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Advance Directive

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Beazley Institute for Health Law and Policy

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ANNALS OF HEALTH LAW
Advance Directive

Editor's Note

The *Annals of Health Law* is proud to present the Twelfth Issue of our online, student-written publication, *Advance Directive*. *Advance Directive* aims to support and encourage student scholarship in the area of health law and policy. In this vein, this issue explores the legal and ethical challenges facing medical providers. The authors examine a variety of issues related to legal ethics, ranging from assisted suicide to minor abortions.

The Issue begins with a concentrated look at legal ethics in Illinois. First, we examine whether the judicial bypass procedure should ethically be used in Illinois to grant abortions to minors. Our authors also explore whether Illinois should pass a death with dignity act that will allow physician assisted suicide and active euthanasia, and we argue that Illinois should allow physicians to refuse to provide futile care. Then, our authors discuss if Illinois should change its Medicaid Asset Recovery to more fairly recover assets from patients. Our authors also discuss if mandatory physician reporting of gun shot wounds in Chicago is a good policy.

Our Issue continues with an analysis of legal ethical policies in other states. First, we consider child immunization waivers, specifically examining California's policy. We also examine whether Michigan should allow medical providers to prescribe expedited partner therapy.

Finally, our Issue concludes an analysis of broad changes to legal ethics throughout the United States. First, we examine whether assisted death is a viable option for terminally ill adolescents in the United States. Then, we look at the United States' blood donor policy unfairly bans the donation of blood by homosexual men. We also look at the dangers of prescribing off-label antipsychotic medications to the elderly and children in foster care. Our authors examine another danger: the use of multiple predicate devices in medical devices. We next look at the ethics involved in physician marketing on Groupon and the ethical considerations for the implementation of electronic medical records. We also discuss how the PPACA affects the moral integrity of corporations in regards to providing contraceptive care. Finally, we argue that stem cell therapy used by athletes should be considered a form of cheating by national sports organizations.

We would like to thank Matthew Newman, our *Advance Directive* Senior Editor, and Donna Miller, our Technical Editor, because without their knowledge and commitment this issue would not have been possible. We would like to give special thanks to our *Annals* Editor-in-Chief, Jamie Levin, for her unwavering leadership and support. The *Annals* Executive Board Members, Serj Mooradian, Christopher MacDonald, Loukas Kalliantasis, and Michael Meyer, provided invaluable editorial assistance with this Issue. The *Annals* members deserve special recognition for their thoughtful and topical articles and for editing the work of their peers. Lastly, we must thank the Beazley Institute for

Health Law & Policy and our faculty advisors, Professor Lawrence Singer, Professor John Blum, and Megan Bess for their guidance and support.

We hope you enjoy your Twelfth Issue of *Advance Directive*.

Sincerely,

Meghan T. Funk
Advance Directive Editor
Annals of Health Law
Loyola University Chicago School of Law

Minor Abortions in Illinois and the
Judicial Bypass Procedure

*Kathleen Murphy**

I. INTRODUCTION

While abortion rates in the United States are decreasing,¹ access to abortion is decreasing as well.² The passage of strict anti-abortion laws is closing clinics and making it difficult in many regions of the country to gain access to abortion services.³ In particular, it is becoming more difficult for minors to obtain an abortion, a group that is already more limited than the general population to accessing abortion options.⁴ One method for a minor to obtain an abortion is through a judicial bypass procedure, which allows a minor to get an abortion without having to get consent from, or notify her parents.⁵ Generally, for a judge to approve an abortion in a judicial bypass

* Juris Doctor Candidate, Loyola University Chicago School of Law, Class of 2015. Ms. Murphy is a staff member of *Annals of Health Law*.

1. Eric Eckholm, *Abortions Declining in U.S., Study Finds*, N.Y. TIMES (Feb. 3, 2014), http://www.nytimes.com/2014/02/03/us/abortions-declining-in-us-study-finds.html?_r=0 (discussing anti-abortion laws having only a minimal impact on the number of woman obtaining abortions because many were passed in 2011 or later, but they also stated that some of the new regulations “undoubtedly make it more difficult and costly for facilities to continue to provide services and for women to access them”).

2. Eric Eckholm, *Access to Abortions Falling as States Pass Restrictions*, N.Y. TIMES (Jan. 4, 2014), <http://www.nytimes.com/2014/01/04/us/women-losing-access-to-abortion-as-opponents-gain-ground-in-state-legislatures.html> (outlining the emerging political campaigns and potential court cases concerning anti-abortion measures across the country).

3. *Id.*

4. Anna C. Bonny, *Parental Consent and Notification Law in the Abortion Context: Rejecting the “Maturity” Standard in Judicial Bypass Proceedings*, 11 U.C. DAVIS J. JUV. L. & POL’Y, 311, 313 (2007) (arguing that judicial bypass proceedings should be objective, rather than subjective, to look to the best interest of the minor seeking an abortion).

5. Satsie Veith, *The Judicial Bypass Procedure and Adolescents’ Abortion Rights: The Fallacy of the “Maturity” Standard*, 23 HOFSTRA L. REV. 453, 455 (1994-1995) (stating that the purpose of the judicial bypass procedure is to replace the presumption that all minors are not able to make important decisions themselves with a judicial case-by-case determination).

procedure a minor must either show that she is mature enough to have an abortion, or if the judge deems her immature, the judge must find that an abortion is in the minor's best interest.⁶

In Illinois, the issue of parental consent and notification had been hotly debated in the legal system for nearly two decades.⁷ The Illinois Supreme Court ended the lengthy debate by ruling that a pregnant female under eighteen years old must now notify her parent or guardian at least forty-eight hours before she can undergo an abortion.⁸ Prior to this ruling, a minor was not required to notify her parent or guardian to get access to an abortion.⁹ As of August 15, 2013, if a minor in Illinois seeks access to an abortion without notifying an adult family member or guardian, she must go through a judicial bypass procedure to gain access to abortion services.¹⁰

The judicial bypass procedure in Illinois is bad policy. This procedure includes an incompatible maturity standard that leads to potential for bias and unclear standards, which is the basis for the long-standing opposition to the bypass option. The process itself does not serve the rights of minors, but rather is like a punishment. This article will address the weaknesses of the judicial bypass procedure and how it could be improved. First, Section II of this article will discuss the historical context of minor abortion. Next, Section III of this article will argue that the judicial bypass procedure is bad policy, exploring the opposition to the policy, the relevancy of the maturity

of the maturity of the minor).

6. Bonny, *supra* note 4, at 316.

7. Kerry Lester, *Illinois Abortion Notification Law Upheld by State Supreme Court*, HUFFINGTON POST (July 11, 2013), http://www.huffingtonpost.com/2013/07/11/illinois-abortion-notific_0_n_3581506.html (stating that the Illinois Supreme Court unanimously upheld a 1995 state law requiring parental notification; for 18 years, the law debated on the legal challenges and what body should write the rules of enforcement of the law).

8. *Id.*

9. *Id.*

10. *Update: The Illinois Parental Notice Law is in effect as of August 15, 2013*, ILL. CAUCUS FOR ADOLESCENT HEALTH (July 22, 2013 2:23 PM), <http://www.ica.org/content/illinois-parental-notification-abortion-act> (providing a brief overview of what a minor in Illinois who is seeking an abortion must do to obtain an abortion with the Illinois Parental Notification Law going into effect in August 2013).

standard, the potential for bias, and the argument that the process itself is like a punishment. Finally, Section IV will suggest possible methods as to how Illinois should proceed with minor abortion in the future.

II. HISTORICAL CONTEXT

The United States Supreme Court has a long line of precedent interpreting the Constitution as protecting a fundamental right of privacy, including freedom of choice in individualized, personal matters like family planning.¹¹ *Griswold v. Connecticut* discussed the issue of contraceptive rights, holding that a state law forbidding the use of contraceptives was unconstitutional because it violated the right of privacy.¹² In 1973, *Roe v. Wade* extended adults' privacy right from the right to prevent pregnancy as was stated in *Griswold*, to the right to terminate unplanned or unwanted pregnancies during part of the pregnancy.¹³ Following *Roe*, minor abortions were discussed in the Supreme Court in *Planned Parenthood of Central Missouri v. Danforth*.¹⁴ In this case, the Court held that the states could not impose blanket provisions that required parental consent, but it also asserted that not all minors are competent to consent to abortion.¹⁵

Finally, in *Bellotti v. Baird*, the Court held that if a state requires a pregnant minor to obtain parental consent before obtaining an abortion, then

11. See Alexandra Rex, *Protecting the One Percent: Relevant Women, Undue Burdens, and Unworkable Judicial Bypasses*, 114 COLUM. L. REV. 85, 89 (2014) (analyzing generally parental involvement laws in abortion regulation, and specifically the effect of these regulations on the intended population, pregnant minors seeking abortions).

12. *Griswold v. Conn.*, 381 U.S. 479, 485-86 (1965) (discussing the right of privacy, holding that this right extends to married couples using contraceptives).

13. *Roe v. Wade*, 410 U.S. 113, 153-54 (1973) (holding that a state criminal abortion statute that prohibited abortions at any point in a pregnancy, except as a life-saving procedure, was unconstitutional because it violated the Due Process Clause of the Fourteenth Amendment).

14. *Planned Parenthood of Cent. Mo. v. Danforth*, 428 U.S. 52, 74 (1976) (discussing a state abortion statute, specifically holding that spousal consent and blanket parental consent for minors were unconstitutional because the State does not have authority to give a third party an absolute veto over the decision of a physician and his patient to terminate a pregnancy).

15. *Id.* at 74-75.

the state must also provide for the minor an alternative method to obtain authorization for the procedure.¹⁶ Specifically, a minor can seek judicial permission for an abortion, and the judge will determine if the minor is mature enough to go through the abortion procedure, and if the procedure is in her best interest.¹⁷ Currently, thirty-nine states require parental involvement in minor abortion decisions, with consent or notice requirements of one or both parents.¹⁸ Seven states also allow a minor to obtain an abortion procedure if a grandparent or other adult relative is involved in the decision.¹⁹ Thirty-eight states require an alternate process besides parental involvement for minors seeking abortion, namely, the judicial bypass procedure.²⁰

In Illinois, there has been a long history of litigation concerning abortion, and recently the Illinois Supreme Court concluded in July 2013 that the Illinois Parental Notice of Abortion Act of 1995 (the Act) was constitutional.²¹ The Act prohibits a doctor from performing an abortion on a minor unless forty-eight hours' notice is given to an adult family member.²² Under the Act, there are only a handful of options for a pregnant minor to get an abortion in Illinois.²³ A pregnant minor can get access to an abortion by either: (1) consent of her parents, (2) notification at least forty-

16. *Bellotti v. Baird*, 443 U.S. 622, 643 (1979) (holding that a state statute which required a pregnant minor seeking an abortion to acquire parental consent or judicial approval after parental notification was an unconstitutional burden on a pregnant minor).

17. *Id.* at 647.

18. See GUTTMACHER INSTITUTE, STATE POLICIES IN BRIEF: PARENTAL INVOLVEMENT IN MINORS' ABORTIONS (2014) (explaining the level of parental involvement in minors' abortions in all fifty states).

19. *Id.*

20. *Id.*

21. See *Hope Clinic for Women, Ltd. v. Flores*, 991 N.E.2d 745, 761 (Ill. 2013) (holding that the statutory requirement that minors who seek an abortion must give notice to an adult family member or acquire a judicial waiver of such notice in a judicial bypass procedure did not violate the state constitutional right to privacy because it was not unduly burdensome).

22. *Id.*; 750 ILL. COMP. STAT. 70/10 (2013) (stating that an adult family member is defined as "a person over twenty-one years of age who is the parent, grandparent, step-parent living in the household, or legal guardian.").

23. See GUTTMACHER, *supra* note 18.

eight hours before the procedure of one adult family member who lives with the minor, (3) or a judicial bypass waiver procedure in front of a judge which waives the notice requirement.²⁴ There are also several exceptions which do not require notice: (4) the minor is married, divorced or widowed, (5) the minor is legally emancipated, (6) there is a medical emergency or (7) where there has been abuse, assault, incest or neglect by a family member.²⁵

The litigation concerning parental notification for abortion in Illinois began in 1983 when a group of doctors who provided abortions filed suit in the United States District Court against the Attorney General of Illinois and the State's Attorney of Illinois, to challenge the constitutionality of the Parental Notice of Abortion Act of 1983.²⁶ The District Court held the 1983 Act was unconstitutional, and the Seventh Circuit Court of Appeals as well as the United States Supreme Court affirmed.²⁷ The District Court placed a permanent injunction on the defendants, the Attorney General of Illinois and the State's Attorney of Illinois, from enforcing the provisions of the 1983 Act.²⁸

In 1995, the Illinois General Assembly repealed the Parental Notice of Abortion Act of 1983, replacing it with the 1995 Act.²⁹ The plaintiff doctors amended their complaint regarding the 1983 Act, and they subsequently challenged the constitutionality of the 1995 Act.³⁰ In February 1996, in response to the amended complaint and because the Illinois Supreme Court

24. *Id.*; See Allie Carter, *Understanding the Illinois Parental Notice of Abortion Act*, ACLU-IL BLOG (Nov. 13, 2013, 5:20 PM), <http://www.aclu-il.org/understanding-the-illinois-parental-notice-of-abortion-act/> (discussing the requirements of the Illinois' Parental Notice of Abortion Act, and the implications of those requirements on the parties involved).

25. See GUTTMACHER, *supra* note 18; Carter, *supra* note 24.

26. See *Hope Clinic for Women*, 991 N.E.2d at 749-50.

27. *Id.* at 750.

28. *Id.*

29. *Id.*; Julia Thiel, *Will the Parental Notice of Abortion Act help or hurt young women?*, CHI. READER (April 28, 2014), <http://www.chicagoreader.com/chicago/illinois-parental-notification-abortion-act-minors-judicial-bypass-aclu/Content?oid=13246305> (stating that the 1983 Act required notification of both parents, while the 1995 Act only required notification to one parent).

30. See *Hope Clinic for Women*, 991 N.E.2d at 751.

had declined to enact judicial bypass rules as requested by the Illinois legislature, the Federal District Court entered a permanent injunction on the Act, barring enforcement.³¹ In September 2006, the Supreme Court of Illinois adopted Illinois Supreme Court Rule 303A, which provided for updates to the judicial bypass procedure.³² The rule stated that the court would issue findings of fact in these bypass procedures within forty-eight hours, the bypass procedures would be confidential, there would be a right to an expeditious appeal, and, at the request of the minor, counsel would be appointed.³³ Yet, even with several more motions and appeals by the defendant to lift the injunction, the courts still enjoined the defendants from enforcing the Act.³⁴ The Illinois Supreme Court finally heard the case in 2013 and held that the Act was constitutional, therefore allowing for judicial bypass procedures.³⁵ Thus, the Illinois judicial bypass procedure has been in effect for less than a year.³⁶

III. JUDICIAL BYPASS PROCEDURE IS BAD POLICY

The judicial bypass procedure is bad policy because there has been long standing opposition to it,³⁷ and there has been difficulty in accommodating the new law.³⁸ Additionally, judges may be biased³⁹ because of the

31. *Id.*

32. *Id.*

33. *Id.*

34. *Id.* at 751-52.

35. *Id.* at 772.

36. See ILL. CAUCUS FOR ADOLESCENT HEALTH, *supra* note 10.

37. See *Hope Clinic for Women*, 991 N.E.2d at 749-53.

38. See Paul Benjamin Linton, *Long Road to Justice: The Illinois Supreme Court, The Illinois Attorney General, and the Parental Notice Abortion Act of 1995*, 41 LOY. U. CHI. L.J. 753, 777 (2010) (outlining the judicial and legislative history of Illinois parental consent or notice laws until July 2009, when the U.S. Court of Appeals for the Seventh Circuit upheld the constitutionality of the Illinois Parental Notice of Abortion Act of 1995).

