State v. Taylor G., 315 Conn. 734 (2015).

[102] *Riley,* 315 Conn. 637 (2015).

differences between a child and an adult offender.[103] The Court held that in order to comport with the Eighth Amendment, the *Miller* factors must given their appropriate mitigating weight in sentencing a juvenile to the harshest penalties.[104] The Court determined that when read in accordance with *Graham* and *Roper,* the decision in *Miller* "logically reaches beyond its core holding."[105] The mandates of *Miller* were applied not only to mandatory schemes, but to discretionary sentencing as well.[106] Arguably, the Connecticut Supreme Court's inclusion of discretionary sentences is reflective of their understanding of the significance of youth and the importance of providing justice-involved youth with appropriate protections. Further support of the significance of youth was illustrated in the *Casiano* decision.[107]

In *Casiano v. Commissioner of Corrections*,[108] which was decided before the U.S. Supreme Court decided *Montgomery*,[109] the Connecticut Supreme Court determined that *Miller* is a watershed rule of criminal procedure and therefore applied retroactively.[110] Additionally, the Court held that the requirements of *Miller* applied to lengthy sentences lesser than life.[111] The Court reiterated the reasoning in *Riley* in continued support of individualized juvenile sentencing and weighing the mitigating factors of youth.[112] The Court noted that, "[a] mandatory sentencing scheme. . . renders these factors irrelevant."[113] Arguably, a mandatory automatic transfer scheme strips the relevancy of the significance of youth as well.

The Connecticut Supreme Court has broadly interpreted and applied *Miller* to the state's juvenile sentencing practices. However, the Court is unlikely to impose constitutional limits on the transfer of juveniles to adult court. Lawmakers must be willing to question whether automatically transferring a juvenile without first considering his or her youth is sound policy, especially considering the emerging awareness of the significance of youth. In light of these judicial

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103 *Id.* at 653.
104 *Id.* at 658.
105 *Riley*, 315 Conn. at 654.
106 *Id.* at 654, 658.
107 Casiano v. Comm'r of Corr., 317 Conn. 52 (2015).
108 *Id.*
109 *Montgomery*, 136 S. Ct. 718 (2016).
110 *Casiano*, 317 Conn. at 62, 69-71.
111 *Id.* at 75-80.
112 *Id.* at 59-61.
113 *Id.* at 60.

decisions, the harmful impact of incarceration on a juvenile, the existence of a juvenile-tailored justice system, and growing national consensus: the answer is a resounding no. "As advocates move forward with keeping more kids out of the adult criminal justice system, states' adoption of appropriate sentencing remedies in light of *Miller* should also reflect a shift in attitude towards keeping kids from automatic prosecution in adult court and out of adult jails and prisons."[114] The understanding of the characteristics of youth illustrated by these cases should be extended to protect a juvenile at every stage of his or her involvement with the justice system. Logically, this consideration would begin before a juvenile is exposed to the adult criminal system. Before transfer, judicial discretion is needed to consider the juvenile's youth and the appropriateness of removing him or her from the juvenile justice system.

IV. Children Sentenced and Incarcerated as Adults

The decision to try a child in adult court poses two fundamental questions: "First, is this a reasonable course of action when the defendant is just a child, and second, what would the larger community gain by doing so?"[115] Being tried in an adult court may arguably have minor advantages for a juvenile, such as the right to trial by jury.[116] However, the potential negative consequences far outweigh any sympathy a jury may provide.

In adult criminal court, a child is subject to more severe sentences.[117] A youth offender transferred to the adult criminal system can face significantly longer terms in the adult court than in the juvenile system, even when there is not great difference in the severity of the crime.[118] Unlike juvenile court judges, judges in the adult system often lack the ability to tailor a youth's punishment or to offer

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[114] *State Trends*, *supra* note 13, at 13.

[115] Mark Mauer, *Charged as Adults, Children are Abandoned When They Could Be Saved*, N.Y. TIMES (Aug. 18 2014), http://www.nytimes.com/roomfordebate/2014/08/18/young-souls-dark-deeds/charged-as-adults-children-are-abandoned-when-they-could-be-saved.

[116] Michon, *supra* note 28; *Juvenile Life Without Parole*, SENT'G PROJECT, http://sentencingproject.org/doc/publications/jj_Juvenile_Life_Without_Parole.pdf (last updated Oct. 2015); *See* McKeiver v. Pennsylvania, 403 U.S. 528 (1971) (holding that juveniles in juvenile criminal proceedings are not constitutionally entitled to a jury trial).

[117] Michon*, supra* note 28.

[118] Duaa Eldeib, *Young killers who stay in juvenile court take vastly different paths*, CHI. TRIB. (Jun. 12, 2015), http://www.chicagotribune.com/news/ct-illinois-juvenile-killers-met-20150611-story.html.

alternative treatment options, such as counseling.[119] Additionally, compared to a juvenile charge, the stigma and impact of an adult conviction on a child is stronger.[120] An adult sentence can result in long term legal consequences for a child, such as having his or her conviction a matter of public record, losing the right to vote or join the military, or having to report the conviction in seeking future employment.[121]

A youth offender is less likely to understand his or her legal rights and the legal process, which can lead to difficulties from the time arrest to sentencing.[122] Difficulties can include giving inappropriate confessions, inadequately recollecting details for trial preparation, and failing to fully understand and benefit from plea negotiations.[123] Further, lawyers and judges in the adult criminal system are not accustomed or trained to understand the special needs of youth, which places a child at a disadvantage compared to a similarly-situated adult in criminal court.[124] Most detrimentally, the youth may be sentenced to serve time in an adult facility as opposed to a more appropriate youth-tailored juvenile placement.[125]

Furthermore, sentencing and incarcerating a child as an adult is unlikely to be justifiable under penological theories.[126] A child who has been sentenced and incarcerated as an adult is unlikely to experience deterrence, and the positive effect on public safety is doubtful.[127] A child that has been incarcerated in an adult system is at an increased risk for recidivism.[128] Compared with juveniles who remained in the juvenile system, youth who were transferred to the adult criminal system were at a higher risk of committing a subsequent felony.[129] A youth often leaves an adult facility unprepared for adult life and is seldom provided adequate support and services that help him

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119 *Id.*

120 *Id.*

121 MALCOLM YOUNG & JENNI GAINSBOROUGH, AN ASSESSMENT OF TRENDS AND CONSEQUENCES, SENT'G. PROJECT 7 (2000), http://www.prisonpolicy.org/scans/sp/juvenile.pdf.

122 *Id.* at 7-8.

123 *Id.* at 8.

124 *Id.* at 7.

125 Michon, *supra* note 28.

126 Wood*, supra* note 11, at 1456.

127 *Id.*

128 Satchel*, supra* note 10, at 1.

129 *Id.* at 2.

or her avoid re-offending.[130] Although transferring a young offender has been suggested as a means to promote public safety, youth incarcerated in the adult system are 34 times more likely to reoffend than a child who was held in the juvenile justice system.[131] On the other hand, a deterrence effect has been noted among offenders who were involved in rehabilitative programs involving therapeutic treatment, such as those provided in the juvenile justice system, due to the receptive and flexible nature of the adolescent brain. [132]

The differences between which type of facility a young offender is placed in are immense. Despite the proclaimed need to incarcerate a "hardened juvenile offender" as an adult, a child's sentence in an adult facility is often comparable to the length it would have been imposed had he or she remained in the juvenile system.[133] Seventy-eight percent of youth incarcerated in adult facilities are released before they turn 21 and almost all are released prior to turning 25—yet they have not received appropriate juvenile-services while in the adult system.[134] Confining a youth in an adult facility harms both the juvenile and the community in which he or she is re-entering post-incarceration as he or she is ill-equipped for a successful return.[135] Further, the harms that adult incarceration impose on a child extend beyond the likelihood he or she will reoffend.

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[130] Nancy Lucas, *Restitution, Rehabilitation, Prevention, and Transformation: Victim-Offender Mediation for First-Time Non-Violent Youthful Offenders*, 29 HOFSTRA L. REV. 1365, 1366. An analysis of reentry services for juvenile offenders is beyond the scope of the paper. *See Youth Reentry*, THE SENT'G PROJECT, http://www.sentencingproject.org/doc/publications/jj_youthreentryfactsheet.pdf (last visited Mar. 15, 2016).

[131] Jessica Lahey, *The Steep Costs of Keeping Juveniles in Adult Prisons*, ATLANTIC (Jan. 8, 2016), http://www.theatlantic.com/education/archive/2016/01/the-cost-of-keeping-juveniles-in-adult-prisons/423201/.

[132] *See* Satchel, *supra* note 10; R. Daniel Okonkwo, *Prison Is a Poor Deterrent, and a Dangerous Punishment*, N.Y. TIMES (Sept. 18, 2013), http://www.nytimes.com/roomfordebate/2012/06/05/when-to-punish-a-young-offender-and-when-to-rehabilitate/prison-is-a-poor-deterrent-and-a-dangerous-punishment; s*ee generally* Mark W. Lipsey et al., *Improving the Effectiveness of Juvenile Justice Programs, A New Perspective On Evidence-Based Practices*, CNTR. FOR JUV. JUST. REFORM, GEO. U. (Dec. 2010), http://cjjr.georgetown.edu/pdfs/ebp/ebppaper.pdf.

[133] Wood, *supra* note 11, at 1457.

[134] *Id.*

[135] *See* Okonkwo, *supra* note 132.

A. A Child is Harmed, Not Rehabilitated, When Treated Like an Adult

Adult penal institutions are not designed for youth. Accordingly, such institutions fail to provide a youth with the rehabilitation essential for his or her restoration.[136] Youth are considerably harmed when confined in an adult facility, especially due to their ongoing cognitive, physical, and emotional development.[137] Adolescent development is not solely a biological process; rather it is impacted by environmental factors.[138] Yet, thousands of children in the United States are confined in the toxic environment of adult facilities.[139] Once a child is incarcerated in an adult facility, little consideration is given for his or her youth.[140] Regardless of the effort that adult facilities put forth in managing youth, it would not change the unsuitability of such placements for children—especially considering the availability of youth-tailored facilities.

The life experiences of a justice-involved youth varies, but many have shared experiences involving troubling upbringings, trauma, and associated mental and behavioral health challenges.[141] Many youth have been raised in environments or under circumstances that have exposed them to violence, physical and sexual abuse, poverty, and substance abuse.[142] Sadly, justice-involved youth experience mental health disorders more than three times more frequently than youth among the general population.[143] Nearly three-quarters of the justice-involved youth have a diagnosable mental health disorder and more than half have a co-morbid disorder.[144] In fact, many children become involved with the juvenile justice system due to a lack of appropriate treatments or services to adequately meet their needs—not because of the severity of their offenses.[145] Adult facilities lack the resources and

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136 Satchel, *supra* note 10, at 4.

137 Wood, *supra* note 11, at 1448.

138 *See generally* Russell Viner et al., *Adolescence and the Social Determinants of Health*, 379 LANCET 1641, *passim* (2012).

139 Wood, *supra* note 11, at 1447.

140 Satchel, *supra* note 10, at 1.

141 *Juvenile Life Without Parole*, *supra* note 116.

142 *Id.*

143 *Better Solutions for Youth*, *supra* note 17, at 1.

144 *Id.* at 2; *See generally* Linda Teplin et al., *Comorbid Psychiatric Disorders in Youth in Juvenile Detention*, 60 ARCH. GEN. PSYCHIATRY 1097 *passim* (2003).

145 MACARTHUR FOUNDATION, *SAMHSA, MacArthur Launch Program to Improve Response to Youth with Behavioral Needs* (2015), http://www.macfound.org/press/from-

ability to provide adults with sufficient mental health services, let alone the ability to meet the unique needs of children.[146]

A child confined in an adult facility is at a high risk for committing suicide—[147] in fact they are 36% more likely to commit suicide.[148] The suicide rate for a child in an adult facility is eight times higher than a child within the juvenile justice system.[149] This is in part due to a youth's underdeveloped emotions and impulsivity which contributes to mood swings, which can abruptly change from stable to suicidal.[150] Adult facilities are not designed to manage a child's emotional needs and lack the adequate staffing to monitor a child as closely as needed to ensure prevention and safety.[151]

Adult facilities are incapable of providing the services and programming that are imperative to healthy adolescent development.[152] Despite the fact that a youth's needs drastically differ from those of an adult, most states provide a youth incarcerated with adults with the same opportunities for education, medical care, social, and mental health services.[153] Most adult facilities do not provide a child with services to help them cope with the environment of incarceration, including prison-survival skills and counseling.[154] Often, a youth lacks the life experiences that would have taught him or her to effectively cope in such a predatory environment; rather, a youth's expressions of fear can be interpreted as weakness and increase his or her susceptibility to victimization.[155] To mask vulnerabilities and blend into the inmate culture, a child is prone to adopting violent

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field/samhsa-macarthur-launch-program-improve-response-youth-behavioral-needs/. The behavioral health conditions largely go unnoticed, they are not receiving appropriate services, and there is a lack of successful cooperation between the behavioral health and justice systems.

146 Satchel, *supra* note 10, at 2.

147 Wood, *supra* note 11, at 1454.

148 T.J. Parsell, *In Prison, Teenagers Become Prey*, N.Y. TIMES (Jun. 5, 2012), http://www.nytimes.com/roomfordebate/2012/06/05/when-to-punish-a-young-offender-and-when-to-rehabilitate/in-prison-teenagers-become-prey.

149 Satchel, *supra* note 10, at 2.

150 *Id.*

151 *Id.* at 2, 4.

152 *See* CAMPAIGN FOR YOUTH JUSTICE, JAILING JUVENILES: THE DANGERS OF INCARCERATING YOUTH IN ADULT JAILS IN AMERICA, 4 (2007), http://www.campaignforyouthjustice.org/Downloads/NationalReportsArticles/CFYJ-Jailing_Juveniles_Report_2007-11-15.pdf.

153 Kristin Choo, *Minor Harships: Jailing Youths as Adults is Gaining Ground – and so are its Critics*, 18 A.B.A. J. 14, 20 (2000).