39. See Bonny, *supra* note 4, at 323, 325; see also Carol Sanger, *Decisional Dignity: Teenage Abortion, Bypass Hearings, and the Misuse of Law*, 18 COLUM. J. GENDER & L. 409, 419-20, 461-62 (2009) (discussing that while most pregnant minors get their petition for an abortion approved in a bypass procedure, minors often have to prove more than just maturity to the judge conducting the procedures, which could be affected by the bias of the judge evaluating the minor).

subjectivity and incompatibility of the maturity standard.⁴⁰ Lastly, the process itself does not serve the rights of minors, but rather is like a punishment that humiliates, embarrasses, and unfairly stresses the minor.⁴¹

A. Difficulty Accommodating the New Act

In Illinois there has been strong opposition to limitations on minor abortions and the judicial bypass procedure in general, as is evidenced by the nearly two decades long legal battle opposed to the enforcement of the Act.⁴² While pro-life leaning supporters argue that the Act provides parents some assurance that their daughter will not proceed with a morally complex and medically serious procedure without their knowledge or before parents have a chance to counsel their daughter,⁴³ opponents to the Act argue that the Illinois courts are not equipped for the burden of providing and implementing minors with constitutionally-sound judicial bypass procedures.⁴⁴ In particular, the Clerk of the Circuit Court of Cook County, Dorothy Brown, stated in 2007 that Cook County, the most populous county in Illinois where most of the abortions in the state occur, would be unduly burdened by the judicial bypass procedures, and that the procedures would require much effort to allocate the resources to allow them to properly function.⁴⁵ Since the passage of the Act in late 2013, it is doubtful that Illinois and specifically Cook County are able to completely accommodate these procedures.

40. See Bonny, *supra* note 4, at 332.

41. See Sanger, *supra* note 39, at 418; Rex, *supra* note 11, at 118.

42. See Hope Clinic for Women, 991 N.E.2d at 750-53.

43. See *Editorial, Common Sense on Minors and Abortion*, CHI. TRIB. July 23, 2013, http://articles.chicagotribune.com/2013-07-22/opinion/ct-edit-abortion-20130722_1_parental-notification-law-abortion-rights-illegal-abortion (arguing that the Illinois parental notification law is good public policy because it balances the rights of minors and their parents).

44. See Linton, *supra* note 38.

45. *Id.*

B. Subjectivity of Maturity Standard Leads to Potential for Bias

The maturity standard can lead to potential bias because the standard is subjective and incompatible.⁴⁶ In other states, minors generally tend to get a waiver approved by a judge who solely determines what is in their best interest, avoiding the maturity standard.⁴⁷ However, courts in other states do not grant waivers in every case. A minor could possibly be considered not mature enough to abort the pregnancy, but mature enough to keep the child, leading to conflicting standards of what maturity means.⁴⁸ In either situation, a minor is not protected by the standard, making the standard incompatible for its purpose.⁴⁹

There is also a strong potential for bias by judges in judicial bypass waiver procedures.⁵⁰ Judges could be biased against a minor because the judge does not find the minor to be mature or dislikes the fact that the minor is seeking an abortion.⁵¹ Specifically, the United States Supreme Court has not provided a definition for how a judge should determine what maturity means.⁵² In fact, in *Bellotti*, the Court stated that maturity is difficult to define or determine, and that the nature of the abortion decision requires individual evaluations of the maturity of each pregnant minor seeking a judicial bypass.⁵³

While some states provide judges with guidance for what maturity means,⁵⁴ Illinois law is silent on this issue.⁵⁵ Because there is no clear standard, the decision for Illinois judges is arbitrary and subject to potential

46. See Bonny, *supra* note 4, at 332.

47. See Sanger, *supra* note 39, at 419; Veith, *supra* note 5, at 459-60.

48. See Rex, *supra* note 11, at 119.

49. *Id.*; see Bonny, *supra* note 4, at 332.

50. See Bonny, *supra* note 4, at 322-23.

51. *Id.*

52. See Veith, *supra* note 5, at 455.

53. *Bellotti*, *supra* note 16, at 643 n.23.

54. See Sanger, *supra* note 39, at 430.

55. 750 ILL. COMP. STAT. 70/75(d)(1) (2013) (declaring the procedure for judicial waiver of notice to determine whether a minor can obtain an abortion).

biases of the individual judge presiding over the judicial bypass procedure.⁵⁶ While the judges are supposed to be a neutral third party representing the state, maturity is a subjective standard, which opens the door to potential bias.⁵⁷ Some judges in other states believe their view of maturity is not the same as someone else's view of maturity.⁵⁸ The lack of a legal standard on what maturity means gives judges absolute discretion when deciding if a minor should receive an abortion.⁵⁹

Further, judges can be biased from political or religious beliefs, generational or gender differences, or from a desire to act as a substitute parent for the minor.⁶⁰ The judge may even make his or her decision before they hear from the minor because the judge may believe that the minor is immature for not telling her parents about wanting to obtain an abortion.⁶¹ Judges are not supposed to be parents in a judicial bypass waiver procedure; rather, they must act as representatives of the State.⁶²

C. The Process Humiliates, Embarrasses, and Unfairly Stresses the Minor

Because the maturity standard is flawed,⁶³ the procedure lacks actual importance, making it a potentially humiliating inconvenience and burden for minors.⁶⁴ The judicial bypass waiver procedures humiliate, embarrass, and unfairly stress a minor for making a decision about accessing an abortion, rather than evaluating the quality of the minor's decision to go through with an abortion without notifying her parents or guardians, leading

56. See Bonny, *supra* note 4, at 322-23.

57. See generally *id.* at 323 (stating that the evaluation process mandated by the Supreme Court of the United States for determining whether a minor is mature is not specifically defined, leaving judges to develop their own criteria, which can lead to a strong danger of bias).

58. See Sanger, *supra* note 39, at 431.

59. *Id.* at 491.

60. See Bonny, *supra* note 4, at 323.

61. See Sanger, *supra* note 39, at 434, 451-52.

62. *Id.* at 451.

63. *Id.* at 419; Veith, *supra* note 5, at 459-60.

64. See Veith, *supra* note 5, at 456.

to a process like punishment.⁶⁵ Even some attorneys, guardians ad litem, and physicians that are involved in the process of the bypass procedures label the procedures as stressful and embarrassing events that do not accomplish much good for minors.⁶⁶

The nature of the judicial bypass procedure itself does not seem to enhance the quality of minors' decisions.⁶⁷ Minors have described feeling intimidated, nervous, and humiliated when they went to court for a judicial bypass procedure.⁶⁸ The outlook of going to court makes some minors panicky, anxious, and some girls even develop a deep shame from the procedure.⁶⁹ In these procedures, minors are forced to explain the most private matters of their lives to complete strangers and forced to be compelling enough in their story to get approval for the procedure.⁷⁰ It is even argued that the actual function of these procedures is for legislatures to use these pregnant teenage girls as a tool in the politically charged fight against abortion rights.⁷¹ The procedures should be altered to serve a more clear, informative, unbiased and protective function for minors.

IV. HOW ILLINOIS SHOULD PROCEED WITH MINORS AND ABORTION

The judicial bypass procedure is still new in Illinois, but the procedure should be improved to better serve and protect pregnant minors who seek access to abortions. First, the maturity standard should be eliminated from the judge's evaluation process because while most minors are found to be mature,⁷² when they are not, an absolute veto is placed on the minor's

65. See Sanger, *supra* note 39, at 418.

66. See Rex, *supra* note 11, at 122.

67. See J. Shoshanna Ehrlich, *Grounded in the Reality of Their Lives: Listening to Teens Who Make the Abortion Decision without Involving Their Parents*, 18 BERKELEY WOMEN'S L.J. 61, 145, 173-74 (2003) (arguing that it is absurd and inconsistent to apply mature decisional capacity with the decision to have an abortion).

68. *Id.*

69. *Id.*

70. See Sanger, *supra* note 39, at 445.

71. See Veith, *supra* note 5, at 477.

72. See Rex, *supra* note 11, at 121.

decision about her personal health.⁷³ Secondly, there should be a mental health professional alternative before the judicial bypass procedure. Other states give decision-making authority to doctors who will not be performing the abortion procedure and to mental health professionals, as opposed to judges in judicial bypass procedures.⁷⁴ This step is a good option to be used before a bypass procedure because of the skilled experience of mental health professionals to act as counselors and get a holistic idea of whether the minor is prepared for the decision of an abortion.⁷⁵ This additional step would leave the judicial bypass as only a last resort option, improved with the elimination of the maturity standard.

Allowing minors to speak with mental health professionals would be a more ethical approach to the judicial bypass procedures in Illinois because it would help prevent potential biases and alleviate part of the shaming aspect of the procedures.⁷⁶ It would more closely address the needs of the population these procedures in Illinois are meant to protect: young girls who feel that they cannot turn to their family but rather are looking to the State for help in making a very important life decision.⁷⁷

V. CONCLUSION

In conclusion, judicial bypass waiver procedures are insufficient and do not meet the needs of minors seeking abortion. In Illinois, there has been long-standing opposition to limitations on minor abortions and the enforcement of these procedures as a substitute for notice.⁷⁸ The procedures have a strong potential for judicial bias that could prevent a minor from

73. See Sanger, *supra* note 39, at 491.

74. See Ehrlich, *supra* note 67, at 177.

75. *Id.*

76. *Id.*

77. See *Roe*, *supra* note 13, at 164 (holding that the Constitution protects a woman's right to choose to terminate a pregnancy before viability); Rex, *supra* note 11, at 98-99; Thiel, *supra* note 29.

78. See Hope Clinic for Women, 991 N.E.2d at 750-53.

getting a waiver of notice.⁷⁹ Even though most minors do end up getting a waiver from the bypass procedure,⁸⁰ the procedure should be used as only a last resort option for minors. The procedures are not conducive to minors in helping them reach a decision; rather minors view them more as a punishment.⁸¹ Illinois should implement counseling with mental health professionals to determine holistically whether a minor can obtain a waiver to get an abortion.⁸² This improvement to Illinois law will help the state better serve the population it is aiming to protect.⁸³

79. See Bonny, *supra* note 4, at 322-23.

80. See Rex, *supra* note 11, at 121.

81. See Sanger, *supra* note 39, at 418; Rex, *supra* note 11, at 118.

82. See Ehrlich, *supra* note 67, at 177.

83. See Roe, *supra* note 13, at 164; Rex, *supra* note 11, at 98-99; Thiel, *supra* note 29.

Illinois Death with Dignity Act: A Case for
Legislating Physician Assisted Suicide and Active
Euthanasia

*Michael Weiss**

I. INTRODUCTION

Over the past century, the average life expectancy of Americans increased by about twenty-five years.¹ Specifically in Illinois, the death rate is on a steady decrease since 2000.² For Illinois patients that qualify for state-provided insurance, end-of-life-care can become extremely expensive.³ With the average life expectancy rising, the amount of people covered by health insurance growing, and the continual advancement of medical technology, the cost of end-of-life-care is likely to remain a growing public financial burden.⁴ Even though people are living longer, they are still burdened by painful diseases and ailments, and some people in Illinois would desire to end their lives if it were legally allowed.⁵

* Juris Doctor Candidate, Loyola University Chicago School of Law, Class of 2015. Mr. Weiss is a staff member of *Annals of Health Law*.

1. See DeWitt C. Baldwin, Jr. MD, *The Role of the Physician in End-of-Life Care: What More Can We Do?*, 2 J. HEALTH CARE L. & POL'Y 258, 259 (1998-99) (explaining that due to advancements of science and technology the average life expectancy has jumped from approximately 50 years in 1900 to about 75.8 years in 1995).

2. *Deaths by County of Residence: Illinois, 2000-2009*, ILL. DEPT. OF PUB. HEALTH, http://www.idph.state.il.us/health/bdmd/death_00-09.htm (last updated Dec. 4, 2012).

3. Dan Gorenstein, *How Doctors Die*, N.Y. TIMES, Nov. 20, 2013, at F1, available at <http://www.nytimes.com/2013/11/20/your-money/how-doctors-die.html>. Seventeen percent of Medicare's \$550 billion annual budget is spent on patients' last six months of life. *Id.*

4. See *id.* ("Between 2007 and 2010, Medicare spending on patients in the last two years of life jumped 13 percent, to nearly \$70,000 per patient.").

5. See Claire Andre & Manuel Velasquez, *Assisted Suicide: A Right or a Wrong?*, Santa Clara Univ., <http://www.scu.edu/ethics/publications/ie/v1n1/suicide.html> (last visited May 5, 2014) ("[T]here are many who want to die, but whose disease, handicap, or condition renders them unable to end their lives in a dignified manner. When such people ask for

This article will argue that the Illinois legislature should propose a Death with Dignity Act modeled after Oregon's Death with Dignity Act (DWDA)⁶; however, Illinois should go a step further and also legalize active euthanasia. First, this article will define the key terms needed to have an informed conversation about this issue. The article will differentiate between such terms as active and passive euthanasia, as well as, unassisted and assisted euthanasia. The second part of this article will explain what the Oregon DWDA entails.⁷ It will explain what procedural safeguards the Oregon DWDA has in place to ensure that its patients are not being coerced or unduly influenced into making a decision to end their life. Finally, this article will argue that Illinois should model legislation after Oregon's DWDA, and it should also legislate active euthanasia. It will support this argument by showing that Illinois does not have an unqualified interest in extending the lives of its residents⁸ and that it is more humane to let a terminally-ill patient die on his own terms rather than spend his last moments of life needlessly suffering.⁹

II. DEFINING THE TERMS

In order to have a constructive discussion about the morality of euthanasia and physician-assisted suicide, one should possess a working knowledge of the key terms. Physician-assisted suicide is when a doctor facilitates a patient in their request to commit suicide by giving them either the drugs necessary or the medical knowledge necessary to commit the act.¹⁰ Euthanasia is similar, but distinct; it is the act of causing, or speeding

assistance in exercising their right to die, their wishes should be respected.”).

6. OR. REV. STAT. §§ 127.800-97 (2013).

7. See *infra* Part III.

8. See *infra* Part IV.A.

9. See *infra* Part IV.B.

10. See BLACK'S LAW DICTIONARY 1475 (8th ed. 2004) (“The intentional act of providing a person with medical means or the medical knowledge to commit suicide.”) [hereinafter BLACK’S].

up, the death of a patient who suffers from either a terminal illness or an especially incurable painful illness in order to alleviate the patient's suffering.¹¹ Voluntary active euthanasia is where a competent person makes a decision or a request to be assisted in dying.¹² Nonvoluntary active euthanasia occurs when an incompetent and mentally incapable person is given medications or other interventions that cause death.¹³ Involuntary active euthanasia occurs when a competent person is put to death without making a request to die or without consent.¹⁴ Passive euthanasia occurs when a terminally ill person is allowed to die by either withholding or withdrawing life-sustaining support.¹⁵

A. Active versus Passive Euthanasia

On the surface, the distinction between active and passive euthanasia seems to be rather simple. Active euthanasia requires a person to take affirmative measures, such as administering a lethal injection, whereas passive euthanasia occurs when a person refuses to prevent an individual's

11. See *Id.* at 594 (“The act or practice of causing or hastening the death of a person who suffers from an incurable or terminal disease or condition, esp. a painful one, for reasons of mercy.”). Euthanasia is sometimes regarded by the law as second-degree murder, manslaughter, or criminally negligent homicide. *Id.* In 2001, the Netherlands became the first nation to legalize euthanasia. *Id.*

12. ROBERT YOUNG, *MEDICALLY ASSISTED DEATH* 2 (2007); see also KEVIN YUILL, *ASSISTED SUICIDE: THE LIBERAL, HUMANIST CASE AGAINST LEGALIZATION* 11 (2013) (defining voluntary euthanasia as ending another person's life at his or her own “explicit request”); see, e.g., Lawrence M. Hinman, *An Introduction to the Moral Issues, in Contemporary Moral Issues: Diversity and Consensus* 102, 103 (Lawrence M. Hinman ed., 3rd ed. 2006).

13. See YUILL, *supra* note 12, at 11 (defining nonvoluntary euthanasia as ending an incompetent and mentally incapable person's life without “explicitly requesting it”); see, e.g., Hinman, *supra* note 12, at 103-104.