154 Wood, *supra* note 11, at 1455.

155 *Id.* at 1453.

behaviors.[156] Further, violent experiences and criminal behaviors, which have a "brutalizing" effect on youth, become normalized due to continuous exposure.[157] The same factors that make a child more amendable to rehabilitation, such as malleability, sensitivity to peer pressure, and unformed character, also increase his or her susceptibility to criminal socialization when incarcerated with adults.[158]

A child confined with adults lacks positive role models that can aid in healthy adolescent development.[159] Positive influences promote a youth's development of positive identity, productive life skills, mediation, and critical problem-solving skills.[160] Rather, adult inmates pose the greatest risk to a youth confined in an adult facility.[161] Additionally, corrections staff are 200% more likely to physically abuse a child in adult corrections than in juvenile facilities.[162] A youth's immaturity contributes to susceptibility, as he or she is less capable of self-protecting from sexual advances or assault.[163] A youth in an adult setting is the easiest target for sexual abuse, which can occurs as early as 48 hours after incarceration.[164] A youth confined with adults is five times more likely to be sexually assaulted, the emotional and psychological impacts of which are severely detrimental and long-lasting.[165]

Many children confined with adults will become victims of abuse, yet many some states do not separate them from the general adult population.[166] One alternative is the double-edged sword that is

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156 *Id.* at 1456.

157 *Id.* at 1457.

158 *Id.* at 1455.

159 *See* JEFFREY A. BUTTS ET AL., COAL. FOR JUVENILE JUSTICE POSITIVE YOUTH JUSTICE: FRAMING JUSTICE INTERVENTIONS USING THE CONCEPTS OF POSITIVE YOUTH DEVELOPMENT (2010), http://www.njjn.org/uploads/digital-library/resource_1548.pdf; Melany Boulton, *Positive Adult Role Models Central to Teens' Success in Juvenile Justice System and Beyond, says Report*, RECLAIMING FUTURES (Jul. 13, 2012), http://reclaimingfutures.org/positive-adult-role-models.

160 Wood, *supra* note 11, at 1455.

161 *Id.* at 1447.

162 Satchel, *supra* note 10, at 2 citing Marty Breyer, *Experts for Juveniles at Risk of Adult Sentences, in* MORE THAN MEETS THE EYE: RETHINKING ASSESSMENT, COMPETENCY AND SENTENCING FOR A HARSHER ERA OF JUVENILE JUSTICE (1997).

163 Wood, *supra* note 11, at 1453.

164 Parsell, *supra* note 148.

165 Wood, *supra* note 11, at 1448-51; *see* Prison Rape Elimination Act of 2003 §2, 42 U.S.C. §15601(4) (2006).

166 Wood, *supra* note 11, at 1450-52.

"protective" isolation.[167] Isolation does achieve the desired effect of removing the child from the harmful adult environment, but the conditions of protective isolation lead to mental and physical trauma or deterioration.[168] A child placed in isolation is often confined for up to 23 hours a day in a small cell that lacks natural light.[169] Even minimal exposure to such a restrictive environment can exacerbate pre-existing mental health challenges, make a youth prone to anxiety and paranoia, as well as increase his or her risk of suicide.[170] Confining a child in an adult facility is a no-win situation that imposes immeasurable harm.

Any incarceration setting for a youth is detrimental.[171] Subsequently, a justice-involved youth in a state that segregates youth from the general adult population or incarcerates them in a different facility is not freed from harm. Healthy adolescent development is impeded by incarceration settings.[172] An incarcerated child is less likely to obtain a high school degree, more likely to build "criminal capital" with the contacts they develop in the facility, and is at an increased risk of reoffending.[173] Even temporary or short term incarceration is capable of harming a youth: a child is stripped of his or her freedom of movement, suffers from stigmatization, adopts a hostile and oppressive view of the world, as well as the perspective that they are "irredeemably delinquent."[174] As Justice Marshall opined, "[f]airly viewed pretrial detention of a juvenile . . . gives rise to injuries comparable to those associated with the imprisonment of an adult."[175]

Notably, Connecticut holds many male youth who have been

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[167] Satchel, *supra* note 10, at 3.

[168] *Id.*

[169] *Youth in the Adult System,* ACT 4 JUV. JUST. (2012), http://www.act4jj.org/sites/default/files/ckfinder/files/ACT4JJ%20Youth%20In%20Adult%20System%20Fact%20Sheet%20Aug%202014%20FINAL.pdf.

[170] CAMPAIGN FOR YOUTH JUSTICE, *supra* note 152, at 4.

[171] BARRY HOLMAN & JASON ZIEDENBERG, JUSTICE POLICY INSTITUTE, THE DANGERS OF DETENTION: THE IMPACT OF INCARCERATING YOUTH IN DETENTION AND OTHER SECURE FACILITIES 1 (2006), http://www.justicepolicy.org/images/upload/06-11_rep_dangersofdetention_jj.pdf .

[172] *See*, *e.g.*, Julia Dmitrieva et al., *Arrested Development: The Effects of Incarceration on the Development of Psychosocial Maturity*, 24 DEV. & PSYCHOPATHOLOGY 1073, *passim* (2012), http://www.pitt.edu/~adlab/People%20pics%20and%20links/Publications%20page/Arrested%20Development%202012.pdf.

[173] *See* Plumer, *supra* note 12.

[174] Schall v. Martin, 467 U.S. 253, 291 (1984) (Marshall, J., dissenting).

[175] *Id.*

transferred to adult court in a facility separate from adult offenders.[176] However, there is no equivalent for female justice-involved youth. York Correctional Institution is Connecticut's only institution for female offenders charged or convicted in adult court.[177] Manson Youth Institution (MYI) is a high security prison run by the Connecticut Department of Corrections (CDOC) and houses juvenile males under the age of 21 charged with or convicted of serious crimes.[178] The MYI information website describes the population as consisting of "chronic disciplinary inmates, close custody program, mental health, high security and general population inmates."[179] The site boasts positive educational, vocational, and addiction services.[180] However, no programming can change the fact that it is a prison. A child at MYI is removed from society, lives in an 8 x 10 foot cell, and is confined with a variety of other offenders.[181] Visits from family or community members must be earned and approved by DOC, and phone calls home are monitored.[182] Outdoor recreation considered a privilege, rather than a right.[183] The threat for sexual and physical abuse remains, as does the risk for suicide.[184] A Connecticut defense attorney concluded that in his experiences with youth at MYI, "rarely are their lives made better for the experience of being housed there."[185]

B. The Treatment of Justice-Involved Youth: Recouping Protection and Rehabilitation

Attempting to protect justice-involved youth and recognizing the harms of adult incarceration are not novel in the history of juvenile justice. Over time, the treatment of justice-involved youth has mimicked a pendulum swinging between two opposing treatment aims;

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176 *Manson Youth Institution*, CONN. DEPT. CORR., http://www.ct.gov/doc/cwp/view.asp?q=265428 (last visited Apr. 5, 2016).

177 *York Correctional Institution*, CONN. DEPT. CORR., http://www.ct.gov/doc/cwp/view.asp?a=1499&Q=265454&docNav=| (last visited Apr. 6, 2016).

178 *Manson Youth Institution*, *supra* note 176.

179 *Id.*

180 *Id.*

181 Karen Floren, *Life stands still for teen murder suspects*, THEDAY (Dec. 21, 2010), http://www.theday.com/article/20101218/nws02/312189946.

182 *Id.*; *see* Manson Youth Institution, *supra* note 176.

183 Floren, *supra* note 181.

184 *Id.*; *see* Manson Youth Institution, *supra* note 176.

185 Floren, *supra* note 181.

punitive and rehabilitative.[186] This can be illustrated by broadly considering the fluxuating consensus beginning with the mid-70's when Congress passed the Juvenile Justice and Delinquency Prevention Act (JJDPA).[187] The JJPDA required, among other things, the separation of young offenders from adults.[188] However, the mid-1970s also came with a media-highlighted rise in violent crime, which sparked public outcry that was squelched by conservative and punitive legislative action.[189] Rather than providing discretionary opportunities for juvenile rehabilitation and treatment, a "tough-on-crime" approach that emphasized punishment and offender accountability began to dominate justice.[190]

Despite this punitive strike, in 1980 the JJDPA was amended to prohibit a juvenile from being placed in an adult facility.[191] However, a detrimental exception remained which permitted a child who was sentenced as an adult to continue to be incarcerated in adult facilities.[192] The next decade brought another publicized spike in young offender crimes, which lead to the "superpredator" label.[193] The uproar countered any efforts to protect justice-involved youth and again resulted harsher treatment.[194] Sentencing trends and attitudes of the 1990s operated under the "adult time, adult crime" mantra.[195] Between 1990 and 1999, the number of youth who were incarcerated in adult facilities rose by an alarming 300%.[196] Fortunately, in the late

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[186] Lucas, *supra* note 130, at 1368; *see generally* OFFICE JUVENILE JUSTICE & DELINQ. PREVENTION, JUVENILE JUSTICE: A CENTURY OF CHANGE, JUV. JUSTICE BULLETIN (Dec. 1999), https://www.ncjrs.gov/html/ojjdp/9912_2/juv1.html.

[187] Juvenile Justice and Delinquency Prevention Act of 1974, Pub. L. No. 93-415 (codified as amended at 42 U.S.C. § 5601-5681 (2002)), http://www.ojjdp.gov/about/jjdpa2002titlev.pdf.

[188] *Child or Adult? A Century Long View*, PBS FRONTLINE, http://www.pbs.org/wgbh/pages/frontline/shows/juvenile/stats/childadult.html (last visited Mar. 15, 2016) [hereinafter *Child or Adult?*]; *Legislation/JJDP Act*, OFFICE JUV. JUST. & DELINQ. PREVENTION, http://www.ojjdp.gov/about/legislation.html (last visited Mar. 15, 2016).

[189] *Child or Adult?*, *supra* note 188.

[190] *Id.*; *see also* Satchel, *supra* note 10, at 1.

[191] *Child or Adult?*, *supra* note 188.

[192] *Id.*

[193] *The Superpredator Myth: 20 Years Later*, EQUAL JUST. INITIATIVE (Apr. 7, 2014), http://www.eji.org/node/893.

[194] *See id.*

[195] Satchel, *supra* note 10, at 1; Marc Schindler, *Mental Health Issues Facing Adolescents in the Juvenile Justice System: Part II: Prosecution of Juveniles as Adults*, AM. ACAD. OF CHILD. & ADOLESCENT PSYCHIATRY NEWS, Apr. 1999, at 47, http://www.ylc.org/wp/wp-content/uploads/MentalHealthIssuesinJJSystem.pdf.

[196] Wood, *supra* note 11, at 1459.

1990's the drive to detain youth began to subside.[197]

The superpredator myth has since been debunked, but during the 1990's, nearly every state passed laws that made it easier for a young offender to be tried as an adult in adult criminal courts.[198] Juvenile justice has evolved substantially since enactment of the JJDPA,[199] but it still requires that states keep justice-involved youth under juvenile jurisdiction and out of adult facilities.[200] Unfortunately, so does the loophole that permits a child charged as adult to be incarcerated in an adult facility.[201] Therefore, it is up to states to protect their justice-involved youth population.[202] Some states continue to incarcerate youth in adult facilities and "tough-on-crime"[203] proponents remain, but many Americans reject the aims of a punishment-centered system.[204] Rather, many Americans believe in the effectiveness of a juvenile justice system that emphasizes prevention, treatment, and rehabilitation.[205]

Furthermore, several states are positively reforming the protections afforded to justice-involved youth.[206] Within the past eight years, twenty-three states have enacted forty pieces of legislation that has changed how children are prosecuted, sentenced, and incarcerated in the adult criminal courts.[207] State legislatures and prison officials have recognized the undeniable dangers that a youth faces in such a setting.[208] Between 2005 and 2010, three states and one local jurisdiction enacted laws that mandate or enable a child in the adult

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[197] *Juvenile Justice History*, CENTER ON JUV. CRIM. & JUST., http://www.cjcj.org/education1/juvenile-justice-history.html (last visited Apr. 6, 2016).

[198] *The Superpredator Myth: 20 Years Later*, *supra* note 193.

[199] *See Liz Ryan, Federal Juvenile Justice Regs: What's the Holdup?* CHRONICLE SOC. CHANGE (Apr. 29, 2014), https://chronicleofsocialchange.org/opinion/federal-juvenile-justice-regs-whats-the-holdup/6422.

[200] Juvenile Justice and Delinquency Prevention, Pub. L. No. 93-415 (1974), http://www.ojjdp.gov/about/jjdpa2002titlev.pdf.

[201] *Ryan*, *supra* note 199.

[202] *See* Gary Gately, *Measure to Revamp JJDPA to be Introduced This Week, Grassley Says*, JJIE.ORG (Apr. 15, 2015), http://jjie.org/measure-to-revamp-jjdpa-to-be-introduced-this-week-grassley-says/. Since this Note was written, JJDPA reauthorization has been introduced. However, exploring congressional remedy is beyond the scope of this paper.

[203] *See generally Modern Tough on Crime Movement*, DEFENDING JUST. PRA, http://www.publiceye.org/defendingjustice/con_agendas/toughcrime.html (last visited Apr. 6, 2015).

[204] Lucas, *supra* note 130, at 1367-68.

[205] *Id.*

[206] *See generally State Trends, supra* note 13, *passim*.

[207] *Id.* at 12.

[208] Wood, *supra* note 11, at 1459.

system to be placed in juvenile facilities as opposed to adult corrections.[209] Significantly, between 2011 and 2013, eight states removed youth from adult jails and prisons; rather youth remains in juvenile facilities appropriate for their age.[210]

C. Treatment and Rehabilitation Aims of the Juvenile Justice System

Rather than automatically and punitively transferring a child to the adult court, the focus should be on determining why the child ended up on the path to offending and what can be done to help him or her to move in a new direction. The juvenile court was created due to the basic recognition that a child differs from an adult offender in maturity, the ability to appreciate the consequences of actions, and the capacity to be rehabilitated.[211] Juvenile courts have traditionally prioritized a model of rehabilitation that takes advantage of a youth's malleable character by providing him or her an opportunity to change, grow, and live a meaningful life post release.[212] Juvenile justice systems are built on the understanding that the adolescent brain is highly receptive to therapeutic treatment.[213] Further, rehabilitative programs are specifically tailored to meet the needs of an adolescent and provide the restorative treatment needed to prevent a young offender from developing into an adult offender.[214]

In the past decade, significant strides in research, programs and resource development have led to improvements in how to address the mental health challenges of children, particularly justice-involved youth.[215] The developments include: research-based screening and assessment tools with guidance protocols for users; cost-effective evidence-based interventions and treatment programs that yield positive results; and advancements in neuroscience and developmental research that has expanded understanding of youth behavior and the unique capacity for change they possess.[216] Furthermore, resource

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209 *State Trends, supra* note 13, at 2. Maine, Virginia, and Pennsylvania, and Multnomah County, Oregon.

210 *Id.* Colorado, Hawaii, Idaho, Indiana, Nevada, Texas, Ohio, and Oregon.

211 Mauer, *supra* note 115.

212 *Id.*

213 Satchel, *supra* note 10, at 4.

214 *Id.*

215 *Better Solutions for Youth*, *supra* note 17, at 3.

216 *Id.*; *see Models for Change Building Momentum for Juvenile Justice Reform*, MODELS

centers are acting as a driving force throughout the United States by providing guidance on how to implement more effective methods to improve juvenile justice systems, particularly through the integration of best practices and research-based methods.[217] In recognizing that a majority of justice-involved youth have a mental health disorder, the aims promote collaboration to help these children receive the support conducive to a healthy, meaningful, and lawful life.[218]

Procedures involving youth in the justice system should reflect the advancing understanding of this population, particular treatment needs, mental health considerations, and the appropriateness of transfer. Every youthful offender should be viewed from a perspective that considers individual characteristics, the innate complexities of adolescence, and his or her capacity for change.

D. Connecticut's Juvenile Justice System

The juvenile justice system in Connecticut is a reflection of national trends, ongoing reform, and sound public policy. The state's juvenile justice system has improved outcomes for juveniles and public safety.[219] Connecticut's juvenile justice system illustrates: a viable alternative for a justice-involved youth for which adult criminal incarceration is not appropriate; the progress that can be made working with a juvenile offender; and the system's ability to adapt to meet the needs of Connecticut's at-risk youth.

Over the past two decades, the juvenile justice system in Connecticut has progressed in effectively protecting and treating justice-involved youth.[220] The current system is based on the aims of

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FOR CHANGE (2006), http://www.justicepolicy.org/uploads/justicepolicy/documents/models_for_change.pdf.

[217] *See, e.g., MacArthur Expands Investment in Juvenile Justice Reform to $165 Million,* MACARTHUR FOUND. (Aug. 14, 2013), www.macfound.org/press/press-releases/macarthur-expands-investment-juvenile-justice-reform-164-million-launches-resource-centers-advance-reform-and-improve-outcomes-youth/; *see also Mental Health and Juvenile Justice Collaborative for Change*, NAT'L. CTR. FOR MENTAL HEALTH AND JUV. JUST., http://www.ncmhjj.com/projects/current-projects/mental-health-and-juvenile-justice-collaborative-for-change/ (last visited Apr. 7, 2016).

[218] *See, e.g., SAMHSA, MacArthur Launch Program to Improve Response to Youth with Behavioral Needs,* MACARTHUR FOUND. (Jan. 22, 2015), http://www.macfound.org/press/from-field/samhsa-macarthur-launch-program-improve-response-youth-behavioral-needs/#sthash.Nq0Qv1Vb.dpuf.

[219] *How Connecticut Changed the Juvenile Justice World*, CT POST (Mar. 14, 2013), http://www.ctpost.com/opinion/article/How-Connecticut-changed-the-juvenile-justice-world-4355677.php [hereinafter *How Connecticut Changed*].

[220] Mendel, *supra* note 20. Though the Connecticut juvenile justice system is imperfect,

restorative justice, emphasizing community protection, promoting offender accountability, and rehabilitation.[221] Individualized assessments have been instituted to identify placements tailored to meet a youth's service needs including treatment, support, educational, recreational, and other developmental opportunities.[222] The progress has resulted in a continuum of high-quality programs and services.[223] The State's expanded investment reflects these efforts, which has come at no additional cost to taxpayers.[224] This shift in focus has led to Connecticut reducing the number of youth offenders that are committed to residential facilities by nearly 70% since 2000.[225]

Significantly, much like the growing national initiatives, Connecticut has aimed to treat the problems that a justice-involved youth presents, as opposed to simply detaining them.[226] The state has expanded treatment options for youth struggling with mental health issues.[227] A state-of-the-art behavioral health model was developed with national experts to ensure youth and their families receive high-quality mental health evaluations and treatment services.[228] Efforts have included providing enhanced mental health screening and assessment to identify mental health and behavioral challenges.[229] Connecticut has implemented treatment programs that have provided effective counseling and worked to reduce the recidivism rates among at-risk children.[230] Additionally, a collaborative approach involving the youth, family, probation staff, and mental health treatment providers aims to comprehensively meet the needs of children requiring treatment and explore alternatives to residential custody.[231]

The system is tailored to provide children with much needed

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deeper consideration is not within the purview of this analysis.

221 *Juvenile Justice and Youth Development*, *supra* note 21.

222 *Id.*; *see generally* Elizabeth Seigel et al., *Core Principles for Reducing Recidivism and Improving Other Outcomes for Youth in the Juvenile Justice System*, COUNCIL OF ST. GOV'T JUST. CENTER (2014), http://csgjusticecenter.org/wp-content/uploads/2014/07/Core-Principles-for-Reducing-Recidivism-and-Improving-Other-Outcomes-for-Youth-in-the-Juvenile-Justice-System.pdf; *How Connecticut Changed*, *supra* note 219.

223 *Court Support Services Division*, CONN. JUD. BRANCH (2014), http://www.jud.ct.gov/cssd/ [hereinafter *CCSD*].

224 Mendel, *supra* note 20.

225 *Id.*

226 *Id.*

227 *See id.*

228 *CCSD*, *supra* note 223.

229 Mendel, *supra* note 20.

230 *See id.*

231 *Id.*

treatment and rehabilitation services, aimed at delivering services and treatment in accordance with evidence-based practices and national trends, and continuing to adapt and change to meet the needs of youth in Connecticut. Unfortunately, this progress does not impact the negative ramifications of the automatic transfer statutes. However, the positive outcomes and continuing reforms serve as a promising sign that Connecticut's juvenile justice system has the ability to meet the needs of justice-involved youth for which transfer to the adult system is not appropriate. Needless to say, it certainly serves as an encouraging alternative for children that would otherwise be automatically be subjected to adult incarceration.

Moreover, as of 2016, aspects of the Connecticut juvenile justice system are under consideration for further improvement,[232] which signals an ideal time for reconsidering the state's automatic transfer laws. A recent poll found that a majority of Connecticut adults supported implementing less restrictive measures and more rehabilitative options for juvenile offenders.[233] Connecticut residents support the shift away from juvenile prisons towards community-based efforts.[234] Public support for reducing the number of youth offenders being transferred to the adult criminal system is also likely, especially considering the resulting detrimental and lasting impact. Representative Toni Walker, D-New Haven, stated that the current movement in Connecticut is focused on understanding how "we work with our children . . . to make sure that their life has an opportunity to grow and develop . . . they're going to touch the hot stove every once in awhile, but that doesn't mean we condemn them for [their lifetime]."[235]

V. Connecticut Needs to Eliminate Automatic Juvenile Transfers in Favor of Discretionary Procedures for Youth.

Connecticut law should recognize the importance of discretion and the relevance of youth when a child faces the possibility of

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[232] *See*, *e.g.*, Thomas & Pazniokas, *supra* note 25; Jacqueline Rabe Thomas, *Closing CT's juvenile jail: Opportunities and obstacles ahead,* CT MIRROR (Jan. 21, 2016), http://ctmirror.org/2016/01/21/closing-cts-juvenile-jail-opportunities-and-obstacles-ahead/.

[233] Christine Stuart, *Poll Finds Support For Juvenile Justice Reform*, CT NEWS JUNKIE (Mar. 9, 2016), http://www.ctnewsjunkie.com/archives/entry/poll_finds_support_for_juvenile_justice_reform/.

[234] *Id.*

[235] *Id.*

punishment in the adult criminal system. The State should eliminate the automatic transfer procedures and align the treatment of every youth in the justice system in accordance with national trends, evidence-based practices, and the best interest of youth. Juvenile transfer proceedings should ensure that a youth's age and its attendant circumstances, treatment needs, and capacity for rehabilitation within the juvenile justice system are taken into consideration in determining the appropriateness of transferring a child to the adult criminal system.

Connecticut General Statute § 46b-127 mandates that children as young as fifteen must be automatically transferred to the adult criminal court upon being alleged of committing certain serious felonies.[236] There is no denying the seriousness of the offenses that subject a young offender to an automatic transfer, however not all justice-involved youth are deserving of the harsh sanctions of adult courts. Automatic transfer statutes have the same negative implications as recently contested mandatory sentencing in that judges lack discretion to consider the significance of youth.[237] Connecticut's automatic transfer statute is based on outdated tough-on-crime methods and fails to consider a child's age, life experiences, characteristics of youth, and capacity for change before exposing him or her to the harmful adult criminal system.[238] Establishing procedural opportunities for discretion when dealing with the transfer of every youth offender is imperative.

Connecticut's § 46b-127 should be amended to eliminate the language of "automatically transfer" in regards to capital felonies, arson-murder, class A felonies and certain class B felonies.[239] Instead, all transfers of youth should be treated according to the language contained in § 46b-127(b)(1):

> Upon motion of a prosecutorial official, the superior court for juvenile matters shall conduct a hearing to determine whether the case of any child. . .shall be transferred from the docket for juvenile matters to the regular criminal docket of the Superior Court. The court shall not order that the case be transferred under this subdivision unless the court finds that (A) such offense was committed after such child attained the age of fourteen years, (B) there is probable cause to believe the child has committed the act

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236 CONN. GEN. STAT. § 46b-127.

237 *See infra* Part III Children are Different From Adults.

238 *See* Satchel, *supra* note 10, at 1.

239 CONN. GEN. STAT. § 46b-127.

> for which the child is charged, and (C) the best interests of the child and the public will not be served by maintaining the case in the superior court for juvenile matters. In making such findings, the court shall consider (i) any prior criminal or juvenile offenses committed by the child, (ii) the seriousness of such offenses, (iii) any evidence that the child has intellectual disability or mental illness, and (iv) the availability of services in the docket for juvenile matters that can serve the child's needs. Any motion under this subdivision shall be made, and any hearing under this subdivision shall be held, not later than thirty days after the child is arraigned in the superior court for juvenile matters.[240]

Adopting this statutory language and providing a hearing for every youthful offender facing transfer, regardless of the offense, will ensure that a child's youth and its attendant circumstances are considered, including the capacity for rehabilitation, and ultimately the appropriateness of transfer. Furthermore, § 46b-127(b)(1)(C) takes the best interest of the child into consideration as well as the public, which would include weighing the harm that incarcerating a child as an adult has on both the child and the community.[241] Additionally, the factors in (iii)-(iv) play the critical role of ensuring that all justice involved youths' mental health and treatment needs are taken into consideration prior to transfer. In considering mental health, the court should weigh *Miller*-like mitigating factors such as relevant family history, trauma, substance abuse. A wholly discretionary transfer statute would not eliminate all juvenile transfers. Significantly, it would ensure judicial discretion, which would: guarantee that a child deemed inappropriate for the adult system will remain in the juvenile system and be shielded from the harms of adult incarceration; move Connecticut in alignment with fully realizing the significance of youth; and create more opportunities to provide justice-involved youth with treatment and services essential for a healthy and lawful future.

Connecticut has the opportunity to make a significant change in the lives of more justice-involved youth and make an important impact on the criminal cycle. With intervention and treatment, a youthful offender is capable of great change and rehabilitation. However, if children are subjected to automatic transfers then the proverbial key to

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[240] *Id.*

[241] CONN. GEN. STAT. § 46b-127(b)(1)(C); *see* Part IV Children Sentenced and Incarcerated as Adults.

his or her future is thrown away without a scintilla of consideration otherwise.

VI. Conclusion

"We cannot always build the future for our youth, but we can build our youth for the future."[242] Connecticut law should acknowledge the significance of the juvenile-adult distinction and eliminate automatic transfers for young offenders.

As science and research advance, awareness for the critical importance of adolescent development is spreading.[243] The Supreme Court has relied on this understanding in recent juvenile sentencing cases, and has conveyed the significance of the fundamental differences between an adult and a child.[244] However, the Court has built up the juvenile-adult distinction to great lengths only to let the distinction fade away at the prison gates.[245] The significance of youth should be taken into consideration before a child is exposed to sentencing in the harsh adult criminal system. When appropriate, the revelation of these factors should serve as a catalyst for change for justice-involved youth by keeping them in the juvenile justice system and affording them the treatment and services they greatly need. Only by maintaining the adult-juvenile distinction at every stage of child's justice involvement will the Supreme Court's ideals of providing each youth with a chance to mature, rehabilitate, and live a meaningful life be realized.[246] Connecticut should adopt discretionary procedures that permit consideration of youth, including *Miller*-like mitigating factors, much earlier in a child's involvement with the adult criminal system than sentencing.

Unfortunately, many youth involved in the justice system have experienced difficult lives prior to offending. A majority have experienced trauma, violence, sexual abuse, and many suffer from one or more mental health disorder.[247] Their troubled life experiences are no longer going unnoticed during sentencing, but there are additional

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[242] Franklin D. Roosevelt, *The Quotations Page*, http://www.quotationspage.com/subjects/youth/ (last visited Apr. 6, 2016).

[243] *See infra* Section III.a. The Advancement of Science and Juvenile Understanding.

[244] *See United States Supreme Court Juvenile Justice Jurisprudence*, *supra* note 69.

[245] *See* Marzorati, *supra* note 99, *passim*.

[246] *See Roper*, 543 U.S. 551 (2005)*; Graham*, 560 U.S. 48 (2010); *Miller*, 132 S.Ct. 2455 (2012).