14. See YUILL, *supra* note 12, at 11 (defining involuntary euthanasia as ending competent person's life without an “explicit request” or without “full informed consent”); see, e.g., Hinman, *supra* note 12, at 104. Involuntary active euthanasia is essentially murder because a person that wants to live is intentionally killed. See Young, *supra* note 12, at 2 (“[N]o matter how honourable the perpetrator's motive is in bringing about such death, it constitutes homicide.”).

15. BLACK'S at 594. A good example of litigation regarding passive euthanasia is the case of Karen Ann Quinlan in *In re Quinlan* 348 A.2d 801, *modified and remanded*, 355 A.2d 647, the parents of Karen Ann Quinlan were allowed to remove artificial respiration, allowing her to die from her illness. YOUNG, *supra* note 12, at 6.

death.¹⁶ In a hospital setting, the most common form of passive euthanasia is a Do Not Resuscitate (DNR) order.¹⁷

The distinction between active and passive euthanasia is particularly crucial in the field of medical ethics.¹⁸ The crucial distinction between active and passive euthanasia lies in a doctor's act¹⁹ or omission²⁰ because some find it acceptable to withhold life-sustaining treatment and allow a patient to die, but unacceptable to take active measures to kill a patient.²¹

The ordinary assessment of ethicists is that active euthanasia is more morally questionable than passive euthanasia because active euthanasia requires taking an affirmative action to bring about the death of another person.²² However, this distinction might not be black and white, because passive euthanasia does in fact require an affirmative action to turn off life-sustaining equipment or an active choice to not administer drugs that would prolong a patient's life.²³ If a doctor switches off a patient's respirator and the patient dies as a result of the doctor turning off the respirator, it is true that the doctor is the immediate cause of the patient's death.²⁴ Thus,

16. Hinman, *supra* note 12, at 102.

17. *Id.*

18. James Rachels, *Active and Passive Euthanasia*, 292 NEW ENG. J. MED. 78 (1975), available at http://www.qcc.cuny.edu/socialSciences/ppectorino/DeathandDying_TEXT/Active%20and%20Passive%20Euthanasia.pdf.

19. An act is "something done or performed." See BLACK'S at 26.

20. An omission is "a failure to do something." See *id.* at 1121.

21. See Rachels, *supra* note 18. The distinction between active and passive euthanasia is important because in some cases it is permissible to withhold life-sustaining treatment, but it is never permissible for a doctor to take active measures designed to kill a patient. *Id.* See also *Active and Passive Euthanasia*, BBC, http://www.bbc.co.uk/ethics/euthanasia/overview/activepassive_1.shtml (last visited Feb. 24, 2014). Some medical professionals agree with this distinction because it allows them to provide for a patient who prefers death to life-sustaining treatment while allowing them to avoid the ethical and legal problems they would face if they were to actively kill a patient that wished to die. *Id.* ("They think it allows them to provide a patient with the death they want without having to deal with the difficult problems they would face if they deliberately killed that person.").

22. See Hinman, *supra* note 12, at 103.

23. See *Active and Passive Euthanasia*, *supra* note 21 ("But some people think this distinction is nonsense, since stopping treatment is a deliberate act, and so is deciding not to carry out a particular treatment.").

24. See *id.* Even though the disease of the patient is an underlying factor in the patient's death, it cannot be argued that the doctor's act of turning off life-sustaining equipment is the

passively letting a patient die by removing life-support is just as much of an act as is administering a lethal injection to a patient.²⁵ Therefore, there is no material difference between active and passive euthanasia because in both instances the patient dies from an affirmative action that was taken for humanitarian reasons.²⁶

At times active euthanasia is preferable to passive euthanasia.²⁷ Active euthanasia is often more compassionate than passive euthanasia.²⁸ The typical case is one in which a patient is dying of an incurable disease and his pain and suffering can no longer be alleviated by the present treatment.²⁹ The patient will inevitably die within the next few days, but he cannot bear to go on living because of the excruciating pain.³⁰ The patient asks the doctor to end his life, and his family supports his request.³¹ At this point in time, a doctor can withhold treatment and let the patient die, passive

proximate cause of the patient's death.

25. See *id.* (“[T]he act of removing life-support is just as much an act of killing as giving a lethal injection.”).

26. *Id.*

27. See Rachels, *supra* note 18 for a good distinction between active and passive euthanasia. Throughout the article Rachels suggests that there is no moral difference between active and passive euthanasia because the end result is the same: the patient dies. *Id.* “The bare difference between killing [active euthanasia] and letting die [passive euthanasia] does not, in itself make a moral difference. If a doctor lets a patient die, for humane reasons, he is in the same moral position as if he had given the patient a lethal injection for humane reasons.” *Id.* In the early 1970’s AMA policy stated that intentional termination of a patient’s life was wrong and then goes on to deny that removing life-sustaining treatment was the intentional termination of a life. *Id.* Yet, it is a mistake to deny that the cessation of treatment is the “intentional termination of the life of one human being by another.” *Id.* Therefore, there can be no moral distinction between active and passive euthanasia. “If one simply withholds the treatment, it may take the patient longer to die, and so he may suffer more than he would if more direct action were taken and a lethal injection given.” *Id.* at 121.

28. Hinman, *supra* note 12, at 103.

29. *Id.*

30. *Id.*

31. See Rachels, *supra* note 18. Suppose a patient is going to die in a few days and the current treatment is not alleviating any pain. The doctor can withhold treatment. *Id.* However, the patient’s agony will continue on needlessly. *Id.* If the doctor simply withholds treatment, the patient would suffer more than if a more direct action, such as lethal injection were taken. *Id.* This is a strong reason for thinking that once the decision to not continue treatment has been made, that active euthanasia is preferable, more humane and compassionate than passive euthanasia. See also Hinman, at 103. (“It is not uncommon for situations to occur in which patients will undoubtedly die . . . their remaining time will be filled . . . with extreme pain or unconsciousness In such situations, passive euthanasia seems to be *crueler* than active euthanasia and therefore morally less preferable.”).

euthanasia, or he can take steps to end the patient's suffering, active euthanasia.³² Currently, only the former is legal in Illinois.³³

B. Assisted versus Unassisted Euthanasia

It is also important to highlight the distinction between assisted and unassisted euthanasia. The difference is important because state initiatives that call for physician assisted suicide that have been accepted have legislated a form of unassisted euthanasia.³⁴ The states conditioned their laws on the patients' ability to personally take the death causing medication himself.³⁵ While the state initiatives that call for physician assisted suicide that have failed attempted to legislate a form of active euthanasia.³⁶ These initiatives have failed because if a patient is unable to self-administer the death-hastening medication, a physician cannot actively assist the patient, because this act would be illegal.³⁷ Therefore, physician-assisted suicide is a misnomer because the only physician assistance comes writing a prescription for a death-hastening medication.³⁸

32. Rachels, *supra* note 18.

33. *Compare In re Longeway*, 549 N.E.2d 292, 321 (Ill. 1989) (holding that guardian of an incompetent patient who is terminally ill and diagnosed as irreversibly comatose may exercise right to refuse artificial nutrition and hydration on behalf of the patient), and *Ficke v. Evangelical Health Sys.*, 674 N.E. 2d 888, 889 (Ill. App. Ct. 1996) ("As a general principle of Illinois law, competent adults have the right to refuse any type of medical care, including life-sustaining treatment. The right to refuse medical care has been recognized under constitutional right-to-privacy principles and is deeply ingrained in common law principles of individual autonomy, self-determination, and informed consent."), with 720 Ill. Comp. Stat. Ann. 5/12-34.5 (2012) (making it a crime for someone to aid another person in the physical act of committing suicide).

34. See YUILL, *supra* note 12, at 29. One major difference between Oregon's successful Measure 16 and the defeated Washington initiative 119 and California's Proposition 161, was that the Oregon proposal explicitly prohibited euthanasia: it was reasonable 'prescribing only' measure that barred any kind of lethal injection or other direct action on a dying patient by the physician. This difference was critical to the bill's success because it silenced the euthanasia threat to certain groups fostered by the opposition by exclusively endorsing the death-by-prescription model.

35. See OR. REV. STAT. §§ 127.800-127.897 (2013) (requiring a terminally ill patient to be able to self-administer a DWDA prescription).

36. See *supra* note 34 and accompanying note.

37. See *supra* note 35.

38. Oregon Health Authority, *Death With Dignity Act*, OREGON.GOV,

III. OREGON'S DEATH WITH DIGNITY ACT

In 1997, Oregon became the first state to legalize physician-assisted suicide³⁹ when it enacted the DWDA.⁴⁰ The DWDA allows terminally-ill patients to end their lives through voluntary self-administration of lethal medications that are prescribed by a physician.⁴¹ Oregon's DWDA is a form of physician-assisted suicide and not a form of voluntary active euthanasia.⁴² The distinguishing feature of physician-assisted suicide is that the drugs are to be self-administered by the patient.⁴³ This distinction allows a physician to distance himself from a patient's action and be legally protected from liability for assisting in his suicide.⁴⁴

A. *How the DWDA Works*

If an Oregon resident is a capable adult who is confirmed terminal by his attending and consulting physicians, and voluntarily expressed his wish to die, then he may make a written request for medication that will end his life in a humane and dignified matter.⁴⁵ The DWDA qualifies and defines what it means to be a capable adult⁴⁶; the patient must be determined to be able to make and communicate his healthcare decisions to his healthcare providers.⁴⁷ Furthermore, the DWDA defines what it means to be terminally

<http://public.health.oregon.gov/ProviderPartnerResources/EvaluationResearch/DeathwithDignityAct/Pages/index.aspx> (last visited Feb. 25, 2014) ("Death with Dignity Act which allows terminally-ill Oregonians to end their lives through the voluntary self-administration of lethal medications, expressly prescribed by a physician for that purpose.").

39. See *Euthanasia*, PROCON.ORG, <http://euthanasia.procon.org/view.resource.php?resourceID=000132> (last updated Dec. 13, 2013). Currently four states have legalized physician-assisted suicide: three states, Oregon, Virginia, and Washington, have done so by enacting legislation, and; one state, Montana, has done so via court ruling. *Id.*

40. OR. REV. STAT. §§ 127.800-127.897 (2013).

41. See Oregon Health Authority, *supra* note 38.

42. See *supra* Part II for a discussion about the differences between physician-assisted suicide and euthanasia.

43. Young, *supra* note 12, at 45.

44. *Id.*

45. OR. REV. STAT. § 127.805.

46. *Id.* at § 127.800(3).

47. See *id.* at § 127.800. The court or the patient's attending or consulting physician,

ill⁴⁸; a patient will be diagnosed terminal if he suffers from an incurable or irreversible disease that has been medically confirmed and the patient, within reasonable medical judgment, will die within six months.⁴⁹

B. Procedural Safeguards

The DWDA sets out numerous procedural safeguards to ensure that the patient's request to die is well-informed, his own, and has not been made in a rash or hasty manner.⁵⁰ In order to provide adequate protection for a competent terminally-ill patient, the DWDA requires that the patient must make a valid request for life-ending medication.⁵¹ The patient must make the request in front of two witnesses, and the witnesses must be able to attest that the patient signed his written request free from coercion and volitionally.⁵² To further ensure that a patient has not been coerced in any way, the DWDA limits the qualifications of valid witnesses to a patient's written request.⁵³ The witness cannot be a relative, by blood or adoption, cannot be entitled to any portion of the patient's estate, cannot be the owner, operator or employee of the center in which the patient is receiving medical care and cannot be the patient's attending physician.⁵⁴

The DWDA also protects a patient from making a rash decision by requiring him to make an oral request, followed by a written request, followed by a second oral request, all within fifteen days.⁵⁵ After the patient makes his second oral request, his attending physician must offer the patient

psychiatrist or psychologist can determine if the patient has the ability to express his wishes.
Id.

48. *Id.* at § 127.800(12).

49. *Id.*

50. *See id.* at §§ 127.805-127.850.

51. *See id.* at §§ 127.805-127.810.

52. *Id.* at § 127.810.

53. *See id.*

54. *Id.*

55. *Id.* at § 127.840.

the opportunity to rescind his request.⁵⁶ No less than fifteen days may elapse between the patient's initial oral request and the writing of a prescription for medicine that will end the patient's life in a humane and dignified manner, and no less than forty-eight hours shall elapse between the patient's written request and the writing of a prescription.⁵⁷ In the interim, the patient's attending physician must fully inform the patient of his decision⁵⁸ and must recommend that the patient notify his next of kin that he made a request for life-ending medication.⁵⁹ The last protection that the DWDA provides to a patient is that he must self-administer the medication⁶⁰; this protection prevents a doctor or a family member from administering the death-hastening drug to the patient.⁶¹ If the patient wants to die, then he must self-administer the drug.⁶²

IV. PROPOSED ILLINOIS DEATH WITH DIGNITY ACT

The Illinois legislature should propose a Death with Dignity Act that models after Oregon's DWDA⁶³; however, Illinois should go a step further and also legalize active euthanasia. Illinois lacks a legitimate state interest in forcing a capable, terminally-ill adult, who wishes to be aided in the act of committing suicide, to live the rest of his days in agony and despair.⁶⁴ Additionally, terminally-ill patients' choices have grave impacts on those that are intimately connected to them, and therefore any decision relating to a terminally-ill patient's final requests should be between him and his

56. *Id.* at §§ 127.840-127.845.

57. *Id.* at § 127.850.

58. *Id.* at § 127.830.

59. *Id.* at § 127.835.

60. *See* Oregon Health Authority, *supra* note 38 (“[A]llows terminally ill Oregonians to end their lives through the voluntary self-administration of lethal medications . . .”).

61. *Id.*

62. *Id.*

63. OR. REV. STAT. §§ 127.800-127.897 (2013).

64. *But see* *Washington v. Glucksberg*, 521 U.S. 702, 728-36 (1997) (in holding that Washington's assisted suicide ban does not violate the Constitution, the Court stated that Washington asserted several legitimate reasons for banning assisted-suicide).

family and not a concern of the State.⁶⁵

A. Illinois Does Not Have an Unqualified Interest in Extending the Lives of its Residents

Illinois does not have an unqualified interest in preserving the lives of its residents despite the holding of *Washington v. Glucksberg*, in which the Supreme Court found that Washington did have this interest.⁶⁶ Washington had a legitimate interest because the patients in *Washington* were asserting an interest absent a state statute; however, if Illinois were to propose a statute allowing for physician-assisted suicide and active euthanasia, then that statute would qualify Illinois' interests in its terminally ill patients.⁶⁷ A state may have an interest in preserving the lives of citizens that are still productive to society, but this interest must be weighed against the medical conditions and the wishes of patients.⁶⁸ This balancing approach is better because end-of-life care is costly⁶⁹; an uninsured terminally-ill patient who wishes to die may end up needlessly costing the state thousands of dollars in order to prolong the patient's life for a few more days or weeks.⁷⁰ Further, if a patient requests medication to end his life and Illinois law continues to forbid it, then it appears that Illinois is mandating the suffering of terminally ill patients.⁷¹

65. See *infra* Part IV.B.

66. *Glucksberg*, 521 U.S. at 728 ("First, Washington has an 'unqualified interest in the preservation of human life.' *Id.* The State's prohibition on assisted suicide, like all homicide laws both reflects and advances its commitment to this interest." [citations omitted]).