[247] *Juvenile Life Without Parole*, *supra* note 116.

opportunities to use these characteristics of youth to better serve our justice-involved youth population. Healthy development and rehabilitation are not achieved when a child is sentenced to unforgiving adult sanctions.[248] Rather, the child is harmed and the aims of justice are not rightfully served. A youth that is confined as an adult is not taught essential life skills or provided rehabilitation.[249] Many fail to thrive post incarceration in adult facilities and have a high chance of re-offending.[250]

In contrast, appropriate rehabilitative and treatment services provided by juvenile justice systems have successfully deterred and rehabilitated children.[251] Nationally, reforms are reflecting an expanded understanding of justice-involved youth, particularly trauma and mental health needs.[252] Increased research and understanding has yielded efforts to move away from the punishment-centered system and to protect, treat and prevent youth from the harms of adult incarceration.[253] Renewed focus is on rehabilitation and treatment: strategies, programming, and intervention have greatly increased the success and effectiveness of the juvenile justice system

Connecticut has reformed its juvenile justice system to meet the needs of this vulnerable population and improve the treatment of justice-involved youth.[254] Connecticut is shifting away from methods of detaining children and has built a system of high quality needs-based programming with a state-of-the-art behavioral health model that is yielding positive results.[255] However, youth offenders who are automatically transferred to the adult system are not afforded an opportunity to be considered for any of these proactive and progressive programs, let alone engage in any of the treatment and rehabilitation they provide.

Positive legislation enacted nationwide reflects the need to protect children and keep them out of the justice system, particularly adult facilities.[256] A handful of states have removed children from adult

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248 *See* Satchel, *supra* note 10, at 1; *see generally* Wood, *supra* note 11, at 1454.
249 *See* sources cited *id.*
250 Satchel, *supra* note 10, at 1.
251 *Id.*
252 *See State Trends*, *supra* note 13.
253 *Better Solutions for Youth*, *supra* note 17, at 2.
254 Mendel, *supra* note 20.
255 *Juvenile Justice and Youth Development*, *supra* note 21.
256 *See State Trends, supra* note 13.

facilities altogether.[257] At the least, sound policy in Connecticut should recognize that no child should automatically be transferred to the adult system without due consideration. Discretion and considering youth and its attendant circumstances are essential when considering transferring a child to an adult prison.

The elimination of the automatic transfer provisions would further decrease Connecticut's adult incarcerated youth population, fully appreciate the significance of youth in the justice system, and align Connecticut with the progressive reform to treat and rehabilitate young offenders, rather than punish and harm them. The advocacy and support for juvenile reform in Connecticut makes it an ideal time to continue with the momentum and push for further protections for justice-involved youth. Connecticut must ensure that the transfer of a child to the adult criminal system is a discretionary decision based on a juvenile's unique characteristics of youth and, when appropriate, afford a youth treatment in the juvenile justice system. Only by adopting laws with that fully recognize the significance of youth will Connecticut embrace the opportunity to intervene and provide their vulnerable justice-involved youth population with much needed help, a chance to live a meaningful life, and the means to contribute positively to Connecticut's future.

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[257] *Id.* Colorado, Hawaii, Idaho, Indiana, Nevada, Texas, Ohio, and Oregon.

SOCIAL SECURITY DISABILITY INSURANCE: THE COMPOUNDING LIMITATIONS OF MEDICAL EVIDENCE THROUGH THE LENS OF STROKE MEDICINE

Dixon Yang*

Introduction

As part of training, I had the opportunity to be involved in the treatment of a patient in our local community-centered San Juan Bosco Clinic, which accepts uninsured patients 200% of the federal poverty level or less.[1] He was 57 years old, coming to be evaluated for

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[1] *San Juan Bosco Clinic*, UNIVERSITY OF MIAMI MILLER SCHOOL OF MEDICINE, http://umdocs.mededu.miami.edu/?page_id=6 (last visited Nov. 9, 2015). For more information

progressively worsening memory loss. Previous clinic and psychiatric visits noted a magnetic resonance image (MRI) scan suggesting possible mild small vessel ischemic disease, a potential source for microscopic stroke[2], and a Mini-mental state examination of 12 out of 30, a screening result that can be interpreted as severe and impairing dementia. Yet during our evaluation, he responded to our questions appropriately and displayed no deficits that would immediately suggest cognitive impairment.

A complete physical examination did not produce remarkable results. Despite the MRI result, the patient had blood pressure within normal limits and was not on any antihypertensive medications. Additionally, he did not have any risk factors for stroke such as smoking, alcohol use, diabetes, or hyperlipidemia.[3] Psychological assessment could not conclude any active depressive disorders. Simply put, we could not pinpoint any particular cause for his memory loss. Though our patient was previously employed as an engineer, he lost his job after becoming divorced and subsequently moved in with his mother, who accompanied him to the clinic. Our best diagnosis at the time was memory loss secondary to severe anxiety, but we recommended that he continue with follow-up. It was later noted that he continued to be seen for disability determination for Social Security Disability Insurance (SSDI).[4] Medical professionals may conclude a diagnosis and evaluate functionality parameters called activities of daily living (ADLs) at the time of examination, but it is unclear how these translate to long-term disability.[5] This case, and many others encountered in San Juan Bosco Clinic, raises implications on the impact of the limitations in medical evidence with respect to fair disability determination for SSDI.

Growing fiscal and administrative challenges elevate the urgency for significant reform with SSDI. A 2014 annual report by the Social

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on the University of Miami Miller School of Medicine student-run clinics and health fairs in Miami, Florida, please visit http://umdocs.mededu.miami.edu/.

[2] *See generally* Marta Grau-Olivares & Adrià Arboix, *Mild cognitive impairment in stroke patients with ischemic cerebral small-vessel disease: a forerunner of vascular dementia?*, 9 EXPERT REV NEUROTHER 1201 (2009).

[3] *Who is at Risk for a Stroke?,* NIH NATIONAL HEART LUNG AND BLOOD INSTITUTE, https://www.nhlbi.nih.gov/health/health-topics/topics/stroke/atrisk (last visited Nov. 9, 2015).

[4] *See generally Disability Benefits*, SOCIAL SECURITY ADMINISTRATION, https://www.ssa.gov/disabilityssi/ (last visited Nov. 9, 2015).

[5] *See generally* Katherine T. Ward & David B. Reuben, *Comprehensive Geriatric Assessment*, UPTODATE (Aug. 6, 2015), http://www.uptodate.com/contents/comprehensive-geriatric-assessment.

Security and Medicare Board of Trustees projects an alarming estimate that funds for SSDI will deplete by 2016.[6] Moreover, a backlog on initial disability claims and administrative hearings has reached dismal levels.[7] Commissioner Michael Astrue of the Social Security Administration (SSA) reported these challenges could not be solved by simply increasing funding of the Social Security Trust Fund, but required efforts to improve all levels of the SSA from basic field employees to administrative law judges (ALJs).[8] In keeping with the medical basis that Congress originally intended, the SSA has placed emphasis on improving medical criteria in order to cut down on delays and introduce better accuracy to disability determination.[9] An attempt to improve medical criteria may benefit the claims process, but to determine disability fairly, the SSA should not lose sight that medicine is limited in its ability to provide long-term prognosis and physicians can only attest to the medical status of a patient at the time of exam.

When Congress decided to make people with disabilities eligible for federal social insurance with the SSA, they required that the disability be sufficiently severe to prevent the person from working.[10] The SSA administers both SSDI and the Supplemental Security Income (SSI) program, which provides benefits to those with limited income and who are disabled, blind, or age 65 or older.[11] The medical standards to qualify for SSI are similar to SSDI, but the two programs do not come from the same source of funding.[12] The U.S. Treasury

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[6] BOARD OF TRUSTEES OF THE FEDERAL OLD-AGE AND SURVIVORS INSURANCE AND FEDERAL DISABILITY INSURANCE TRUST FUND, STATUS OF SOCIAL SECURITY AND MEDICARE PROGRAMS: AN SUMMARY OF THE 2014 ANNUAL REPORTS, H.R. Doc. No. 113-139, at 2-3 (2d Sess. 2014), http://www.ssa.gov/oact/tr/2014/tr2014.pdf.

[7] *Joint Hearing on the Social Security Disability Claims Backlogs Before the H. Comm. On Ways and Means* (2010) (statement of Patrick P. O'Carroll, Jr., Inspector Gen., Social Security Administration), http://oig.ssa.gov/sites/default/files/04272010testimony.txt [hereinafter *Joint Hearing on Disability Claims Backlog*].

[8] *Hearing on Clearing the Disability Backlog: Giving the Social Security Administration the Resources It Needs to Provide the Benefits Workers Have Earned: Before the H. Comm. On Ways and Means,* 110th Cong. (2008) (statement of Michael J. Astrue, Commissioner, Social Security Administration).

[9] *Id.* at 12-16; *see generally* OIG, *Improve the Responsiveness and Oversight of the Hearings Process*, http://oig.ssa.gov/audits-and-investigations/top-ssa-management-issues/social-security-disability-hearings-backlog (providing information on the SSA management issues and ongoing efforts to reduce backlog and delays).

[10] *See* Social Security Act, 42 U.S.C. §§ 1381-1385 (1972).

[11] *See id.*; *Understanding Supplemental Security Income (SSI)*, SSA (2015), http://www.ssa.gov/ssi/text-understanding-ssi.htm [hereinafter *Understanding SSI*].

[12] *Understanding SSI*, *supra* note 11.

finances SSI, while SSDI is supported by the Social Security Trust Fund.[13] This discussion will focus on SSDI.

This Note addresses the limitations of medicine in identifying impairment prognosis as outlined by the SSA's definition of disability and examines this premise through stroke research. Stroke medicine has benefitted from recent decades of research and progress in care, but strokes are still a leading cause of long-term adult disability in the United States.[14] Given its increasing prevalence, advances in medical research, and large variety of post-stroke deficits, stroke is an important consideration for the future of SSDI in an aging population.[15] Part I documents the burden of stroke disability and current rehabilitation guidelines to better understand current research and gaps in knowledge. Part II discusses SSA disability claim and administrative court procedure through the scope of *Richardson v. Perales*[16] and the Administrative Procedure Act of 1964 (APA).[17] In the context of a growing claims and hearings backlog, this Part argues that limitations of medical evidence must be recognized to reach fair and accurate disability determination. With a non-adversarial disability court procedure and an outdated criteria system, the SSA has lost a crucial capacity to distinguish disability. This loss not only adds to expenditure woes for the SSA, but also presents challenges in fair determination of disability. Part III analyzes current, ongoing solutions and potential strategies to reconcile medical limitations in hopes for long-term reformation to ensure an ability to meet a growing burden of disability.

I. Growing Burden of Stroke Disability and Issues with Predicting Prognosis

A stroke is a sudden neurologic injury characterized by compromised cerebrovascular blood flow.[18] It is divided into two

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[13] *Id.*

[14] *Stroke: Hope Through Research*, NAT'L INST. OF NEUROLOGICAL DISORDERS AND STROKE, http://www.ninds.nih.gov/disorders/stroke/detail_stroke.htm (last modified Oct. 18. 2015); *see* Centers for Disease Control and Prevention (CDC), *Prevalence and Most Common Causes of Disability Among Adults* 58 MORB. MORTAL WKLY. REP. 421–6 (2009).

[15] *See generally* Thomas C. Ricketts, *The Health Care Workforce: Will It Be Ready as the Baby Boomers Age? A Review of How We Can Know (Or Not Know) the Answer*, 32 ANN. REV. PUB. HEALTH 417 (2011).

[16] Richardson v. Perales, 402 U.S. 389 (1971).

[17] Administrative Procedure Act, 5 U.S.C. § 556(d) (1970).

[18] Louis R. Caplan, *Etiology, classification, and epidemiology of stroke*, UPTODATE

broad categories – ischemic or hemorrhagic – that must be distinguished in an emergency setting for treatment purposes.[19] Approximately 80% of stroke patients experience an ischemic stroke where the brain receives too little blood that supplies oxygen and nutrients needed for proper function.[20] Hemorrhagic stroke patients present oppositely with bleeding directly into the brain and resulting in blood in the closed cranial cavity.[21] Therefore, clinicians face a significant challenge in quickly and accurately assessing onset and type of stroke because the standard treatment for ischemic stroke is to restore better blood flow, while this could likely cause death from excessive bleeding in hemorrhagic events.[22]

In 2001, the Senate recognized the need for and granted further state funding towards both acute care and long-term rehabilitation in specialized hospital stroke units.[23] These units can provide a patient with coordinated and multidisciplinary evaluation to more effectively treat and assess stroke patients.[24] In addition to efforts in governmental, research, and clinical sectors, campaigns such as the Stroke Heroes Act FAST initiative promoted "time lost is brain lost" to increase public awareness for identifying stroke onset and seeking medical attention as soon as possible.[25] An analysis at the end of 2014 indicated stroke had fallen from fourth leading cause of death to the fifth.[26] Overall, an improvement in public health policy has reduced stroke mortality and continues to decline.[27]

(NOV. 26, 2014), http://www.uptodate.com/contents/etiology-classification-and-epidemiology-of-stroke.

[19] *Id.*

[20] *Id.*

[21] *Id.*

[22] *See* Owen B. Samuels, *Intravenous Fibrinolytic (Thrombolytic) Therapy in Acute Ischemic Stroke: Therapeutic Use*, UPTODATE, http://www.uptodate.com/contents/intravenous-fibrinolytic-thrombolytic-therapy-in-acute-ischemic-stroke-therapeutic-use (last updated July 1, 2015).

[23] *See* Stroke Treatment and Ongoing Prevention Act of 2001, S. 1274, 107th Cong. §2821 (2001).

[24] Pamela W. Duncan et al., *Management of Adult Stroke Rehabilitation Care: A Clinical Practice Guideline*, 36 STROKE e104 (2005).

[25] *See* Hilary K. Wall et al., *Addressing Stroke Signs and Symptoms Through Public Education: the Stroke Heroes Act FAST Campaign*, 5 PREV. CHRONIC DIS. 1, 6 (2008); *With a Stroke, Time Lost is Brain Lost*, AMERICAN STROKE ASSOCIATION (2012), http://www.strokeassociation.org/idc/groups/heart-public/@wcm/@global/documents/downloadable/ucm_312284.pdf.

[26] Kenneth D. Kochanek et al., *Mortality in the United States, 2013*, 178 NCHS DATA BRIEF 1, 5 (2014).