67. *Id.* The holding *Washington v. Glucksberg* was valid and can be distinguished from what I am proposing because in *Washington* the plaintiffs were asserting that the patients had a right to die absent a state statute; therefore the standard for review was that Washington had a compelling state interest. *Id.* If Illinois were to pass a DWDA, then the compelling state interest is legislated into the Act. *Id.*

68. See *id.* at 729 ("[T]he State has a real interest in preserving the lives of those who can still contribute to society and have the potential to enjoy life."). The court of appeals went on to say that Washington's interests must be weighed against the "medical condition and the wishes of the person whose life is at stake." *Id.*

69. See Gorenstein, *supra* note 3 and accompanying text.

70. *Id.*

71. See Rita L. Marker & Kathi Hamlon, *Euthanasia and Assisted Suicide: Frequently*

Critics of this assertion and defenders of banning physician-assisted suicide and active euthanasia argue that the laws are in place to prevent abuse and protect the patient.⁷² In response to critics, the Oregon DWDA has procedural safeguards in place to ensure that a patient wishing to die is not taken advantage of by unscrupulous doctors or being coerced by family members.⁷³ Meanwhile, the DWDA allows a patient to have full autonomy in making the critical decision on how to spend his final moments.⁷⁴ If Illinois legislated physician-assisted suicide, modeled after Oregon's DWDA and all of the procedural safeguards that come with it, it would ensure that a patient in Illinois would not be taken advantage of.⁷⁵ Additionally, if Illinois were to give a terminal patient the choice to end his life with dignity, it does not necessarily follow that he will choose to end his life.⁷⁶

B. A Terminally-Ill Patient's Care Impacts Those Who are Connected to Them

Illinois' terminally-ill patients should have the option to be assisted in suicide by their physician or be actively administered life-ending drugs if they are unable to physically act themselves because their choices and decisions have a grave impact on those around them.⁷⁷ As people get older

Asked Questions, PATIENTS RIGHTS COUNCIL, <http://www.patientsrightscouncil.org/site/frequently-asked-questions/> (last visited Feb. 26, 2014) ("Activists often claim that laws against euthanasia and assisted suicide are government mandated suffering.").

72. *Id.* ("Laws against euthanasia and assisted suicide are in place to prevent abuse and to protect people from unscrupulous doctors and others. They are not, and never have been, intended to make anyone suffer.").

73. *See infra* Part IV.B.

74. *Id.*

75. *See supra* Part III.B.

76. *See* OREGON PUBLIC HEALTH DIVISION, 2013 DWDA REPORT (2014), *available at* <http://public.health.oregon.gov/ProviderPartnerResources/EvaluationResearch/DeathwithDignityAct/Documents/yeay16.pdf>. Since the DWDA was passed in Oregon, a total of 1,173 people have received prescriptions written under the DWDA, while only 752 patients have died from taking the medications. *Id.*

77. *See* John Hardwig, *Is There a Duty to Die?*, 27 *Hastings Ctr. Report* 34 (1997), *reprinted in* *Contemporary Moral Issues: Diversity and Consensus* 110 (Lawrence M.

and are closer to dying, many have reported that their last goal in life is to not be a burden to their loved ones.⁷⁸

The lives of a terminally-ill patient's loved ones are impacted in many ways and can be seriously compromised by the patient's need for medical attention.⁷⁹ The burden and stress of providing around-the-clock-care can be overwhelming and often leaves the caregiver emotionally and physically exhausted.⁸⁰ There are severe economic consequences that can affect a patient's family.⁸¹ End of life care can be very expensive⁸² and it also results in many lost opportunities such as quitting a job or losing money to fund college.⁸³

*C. A Death with Dignity Act in Illinois Would be More Humane Than
Having Patients Needlessly Suffer*

When a patient cannot self-administer his own drugs it would be more humane to allow the doctor to administer the life-ending drugs than to let

Hinman ed., 3rd ed. 2006). (Explaining that end-of-life decisions have an impact on the patient, the family and society as a whole). In this essay, Hardwig goes on to say that under certain circumstances a person has a duty to die. I do not go to this extreme, but I use his reasoning on being a burden to loved ones to support my argument that physician-assisted suicide and active euthanasia should be legislated. *Id.*

78. *Id.*

79. *Id.* at 111.

80. *Id.* When I was in college, my maternal grandmother became bed bound. *Id.* She was never terminally ill, but my parents had to hire a live-in caregiver to feed, bath and cloth my grandmother. *Id.* In addition to this financial burden, my parents, younger brother and my uncle had a rotating schedule in which they would assist the caregiver in changing my grandmother's diapers daily. *Id.* The duties of my family in caring for my grandmother went on for three years and took an emotional and financial toll on everyone involved. *Id.* When my grandmother passed away in May 2010, the family was relieved, not because they were cruel and heartless, but because my grandmother died peacefully with the dignity that she deserved as the matriarch of the family. *Id.*

81. *See id.* ("We must also acknowledge that the lives of our loved ones can be devastated just by having to pay for health care for us."); *see also* Amanda Bennett, *End-of-Life Warning at \$618,616 Makes Me Wonder Was It Worth It*, BLOOMBERG (Mar. 4, 2010, 00:01 EST), http://www.bloomberg.com/apps/news?pid=newsarchive&sid=avRFGNF6Qw_w ("In just the last four days of trying to keep him alive—two in intensive care, two in a cancer ward—our insurance was charged \$43,711 for doctors, medicines, monitors, X-rays and scans. Two years later, the only thing I know for certain that money bought was confirmation that he was dying.").

82. Bennett, *supra* note 81 and accompanying text.

83. *See* Hardwig, *supra* note 77, at 111.

the patient needlessly suffer.⁸⁴ Some believe that active euthanasia is more common than what is actually reported. When the final hours or days of a patient's life are affected by pain and suffering, it is common for his doctor to try and alleviate suffering based on his experience with the progression of a particular disease.⁸⁵ The doctor is in a privileged position to end the patient's suffering in accordance with the patient's wishes.⁸⁶ In a minority of situations, continued living means needless suffering.⁸⁷

A doctor's active euthanasia of a patient is already more common than people think, regardless of its legality, because it is a private action that will rarely be known to anybody outside of the deathbed scene.⁸⁸ When a doctor sees a patient in extreme agony and pain, he should try and do whatever is possible to alleviate the patient's suffering in accordance with the patient's wishes.⁸⁹ In Illinois, and countless other jurisdictions, if a physician were to administer a death-hastening drug to his patient it would be considered murder⁹⁰; however, this scenario does not seem more humane than allowing patients to suffer needlessly for their last days. Illinois should legalize active euthanasia in order to let a patient die on his terms rather than needlessly suffer.

84. This statement presupposes the condition that all the procedural safeguards of the DWDA have been met.

85. Yuill, *supra* note 12, at 27-28.

86. *Id.* at 28. Yuill suggests that this is "akin to the soldier who is begged by his comrade, who has just had his legs and lower torso blown off, to shoot him."

87. *Id.*

88. *Id.*

89. Peter Tyson, *The Hippocratic Oath Today*, PBS.ORG (Mar. 27, 2001), <http://www.pbs.org/wgbh/nova/body/hippocratic-oath-today.html>. The modern Hippocratic Oath takes into account the personal nature of a patient. *Id.* The modern oath also acknowledges the delicacy that must be acknowledged in end of life situations. *Id.*

90. 720 ILL. COMP. STAT. 5/12-34.5 (2012)

V. CONCLUSION

There is no moral or ethical difference between passive and active euthanasia⁹¹; however, legally there is a difference.⁹² Passive euthanasia is an accepted medical treatment in some jurisdictions, whereas active euthanasia constitutes murder in all jurisdictions.⁹³ Several states passed legislation that allows terminally-ill residents to make a choice to die on their own terms.⁹⁴ In Oregon, the DWDA allows a terminally-ill patient's doctor to prescribe them barbiturates to peacefully end their life⁹⁵; however, the physician cannot actively administer the drugs to their patients.⁹⁶

Illinois should model a law after Oregon's DWDA.⁹⁷ In addition, the state should legislate active euthanasia to allow a doctor to actively administer lethal drugs to its patients who cannot self-administer the drugs.⁹⁸ It would be more humane to allow a doctor to actively administer a death-hastening drug to a consenting patient than to allow the patient to suffer needlessly.⁹⁹ If Illinois modeled its own version of Oregon's DWDA, then a terminally ill patient will be legally protected from coercion by his doctors or family.¹⁰⁰ If a terminally ill patient can consent to any treatment that would prolong his life, it seems logical to allow him to consent to a treatment that would end his life.¹⁰¹

91. See *supra* Part II.A.

92. See *supra* note 14 and accompanying text.

93. See *supra* note 90.

94. See *supra* note 39 and accompanying text.

95. See YOUNG, *supra* note 12, at 45.

96. See Oregon Health Authority, *supra* note 38.

97. See U.S. CONST. amend. X. granting this power to the states.

98. See *supra* Part IV.C.

99. See *supra* note 27, and accompanying text.

100. See *supra* Part III.B.

101. See Andre, *supra* note 5 ("Supporters of legislation legalizing assisted suicide claim that all persons have a moral right to choose freely what they will do with their lives as long as they inflict no harm on others. This right of free choice includes the right to end one's life when we choose.").

Futile Care: Why Illinois Law Should Mirror the
Texas Advanced Directives Act

*Mary Johnston**

I. INTRODUCTION

Futile care is medical care that will not improve the patient's condition, and it is frequently provided in the United States.¹ These unnecessary procedures increase spending, waste scarce healthcare resources, and fail to meaningfully improve patients' medical conditions.² The futile care problem is growing due to technological developments that can effectively prolong life for years, or even decades, without regards to the quality of life.³ Currently, in Illinois, physicians can only refuse to provide services if they object based on deeply held moral convictions that typically stem from a religious belief.⁴ This limitation prevents physicians from being able to exercise their professional judgment and refuse treatments they believe violate their ethical responsibilities as physicians.⁵ This problem needs to be ad-

* Juris Doctor Candidate, Loyola University Chicago School of Law, Class of 2015. Ms. Johnston is a staff member of the *Annals of Health Law*.

1. Than N.N. Huynh et al., *The Frequency and Cost of Treatment Perceived to Be Futile in Critical Care*, 173 JAMA INTERN MED. 1887 (2013), available at, <http://archinte.jamanetwork.com/article.aspx?articleid=1735897>.

2. Michael Ash & Stephen Arons, *Economic Parameters of End-of-Life Care: Some Policy Implications in an Era of Health Care Reform*, 31 W. NEW ENG. L. REV. 305, 306 (2009); see Deborah L. Kasman, *When is Medical Treatment Futile? A Guide for Students, Residents, and Physicians*, 19 J. GEN. INTERNAL MED. 1053, 1053 (2004).

3. Robert D. Truog, *Medical Futility*, 25 GA. ST. U. L. REV. 985, 986 (2009) ("As technology has become increasingly effective at prolonging life, the dark side of this success has emerged in the demands of families to use this technology to sustain life in situations that offer at best no hope of meaningful existence . . ."); Kasman, *supra* note 2, at 1056 ("Modern medicine has made it feasible to support human life for an indeterminate period.).

4. 745 ILL. COMP. STAT. 70/3(e) (1998).

5. 22 ILL. PRAC., THE LAW OF MEDICAL PRACTICE IN ILLINOIS § 32:12 (3d ed.) ("This definition arguably limits the scope of the Act to decisions based on religious or closely

dressed on a legislative level so that a physician can refuse to provide a futile service on ethical grounds.⁶ In Part II this article explains what constitutes futile care. In Part III this article outlines the main arguments of those who oppose providing futile care and discusses the shortcomings of the argument that physicians are required to provide futile services if the patient wishes. Part IV of this article discusses how futile care negatively impacts healthcare systems. Finally, Part V of this article explains why Illinois should change its legislation to reduce futile care by mirroring the Texas Advanced Directive Law.

II. WHAT IS FUTILE CARE?

Deciding when to stop medical treatment, like any end of life decision, is fraught with intense and often overwhelming emotions⁷ This difficulty is exacerbated by the fact that there is no bright-line test for determining when care is futile.⁸ The literal definition of futile care is that which serves no useful purpose.⁹ Given the complexities involved in making healthcare decisions, determining when care is futile is no small task.¹⁰ One of the most

analogous beliefs, as opposed to professional ethical judgments.”); Having to provide futile care contradicts a widely accepted version of the current Hippocratic Oath requires physicians to avoid overtreatment. LOUIS LASAGNA, HIPPOCRATIC OATH (MODERN VERSION) (1964), available at <http://guides.library.jhu.edu/content.php?pid=23699&sid=190964>.

6. Truog, *supra* note 3 at 990 (“If a treatment is futile, it is not worth doing”); Thaddeus Mason Pope, *Medical Futility Statutes: No Safe Harbor to Unilaterally Refuse Life-Sustaining Treatment*, 75 TENN. L. REV. 1, 2 (2007) (“Therefore, while the specific contours of TADA must be refined, policymakers in other states should look to the TADA as a model.”).

7. Ash & Arons, *supra* note 2, at 205; see Phillip Kim, *Navigating the Maze of End-of-Life Decisions Regarding the Rejection of Life Sustaining Treatment, Medical Futility, Physician-Assisted Death, and Abortion*, 14 SMU SCI. & TECH. L. REV. 127, 128 (2010).

8. See Kasman, *supra* note 2, at 1054; Maureen Kwiecinski, *To Be or Not to Be, Should Doctors Decide? Ethical and Legal Aspects of Medical Futility Policies*, 7 MARQ. ELDER’S ADVISOR 313, 333\2 (2006); Mary S. McCabe & Courtney Storm, *When Doctors and Patients Disagree About Medical Futility*, 4 J. OF ONCOLOGY PRAC. 207, 207 (2008).

9. Futile is defined as “serving no useful purpose” *futile*, MERRIAM-WEBSTER, <http://www.merriam-webster.com/dictionary/futile> (last visited March 28, 2014).

10. See TL Beauchamp, *Methods and Principles in Biomedical Ethics*, 29 J. Med. Ethics 269, 270 (2003); see Kwiecinski, *supra* note 8, at 233 (discussing how medical decisions are value-laden and can be based on personal beliefs and values.)

accepted definitions of futile care is a clinical action that does not serve a useful purpose in achieving a patient's specific goal.¹¹ Futile care could be an additional round of chemotherapy, keeping a patient on life-support, or using feeding tubes.¹² The relationship between the care being provided and the patient's goals is fact-specific, and it requires open communication between physicians and a patient or his proxy,¹³ if the patient is unable to communicate their desires.¹⁴

While it is difficult to concretely define futile care it is imperative to understand that all end-of-life care is not futile.¹⁵ For example, futile care is not palliative care.¹⁶ Palliative care strives to reduce a patient's suffering through the assessment and treatment of their pain.¹⁷ Futile care will not achieve the patient's desired goal or improve the patient's prognosis, and therefore will not ultimately ease his suffering.¹⁸ This care differs from palliative care, where the goal is not to treat the underlying condition or pro-

11. Kasman, *supra* note 6, at 1053; *Opinion 2.037 – Medical Futility in End-of-Life Care*, AM. MED. ASS'N (1997), <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion2037.page>.

12. See Erin Alesi et al., *How we do it: Guiding Patients Facing Decisions about “Futile” Chemotherapy*, 9 J. Supportive Oncology 1, 2 (2011), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3205415/>; see generally Robert L. Fine, *From Quinlan to Schiavo: Medical, Ethical, and Legal Issues in Severe Brain Injury*, 18 BAYLOR UNIV. MED. CTR. PROC. 303, 309 (2005).

13. *OPINION 8.081 – SURROGATE DECISION MAKING*, AM. MED. ASSN (2001), <https://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8081.page> (Stating that a proxy, or surrogate decision maker, is an individual who makes health care decisions when the patient is unable to make their own decisions.). Throughout this article proxies will be inferred whenever patients or patients' rights are discussed.

14. See Kwiecinski, *supra* note 8, at 333; Amir Halevy & Baruch A. Brody, *Medical Futility in End-of-Life Care: Report of the Council on Ethical and Judicial Affairs*, 281 JAMA 937, 940 (1999) (discussing how futility is a fact-specific inquiry that cannot be objectively defined).

15. See generally John M. Luce & Ann Alpers, *Legal Aspects of Withholding and Withdrawing Life Support from Critically Ill Patients in the United States and Providing Palliative Care to Them*, 163, AM. J. OF RESPIRATORY & CRITICAL CARE MED. 2029 (2001) (Discussing what constitutes palliative care.).