[27] *See generally* Alan S. Go et al., *Heart Disease and Stroke Statistics – 2014 Update: A*

Despite these efforts, the number of stroke patients in the United States continues to increase. According to 2013 estimates, 6.8 million Americans above the age of 20 have had a stroke and about 795,000 people per year experience a stroke.[28] Projections show a 20% increase of stroke prevalence from 2012 to 2030, which consists of over 3 million individuals.[29] With increased survival of stroke, more patients experience functional and cognitive deficits.[30] Patients may continue to suffer from limb paralysis, inability to walk independently, cognitive deficits, depression, aphasia, visual impairments, or dependency in ADLs as a result of stroke.[31] Many of these patients can receive SSDI benefits if found unable to sustain work.[32]

With 18 diseases contributing to long-term disability in the United States, age-adjusted rates for stroke disability alone increased significantly in the last decade.[33] In parallel, hosts of studies have identified risk factors and co-morbidities that are widespread public health concerns, including high blood pressure, diabetes, high blood cholesterol, and physical inactivity.[34] Self-reported prevalence of cardiovascular disease, obesity, diabetes, and lung disease have increased for the Baby Boomer generation as they approach 60 years of age.[35] Over a 30-year span, the Institute of Medicine (IOM) predicted not only a 14 million increase in Americans with late life impairments partly driven by chronic medical conditions, but also a 4 million increase in SSDI caseloads from 2000 to 2015.[36]

While stroke prevention, stroke care in an acute or emergency setting, and the growing burden of stroke disability are well documented, the understanding of stroke recovery is variable. Immediately following stabilization of the patient, stroke rehabilitation begins with initial assessment of stroke severity and functional

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Report From the American Heart Association, 128 CIRCULATION 1, 141-42 (2014).

[28] *Id.* at 139.

[29] *Id.*

[30] *See id.* at 146.

[31] *Id.*

[32] Social Security Act, 42 U.S.C. § 1382.

[33] Go et al., *supra* note 27, at 146.

[34] *See id.* at 142-46.

[35] Linda G. Martin et al., *Health and Functioning Among Baby Boomers Approaching 60*, 64B GERONTOL. B. PSYCHOL. SCI. SOC. SCI. 369, 372-74 (2009).

[36] COMMITTEE ON DISABILITY IN AMERICA, THE FUTURE OF DISABILITY IN AMERICA, 96-97 (Marilyn J. Field & Alan M. Jette eds., National Academies Press) (2007).

deficits.[37] Among the large variety of deficits possible from stroke, motor deficits are the most common.[38] Current trends lean towards shortening the length of acute hospital stay[39] and transferring to rehabilitation as soon as possible.[40] The Agency for Health Care Policy and Research (AHCPR) recommends use of disability screening tools by a stroke team within the first 24 hours in the hospital.[41]

There are several scaling systems designed to measure impairments and predict prognosis. Some of the most commonly used are the National Institutes of Health Stroke Scale (NIHSS), Barthel Index, and Modified Rankin Scale (mRS).[42] These scales have been reliable in a clinical and research setting for assessing severity of individual deficits such as limb paralysis, aphasia, and ability to walk independently, but cannot fully describe all dimensions of stroke recovery.[43] The NIHSS does not assess global functioning after stroke.[44] The Barthel Index does not capture a patient's high-level cognition such as processing of language and emotion.[45] The mRS does not account for the source of impairment and does not directly measure cognition.[46] Other tests look directly at aphasia, mobility, and depression individually, but not all of their accuracies have been completely validated.[47]

Clinical practices have not readily accepted prognostic models due to issues with predictive accuracy and generalizations to standard populations.[48] The hallmark for medicine in determining functional

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[37] Duncan et al., *supra* note 24, at e104.

[38] Enas S. Lawrence et al., *Estimates of the Prevalence of Acute Stroke Impairments and Disability in a Multiethnic Population*, 32 STROKE 1279, 1282 (2001).

[39] Janne M. Veerbeek et al., *Early Prediction of Outcome of Activities of Daily Living After Stroke: A Systematic Review*, 42 STROKE 1482, 1482 (2011).

[40] *See* Elliot J. Roth et al., *Delay in Transfer to Inpatient Stroke Rehabilitation: the Role of Acute Hospital Medical Complications and Stroke Characteristics*, 14 TOP STROKE REHABIL 57 (2007).

[41] Duncan et al., *supra* note 24, at e106.

[42] Linda Brewer at el., *Stroke Rehabilitation: Recent Advances and Future Therapies*, 106 Q. J. MED. 12, 13 (2013); Scott E. Kasner, *Clinical Interpretation and Use of Stroke Scales*, 5 LANCET. NEURO. 603, 603-12 (2006).

[43] Kasner, *supra* note 42, at 603.

[44] Brewer et al., *supra* note 42, at 13.

[45] *Id.*

[46] *Id.*

[47] *Id.*

[48] *See generally* F. Randy Vogenberg, *Predictive and Prognostic Models: Implications for Healthcare Decision-Making in a Modern Recession*, 2 AM. HEALTH DRUG BENEFIT 218-222 (Sept.-Oct. 2009), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4106488/.

deficits lies in evaluation of the ability to perform ADLs, which are characteristic activities of independent living that includes bathing, dressing, toileting, maintaining continence, grooming, feeding, and mobility.[49] Several variables have been named to play a role in stroke's affect on a patient's ADLs.[50] These can be as directly observable as extremity paralysis to a factor as subtle as "adequacy of home and neighborhood".[51] Unfortunately, only age and arm paralysis have strong evidence suggesting their valid application towards evaluating ADLs.[52] Regardless of ambiguity in validating these variables, the great number of factors involved in stroke disability alone underscores the challenge a physician faces in assessing a patient.

Additionally, advances in neuroimaging have helped clinicians in acute stroke diagnosis and management, but their usefulness in assessing functional limitations and disability is unclear.[53] Some propose neuroimaging techniques may bring a novel level of objectivity to disability determination.[54] This may be true for certain conditions, but many unclear cases will be left up to the interpretation of the examining physician. Computed tomography (CT) and MRI techniques are well-established methods to identify patients who will benefit from thrombolytic therapy.[55] However, rehabilitation clinics do not routinely consider imaging evidence and focus their evaluation on ADLs.[56] Due to the difficult nature of assessing a patient during a single visit, we could not conclude with absolute certainty that our San Juan Bosco Clinic patient's MRI results were conclusive for a cerebrovascular cause for memory loss. Despite his lack of risk factors and normal physical examination, we requested continued follow-up to

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[49] Ward & Reuben, *supra* note 5.

[50] *See* Veerbeek et al., *supra* note 39.

[51] *Id.* at 1485.

[52] *Id.* (explaining strong evidence is qualified as "generally consistent findings" in two or more studies with low risk of bias).

[53] *See generally* Tracy D. Farr & Susanne Wegener, *Use of Magnetic Resonance Imaging to Predict Outcome After Stroke: a Review of Experimental and Clinical Evidence*, 30 J. OF CEREBRAL BLOOD FLOW AND METABOLISM 703-17, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2949172/.

[54] *See* Amanda C. Pustilnik, *Painful Disparities, Painful Realities*, U. OF MARYLAND LEGAL STUDIES RESEARCH Paper No. 2014-18, March 10, 2014, at 1, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2407265 (arguing the potential of structural and functional MRI in describing chronic pain on objective terms for disability hearings).

[55] *See* Cathy M. Stinear & Nick S. Ward, *How Useful is Imaging in Predicting Outcomes in Stroke Rehabilitation?*, 8 INT. J. STROKE 33-7 (2013).

[56] *Id.*

ensure diagnosis of a potentially serious multi-infarct dementia, which would worsen over time in a step-wise fashion.[57]

Although researchers and clinicians seek to create models to evaluate populations as a whole, disease is inherently a personal experience. The consequences for a stroke in a large metropolis differ than one in a rural setting.[58] An older patient faces different challenges than a younger one.[59] Social determinants such as race, gender, previous employment, education, neighborhood, and family support affect the extent to which a stroke survivor is limited.[60] Recent studies highlight the importance of emotion regulation with social participation and quality of life[61] and the need for stroke disability to consider an individual's changed perception of self, body, and their homes and communities.[62] In a clinical landscape where objectivity is valued, these subjective qualities are also important considerations in a patient's functional limitations that are not assessed by physicians.

These studies and reports highlight the increasing obstacles SSDI will face with growing stroke disability. Medicine has benefited from research that has continually improved care, but gaps in knowledge remain with post-acute stroke care. Functional limitations may be effectively measurable at one point in time, but generalized models cannot evaluate prognosis and duration of impairments entirely. Moreover, the individual experience of disease that is shaped in the context of social and cultural factors is not documented in a clinical assessment, but can be important in considering disability. Imaging, scales, and models are frequently left for interpretation. This limit of medicine in determining prognosis has been well understood by original SSDI policymakers and should be reflected in SSA disability evaluation during efforts to improve the disability claims process.

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[57] *See* Lawrence Robison et al**.,** *Vascular Dementia*, HELPGUIDE.ORG, (last updated Oct. 2015), http://www.helpguide.org/articles/alzheimers-dementia/vascular-dementia.htm.

[58] *See generally Social Determinants of Health*, CDC, http://www.cdc.gov/nchhstp/socialdeterminants/faq.html (last updated March 21, 2014).

[59] *Id.*

[60] *Id.*

[61] Claire L. Cooper et al., *The Role of Emotion Regulation on Social Participation After Stroke*, 54 BR. J. CLIN. PSYCHOL. 181, 181-82 (2015).

[62] Christa S. Nanninga et al., *Place Attachment in Stroke Rehabilitation: A Transdisciplinary Encounter Between Cultural Geography, Environmental Psychology and Rehabilitation Medicine*, 37 DISABILITY REHABILITATION 1125, 1133 (2014).

II. SSDI Disability Claims, ALJs, and Limitations of Medical Evidence

Social Security did not include disability insurance until 1956 after years of discussion that began after the Great Depression.[63] Early considerations recognized the difficulty in making disability determinations and anticipated that the cost of these insurance programs would depend on the definition of disability.[64] They sought a strict and cautious definition to limit abuse, which could be relaxed if socially warranted.[65] By the 1950s, Congress recommended that disability benefits be granted to the permanently disabled.[66] Proof of lifetime impairment rested in a medical prognosis of permanency, but added that benefits would not be paid until demonstrating an inability to work after 6 months.[67] Further, they drew focus on the intention to support these disabled patients with vocational rehabilitation in order to return them to productive lives.[68]

Disability is an elastic concept that Professor Berkowitz stated in his address to the Subcommittee on Social Security of the Committee on Ways and Means required a "historical eye. . .to [see] which aspects of the system are worth changing. . .and spot emerging trends."[69] Shortly following 1956, the criteria to qualify as disabled quickly expanded, but the medical-vocational standard remained fundamentally unchanged.[70] In just over a decade, the age requirement to qualify for disability benefits was removed and benefits could be granted to those who were predicted to be functionally impaired for at least a year.[71] This led to a higher number of disability determinations than expected,

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[63] *See* Patricia P. Martin & David A. Weaver, *Social Security: A Program and Policy History*, 66 SOC. SEC. BULL. at 1 (2005), https://www.ssa.gov/policy/docs/ssb/v66n1/v66n1p1.pdf.

[64] *See generally Committee Staff Report on the Disability Insurance Program,* SSA (1974), www.ssa.gov/history/pdf/dibreport.pdf.; Jeffrey S. Wolfe & David W. Engel, *Restoring Social Security Disability's Purpose*: *Does the Decisionmaking Process Serve the Purposes of the Program?*, 36 CATO REGULATION 46, 47 (2013).

[65] *See* sources cited *supra* note 64.

[66] *Committee Staff Report on the Disability Insurance Program, supra* note 64, at 108.

[67] *Id.*

[68] *Id.; see also id.* at 116.

[69] *Disability Policy and History: Hearing Before Subcomm. on Social Security of the Comm. on Ways and Means* (2000) (statement of Edward D. Berkowitz, George Washington University), http://www.ssa.gov/history/edberkdib.html [hereinafter *Berkowitz Statement*].

[70] *See* Wolfe & Engel, *supra* note 64.

[71] *Id.*

causing concern in court interpretation of the definition of disability.[72] In response, Congress refined their definition in 1967 amendments:

> An individual shall be determined to be under a disability only if his physical or mental impairment or impairments are of such severity that he is not only unable to do his previous work but cannot, considering his age, education, and work experience, engage in any other kind of substantial gainful work which exists in the national economy, regardless of whether such work exists in the immediate area in which he lives, or whether a specific job vacancy exists for him, or whether he would be hired if he applied for work.[73]

This came with a reemphasis on the "predominant importance" of medical evidence in objectively supporting the nature and extent of physical and mental impairments.[74] Though it was intended to slow the growth of allowances, SSDI experienced a rise in rolls that has continued into the present day.[75] In many ways, Professor Berkowitz and Social Security policy researchers are correct to look to original intentions of federal disability programs – Congress cautiously understood the fact that medical prognoses would be insufficient to accurately determine a social definition of disability.[76] Half a century later, the SSA continues to shift and clarify qualifications of disability and has done so in part by further refining medical criteria.[77] With noted gaps in knowledge, how capable is medicine with keeping the current criteria?

This section will analyze legal evaluation of disability by the SSA. Part IIA will discuss the initial disability claim and the sequential steps to qualify as disabled. It finds that current diagnostic tools may not be sufficient to meet medical criteria listed by the SSA. Part IIB examines the administrative courts and ALJs to show how an overemphasis on the capabilities of medicine can detract from the goal of fair disability rulings. Especially with ongoing fiscal and bureaucratic pressures of the SSA, medical evidence may not be

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[72] *Id.* at 50.

[73] 42 U.S.C. §423(d)(2)(A).

[74] *Committee Staff Report on the Disability Insurance Program*, *supra* note 64, at 117.

[75] *Berkowitz Statement*, *supra* note 69.

[76] *See generally* sources cited *supra* note 64; *see also Berkowitz Statement*, *supra* note 69.

[77] *See generally* Frank S. Bloch, *Medical Proof, Social Policy, and Social Security's Medically Centered Definition of Disability*, 92 CORNELL L. REV. 189 (2007), http://scholarship.law.cornell.edu/cgi/viewcontent.cgi?article=3047&context=clr.

scrutinized carefully enough. Part IIC looks at the role of non-medical considerations and the vocational expert program. Expert testimony may be confounded by imperfect medical evidence.

A. Initial Disability Claims

The SSA evaluates disability through a sequential five-step process that includes determining a claimant's occupational status, severity of medical impairment, and ability to work based on medical condition.[78] The first two steps look to identifying vocational and medical parameters separately: (1) whether one is working and (2) whether one has a medically diagnosed impairment.[79] The third step details that certain severe medical conditions are categorized as generally sufficient qualifiers for SSDI under Listings of Impairments.[80] Stroke can be classified under "central nervous system vascular accident" if the patient has experienced ineffective communication and speech from aphasia or significant and persistent impairment of motor function in two extremities.[81] These deficits must be present three months after stroke onset and be expected to cause death or persist for at least a year.[82]

The rationale behind deferring cases until three months post-stroke is to better judge limitations.[83] As already seen with current research in predicting ADLs after stroke, most variables including speech deficits, limb paralysis, ability to walk independently, and gait are questionably accurate prognostic indicators of future functionality.[84] Moreover, prospective studies of factors that affected prognosis of post-stroke functionality indicated that domains as subjective as pain and emotional reaction to rehabilitation played roles in outcomes, whereas the Barthel Index, a general clinical measure of ADLs, did not conclusively predict functional outcome at time of discharge.[85] At this stage in research, there is little definitive proof that

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[78] *Disability Benefits*, SSA, at 9-10 (May 2015), http://www.ssa.gov/pubs/EN-05-10029.pdf.

[79] *Id.*

[80] *Id.*

[81] *Blue Book*: *Part A*, § 11.04, SSA, http://www.ssa.gov/disability/professionals/bluebook.

[82] *Id.*

[83] *See id.*

[84] Veerbeek et al., *supra* note 39, at 1484-85.

[85] *See generally* Peter J. van Bragt et al., *Predicting Outcome in a Postacute Stroke*

clinicians possess accurate and valid tools that would be able to predict chronic impairments in stroke patients.[86] Subjective factors that may also have important implications in long-term disability are not assessed in medical reports and difficult to characterize in a way that would be consistent with disability claims.

Additionally, observational studies have indicated that maximal functional gains in recovery are made by three months post-onset.[87] The AHCPR lists several studies as early as 1965 that have found recovery initiation as soon as a few days post-stroke is strongly associated with better functional outcomes.[88] Large-scale trials have found that structured rehabilitation may promote improvement in motor function as early as two weeks post-stroke.[89] Importantly, interventions in mobility are a progressive practice that may produce gains at any time after stroke onset.[90] The earliest starters in a structured rehabilitation program, however, experienced significantly higher effectiveness of treatment than did medium or latest groups.[91] Early is defined as initiation of therapy within 20 days and later categories are an additional 20 days.[92] One fundamental principle of neurologic rehabilitation is that the brain is plastic and adapts.[93] Therefore, medical evaluations can be a dynamic process. An evaluation at three months may not be an accurate indication of a patient's limitations a year from now.

To increase complexity, stroke is a multi-faceted disability. Patients who do not present with aphasia or paresis may manifest with criteria in other listing categories such as "Special Senses and Speech" and "Mental Disorders".[94] Those who do not meet any listed impairments must present evidence that their "residual functional

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Rehabilitation Programme, 37 INT. J. REHABILITATION RES. 110 (2014).

[86] *See generally* Duncan et al., *supra* note 24.

[87] Bruce H. Dobkin & Andrew Dorsch, *New Evidence for Therapies in Stroke Rehabilitation*, 15 CURR. ATHEROSCLER. REP. 1, 2-3 (2013).

[88] *See* Duncan et al., *supra* note 24, at 107–08.

[89] *See, e.g.,* Dobkin & Dorsch, *supra* note 87, at 3.

[90] *Id.*

[91] Duncan et al., *supra* note 24, at e108.

[92] *Id.*

[93] Dobkin & Dorsch, *supra* note 87, at 2.

[94] *Blue Book: Part A*, § 2.00, SSA, http://www.ssa.gov/disability/professionals/bluebook/2.00-SpecialSensesandSpeech-Adult.htm (last visited Nov. 20, 2015); *Blue Book: Part A*, § 12.00, SSA, http://www.ssa.gov/disability/professionals/bluebook/12.00-MentalDisorders-Adult.htm (last visited Nov. 20, 2015)(These conditions may be qualified by any disorder or cause.).

capacity" is enough to prevent meaningful employment, after full consideration of non-medical characteristics.[95] The claimant's residual capacity can be challenging to assess even among medical professionals that are experienced in disability determination.[96] Aside from adequacy of prognostic models, factors contributing to these hurdles stem from variability in clinicians: availability of time to properly assess a patient in a demanding clinical setting, hesitancy in reducing a doctor-patient relationship by assessing a patient against his or her preference to qualify for disability programs, and lack of training in proper interactions with administrative agencies and legal entities.[97]

The last steps of deciding whether one is disabled combine the medical and vocational parameters: is your medical condition severe enough to prevent you from continuing your previous employment and preclude you from any substantial and gainful activity?[98] Claimants over the retirement age of 65 who desire to continue working but cannot because of medical impairments may qualify for SSDI through special rules that consider vocational criteria.[99] This step is the synthesis of clinical and nonclinical judgment, thereby carrying out Congress' intent as expressed in the Social Security Amendments of 1967.[100] Further, the amendment explicitly states employment may qualify as any found in this country's economy regardless of geography, availability, or whether or not the applicant would be hired.[101] As written, medicine serves as a threshold for severity, but at times this can be a difficult distinction between functional and disabled or a hazy boundary between short-term and long-term.[102]

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[95] *See* 20 CFR § 416.945.

[96] *See* Linda Cocchiarella, *Disability Assessment and Determination in the United States*, UPTODATE, http://www.uptodate.com/contents/disability-assessment-and-determination-in-the-united-states (last updated Sept. 17, 2015).

[97] *Id.*

[98] *Disability Benefits*, *supra* note 78, at 12.

[99] *See* Melissa Linebaugh, *Applying for Disability at Age 60 or Older: Using Social Security's Medical-Vocational Grids*, DISABILITYSECRETS, http://www.disabilitysecrets.com/resources/disability/applying-disability-age-60-or-older-using-soci, (last visited Nov. 20, 2015).

[100] *See* Wilbur Cohen & Robert Ball, *Social Security Amendments of 1967: Summary and Legislative History*, SSA BULLETIN (Feb. 1968), https://www.ssa.gov/policy/docs/ssb/v31n2/v31n2p3.pdf.

[101] Social Security Amendments of 1967, H.R. 12080 (Jan. 2, 1968); 42 USC 1382(c)(1)(B) (1967).

[102] *See id.*

B. Appeals and the ALJ

The APA organizes formal due process in federal administrative agencies in order to regulate their roles.[103] To this end, claimants are afforded the opportunity to present their case from anew in court.[104] Among the four levels of appealing an unfavorable initial disabilities claim, the ALJ serves to conduct hearings and consider all evidence in re-determining disability as defined by the SSA.[105] The ALJ functions similarly and their decisions can impact individuals greatly, though they are distinct and separate in power from trial judges in the judicial branch.[106] Like clinical evaluations, medical experts are not asked to make an opinion on disability when called to testify, but only add to the body of evidence with a justifiable description of the claimant's functional limitations.[107] It is up to the ALJ to decide disability after considering the weight of the medical experts opinion and nonclinical evidence, which may constitute vocational considerations such as past work experience.[108]

In 1971, the Supreme Court decision in *Richardson v. Perales* carried pivotal delineations on administrative court procedure with admissibility of medical evidence and the extent of due process in SSA disability hearings.[109] This began with an SSDI claim filed by Mr. Perales in 1966 due to a sustained back injury.[110] The state agency initially denied his claim for lack of substantial medical evidence provided by his physicians, which was later unfavorably reviewed through medical reports by an independent medical advisor.[111] Conflicting medical opinions were presented at the hearing and the issue became whether physicians' written reports of medical examinations may constitute "substantial evidence."[112]

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[103] APA, 5 U.S.C. §556; *see* Vanessa K. Burrows, *Administrative Law Judges: An Overview*, CONG. RES. SERVICE (April 13, 2010), http://ssaconnect.com/tfiles/ALJ-Overview.pdf.

[104] *See* sources cited *supra* note 103.

[105] *The Appeals Process*, SSA (2008), http://www.ssa.gov/pubs/EN-05-10041.pdf.

[106] Burrows, *supra* note 103, at 1.

[107] *See Medical Expert Handbook*, SSA (June 2011), https://ssa.gov/appeals/public_experts/Medical_Experts_(ME)_Handbook-508.pdf.

[108] OFFICE OF HEARINGS AND APPEALS, SOCIAL SECURITY ADMINISTRATION, HEARINGS APPEALS AND LITIGATION LAW MANUAL (1992).

[109] *Perales*, *supra* note 16.

[110] *Id.* at 390-93.

[111] *Id.* at 393.

[112] *Id.* at 394–99.

When Mr. Perales was found ineligible for SSDI, he appealed on the basis that the court denied him a fair hearing and violated his constitutional right to due process by not subpoenaing doctors who gave conflicting reports for cross-examination.[113] The Supreme Court held that relevant and authenticated written medical reports may constitute substantial evidence in SSA disability hearings, despite their nature as uncorroborated hearsay.[114] Substantial evidence is defined as "more than a mere scintilla", such that a reasonable mind may accept as relevantly supportive of a conclusion.[115]

Moreover, the Supreme Court held that the nature of Social Security benefits determines the necessary due process.[116] The "precise nature of the government function involved as well as of the private interest that has been affected by governmental action" must be taken into account.[117] Unlike other welfare entitlements, Social Security disabilities are essentially an "earned" benefit.[118] The Court emphasized that SSDI is not a termination of welfare where the recipient may be "condemned to suffer grievous loss", and therefore, not subject to the same level of due process.[119] Claimants still hold the right to request subpoena and cross-examination of adverse medical testimony, but the ALJ may determine validity and weight of medical reports without necessary oral testimony or direct physical and mental examination.[120]

Justice Blackmun's majority opinion notes that the Social Security Act emphasizes the informal over formal so as to include the "layman claimant".[121] Indeed, the APA sought to include the public in agency policy and rulemaking with transparency and formal adjudication.[122] ALJs, therefore, are responsible for a unique representation of interests. On one hand, the ALJ acts in favor of the patient, while on the other, the ALJ represents the public and taxpayers

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113 *Id.* at 397-99.

114 *Id.* at 398–402.

115 *Perales*, *supra* note 16, at 401 (citing Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229 (1938)).

116 *Id.* at 401-03.

117 *Id.* at 401-02 (citing Goldberg v. Kelly, 397 U.S. 254, 262–63 (1970)).

118 *See id.*

119 *Goldberg*, *supra* note 117, at 262–63.

120 *Perales*, *supra* note 16, at 402.

121 *Id.* at 400–01.

122 *See, e.g.*, APA, 5 U.S.C. §§ 553, 554.

to safeguard SSDI to those who truly qualify.[123] These seats must be filled simultaneously in an administrative court. Given the admissibility of medical reports and relaxed due process requirements, "SSDI adjudication impedes the determination of SSDI awards based on a comprehensive and fair review of the claimant's record."[124] This SSA administrative court procedure [potentially] opens the door for system abuse if inappropriate weight is given to medical evidence and if interests between safeguarding Social Security funds and awarding benefits are not appropriately represented in the courtroom.[125]

Certainly with stroke, patients can experience conditions that are often described in subjective terms, such as chronic pain, migraine, headache, and depression.[126] Therefore, the levels to which these are debilitating are up for interpretation and may vary with each involved individual, including physicians, vocational experts, and the ALJ. Functional and structural neuroimaging may provide some insight into a patient's condition that cannot be easily described in objective terms, but their results can still come down to individual interpretation as with many objective tests.[127] Other conditions, not necessarily related to stroke care, have been subject for debate on their merits in an administrative court disability hearing, including: chronic pain[128], obesity[129], and alcoholism.[130] They share a characteristic of difficulty in objectively characterizing through medical examination.

While the Supreme Court's decision in *Perales* can be interpreted to favor patients, they may be overstating the weight of medical

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[123] Jagadeesh Gokhale, *SSDI Reform: Promoting Gainful Employment while Preserving Economic Security*, 762 CATO POLICY ANALYSIS 1, 11 (2014).

[124] *Id.*

[125] *Id.* at 12.

[126] *See generally* Laura Spurgeon et al., *A Q-Methodology Study of Patients' Subjective Experiences of TIA*, 2012 STROKE AND TREATMENT RESEARCH at 1, http://www.hindawi.com/journals/srt/2012/486261/; R. Murphy et al., *Effect of Experience of Severe Stroke on Subjective Valuations of Quality of Life After Stroke*, 70 J. NEUROL. NEUROSURG. PSYCHIATRY. 679, 679-81, http://jnnp.bmj.com/content/70/5/679.full.pdf+html.

[127] *See* Stinear & Ward, *supra* note 55; Pustilnik, *supra* note 54.

[128] *See* Pustilnik, *supra* note 54.

[129] Christopher E. Pashler, *Smithers, What's the Name of This Gastropod? King-Size Homer and the Social Security Administration's Subjective Evaluation of Fatness*, 29 GA. ST. U. L. REV. 359 (2012-2013); BUFFALO LEGAL STUDIES RESEARCH PAPER SERIES PAPER No. 2012 – 043 (2012) (analyzing the termination of obesity as a qualifier for SSDI).