16. *Id.*

17. *WHO Definition of Palliative Care*, WORLD HEALTH ORG., <http://www.who.int/cancer/palliative/definition/en/> (last visited May 2, 2014); See Luce & Alpers, *supra* note 15 at 2031 (Discussing how providing comfort is the goal of palliative care.).

18. Kwiecinski, *supra* note 8, at 324.

long life, but to provide comfort and relief.¹⁹ Treatment that provides the patient with comfort and helps them maintain their dignity during their final stages of life is not futile and should not be withheld.²⁰

III. THE FUTILE CARE DEBATE

There are four bioethical principles that are generally accepted when analyzing medical situations, such as the use of futile care: respect for autonomy, beneficence, nonmaleficence, and justice.²¹ Autonomy refers to the patient's right to make his own healthcare decisions.²² Supporters of providing futile treatments think that the decision to end treatment should lie entirely with the patient.²³ These individuals believe that patients are in the best positions to understand the value of a treatment and that allowing physicians to refuse to provide futile care is unacceptable medical paternalism.²⁴ This logic is flawed and opponents of providing futile care recognize that autonomy applies to physicians as well as patients.²⁵ Accordingly, respecting patient autonomy refers to respecting a patient's decision to refuse treatment and does not extend to requiring physicians to provide unnecessary treatment based on the patient's demands, as this violates the physi-

19. See WORLD HEALTH ORG, *supra* note 17.

20. Harvey Max Chochinov, *Dignity-Conserving Care – A New Model for Palliative Care*, 287 JAMA 2253, 2253 (2002) (“The Basic tenets of palliative care can be summarized as the goal of helping patients to die with dignity.”); Ash & Arons, *supra* note 2, at 307.

21. OFFICE OF THE SEC’Y, U.S. DEP’T OF HEALTH & HUMAN SERVS., THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979), available at <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>.

22. Kwiecinski, *supra* note 8, at 337 (quoting *Union Pac. Ry. Co. v. Botsford*, 141 U.S. 250, 251 (1891). “No right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person”).

23. *Id.*

24. Raanan Gillon, *Paternalism and Medical Ethics*, 290 BRIT. MED. J. 1971, 1971 (1985) (Explaining that medical paternalism is the belief that sometimes a physician must do what they believe is best even if their belief conflicts with their patient's wishes.).

25. Mary Ann Bailey, *Futility, Autonomy, and Cost in End-of-Life Care*, 39 J.L. MED. & ETHICS 172, 173 (2011) (“Other people deserve to have their autonomy respected also, and to make their own decisions about what they will or will not do.”).

cian's autonomy.²⁶

The second principle, beneficence, requires physicians to promote the well-being of their patients.²⁷ The beneficence argument used by proponents of letting patients demand futile treatment is closely linked to their autonomy argument.²⁸ Supporters of futile care rely heavily on how fact-specific the determination of what constitutes futility is for the individual patient.²⁹ This argument is incorrect; when a physician provides services that do not meaningfully benefit a patient's condition, he is not acting in a patient's best interest.³⁰ Further, while determining what is futile is a fact-specific inquiry, physicians can discuss desired goals with their patients and use that information in addition to their medical expertise to determine if a specific treatment is futile.³¹ The combination of specialized knowledge and experiences place physicians in the best position to determine if a treatment is futile, and that decision should be respected.³²

The third bioethical principle is nonmaleficence. Nonmaleficence is a complementary imperative to beneficence.³³ Beneficence imposes a positive duty on physicians to act in a patient's best interest while nonmalefi-

26. Kwiecinski, *supra* note 8 at 337; Baily, *supra* note 25 ("Refusing to let people do something to you is one thing, but *demanding* that people do things *for* you is quite another.") (emphasis in original).

27. Fine, *supra* note 12, at 309.

28. Both the autonomy and beneficence arguments of futile care supporters focus on the idea that the patient is in the best position to determine whether or not a procedure has value. Kwiecinski, *supra* note 8, at 332.

29. *Id.* at 339 ("The lack of a common understanding as to what constitutes futile treatment is also problematic when futility is used to override the individual's autonomous choices.").

30. *Id.* at 332 ("[P]hysicians are only morally obligated to provide care that has a reasonable chance of achieving some therapeutic benefit."); McCabe & Storm, *supra* note 8, at 209 ("[Physicians] are not obligated to pursue medically futile treatments.").

31. Alesi et al., *supra* note 12, at 2; Kasman, *supra* note 2, at 1054.

32. McCabe & Storm, *supra* note 8, at 209 ("Ongoing, open communication is likely to ease a patient's transition to appropriate and beneficial treatment options at the end of life. Physicians should act in concert with their ethical obligation to be a steward of this transition . . .").

33. Kwiecinski, *supra* note 8, at 332.

cence imposes a duty on physicians to avoid causing unnecessary harm.³⁴ Determining what constitutes nonmaleficence is particularly challenging in futile care cases because physicians can have difficulty assessing whether or not a patient will view treatment as beneficial.³⁵ Despite this difficulty, there are still situations in which physicians adamantly believe that certain treatments or procedures will only create pain and prolong inevitable death.³⁶ In such situations, it is a violation of a physician's ethical duty to do no harm if he continues to provide care that does not further any legitimate medical benefit to the patient.³⁷ These situations illustrate why it is wrong to require physicians to provide futile treatments against their best judgment, and why the law in Illinois should be amended so that physicians can refuse to provide futile treatments based on ethical objections.

The final bioethical principle to consider when analyzing medical situations is justice.³⁸ Justice refers to the appropriate allocation of scarce resources and the obligation to fairly distribute these resources.³⁹ The question of justice is particularly relevant considering the limited healthcare resources available and the key role physicians play in limiting unnecessary spending.⁴⁰ For example, families caring for patients in a vegetative state frequently run out of money, at which point Medicaid starts covering the

34. *Id.*

35. See Sonia Frick et al., *Medical Futility: Predicting Outcome of Intensive Care Unit Patients by Nurses and Doctors—A Prospective Comparative Study*, 31 CRIT. CARE MED. 456, 460 (2003).

36. Eugene Cauvin, *The Toll of Prolonging Life*, (Mar. 12, 2010), available at <http://healthcarecostmonitor.thehastingscenter.org/eugenecauvin/the-toll-of-prolonging-life/> (“I wish to go on record as saying that many patients at the end of life whose families opt for inappropriate life-sustaining treatments are subjecting them to an indignity and suffering akin to being tortured.”).

37. *Id.*

38. Kwiecinski, *supra* note 8, at 334.

39. See Beauchamp, *supra* note 10, at 269 (discussing how justice is the “obligation of fairness in the distribution of benefits and risks.”).

40. Kwiecinski, *supra* note 8, at 334; Cauvin, *supra* note 36; Maxwell J. Mehlman, *The Patient-Physician Relationship in an Era of Scarce Resources: Is There A Duty to Treat?*, 25 CONN. L. REV. 349, 350-51 (1993) (“If costs are to be controlled, it is generally recognized that physicians must be induced to change their practice patterns.”).

costs.⁴¹ Further, when a physician is providing futile services they are spending valuable time that could be spent with patients who may survive.⁴² These wasteful uses of limited resources violate the bioethical principle of justice.⁴³

IV. THE CONSIDERABLE COSTS OF FUTILE CARE

Futile care is especially prevalent when patients are in intensive care units (ICUs), in their final months of life, or in persistent vegetative states.⁴⁴ The costs incurred providing futile treatments in these three areas alone have a serious effect on the United States healthcare system.⁴⁵ These costs should not be ignored, especially considering how many people currently go without any medical treatment due to lacking resources.⁴⁶ Opponents to providing futile care recognize that providing a treatment that does not serve a patient's goal, especially considering how many people go without basic care, violates the concept of justice.⁴⁷

In 2013 the Journal of the American Medical Association (JAMA) conducted a study on futile care in five ICUs that spanned three months.⁴⁸ The results of this study showed that 232 of 1,136 patients, or 19.6 percent, received care that was either probably futile (8.6%), futile (11%), or futile on the day that the patient transitioned to palliative care (1%).⁴⁹ Overall, the JAMA study found that these five ICUs spent approximately \$2.6 billion on

41. Fine, *supra* note 12, at 310.

42. Mehlman, *supra* note 40 at 388 (discussing the scarcity of healthcare resources.).

43. See Beauchamp, *supra* note 39 (discussing bioethical principle of justice.).

44. See generally Fine, *supra* note 12 (discussing futile treatments and patients in persistent vegetative states); see generally Kasman *supra* note 2 (discussing futility in end-of-life care); see generally Huynh et al., *supra* note 1.

45. Fine, *supra* note 12, at 310; Huynh et al., *supra* note 1.

46. See Baily, *supra* note 25, at 175 (discussing how the public does not understand the need for limits on health care).

47. Fine, *supra* note 12, at 310 ("According to the Institute of Medicine, 18,000 deaths per year are directly attributable to a lack of health insurance.").

48. See generally Huynh et al., *supra* note 1.

49. *Id.*

futile care over the course of the study.⁵⁰ The Centers for Medicare and Medicaid Services (CMS) conducted a study that further demonstrates how considerable the costs associated with futile care are on the already strained healthcare system.⁵¹ According to CMS, each year approximately \$107 billion of the \$446 billion Medicare and Medicaid budget is spent on aggressive life-sustaining procedures that prove to be futile.⁵²

These studies demonstrate how significantly futile procedures impact the healthcare system, including patients and their families. For example, the leading cause of bankruptcy is medical costs.⁵³ One example of futile care that may lead to bankruptcy is providing care to a patient who is in a persistent vegetative state as that care costs between \$40,000 and \$100,000 a year.⁵⁴

Futile care proponents incorrectly believe that the costs associated with futile care do not place a sizeable burden on the healthcare system.⁵⁵ They also argue that limiting treatments that a patient desires, based on cost, is an unethical method of rationing healthcare.⁵⁶ However, it is important to realize that stopping futile care is not rationing because rationing involves denying beneficial treatments, and futile treatments provide no benefits.⁵⁷ Further, based on how many people are currently uninsured, this argument

50. *Id.*

51. Cauvin, *supra* note 36 (In addition to the emotional and physical costs, there are the financial costs to society to be considered as we underwrite medically futile treatment.”).

52. *Id.* (“About 80% of that money is spent during the final month, often on mechanical ventilators, resuscitation and other aggressive life-sustaining care. More often than not, the aggressive steps taken to save someone’s life are futile.”).

53. Fine, *supra* note 12, at 310 (“Medical costs are the leading factor in bankruptcy.”).

54. *Id.* (discussing how there are between 10,000 and 100,000 patients in persistent vegetative states in the United States at any given time).

55. John Luce & Gordon Rubenfeld, *Can Health Care Costs be reduced by Limiting Intensive Care at End of Life?*, 165 AM. J. RESPIRATORY CRITICAL CARE MED. 750, 750 (2002) ([C]hanges in the use of expensive critical care resources near the end of life and efforts to reduce suffering are desirable, they are unlikely to yield significant cost-savings.”).

56. Kwiecinski, *supra* note 8, at 336; Ash & Arons, *supra* note 2, at 306 (“Some people find it unpleasant, even morally offensive, to contemplate how the economics of health care policy might affect end-of-life care.”).

57. Halevy & Brody, *supra* note 14, at 938 (“Rationing refers to the withholding of efficacious treatments which cannot be afforded. Futility refers to ineffective treatment.”).

is unpersuasive.⁵⁸ Lastly, providing futile care places strains on the facilities and physicians by increasing costs and using limited time and resources.⁵⁹ The negative impact that providing futile care has on the entire healthcare system, by using scarce monies and resources, demonstrates that futile care violates the bioethical principle of justice and should not be provided.

V. REDUCING FUTILE CARE IN ILLINOIS

The Illinois Health Care Right of Conscience Act (the Act) currently allows physicians to refuse to provide certain treatments.⁶⁰ However, the language of the Act is broad and does not directly address futile treatments.⁶¹ Instead, the Act states that providers will not be held liable for refusing to perform treatments that are contrary to their conscience.⁶² According to the Act, the conscience includes deeply held moral convictions that typically stem from a belief in God.⁶³

This language is problematic because it fails to protect physicians who believe that providing futile care violates their ethical duties as physicians.⁶⁴

58. There were 47 million uninsured Americans in 2012. *Key Facts about the Uninsured Population*, THE HENRY J. KAISER FAM. FOUND. (Sep. 26, 2013), <http://kff.org/uninsured/fact-sheet/key-facts-about-the-uninsured-population/>; In 2012 45 percent of Illinois residents were either uninsured or on some form of public insurance. *Health Insurance Coverage of the Total Population*, THE HENRY J. KAISER FAM. FOUND., <http://kff.org/other/state-indicator/total-population/>.

59. Hyunh et al., *supra* note 1; Nicholas Bakalar, *Risks: Futile Care at Life's End*, N.Y. TIMES, Sep. 17, 2013, at D6, available at http://well.blogs.nytimes.com/2013/09/11/futile-care-at-lifes-end/?_php=true&_type=blogs&_php=true&_type=blogs&_r=1.

60. 745 ILL. COMP. STAT. 70/4 (1998).

61. 745 ILL. COMP. STAT. 70/3(a) (1998) ("Health care" means any phase of patient care, including but not limited to, testing; diagnosis; prognosis; ancillary research; instructions; family planning, counseling, referrals, or any other advice in connection with the use or procurement of contraceptives and sterilization or abortion procedures; medication; or surgery or other care or treatment rendered by a physician or physicians, nurses, paraprofessionals or health care facility, intended for the physical, emotional, and mental well-being of persons.").

62. 745 ILL. COMP. STAT. 70/4 (1998).

63. 745 ILL. COMP. STAT. 70/3(e) (1998).

64. 22 ILL. PRAC., THE LAW OF MEDICAL PRACTICE IN ILLINOIS § 32:12 (3d ed.) ("This definition arguably limits the scope of the Act to decisions based on religious or closely

Further, in Illinois the language for the Power of Attorney for Health Care implies that a patient or his proxy can require futile treatments in all situations.⁶⁵ This language, when read with the Act, indicates that a patient or their proxy can require futile care even when the physician objects to the procedures on an ethical ground.⁶⁶

To protect physicians who do not wish to provide futile care, Illinois should adopt legislation that is analogous to Texas's Advanced Directive Act. Under the Advanced Directive Act, a physician can refuse to provide life-sustaining treatment so long as they provide the patient with a reasonable amount of time to transfer to another facility or physician that will provide the life-sustaining procedures.⁶⁷ The Advanced Directive Act provides the patient with procedures giving them a meaningful opportunity to contest the physician's decision.⁶⁸ Before a physician can stop life-sustaining treatment there is a review by an ethics or medical committee.⁶⁹ The patient receives notice of the time and procedures of the committee, can attend the meeting, and can receive a written explanation of the decision the committee reaches.⁷⁰ If the committee decides that treatment is futile and the patient or proxy still wants to pursue treatment the facility will assist the patient in transferring to a different facility and continue to provide the life-sustaining treatment for ten days.⁷¹ These procedures provide the patient with adequate options and protect both the physicians and healthcare facilities involved.⁷²

Illinois should adopt a policy that mirrors Texas's Advanced Directive

analogous beliefs, as opposed to professional ethical judgments.”).

65. 755 ILL. COMP. STAT. 45/4-10(b)(2) (1998) (“I want my life to be prolonged to the greatest extent possible in accordance with reasonable medical standards without regard to my condition, the chances I have for recovery, or the cost of the procedures.”).

66. 745 ILL. COMP. STAT. 70/3(e) (1998); 755 ILL. COMP. STAT. 45/3-10(b)(2) (1998).

67. TEX. HEALTH & SAFETY CODE ANN. § 166.045(c).

68. TEX. HEALTH & SAFETY CODE ANN. § 166.046.

69. *Id.*

70. *Id.*

71. *Id.*

72. *Id.*

Act so that physicians are not required to provide futile care that conflicts with their ethical beliefs regarding what healthcare is appropriate. Mirroring Texas's Advanced Directive Act will provide legal and moral safe harbors for Illinois physicians who want to stop providing futile treatments.⁷³ In addition to protecting physicians who believe that providing futile care violates their ethical duties, adopting a policy similar to the Texas Advanced Directives Act will reduce the burden on Illinois physicians and hospitals.