[130] Judith J. Johnson, *Rescue the Americans With Disabilities Act from Restrictive Interpretations: Alcoholism as an Illustration*, 27 N. ILL. U. L. REV. 169, 171, 174 (2006-2007) (discussing the persisting stereotype and prejudice alcoholism faces in disability claims under the ADA).

reports, especially if treating physicians are not required to testify. Justice Douglas, in his dissenting opinion, emphasized the troubling nature of admitting hearsay evidence without complete due process.[131] Out of six doctors who had personally examined Mr. Perales, only one testified at his disability hearing.[132] Justice Douglas goes on to state that cross-examination is necessary for a "full and fair disclosure of facts."[133] Problematically, Social Security disability hearings without cross-examination lends to the possibility that medical reports can be controlling.[134] This permits easy solicitation of reports from treating physicians, who are already naturally sympathetic with their patients.[135] "The treating physician is never subjected to cross-examination, let alone prosecution for misrepresentation."[136] "Thus an Administrative Law Judge is boxed into a corner, and forced to grant benefits, even when knowing the individual is not truly disabled."[137]

This process is further complicated in the context of a huge case backlog, where the SSA places pressure on ALJs to meet a high volume of cases within a year.[138] The SSA entered 2013's fiscal year with over 700,000 pending disability claims and ended with just under 700,000 pending claims, with an average processing time of 107 days.[139] Estimates into the next few years by the SSA and Office of the Inspector General (OIG) do not boast a reduction in processing time or delay to hearing.[140]

Data shows a positive association between annual case dispositions and annual award rate.[141] In other words, the data suggests that a judge with higher caseload will award more benefits.[142] This may simply be a reflection that if a judge hears more cases, more claimants will exhibit qualified disability. Unfortunately, a recent OIG report reveals that 13.8% of sample cases from outlier ALJs, who had

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131 *Perales*, *supra* note 16, at 411.

132 *Id.* at 395.

133 *Id.* at 412.

134 Gokhale, *supra* note 123, at 12.

135 *Id.*

136 *Id.*

137 *Id.*

138 *Id.*

139 Office of the Inspector Gen., A-07-13-13073, The Social Security Administration's Progress in Reducing the Initial Disability Claims Backlog Baltimore, MD: Office of Audit (April 2014).

140 *Id.*

141 Gokhale, *supra* note 123, at 15.

142 *Id.* at 15-16.

both the highest deposition load and allowance rates over two fiscal years, would have been denied or dismissed if under proper review.[143] These disability benefits were extrapolated over a 7-year period to estimate that improper benefits would be allowed on over 24,000 cases that would amount to $2 billion in questionable costs,[144] a small expense compared to total SSDI costs of $119 billion, but excessive nonetheless.[145]

Additionally, the SSA and OIG explicitly state that they are aware some individuals will withhold, exaggerate, or fabricate medical information to improve their chances of collecting benefits they are not eligible to receive.[146] Hundreds of thousands of cases are reported to have incomplete medical information that was not obtained at the initial claims process for varying reasons, resulting in determination without all sources of evidence.[147] Overall, it is unclear if incomplete medical information affected case outcomes, as the hearing allowance rate for these cases without complete information is similar to those of national average allowance rate for all cases.[148] However, some medical conditions with high denial rates at initial claims process are subsequently allowed at high rates before a court hearing.[149] The overwhelming majority of these claims acquired legal representation at court and a large proportion were decided on impairments other than one initially presented, with up to 12% of these cases changed to affective or mood disorders.[150] The OIG speculates these changes were due to impairments not evident at initial claim, assistance by legal aid

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[143] Office of the Inspector Gen. A-12-14-24092, Administrative Law Judges with Both High Dispositions and High Allowance Rates Baltimore, MD: Office of Audit (November 2014) ("In a January 2014 letter, the Chairmen of the House Committee on Oversight and Government Reform and the Subcommittee on Energy Policy, Health Care, and Entitlements asked [the OIG] to identify ALJs who had 700 or more dispositions and allowance rates of 85 percent or higher in any 2 fiscal years (FY) from FYs 2007 through 2013.").

[144] *Id.*

[145] *The Social Security Disability Insurance Program – Infographic*, CONGRESSIONAL BUDGET OFFICE (July 16, 2012), https://www.cbo.gov/publication/43432.

[146] H.R., Committee on Ways and Means Subcommittee on Social Security, *Challenges of Achieving Fair and Consistent Disability Decisions*, (March 20, 2013), http://oig.ssa.gov/newsroom/congressional-testimony/march20 [hereinafter *Challenges of Achieving*].

[147] OIG., A-01-13-23082, Completeness of the Social Security Administration's Disability Claims Files Baltimore, MD: Office of Audit (July 2014).

[148] *Id.*

[149] OIG, A-07-09-19083, *Disability Impairments on Cases Most Frequently Denied by Disability Determination Services and Subsequently Allowed by Administrative Law Judges Baltimore, MD*: *Office of Audit* (Aug. 2010).

[150] *Id.*

in developing medical proof, or progression of disease or mental impairment.[151]

Together, these reports overwhelmingly bring attention to the fallibility of medical evidence in an administrative court. Not only is there questionable completeness of medical evidence throughout the disability claims process, but also questionable accuracy of medical reports without proper examination and consideration of all facts. As stated before, physicians are ill equipped to give a conclusive medical prognosis in many cases, making it more difficult to translate this to disability as defined by the SSA.

C. Vocational Experts and the Daubert Standard

Since early discussions about federal disability insurance, Congress has not been completely satisfied by a medical prognosis, and has therefore chosen to pay disability benefits until six months after the date of disability onset.[152] This maintained a vocational requirement that would be reaffirmed in 1960 by the landmark case, *Kerner v. Flemming*.[153] The case established the requirement of the SSA to demonstrate that the claimant was capable of engaging in any other work known as Kerner criteria.[154] In this manner, the SSA holds the burden to safeguard funds for patients who truly qualify as deemed by the definition of disability.

The *Kerner* decision paved the way to the inception of the vocational expert and consulting programs that would independently consider the non-medical, vocational factors relevant to a disability claim.[155] The vocational consultant is charged with providing guidance in hearings by considering employment criteria including age, education, training and work experience, as detailed in 1967 amendments.[156] A vocational testimony may be required if a claimants medical condition did not fall under the Listing of Impairments and additional evidence is needed to determine the extent of severity and

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[151] *Id.*

[152] *Disability Benefits*, *supra* note 78, at 12.

[153] Kerner v. Flemming, 283 F.2d 916 (2nd Circ. 1960).

[154] *Id.* at 922.; *History of SSA During the Johnson Administration 1963-1968*, SSA, http://www.ssa.gov/history/ssa/lbjoper5.html (last visited Nov. 22, 2015) (documenting the impact of the Kerner case and the establishment of the vocational expert programs).

[155] *See History of SSA During the Johnson Administration 1963-1968*, *supra* note 154; *Committee Staff Report on the Disability Insurance Program, supra* note 64, at 108.

[156] Social Security Amendments of 1967, Pub. L. No. 90-248, 81 Stat. 821, 868 (1976).

work capabilities.[157] This can be especially crucial for claimants over the age of 65 where special rules are in place to consider vocational criteria.[158] Lastly, the claimant bears the burden of proving an inability to hold gainful employment due to his medical condition.[159] The ALJ must specify jobs that the claimant is able to perform with substantial supporting evidence.[160] Given a claimant's residual functional capacity, age, education and previous work experience, medical-vocational guideline grids may be used to determine appropriate sedentary, light, or medium employment that exists in the national economy.[161] These grids act like a flowchart to assist the ALJ in determining disability and often follow a pattern that makes vocational testimony unnecessary, but "[t]he preferred method of demonstrating job availability when the grids are not controlling is through expert vocational testimony."[162]

In hearings, a judge derives a reliable opinion from a vocational expert by asking hypothetical questions that account for the claimant's physical or mental impairments.[163] In order for the opinion to constitute substantial evidence, the hypothetical question must comprehensively include all impairments, deficits, and restrictions.[164] Further, it must adequately and accurately present these facts for the vocational expert's response to be reliable.[165] This requires complete medical information, a reliable medical report, and an understanding of the medical evidence by the ALJ that allows articulation of inquiries to clearly portray medical impairments to their full extent.[166] Without such, a disability determination may be reached erroneously.[167]

To place checks on vocational expert testimony, the ALJ is

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[157] *See generally Vocational Expert Handbook*, SSA, (June 2001), https://ssa.gov/appeals/public_experts/Vocational Experts (VE) Handbook-508.pdf; *Blue Book*. Publication No. 64-039, SSA, issued September 2008, http://www.ssa.gov/disability/professionals/bluebook/ (last visited Dec. 28, 2015).

[158] *See generally* sources cited *supra* note 157.

[159] *See* 20 C.F.R. § 404.1512(a) (2006); *see also* 42 U.S.C. § 423(d)(5)(A) (2000).

[160] Allen v. Sullivan, 880 F.2d 1200, 1201 (11th Cir.1989).

[161] *See* Medical Vocational Guidelines, SSA, 20 C.F.R. Appendix 2 to Subpart P of Part 404 §§ 200.00-204.00 (2008), https://www.ssa.gov/OP_Home/cfr20/404/404-app-p02.htm.

[162] Francis v. Heckler, 749 F.2d 1562, 1566 (11th Circ.1985).

[163] Daniel F. Solomon, *Vocational Testimony in Social Security Hearings*, 18 J. NAT. ASSOC. OF ADMIN. LAW JUDICIARY 197, 209 (1998).

[164] *Id.*

[165] *Id.*

[166] *See generally id.*

[167] *See* Green v. Sullivan, 923 F.2d 99, 101 (8th Cir. 1991).

required to ensure that the expert opinion adheres to data found in the *Dictionary of Occupational Titles* (*DOT*) or more recently replaced online database, the *Occupational Information Network* (*ONET*), which provides reference to existing employment in the United States economy.[168] There are many issues with the *DOT* and *ONET* that add to the list of doubts with vocational expert reliability. Changes in the national economy and work force have "eroded SSDI's ability to link medical conditions with (in)ability to work."[169]

Further, medical assistive devices and rehabilitation medicine have added significant restorative capacity that changes the extent of functionality.[170] Thus, another component must be accounted for in an already challenging assessment of impairment by clinicians that vocational criteria may not have appropriately incorporated.[171] This erosion is evident in an analysis of disability determination trends. Allowances based on medical evidence alone appear less frequently than a quarter of a century ago. This may be the result of an increasingly noticeable and prevalent difficulty in clinical establishment of functional and work limitations causing a shift towards more consideration of vocational and nonclinical factors.[172] OIG data reports a steady increase in serious assessment of nonmedical criteria, with up to 76% of dispositions in 2010 included testimony by vocational experts.[173]

There has been extensive controversy over the reliability of vocational experts in court due to either lack of education and experiential qualifications or accuracy of medical evidence.[174] Vocational experts often face cross-examination by claimant

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[168] *See generally The Social Security Administration's Ability to Prevent and Detect Disability Fraud*, SSA (September 2014), http://oig.ssa.gov/sites/default/files/testimony/SSA's%20Ability%20to%20Prevent%20and%20Detect%20Disability%20Fraud_0.pdf; *Vocational Expert Testimony Which Conflicts with the Dictionary of Occupational Titles ("DOT")*, SSA, http://www.ssas.com/appeals-council-and-federal-court/selected-issue-topics/selected-issue-topic-assessment-of-disability-issues/vocational-expert-testimony-conflicts-with-dot/ (last visited Dec. 28, 2015).

[169] Gokhale, *supra* note 123, at 6.

[170] *Id.* at 9.

[171] *Id.*

[172] *Id* at 8.

[173] OIG, A-12-11-11124, Availability and Use of Vocational Experts, Baltimore, MD: Office of Audit (May 2012).

[174] *See* Nathaniel O. Hubley, Note, *The Untouchables: Why a Vocational Expert's Testimony in Social Security Disability Hearings Cannot Be Touched*, 23 VAL. U. L. REV. 353, 353-406 (2008), http://scholar.valpo.edu/cgi/viewcontent.cgi?article=1103&context=vulr.

counsel.[175] Common avenues of dispute, aside from an expert's qualifications, are arguments into competing schools of thought in medicine on the subject at hand and the idea that medicine and rehabilitation is not an exact science.[176] As explained, stroke rehabilitation is an ongoing field of research and clinicians experience significant challenges in accurately and reliably assessing impairments left by stroke. If a vocational expert offers testimony that is not founded on accurate medical science, then their opinions cannot be made reliably.[177]

The *Daubert* standard applies rules of evidence for admissibility of expert witness testimony in federal courts. Under the *Daubert* standard, federal judges are to be "gatekeepers" in assuring that expert testimony is based on reliable and relevant scientific evidence.[178] Deferring to an expert only based on credentials within a field invites unwarranted speculation instead of actual knowledge.[179] The Court set out general guidelines to consider validity of scientific evidence.[180] First the key question must be that proper scientific method and empirical testing established the evidence.[181] Second, the judge should consider whether the evidence has been subject to peer review.[182] Third, known or potential error rates are relevant factors to determine.[183] Finally, minimal support of evidence or technique within the scientific community may promote skepticism on validity or admissibility.[184]

Through these standards, the ALJ should carefully scrutinize the proffered medical evidence before turning to vocational criteria.[185] This may call into question some prognostic models to assess severity and outcome of stroke impairments, which possess the potential for large error, have not been readily accepted in clinical practices, or simply lack enough evidence to support their validity.[186] Under

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175 Solomon, *supra* note 163, at 211.
176 *Id.* at 214.
177 *See* Hubley, *supra* note 174, at 389.
178 *Id.* at 380.
179 Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579, 590 (1993).
180 *See id.*
181 *Id.* at 593.
182 *Id.*
183 *Id.* at 594.
184 *Id.*
185 *See* Hubley, *supra* note 174, at 400-04.
186 *See generally* Vogenberg, *supra* note 48.

Perales, the emphasis on the informal over the formal, relaxed standards for due process and cross-examination, and admissibility of substantial evidence otherwise inadmissible in federal court proceedings, sets SSA disability hearings apart.[187] Scrutiny of evidence and validity of expert testimony "should be liberal and not strict in tone and operation."[188] It seems unrealistic to expect an ALJ to stay current on all medical and vocational aspects of disability. Therefore, to maintain standards of evidence and prevent overemphasis of medical reports, SSA disability hearings should have counsel on both sides of the disability argument.