VI. CONCLUSION

Millions of Americans are unable to afford basic healthcare.⁷⁴ Public healthcare providers, such as Medicare and Medicaid, are already struggling financially, and this problem will continue to grow as the baby-boomers reach age sixty-five, drastically increasing the number of Medicare beneficiaries.⁷⁵ In light of the number of people without any health care, it is irresponsible to continue using scarce resources on valueless procedures. Futile services provide no benefit to the patient, the families, or the healthcare system.

Providing futile care violates all four basic bioethical principles.⁷⁶ Because providing futile services is ethically irresponsible, physicians should not be required to supply futile services when they find the services ethically objectionable. To address this dilemma, Illinois should follow Texas's

73. Robert L. Fine, *Medical Futility and the Texas Advanced Directives Act of 1999*, 13 BAYLOR UNIV. MED. CTR. PROC. 144, 146 (2000).

74. There were 47 million uninsured Americans in 2012. *Key Facts about the Uninsured Population*, THE HENRY J. KAISER FAM. FOUND. (Sep. 26, 2013), <http://kff.org/uninsured/fact-sheet/key-facts-about-the-uninsured-population/>.

75. Kenneth S. Baer & Jeffrey B. Liebman, *The Baby Boom Bump*, N.Y. TIMES, Dec. 7, 2012, at A39, available at http://www.nytimes.com/2012/12/07/opinion/the-baby-boom-bump.html?hp&_r=0.

76. OFFICE OF THE SEC'Y, U.S. DEP'T OF HEALTH & HUMAN SERVS., THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979), available at <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html> (The four bioethical principles are autonomy, beneficence, nonmaleficence, and justice.)

lead and change its legislation on futile care to mirror the Texas Advanced Directive Act in order to allow physicians to stop providing futile care that they find ethically objectionable.

Changing Illinois Medicaid Asset Recovery: What Does the Future Hold for Illinois?

*Carrie Classick**

I. INTRODUCTION

In 2013 the State of Illinois passed House Bill 26 that, beginning January 1, 2014, implemented the Patient Protection and Affordable Care Act (PPACA) in Illinois.¹ Two significant impacts of implementing the PPACA are: 1) expanded eligibility of Medicaid for non-elderly adults with incomes at or below 138 percent of poverty²; and 2) a health insurance mandate, requiring most people to have coverage, and issuing a financial penalty to those who do not.³ Illinois expects that between 500,000 and 800,000 new individuals will be covered under this expanded Medicaid program.⁴ In light of this change, one aspect of Medicaid that will need to be considered is Medicaid Estate Recovery.⁵ As health insurance is now required in order

* Juris Doctor Candidate, Loyola University Chicago School of Law, Class of 2015. Ms. Classick is a staff member of *Annals of Health Law*.

1. See The Kaiser Commission on Medicaid and the Uninsured, *How will the Uninsured in Illinois Fare Under the Affordable Care Act?*, THE HENRY J. KAISER FAM. FOUND. (Jan 6, 2014), <http://kaiserfamilyfoundation.files.wordpress.com/2014/01/8531-il.pdf>. According to the Supreme Court, Medicaid expansion was optional for states, with Illinois being one of the states to choose to implement the expansion. *Id.* The PPACA is also commonly referred to as the Affordable Care Act (ACA) or Obamacare.

2. *Id.* Historically, Medicaid eligibility was reserved only for specific low-income populations, including children, pregnant women, the elderly, and people with disabilities. *Id.* The expanded Medicaid eligibility is intended to fill the gaps in coverage for adults who did not previously fit into one of these categories, but who are low-income individuals. *Id.* One example of a newly eligible population is an adult without dependent children. *Id.*

3. *What if I don't have health coverage?*, HEALTHCARE.GOV., <https://www.healthcare.gov/what-if-i-dont-have-health-coverage/> (last visited Mar. 30, 2014).

4. *Health Care Reform in Illinois- What it Means to You*, ILLINOIS.GOV, <http://www2.illinois.gov/gov/healthcarereform/Pages/TheAffordableCareAct.aspx> (last visited Feb. 28, 2014).

5. See Virgin Dickson, *Reform Update: Medicaid estate-recovery law may hamper en-*

to avoid a penalty, is it unethical for the state to require enrollment in Medicaid and then recover from that recipient's estate upon his death.⁶ This article argues that because it is unethical to recover from the estates of the newly eligible population, Illinois should cut back their current aggressive recovery program. It instead should mirror Washington and Oregon in their efforts to minimize the impact of estate recovery on Medicaid recipients. This article will provide a brief overview of Medicaid and its intent, Section III will explore the Medicaid Recovery Act, focusing specifically on what changes Illinois implemented from the federal mandate, and finally the conclusion will discuss recommendations for Illinois moving forward.

II. MEDICAID

Enacted in 1965, Medicaid was established to provide medical care for low-income individuals with minimal assets.⁷ Prior to the PPACA, Medicaid eligibility was determined by both an income and assets test, where people who only had the very bare minimum of assets qualified.⁸ Under the PPACA, Medicaid eligibility changed and is now based solely on income and does not take into assets into consideration.⁹ As a result, the amount of recipients who are eligible for Medicaid will increase.¹⁰ It is shown that an

rollment efforts, MODERN HEALTHCARE (Feb. 25, 2014, 4:15 PM), <http://www.modernhealthcare.com/article/20140225/NEWS/302259964/reform-update-medicaid-estate-recovery-law-may-hamper-enrollment>. Though the law has not changed, it is unclear whether the states that have expanded Medicaid will seek to recover the assets of low-income residents who enroll in the expanded program. *Id.* States have been urged to not pursue estate recoveries against those who sign up for expanded Medicaid under the PPACA, but many states have not yet made their decision. *Id.*

6. *Id.*

7. See Office of Assistant Sec'y for Pol'y & Evaluation, *Medicaid Eligibility for Long-Term Care Benefits: Medicaid Liens*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (April 2005), <http://aspe.hhs.gov/daltcp/reports/liens.pdf> [hereinafter Medicaid Liens]. (stating "[t]he purpose of Medicaid program has been to provide medical care for very low incomes with limited assets.").

8. *Id.*

9. *Id.* This means that now, people who might have a house or other assets, but do not have an income (such as early retirees) could qualify for Medicaid. *Id.*

10. See Nancy Metcalf, *Will Medicaid take my house when I die?*, CONSUMERREPORTS.ORG (Jan. 27, 2014, 12:30PM), <http://www.consumerreports.org>

estimated seventy percent of people over the age of sixty-five will require long-term services throughout their lifetime.¹¹ With the cost averaging almost \$70,445 dollars a year for a private room in an Illinois nursing home, it is clear that many seniors will not have the savings to sustain this type of payment.¹² With more people eligible for services, paying for Medicaid and long-term care coverage is a topic that is on the minds of individuals as well as the Illinois State Government.¹³

III. MEDICAID ESTATE RECOVERY

Though Medicaid Estate recovery programs have been authorized since 1965 when Medicaid was enacted, the vast majority of states chose not to implement such a program.¹⁴ The 1965 Medicaid Law authorized liens to be placed on property, preventing property from being distributed to heirs until all claims, including Medicaid claims, had been satisfied.¹⁵ Almost thirty years later, in an effort to fund Medicaid, Congress included a provision in the Omnibus Budget Reconciliation Act of 1993 that required each state implement a Medicaid Estate Recovery program.¹⁶ This legislation required

/cro/news/2014/01/will-medicaid-take-my-house-when-i-die/index.htm.

11. See *The Basics*, LONGTERMCARE.GOV, <http://longtermcare.gov/the-basics/> (last visited February 28, 2014).

12. See *Genworth 2013 Cost of Care Survey*, GENWORTH (2013), https://www.genworth.com/dam/Americas/US/PDFs/Consumer/corporate/130568_032213_Cost%20of%20Care_Final_nonsecure.pdf. This is the average cost for Illinois in 2013, based on 365 days of care. Nationally, the Median Annual Rate was \$83,950, with residents in Massachusetts averaging \$133,225 annually for the same care. *Id.* Results were obtained by surveying 15,300 long term care providers in 437 regions nationwide. *Id.*

13. See Steve Moses, *The Long-Term Care Dilemma What States Are Doing Right- And Wrong*, THE COUNCIL FOR AFFORDABLE HEALTH INS. (Sept. 2004), http://www.cahi.org/cahi_contents/resources/pdf/LTCStudy2004.pdf. (stating that nursing homes are “financially stressed” and factors such as high employee turnover, staff shortages, inadequate compensation for caregivers, and that most assisted living facilities fill up too slowly to be profitable are all contributing to the imminent financial collapse of the country’s long-term care system).

14. See Office of Assistant Sec’y for Pol’y & Evaluation, *Medicaid Eligibility for Long-Term Care Benefits: Medicaid Estate Recovery*, U.S. DEP’T OF HEALTH & HUMAN SERVS. 1, 2 (2005) [hereinafter *Medicaid Estate Recovery*], <http://aspe.hhs.gov/daltcp/reports/estaterec.pdf> (stating that only twelve states had an estate recovery program before 1990).

15. *Id.*

16. *Id.* In addition to offsetting costs, reports claiming that estate recovery programs

that states try to recover money from the estates of individuals who received Medicaid services.¹⁷ Though federally mandated, estate recovery programs vary from state to state, ranging from programs that tap into estates to recover the cost of all Medicaid services to some states recouping only money for long-term care.¹⁸ Depending on the structure of the program and the tenacity with which the state seeks to recover funds, the annual amount of recovery has fluctuated from a low of \$86,000 in the state of Louisiana to a high of \$54 million in California.¹⁹ Oregon, for example, recovered \$41 million from about 8,900 people between July 2011 and June 2013.²⁰

This background is particularly important in order to understand the current state of Medicaid estate recovery and why it is unethical for Illinois to agree to expand its estate recovery to the newly eligible population.²¹ As part of the insurance mandates in the PPACA, there is a larger population of people who may face asset recovery.²² Currently, states have discretion in what they recover, but are allowed to recover all medical costs from a client

promote “more equitable treatment of Medicaid recipients”. *Id.*

17. Sandhya Somashekhar, *Little known aspect of Medicaid now causing people to avoid coverage*, WASH. POST (Jan. 23, 2014), http://www.washingtonpost.com/national/health-science/little-known-aspect-of-medicaid-now-causing-people-to-avoid-coverage/2014/01/23/deda52e2-794e-11e3-8963-b4b654bcc9b2_story.html.

18. See Sam Stein, *Medicaid Estate Recovery, Latest Obamacare Horror Story, Was Backed by ALEC*, THE HUFFINGTON POST, (Jan. 27, 2014,) http://www.huffingtonpost.com/2014/01/27/medicaid-estate-recovery-program-alec_n_4674277.html.

19. See Eugene Kiely, *Medicaid Estate Recovery Program*, FACTCHECK.ORG, <http://www.factcheck.org/2014/01/medicaid-estate-recovery-program/>. (last updated Jan 15, 2014). From a 2005 AARP report showing that in fiscal year 2003 states recovered a total of \$347.4 million dollars, .13 percent of the Medicaid spending for that year. *Id.*

20. See Somashekhar, *supra* note 17.

21. See Dickson, *supra* note 5. CMS issued a State Medicaid Directors Letter on February 23, 2014 saying that they would explore options to use Medicaid estate recovery only for long-term care cost recovery for those individuals who are newly eligible. *Id.* However, there is currently no policy stating that Illinois will follow these recommendations. *Id.*

22. See HEALTHCARE.GOV, *supra* note 3. If an individual does not have insurance, a financial penalty is calculated by either a lump sum of \$95 per person for the year, or 1% of yearly household income. *Id.* Once the penalty is paid, the person still does not have insurance, and will be required to pay their own medical costs, in addition to the penalty each year. *Id.*

after death.²³ States are allowed to recover from the new population of Medicaid recipients aged fifty-five to sixty-five.²⁴

IV. ELIGIBILITY IN ILLINOIS

Congress imposed no changes or new legislation regarding estate recovery after 1993 until the passing of the Deficit Reduction Act of 2005.²⁵ The Federal Deficit Reduction Act (DRA), passed at the Federal level in 2006, has been effective in Illinois since January 1, 2012.²⁶ These new rules provide key changes for Medicaid recipients receiving long-term care.²⁷ Though the program was intended only to recoup from long-term nursing home stays, states have the option to recover payment for medical services, which could include visits to the doctor, surgeries, and prescription drugs.²⁸

Though Illinois didn't implement the changes required under DRA until January 2012, they implemented changes beyond the federal requirements in July 2012 through the Save Medicaid Access and Resources Together (SMART) act.²⁹ While there were important changes in Illinois after the

23. See Dickson, *supra* note 5.

24. *Id.* Take a hypothetical example; Joe is a single adult who lives in State X, who retires at age 56 with a sizeable bank account, and a house. Joe has no salary now, and is eligible for Medicaid. Joe requires medical services, and Medicaid pays for those needs. When Joe dies, State X is able to recover the cost of his medical services by taking the money from Joe's estate, from his bank account, or his house. Currently, there is no federal guidance on this issue, but some states, like Washington and Oregon, have implemented policies which allow the states to only recover payments for long-term care, like nursing home stays. *Id.*

25. Diana Law & William Siebers, *New Long-term Care Medicaid Rules Finally Come to Illinois*, ILL. STATE BAR ASSOC. 1, 1 (Jan. 2012), available at <http://www.isba.org/sites/default/files/cle/William%20Siebers.pdf>.

26. *Id.* The Deficit Reduction Act was passed on a federal level on February 8, 2006. *Id.* Medicaid is a joint federal/state program, meaning that the DRA becomes effective not only after the Federal Government enacts the program, but also when the individual states adopt and the program. *Id.* Illinois was the 49th state to implement these new provisions, trailed only by California. *Id.*

27. *Id.* at 1-5.

28. Eryn Brown, *Loophole in healthcare law may put Medi-Cal patients' assets at risk*, L.A. TIMES (Feb 20, 2014, 9:51PM), <http://www.latimes.com/local/la-me-obamacare-cost-recovery-20140220,0,545100.story#ixzz2uYxLMYEW>.

29. William Siebers & Zach Hesselbaum, *Estate Planning, Paying for Long-Term Care in Illinois*, 100 ILL. ST. B. J. 536 (Oct. 2012), available at <http://www.isba.org/ibj/2012/10/payingforlongtermcareinillinois>, Public Act 97-0689 ("Save Medicaid Access and

SMART act, the basic Medicaid Eligibility Requirements remain the same.³⁰ To be eligible for long-term Medicaid Assistance in Illinois, applicants must meet basic criteria, including being a resident of Illinois³¹, age restrictions³², income limitations, and asset limitations.³³ The major changes implemented in response to the SMART Act were those relating to Medicaid eligibility rules for long-term care.³⁴ Significant changes impacting Medicaid recipients include modifications regarding community spouses³⁵, changes to homestead property, and perhaps most importantly, expanding the look-back period for asset transfers.³⁶

The Community Spouse Resource Allowance (CSRA) has been reduced to \$109,560, and the Community Spouse Monthly Maintenance Needs Allowance has been reduced to \$2,739.³⁷ This reduction means that if an ill spouse enters a nursing home for long-term care, the community spouse who is still at home can have non-exempt, also known as available, assets

Resources Together Act"). The Act was implemented in part to "impose controls on use of Medicaid services to prevent over-use or waste." Section 5.

30. *Id.*

31. ILL. ADM. CODE tit. 89 § 113.10 (stating the applicant must be a United States citizen).

32. ILL. ADM. CODE tit. 89 § 113.30 (stating the applicant must be 65 years of age or older to qualify, however, under the Affordable Care Act, applicants can be younger than 65).

33. *See* Law & Siebers, *supra* note 25, at 2. There are two categories of assets: exempt and available. *Id.* Available assets are those that are required to be liquidated and put towards the cost of care before an applicant can be eligible for Medicaid benefits, while exempt assets do not have an impact on Medicaid eligibility. *Id.*

34. *See* Anthony B. Ferraro, *Did we just get SACT? The SMART ACT of 2012—The unfolding implications and anecdotes*, 18,2 ILL. ST. B. ASS'N 1, 2 (Dec. 2012), available at <https://www.isba.org/sections/elderlaw/newsletter/2012/12/didwejustgetsactthesmartactof2012th>.

35. *See* Office of Assistant Sec'y for Policy & Evaluation, *Spouses of Medicaid Long-Term Care Recipients*, DEP'T OF HEALTH & HUMAN SERVS. (April 2005), <http://aspe.hhs.gov/daltcp/reports/spouses.pdf>. The community spouse, also known as the at-home spouse, is the spouse who remains in the community while the institutionalized spouse is the spouse who is receiving Medicaid long-term care services. *Id.*

36. *See* Ferraro, *supra* note 34.

37. *See* Constance B. Renzi, *And it's another curve ball- The SMART Act brings more changes to the Medicaid eligibility rules* 18, 1 ILL. ST. B. ASS'N Elder L. Section Council Newsletter 1, 3 (Sept. 2012). This is one instance in which a state has implemented a regulation in excess of the federal minimum required. *Id.* These numbers will remain in effect until Illinois amends the law, or the federal minimums required exceed Illinois's allowance. *Id.* Additionally, a court order can be issued to increase the allowances after a fair hearing. *Id.*

which amount to no more than \$109,560 in order to still have the ill spouse qualify for Medicaid benefits.³⁸ In addition, the SMART act eliminated a policy allowing a community spouse to refuse to disclose her assets, and this refusal to cooperate could result in denial of eligibility for the ill spouse.³⁹

The implementation of the SMART act also brought changes to home-
stead property.⁴⁰ When Illinois implemented the DRA, the home equity
equivalent amount was set to \$750,000.⁴¹ This rule meant that an individual
receiving long-term care services being paid for by Medicaid could keep his
home, even if nobody was living there, as long as the home value was less
than or equal to \$750,000.⁴² The SMART act drastically changed this rule,
reducing the home equity equivalent amount to the federal minimum of
\$525,000.⁴³ In addition, the SMART Act added a provision that any home-
stead property that was transferred to a trust would not be considered home-
stead property.⁴⁴ This provision results in a denial of Medicaid eligibility to
individuals who have homes in trusts that are not occupied by the Medicaid
applicant's spouse, minor child, or disabled adult child.⁴⁵

Under the new SMART Act, all asset transfers are subject to a sixty-
month look-back period, an increase from the previous thirty-six-month

38. See Ferraro, *supra* note 34.

39. *Id.* at 3; See also Siebers & Hesselbaum, *supra* note 29. Before this change, a community spouse who owned assets separate from the institutionalized spouse could decline to have those assets considered in the application process. *Id.* This situation is common amongst parties in a second marriage, where the spouses did not commingle assets upon marriage. *Id.*

40. See Ferraro, *supra* note 34, at 3.

41. *Id.* Homestead property is a property where no qualified person, including a community spouse, minor, blind, or disabled child is residing. *Id.*

42. *Id.*

43. *Id.*

44. *Id.* The SMART Act does not include a definition of the term trust, but it appears that the rule continues to treat property as exempt homestead property as long as a person's spouse, minor child, or disabled child resides in the property. *Id.*

45. See Ferraro, *supra* note 34, at 3.

look back period.⁴⁶ To qualify as a transfer for Medicaid purposes, there has to be a change in the way an asset is held, which includes selling or gifting assets.⁴⁷ Though there are allowable transfers with no penalty, transfers that are not allowable result in a penalty.⁴⁸ The penalty is normally calculated as the number of months of healthcare services that could have been paid with the money if the transfer had not been made.⁴⁹ The presumption is that transfers for less than fair market value are being done to spend down assets and qualify for Medicaid.⁵⁰ The transfer penalties were increased under the SMART Act by changing the old calculation of rounding to the nearest whole month to calculating the penalties by months, days, and even portions of days.⁵¹ Additionally, under the new rules, additional requirements and restrictions are implemented to qualify a transaction as an allowable transfer.⁵² Before the changes, seniors who received in-home assistance from friends or family were allowed to compensate their friends and family for the help, paying for the services they were providing.⁵³ Under the new rules, this type of help carries a presumption that the help should be given

46. See Law & Siebers, *supra* note 25, at 2. (defining look-back period as the time prior to the application for Medicaid that the state may review asset transfers and impose transfer penalties). Under pre-DRA law, a most asset transfers were subject to a 36-month look-back period, with some transfers from trusts extending to 60 months. *Id.* Under the new Illinois rules, all transfers to trusts and individuals are subject to the 60-month look-back period. *Id.*

47. *Id.* at 3.

48. *Id.*

49. *Id.* The most common allowable transfer is one in which there is an exchange for fair market value. *Id.* However, if an asset is gifted, like gifting money to a charity, and the applicant receives nothing in return, this is considered to be less than fair market value. *Id.* The penalty period is then determined by dividing the amount of the gift by the cost of the care the applicant would be receiving. *Id.* For example, a 10,000 gift to charity from an applicant that resides at a nursing home with a fee of \$2500 per month would have a 4 month penalty ($\$10,000 \text{ gift} / \$2500 \text{ private rate} = 4 \text{ months}$). *Id.*

50. See *Id.* However, a participant could rebut this presumption in certain circumstances, by showing the charitable gift was consistently made over a period of time before applying for Medicaid. *Id.* A charitable gift might then be considered “harmless” from a Medicaid perspective, and will not be subject to a penalty for the Medicaid applicant. *Id.*

51. *Id.* at 4. Showing the following example: If a “\$65,000 transfer for less than fair market value was made 4.5 years prior to the application (during the 60 month look-back period) and the average private pay rate is \$4,000 per month, the Medicaid eligibility would be $\$65,000 / \$4,000 = 16.25$ month penalty (16 month and 7.5 days). *Id.*

52. *Id.* at 3.

53. *Id.*

free of charge; and if the seniors do try to compensate their family for the help, that payment could still result in penalties.⁵⁴

V. ANALYSIS: WHAT ILLINOIS SHOULD DO

A. Illinois Should Return to the Pre-SMART Act Implementation to Allow Medicaid Recipients Greater Autonomy Regarding their Estate Planning Decisions

When Illinois brought their Medicaid rules for long-term care into compliance with the federal requirements, they not only met the federal minimums, but also expanded their reach and added additional hurdles for Medicaid enrollees.⁵⁵ Proponents of estate recovery argue that Medicaid is supposed to be a program for the poor, and they hope that states can spend their share of recovered funds to expand their Medicaid services for the truly needy population.⁵⁶ However, with solutions like estate planning, the bulk of assets that are recovered are from those individuals with minimal assets.⁵⁷ Taking a person's house after they die is an unethical way to pay for the care they received during life. In a nation-wide study that looked at data over a two year period, it was discovered that while the average state recovery increased by twenty-four percent, estate recovery only made a modest contribution to the state budget, moving from .61% to .63%.⁵⁸ The minimal impact to the state budget, however, has a huge impact to a family that lost a loved one, and now is faced with notices of liens and claims against the estate they thought they were receiving.⁵⁹ When Illinois changed

54. *Id.*

55. *Id.*

56. See Medicaid Estate Recovery, *supra* note 14, at 10.

57. *Id.*

58. See Erica F. Wood & Ellen M. Klem, *Protections in Medicaid Estate Recovery: Findings, Promising Practices, and Model Notices*, ABA COMMISSION ON LAW AND AGING v, xi (May 2007), available at http://199.237.228.160/reports/2007/2007_07_medicaid_protections.pdf. The amount of money that is collected through estate recovery programs represent between .01% and 2.09% of total state long-term expenditures paid for by Medicaid. *Id.* at v.

59. *Id.* at xi.

the federally mandated requirements for estate recovery and made it even harder for individuals to maintain their estate, they hurt the families and loved ones of Medicaid recipients who have recently died by taking away what little estate the departed had worked for.⁶⁰ Illinois should return to the federally mandated requirements outlined in the DRA and reverse the changes they implemented with the SMART act. This change will allow families to retain more of their estate after the death of a loved one while avoiding a confusing process and will not have a large financial burden on the state budget.⁶¹

B. Illinois Should Implement a Policy that Mirrors Oregon and Washington's Policies for Estate Recovery for the Newly Eligible Population under the PPACA

The PPACA's intent was to expand health care to reach all people and to encourage people to sign up for affordable insurance.⁶² However, there seems to be a conflict in policy because many people across the country are avoiding signing up for Medicaid because they fear they will have their assets seized after they die, leaving nothing to their family.⁶³ A Los Angeles Times article reported that a quarter of potential California Medicaid recipients walked away and did not enroll, citing the fact that they were worried about losing their estates upon their death.⁶⁴

To combat these fears, Oregon and Washington decided to recover only from the estates of beneficiaries who receive Medicaid payments for long-

⁵⁸ *Id.*

61. See Naomi Karp et al., *Medicaid Estate Recovery: A 2004 Survey of State Programs and Practices*, ABA COMM'N. ON LAW AND AGING 1, 17 (June 2005), available at http://assets.aarp.org/rgcenter/il/2005_06_recovery.pdf. A study in Ohio found that family members attempt to prevent their parents from accessing necessary services in light of Medicaid estate recovery provisions. *Id.*

62. See The Kaiser Commission on Medicaid and the Uninsured, *supra* note 1.

63. See Karp et al., *supra* note 61, at 19 (stating that people drop out of programs for low-income individuals when they hear about estate recovery, and that the notion of estate recovery discourages people from applying for Medicaid in the first place).

64. See Dickson, *supra* note 5. See also Brown, *supra* note 28.

term care support and services.⁶⁵ Oregon declared that for coverage beginning after October 1, 2013, members who do not receive long-term care services would not be subject to estate recovery.⁶⁶ Washington also now protects new Medicaid enrollees and limits recoveries to those who are in long-term care and have related costs.⁶⁷ Washington expects that this change will have a minimal financial impact on the state, which recovered approximately \$17 million in fiscal year 2013.⁶⁸

Currently, there is no guidance from the State of Illinois or the Federal Government regarding what recovery efforts will be made involving the estates of the newly eligible Medicaid population.⁶⁹ Policy experts do say it is unlikely that states will go after assets of Medicaid patients who are newly eligible, but without formal policy, there can be no certainty.⁷⁰ Newly eligible Illinoisans are left with uncertainty and ambiguity about whether or not the healthcare services they receive under their Medicaid plan will result in the state seizing their house upon their death to recoup the costs of their services.⁷¹ Therefore, to avoid additional confusion for the newly eligible population, Illinois needs to proactively follow the lead of Washing-

65. See Dickson, *supra* note 5. One example of a long-term care support facility is a nursing home. *Id.*

66. See *Estate Recovery and the Oregon Health Plan*, OR. HEALTH AUTH. (Nov. 27, 2013), <http://www.oregon.gov/oha/healthplan/OHPSuppDocs/Estate%20Recovery%20and%20the%20Oregon%20Health%20Plan.pdf>. Oregon changed their policy because they believe the estate recovery was not intended for people receiving services other than long-term care. *Id.* Oregon includes in the categorization of long-term care services care in a nursing home, community-based care, or full time assistance with daily living in an individual's own home. *Id.*

67. Dorothy F. Teeter et al., *HCA says state's recovery policy will be adjusted to protect new Medicaid enrollees*, WASH. ST. DEP'T OF SOC. AND HEALTH SERVS. (Dec 16, 2013), <http://www.hca.wa.gov/Releases/HCA%20news%20release%20-%20State%20Medicaid%20recoveries%2012-16-13.pdf>.

68. *Id.* Washington had previously only actively sought recovery from estates of Medicaid recipients who received long-term care services. *Id.* See Dickson, *supra* note 5. This is due to the high legal costs associated with recovery. *Id.*

69. Peter Frost, *Some Illinois Medicaid Patient's assets at risk*, CHI. TRIBUNE (Feb 5, 2014), http://articles.chicagotribune.com/2014-02-05/site/ct-medicaid-liens-illinois-biz-0205-20140205_1_health-insurance-expansion-health-care-law-provision.

70. *Id.*

71. *Id.*

ton and Oregon and limit the reach of the estate recovery for the newly eligible population.

VI. CONCLUSION

Recovering from the estate of a deceased person to recoup the medical costs they have received in their lifetime is a way for the state to pay for the mammoth costs they incur for Medicaid services.⁷² Though there are circumstances that warrant such a recovery, Illinois has gone beyond what seems fair and is targeting too broad of a population for recovery on too many services.⁷³ Illinois should return to the original recovery strategies as outlined in the DRA passed by the federal government, and it should not expand its reach beyond the federally mandated minimums. Returning to the federally mandated minimums will not have a large economic impact on the state, and it will allow Illinois residents to have control and certainty in understanding what they will pass along to their loved ones upon their death upon their death.⁷⁴ Illinois also should follow the lead of states such as Washington and Oregon, which recognize the potential harm estate recovery for all Medicaid services could have on newly eligible Medicaid enrollees and limit the Medicaid estate recovery only to recipients of Medicaid long-term care.⁷⁵

72. See Medicaid Liens, *supra* note 7, at 10. Medicaid estate recovery continues to evolve as states are trying to cope with ever growing deficits in their budgets. *Id.*

73. *Id.*

74. See Medicaid Estate Recovery, *supra* note 14, at 3 (stating that in 2003, estate recovery amounted to 0.13% of total Medicaid spending in all states).

75. See generally Teeter et al., *supra* note 67

Mandatory Physician Reporting of Gunshot
Wounds: A Chicago Perspective

*Chris Conway**

I. INTRODUCTION

Respect for patient privacy and confidentiality are affirmatively stated by every practicing physician when they take the famous Hippocratic Oath, asserting they will not spread what they see or hear during the course of treatment.¹ While the words of this oath allude to an absolute protection of patient confidentiality, in reality there are many exceptions where the law places a duty upon healthcare professionals to disclose patient information.² One such exception in Illinois is the Criminal Identification Act (the Act), which requires healthcare professionals to notify local law enforcement of a person requesting treatment for any injury resulting from the discharge of a firearm.³ This law weighs the duty owed to the patient in respecting per-

* Juris Doctor Candidate, Loyola University Chicago School of Law, Class of 2015. Mr. Conway is a staff member of *Annals of Health Law*.

1. John C. Moskop et al., *From Hippocrates to HIPAA: Privacy and Confidentiality in Emergency Medicine—Part I: Conceptual, Moral, and Legal Foundations*, 45 ANNALS EMERGENCY MED. 53, 53 (2005) (“What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself, holding such things shameful to be spoken about”) (quoting ENCYCLOPEDIA OF BIOETHICS 2632 (Reich WT ed., 1995)).

2. See Malkeet Gupta, *Mandatory Reporting Laws and the Emergency Physician*, 49 ANN. EMERGENCY MED. 369, 373 (2009) (41 states and the District of Columbia have mandatory reporting laws from injuries from weapons, while nine states do not have a mandatory reporting law).

3. 20 ILL. COMP. STAT. ANN. 2630/3.2(1) (2013) (“It is the duty of any person conducting or operating a medical facility, or any physician or nurse as soon as treatment permits to notify the local law enforcement agency of that jurisdiction upon the application for treatment of a person who is not accompanied by a law enforcement officer, when it reasonably appears that the person requesting treatment has received: (1) any injury sustained from the discharge of a firearm; or (2) any injury in the commission of or as a victim of a criminal offense.”).

sonal autonomy and privacy against the societal duty of public safety through mandatory police involvement, raising conflicting ethical concerns for physicians.⁴ This article argues that mandatory reporting of gunshot wounds may appear beneficial in theory, but not effective when practiced in a city like Chicago where community members have widespread distrust of the police.