III. Addressing Administrative Challenges Without Compromising Fair and Accurate Disability Determination

In 2008, an investigation by the OIG reported that, among surveyed individuals, almost 80% of claimants believed their finances were impacted by the delays in claims processing and 30% of patients felt that their access to medical care was affected.[189] The SSA is the largest adjudicatory agency in the world that faces a growing need to re-evaluate and reform its procedure.[190] If not for the sake of fiscal solvency,[191] then for the moral and ethical imperative to maintain and improve fairness and consistency to patients who often rely on benefits from disability insurance.[192] To address these concerns, the SSA must base their efforts on not only what medical and social research can conclude, but also an understanding on their limitations.[193]

If properly understood, medicine acts as a threshold for disability evaluation.[194] From opening an initial claim with a local field office to a hearing before an ALJ, validity and accuracy of medical reports must

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[187] *Perales*, *supra* note 16, at 400-02.

[188] *Id.* at 400-401

[189] *See Joint Hearing on Disability Claims Backlog*, *supra* note 7.

[190] Hubley, *supra* note 174, at 345; *see also* John C. Dubin, *Social Security Disability Adjudicative Reform: Ending the Reconsideration Stage of SSDI Adjudication after Sixteen Years of Testing and Enhancing Initial Stage Record Development*, 7 SSDI SOLUTIONS at 1 (2015), http://ssdisolutions.org/sites/default/files/dubin.pdf.

[191] *See* Stephen C. Goss, *The Future Financial Status of the Social Security Program,* 70 SOC. SEC. BULL. 111 (2010), https://www.ssa.gov/policy/docs/ssb/v70n3/v70n3p111.pdf.

[192] *Goldberg*, *supra* note 117, at 263-66.

[193] *See generally* Mark Green, Barry Eigen, John Lefko, & Scott Ebling, *Addressing the Challenges Facing SSA's Disability Programs*, 66 SOC. SEC. BULL. 29, 29-39 (2005-2006), https://www.ssa.gov/policy/docs/ssb/v66n3/v66n3p29.pdf.

[194] Bloch, *supra* note 77, at 234.

be considered appropriately to prevent a compounding of unreliable evidence, testimony, and judgment.[195] This final part discusses the strategies that the SSA uses to tackle current performance challenges and recommendations towards improving standards of evidence and updating clinical and nonclinical criteria.

A. Current Measures

Some of the top issues recognized by the SSA and OIG include reducing claim backlogs and delays and minimizing inaccurate payments.[196] These issues are intricately tied to fiscal projections and the economic challenge of encouraging return to work through rehabilitation.[197] In 2004, the SSA commissioned the IOM to address some of these pressing management issues.[198]

As stipulated by the APA, the SSA is charged with accommodating to public comment before final publication of new rules.[199] The Listing of Impairments, in use since 1955, has been continually revised with input and involvement from clinicians, advocates, adjudicators, and disabled individuals.[200] Until recent years, however, the SSA rarely revised the Listings in a comprehensive manner.[201] The shift towards disability allowances decided on vocational and nonclinical evidence instead of medical evidence alone caused concern in the validity of the Listings.[202] The IOM was commissioned to review medical aspects of disability determination due to a substantial drop in percentage of claims referring to the Listings.[203]

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[195] *See, e.g.,* Edwards v. Sullivan, 985 F.2d 334, 337 (7th Cir. 1993). Any medical reports that are unsupported by medically acceptable findings may be discounted.

[196] *See IG Statement on SSA'S Major Management and Performance Challenges*, OIG SSA (Nov. 10, 2014), https://ssa.gov/finance/2014/OIG%202014%20Mgmt%20Challenges.pdf.

[197] *See* Gokhale, *supra* note 123; *see also Fiscal Year 2015 Audit Work Plan*, OIG SSA (October 2014), http://oig.ssa.gov/sites/default/files/audit/full/pdf/FY%202015%20Audit%20Plan.pdf.

[198] INST. OF MED. OF THE NAT'L ACAD., IMPROVING THE SOCIAL SECURITY DISABILITY DECISION PROCESS 150 (John D. Stobo, Michael McGeary & David K. Barnes eds., National Academies Press. 2006) (2007) [hereinafter IMPROVING THE SOCIAL SECURITY DISABILITY PROCESS].

[199] Administrative Procedure Act, 5 U.S.C. § 553(c) (2015).

[200] *Teleconference on Proposed Medical Criteria for Evaluating Neurological Disorders in the Listing of Impairments*, SSA (May 12, 2014), http://www.ssa.gov/disability/Documents/SSA-2006-0140-24741.pdf.

[201] Bloch, *supra* note 77, at 215.

[202] *See* IMPROVING THE SOCIAL SECURITY DISABILITY PROCESS, *supra* note 198, at 78-88.

[203] *Id.* at 16.

The SSA began an effort to comprehensively update the Listings in 2001, but discontinued the attempt because the SSA could not find any gold standard with which to evaluate their medical criteria.[204] Logically, the Listing severities should correlate well with being unemployed.[205] Despite the absence of an objective foundation, the IOM suggested that the SSA continue using the Listings as a decision-making model because there are no better alternatives.[206] To improve upon the medical criteria, they stressed the need to analyze data from disability cases and remain aware of new external medical technologies and rehabilitation research.[207] This should also include an understanding of areas without clear research to correctly frame the weight of medical evidence.[208]

The IOM suggested that though the Listings were introduced to increase speed of the process, it may have come at the price of reduced accuracy.[209] The "accuracy problem is mitigated, because the SSA uses a stricter standard (i.e., *any* gainful activity). Although this diminishes sensitivity, SSA can tolerate having more truly disabled claimants fail the screen, because. . .they are considered in the next phase of the process (steps 4 and 5)."[210] The IOM did not evaluate the medical-vocational standards set out in the last two steps and explicitly added that the accuracy problem would be mitigated unless Steps 4 and 5 functioned correctly, which are up for debate.[211]

Further, the committee did not recommend expansion of the Listings to consider variable access to healthcare.[212] Though difficult to incorporate into the Listings, "medical evaluation is involved in gauging the severity and functional impacts of an untreated condition, [thus] the circumstances limiting access to health care and assistive technology should be considered separately."[213] This brings out socioeconomic implications in disability that may require consideration when evaluating for medical severity and possibly

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204 *Id.* at 5.
205 *Id.* at 91.
206 *Id.* at 5.
207 *Id.* at 7–9.
208 *Id.* at 7.
209 *Id.* at 91.
210 *Id.*
211 *Id.*
212 *Id.* at 9.
213 *Id.*

extends into nonclinical assessment.[214] The United States can expect a rise in healthcare costs associated with stroke and, problematically, patients of minority races and lower socioeconomic background shoulder a larger proportion of this increased cost than their non-minority counterparts.[215] The per capita cost of stroke from 2005 to 2050 is estimated to be over $25,782 in blacks, $17,201 in Hispanics, and $15,597 in non-Hispanic whites, with loss of earnings expected as the highest cost contributor for each race and or ethnicity.[216]

The IOM also recognized reports that detail variability in decisions by region[217] and a high rate of overturned decisions during hearings.[218] This may be regional variability among claimants or differences in court interpretation of hearings.[219] Since 2007, the SSA has taken some steps towards greater oversight of hearings by periodically reviewing ALJs with outlier caseloads, limiting disposition volume, and creating tools to allow judges to track their performance.[220] The APA expressly insulates and establishes independence of ALJs from the SSA, thus limiting the extent to which SSA, or any federal agency, can influence ALJ performance.[221] Though theoretically immune, the high case volume and hearings delays poses interesting questions on the existence of confounding factors that may sway judge performance. Regardless, judge variance should be ironed out in final appeals and by a consistent and accurate interpretation on the definition of disability. Aside from updating the Listings, the SSA has taken measures to train field staff, increase availability of medical and vocational experts, and continued reevaluation of disability allowances.[222] These efforts, while increasing productivity modestly, seem to be inadequate against the

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214 *Id.*

215 Bruce Ovbiagele et al., *Forecasting the Future of Stroke in the United States: A Policy Statement From the American Heart Association and American Stroke Association*, 44 STROKE 2361, 2361-66 (2013).

216 Go et al., *supra* note 27, at 149.

217 *See* IMPROVING THE SOCIAL SECURITY DISABILITY PROCESS, *supra* note 198, at 62.

218 *Id.* at 150.

219 *Id.* at 58-62.

220 OIG, A-12-14-24092, *Administrative Law Judges with Both High Dispositions and High Allowance Rates*, Baltimore, MD: Office of Audit (November 2014).

221 Administrative Procedure Act, 5 U.S.C. § 554(d) (2015).

222 OIG, A-13-08-18029, *The Social Security Field Offices' Training of Staff*. Baltimore, MD: Office of Audit (July 2008); OIG, A-01-13-23065, *The Medical Improvement Standard During Continuing Medical Reviews*, Baltimore, MD: Office of Audit (May 2014).; OIG, Availability and Use of Vocational Experts, *supra* note 173.

magnitude of the SSA's fiscal spiral. Some would argue that these "front-end" initiatives are halting the delays, but not solving the underlying problem that the SSA has lost its ability to draw the line between functional and nonfunctional.[223] The more overarching solution may therefore lie in fine-tuning the definition of disability to meet our modern medical knowledge and national economy.[224]

B. The Line Between Medicine and Vocation: Jurisprudence in Disability Hearings

Tracing out areas within SSDI policy that can benefit from reform reveals better approaches to disability determination may lie in recalling the original foundations of SSDI.[225] Analysts and lawmakers propose changing fee structures to benefit an incentive of rejoining the workforce, thereby cutting payments and increasing revenue.[226] These economic solutions are beyond this discussion, but as Congress initially predicted, the cost of federal disability insurance is linked with the definition of disability.[227]

With expansions in the eligibility of disability benefits and weakening medical and vocational criteria in our modern economy, revising the criteria to meet a fundamental definition of disability would improve the process greatly by increasing sensitivity to screen those who truly cannot sustain gainful activity. Strengthening medical criteria is a step in the right direction, but efforts will need to be made on all fronts to ensure more accurate determination because the definition is rooted in medical and nonmedical factors. Several ideas have been proposed to remove the vocational grid system for one that is matched with typical age-related functional decline, mandating the use of a modern occupational database, and applying *Daubert* standards to SSDI hearings.[228] For this to work, this Note recognizes the need to change the non-adversarial disability court procedure.

As discussed, government interests are not properly represented in SSDI court proceedings.[229] The ALJ carries a "three-hat

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[223] *See* Gokhale, *supra* note 123, at 3.

[224] *See id.* at 4.

[225] Wolfe & Engel, *supra* note 64, at 50.

[226] Gokhale, *supra* 123, at 4.

[227] *Committee Staff Report on the Disability Insurance Program*, SSA, *supra* note 64, at 107.

[228] Wolfe & Engel, *supra* note 64, at 51–52; Hubley, *supra* note 174, at 399–402.

[229] Wolfe & Engel, *supra* note 64, at 52-53.

jurisprudence" and it becomes difficult to maintain balance as a neutral decision maker.[230] A government representative is not a new idea and has been examined in court before.[231] It was thought they would simply act as an extension of the ALJ, but if properly considered, a government representative should ensure that evidence is appropriately scrutinized. This is to ensure that limitations and interpretations of clinical and nonclinical evidence are understood, and that justice is reached either for or against awarding benefits after full development of the record.[232]

A government representative could potentially address all shortcomings of medical and vocational evidence and place checks on expert testimony.[233] They would represent the public interest in ensuring correct determination of disability by upholding the fundamental definition of disability.[234] Though costly, the savings associated with increasing efficiency in the process and better preventing overpayments or incorrect awards would likely outweigh their expense.[235] Some beneficiaries undergo Continuing Disability Reviews to re-determine if an individual is still disabled and receiving the correct amounts for payment.[236] These have been effective in reducing improper payments, but do not detract the need to reform initial disability determination. Once awarded, it becomes difficult to terminate SSDI benefits. Not only can terminating disability insurance benefits be contended as a loss of private interests[237], but also "[a]dministrative finality dictates that determinations for payments and payment amounts become binding and final, unless they are timely appealed. . . Consequently, if conditions to reopen a determination do not exist, or time limits expire, SSA generally will *not* revise the determination, and will continue to pay the erroneous benefits throughout a beneficiary's lifetime."[238]

Overall, the representatives could restore balance to the disability

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230 *Id.* at 52.

231 Salling v. Bowen, 641 F. Supp. 1046, 1053 (W.D. Va. 1986).

232 Wolfe & Engel, *supra* note 64, at 53.

233 *See id.* at 52-53.

234 *See id.* at 53.

235 *Id.*

236 H.R., Committee on Oversight and Government Reform, *Statement on Continuing Oversight of Social Security Disability Programs* (Nov. 19, 2012), http://oig.ssa.gov/newsroom/congressional-testimony/nov19.

237 *Goldberg*, *supra* note 117, at 263.

238 *Challenges of Achieving*, *supra* note 146.

court system and add expertise to recognize limitations in evidence. The ALJ would remain as the decider of disability but maintain a truly neutral position. Evidence and testimony would be more carefully scrutinized and their limitations made aware. Further, a government representative would serve as an early communicative channel between the claimant's counsel and the government, allowing many cases to be made in early disposition as opposed to all cases requiring the hearing of a federal judge.[239]

Conclusion

As the population ages, administrative courts, Social Security, and the nation's healthcare system will face an increased burden of disability, thus bolstering the urgency to introduce significant reform in SSDI that maintains fair and accurate determination of disability. Medicine is a continually changing landscape that is molded by research. Professors of medicine will often quote in their lectures that the information and treatments they present will likely be outdated by the time students finish their training.[240] Likewise, SSA must initiate significant reform and appropriate updates to preserve its ability to provide relief and assistance to often the most vulnerable American citizens.

As Congress envisioned, physicians are limited in their ability to meet medical criteria in disability determination. If medicine is to be a threshold of severity, there must be an understanding that predictions in prognosis may be variable. Comprehensively revising criteria is commendable action, but there will always be cases that are left up for interpretation. To correctly and accurately interpret evidence, the administrative court procedure must seek to carefully scrutinize expert testimony, medical reports, and vocational criteria.

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[239] Wolfe & Engel, *supra* note 64, at 52.

[240] *See*, *e.g.*, Paul J. Gorman et al., *The Future of Medical Education is No Longer Blood and Guts, It is Bits and Bytes*, 180 AM J SURG 353 (2000) (referring to commonly understood idea that facts taught a medical education have a short half-life, or high rate of decay, and are often declared obsolete by the time of completed training).

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