In Section II, this article will discuss the historical and legal basis of breaching patient confidentiality to protect the general public. Section III will explore the counter argument in favor of absolute confidentiality as a necessary procedure in order to maintain patient safety and trust. Finally, Section IV will examine these different opinions on patient confidentiality through the lens of the murder problem in Chicago and explains why the negative aspects of the law outweigh the potential benefits.

II. THE HISTORICAL AND LEGAL BASIS FOR MANDATORY REPORTING

Patient privacy and confidentiality are professional responsibilities of physicians.⁵ To protect confidentiality and privacy is to respect the human dignity of a patient and recognize that patients have intrinsic moral worth.⁶ Privacy is a broader concept that envelopes physical seclusion, protection of personal information, identity, and the ability to make personal choices without interference.⁷ Confidentiality refers to the duty not to disclose patient information without first obtaining the patient's consent.⁸ Physicians not only have an ethical professional duty to not disclose patient infor-

4. See A. Frampton, *Reporting of gunshot wounds by doctors in emergency departments: A duty or a right? Some legal and ethical issues surrounding breaking patient confidentiality*, 22 EMERGENCY MED. J. 84, 85 (2005); Stephen W. Hargarten & Joseph F. Weackerle, *Docs and Cops: A Collaborating or Colliding Partnership?*, 38 ANNALS EMERGENCY MED. 438, 439 (2001).

5. Moskop et al., *supra* note 1 ("Respect for patient privacy and confidentiality has been affirmed as a professional responsibility of physicians since antiquity").

6. Joel Martin Geiderman & John C. Moskop, *Privacy and Confidentiality in Emergency Medicine: Obligations and Challenges*, 24 EMERGENCY MED. CLINICS N. AM. 633, 635 (2006).

7. *Id.* at 634.

8. *Id.*

mation without proper consent, but they are also members of society, having a duty as citizens to further public safety.⁹ If physicians act in a way that breaches their professional code, these actions may bring shame, guilt, and regret, even if the breach was in furtherance of their duty as citizens and wards of public health.¹⁰ On the other hand, if a physician fails to take necessary steps to prevent foreseeable injury, he must live with the consequences both personally and in the community, potentially receiving severe criticism from the general public.¹¹

A modern example of these prevailing pressures was highlighted in *Tarasoff v. Regents of the University of California*.¹² In this case, a student at the University of California, Berkeley confided in a university psychologist that he intended to kill a young woman who spurned his affections.¹³ The psychologist decided to breach patient confidentiality and alert the campus police, who briefly detained the patient and then set him free.¹⁴ Shortly thereafter, the patient stabbed the young woman to death.¹⁵ In a landmark decision, the Supreme Court of California held that the psychologist's breach of confidentiality was warranted, and doctor-patient confidentiality is limited by the possibility of public danger.¹⁶ Since this decision, United States courts broadened the acceptable breach of patient confidentiality to situations where there is an identifiable victim, allowing physicians to warn relevant authorities of a patient's general violent tendencies.¹⁷

The *Tarasoff* opinion paved the way for physician mandatory reporting

9. Frampton, *supra* note 4.

10. Michael H. Kottow, *Medical confidentiality, an intransigent and absolute obligation*, 12 J. MED. ETHICS, 117, 118 (1986).

11. Frampton, *supra* note 4.

12. *Tarasoff v. Regents of Univ. of Cal.*, 551 P.2d 334 (Cal. 1976).

13. *Id.* at 339.

14. *See id.*

15. *Id.*

16. *Id.* at 347 (“[t]he protective privilege [of doctor-patient confidentiality] ends where the public peril begins”).

17. Frampton, *supra* note 4, at 86.

of gunshot requirements such as Illinois' Act.¹⁸ As of 2006, forty-one states and the District of Columbia had laws requiring physicians to report to the police any injuries sustained from the discharge of a firearm.¹⁹ The rationale oftentimes asserted is that physicians are in the business of public safety and injury prevention, and these laws are tailored to those ends.²⁰ Because the patient is not accused of a crime, advocates believe that the reporting of gunshot victims will not lead to patient's refusing to seek medical care.²¹ Empirical evidence supports the notion that victims of domestic violence are not deterred from seeking medical attention based on mandatory reporting laws.²² There is no similar study conducted to determine if mandatory reporting of gunshot wounds deters patients from seeking medical attention.

The law aims to reflect an ethical consensus that society is willing to enforce through civil and criminal sanctions.²³ In this vein, laws can be seen as the common ethos of American society, making it the proper domain to resolve controversial medically ethical issues.²⁴ The notion that the law and broad public health concerns trumps other ethical concerns is found in modern medicine decrees such as the Code of Ethics of the American College of Emergency Physicians, which says emergency physicians shall only disclose confidential patient information with consent or when required by

18. See Gupta, *supra* note 2.

19. *Id.*

20. See Howard Ovens, *Why mandatory reporting of gunshot wounds is necessary: A response from the OMA's Executive of the Section on Emergency Medicine*, 170 CAN. MED. ASS'N J. 1256, 1257 (2004).

21. *Id.*

22. Debra Houry et al., *Mandatory Reporting Laws Do Not Deter Patients From Seeking Medical Care*, 34(3) ANNALS EMERGENCY MED. 336, 339 (1999) (In a Colorado study, 62% of respondents said that the law would make no difference in the health care seeking behavior, and 27% said the law made them more likely to seek help. *Id.* Only 12% stated that the law would make them less likely to seek care). *Id.*

23. Arthur R. Derse, *Law and Ethics in Emergency Medicine*, 17 EMERGENCY MED. CLINICS N. AM. 307, 312 (1999).

24. *Id.* at 313.

an overriding societal duty.²⁵ While the Hippocratic Oath may be seen as a triumphant declaration of the protection of patient confidentiality over all other considerations, the modern trend shows that this protection is not without limits.²⁶

III. THE OTHER SIDE OF THE COIN: MEDICAL CONFIDENTIALITY VIEWED AS AN ABSOLUTE

Though the modern legal trend seems to support the breach of patient confidentiality in defense of public safety, many contrarians believe it to be a dangerous practice.²⁷ Opponents quickly point out that just because breach of patient confidentiality is required by law does not make it morally right.²⁸ The opposition finds mandatory reporting requirements to be directly contrary to the core values physicians practice.²⁹ The core values of trustworthiness, beneficence toward the patient's health needs, and respect for patient autonomy are not just values that doctors care about, but also are what the general public wants doctors to care about.³⁰ Patient confidentiality is both a moral desire and an interpersonal communication strategy that is foundational to the medical profession.³¹ Patients seek medical attention in order to get well and must trust that their physicians intend to achieve the same goal.³² The interactions between patients and physicians are nurturing and curative, while the interactions between police and victims are inquisi-

25. Moskop et al., *supra* note 1 (“[e]mergency physicians shall respect privacy and disclose confidential information only with consent of the patient or when required by an overriding duty such as the duty to protect others or to obey the law”) (*quoting* AM. C. OF EMERGENCY PHYSICIANS, CODE OF ETHICS FOR EMERGENCY PHYSICIANS (2003)).

26. *See id.*

27. *See* Kenneth Kipnis, *A Defense of Unqualified Medical Confidentiality*, 6 AM. J. BIOETHICS 7, 16 (2006) (doctor's breaching confidentiality does not prevent public peril, but only erodes patient confidence); *see* Kottow, *supra* note 9 at 117 (the benefits of breaching confidentiality do not overcome the harms to patients).

28. Frampton, *supra* note 4.

29. Kipnis, *supra* note 27.

30. *Id.* at 11-12.

31. Kottow, *supra* note 9, at 117.

32. Merrill A. Pauls & Jocelyn Downie, *Shooting ourselves in the foot: why mandatory reporting of gunshot wounds is a bad idea*, 170 CAN. MED. ASS'N J. 1255, 1256 (2004).

tive and correctional;³³ blurring these two exchanges upsets patient confidence.³⁴ If physicians are viewed as an extension of the police, patients may have difficulty in revealing intimate medical details such as drug use, sexual practices, and acts of violence.³⁵ Because of this concern, mandatory reporting laws make it less likely that vulnerable populations will seek medical help when necessary.³⁶

Opponents of mandatory reporting laws argue that these provisions do not achieve their intended goal of protecting the general public health and in fact, directly harm the patient whose confidentiality was breached.³⁷ Little data has been presented to demonstrate that mandatory reporting laws lead to curbing criminal activity.³⁸ Anecdotal evidence pertaining to mandatory reporting of domestic abuse cases reveals that some women are concerned that these types of laws infringe on their personal autonomy and believe they should retain sole control over the decision to involve the police.³⁹ Reliable data is difficult to gather on embarrassing, criminal, or irresponsible behavior.⁴⁰ Therefore, the chilling effect of mandatory reporting cannot be accurately stated, and is likely more significant than currently understood.⁴¹ With this in mind, preservation of confidentiality is the only way of securing public health.⁴² Protecting a patient's confidentiality who seeks care with a gunshot wound makes it more likely for a patient to tell all relevant health information to his physician.⁴³ Thus, absolute confidentiality allows

33. Hargarten & Waeckerle, *supra* note 4.

34. *Id.*

35. Pauls & Downie, *supra* note 32, at 1255-56.

36. See Kipnis, *supra* note 27, at 16.

37. See Pauls & Downie, *supra* note 32, at 1255-56.

38. Hargarten & Waeckerle, *supra* note 4.

39. Michael A. Rodriguez et al., *Patient Attitudes About Mandatory Reporting of Domestic Violence: Implications for Health Care Professionals*, 169 W. J. MED. 337, 340 (1998).

40. See Kipnis, *supra* note 27, at 14.

41. See *id.*

42. Frampton, *supra* note 4.

43. Kipnis, *supra* note 27, at 15.

doctors to complete their best work, increasing public safety.⁴⁴

Exception-less confidentiality is the only way to prevent harm to a patient who otherwise would be subject to investigation and constraints.⁴⁵ Physicians are not instrumental in deciding or carrying out preventative actions, as their duties remain in the clinical realm and not the political arena.⁴⁶ It is improper for physicians to enter the political arena by informing police of patient injuries because it is an act beyond the core values patients rely on when seeing a doctor.⁴⁷ The harm mandatory reporting laws intend to avert by involving the police without patient consent is only potential harm, while breaches of confidentiality directly and immediately harm a patient.⁴⁸

IV. EYES TOWARD THE MURDER CAPITAL

The Act requires healthcare employees to report an injury sustained from the discharge of a firearm as soon as treatment permits.⁴⁹ The Act intends to further public safety by requiring some basic information, such as the patient's identity and nature of the injury.⁵⁰ An Illinois Appellate Court found in *People v. Hillsman* that a patient does not have a reasonable expectation of privacy in emergency rooms because police presence is an obvious consequence of the Act.⁵¹ Consequently, any Chicago resident that receives medical treatment for a gunshot wound can reasonably expect to be paid a visit by the police while recuperating.⁵²

Police visits to recovering gunshot wound victims is a regular occurrence in Chicago, as the city was deemed the murder capital of America by a

44. *See id.* at 16.

45. *See Kottow, supra* note 9.

46. *Id.* at 120.

47. *See id.*

48. *See id.*

49. 20 ILL. COMP. STAT. 2630/3.2(1) (2013).

50. *People v. Kucharski*, 806 N.E.2d 683, 688 (Ill. App. Ct. 2004).

51. *People v. Hillsman*, 839 N.E.2d 1116, 1125 (Ill. App. Ct. 2005).

52. *See id.*

2013 Federal Bureau of Investigations (FBI) report.⁵³ Murders in Chicago followed the national downward trend in the 1990s, but rates declined in Chicago at a slower rate than other major cities.⁵⁴ Of the total murders committed in 2009, roughly eighty-two percent of Chicago homicides were committed with a firearm.⁵⁵ Aggregate studies based on police studies show that rates of violent crimes are highest among disadvantaged communities that contain large concentrations of minority groups, consolidating murders to a few Chicago districts.⁵⁶ This focused police presence in specific districts led to approximately seventy-five percent of Chicago murder arrests targeting African Americans in 2009.⁵⁷

Studies show that the murder rate in major cities dropped during the 1990s based on factors such as increases in the number of police and rising prison population, while different police strategies and gun control laws had no effect.⁵⁸ Specifically in Chicago, the lowest murder rate since the early 1960s was achieved in 2012 partially because of an increased police presence in twenty small zones deemed most dangerous, and dampened retaliatory gang shootings through comprehensive analysis of the city's gang

53. Reid Wilson, *FBI: Chicago passes New York as murder capital of U.S.*, WASHINGTON POST (Sept. 18, 2013, 9:00 AM), <http://www.washingtonpost.com/blogs/govbeat/wp/2013/09/18/fbi-chicago-passes-new-york-as-murder-capital-of-u-s/> (500 murders occurred in Chicago in 2012, the highest city total in the nation).

54. See Erica Haft & Colin Johnson, *Background Memo on Homicide Tracking in Chicago and Cook County*, NORTHWESTERN SCHOOL OF LAW (July 2011), <http://illinoismurderindictments.law.northwestern.edu/docs/Homicide-Trends-in-Chicago-and-Cook-County.pdf>.

55. *Id.*

56. Robert J. Sampson et al., *Social Anatomy of Racial and Ethnic Disparities in Violence*, 95 AM. J. PUB. HEALTH 224, 224 (2006); see Haft & Johnson, *supra* note 54.

57. Haft & Johnson, *supra* note 54.

58. See Steven D. Levitt, *Understanding Why Crime Fell in the 1990s: Four Factors that Explain the Decline and Six that Do Not*, 18 J. ECON. PERSP. 163, 163, 172-74, 176-79 (2004) (The four factors cited that explained the decline in crime were: increases in the number of police, the rising prison population, the receding crack epidemic, and the legalization of abortion. *Id.* at 176-81. Six factors that played little or no role in the crime decline were: the strong economy of the 1990s, changing demographics, better policing strategies, gun control laws, laws allowing the carrying of concealed weapons, and the increased use of capital punishment. *Id.* at 170-75).

members.⁵⁹ Community-oriented programs such as part-time jobs for the city's disadvantaged youth also saw positive results in reducing gun violence.⁶⁰ Though the murder rate dropped, police solved only thirty percent of the shooting homicides and twenty percent of the nonfatal shootings in 2012.⁶¹ Police cite the difficulty to find witnesses willing to discuss violent events as the main reason a large majority of the city's gun-related crimes remain unsolved.⁶² Witnesses fall silent even when they have information about gun-related crimes for fear of retribution from gang members.⁶³ For example, on April 12, 2012, seventeen year-old Robert Tate was fatally shot in the chest, but refused to cooperate with police in his dying minutes even though he knew the identity of the shooter.⁶⁴ While gang culture plays a role in witness silence, community members and experts agree there is a deep seeded mistrust of police because they have not created an atmosphere that encourages residents to come forward and cooperate with them in solving crimes.⁶⁵

59. Monica Davey, *Chicago Tactics Put Major Dent in Killing Trend*, NEW YORK TIMES (June 11, 2013), available at http://www.nytimes.com/2013/06/11/us/chicago-homicides-fall-by-34-percent-so-far-this-year.html?pagewanted=all&_r=0.

60. Stephanie Kollmann & Dominique D. Nong, *Combating Gun Violence in Illinois: Evidence-Based Solutions*, NORTHWESTERN SCHOOL OF LAW 6 (October 17, 2013), <http://www.law.northwestern.edu/legalclinic/cfjc/documents/Gun%20Violence%20Memo%20-%20Final.pdf>. Chicago has implemented One Summer Plus (OSP), which provides part-time jobs to youth from high-violence neighborhoods for seven weeks during the summer. *Id.* The University of Chicago Crime lab has found "convincing evidence than OSP was highly successful in reducing violence among adolescents[.]" *Id.*

61. David Schaper, *In Chicago, Violence Soars and Witnesses Go Silent*, NPR (Nov. 13, 2012, 3:32 AM), <http://www.npr.org/2012/11/13/163242604/in-chicago-violence-soars-and-witnesses-go-silent>.

62. *Id.*

63. Frank Main, *Police: Even while dying, teen won't talk*, CHICAGO SUN-TIMES (April 18, 2011, 6:03 PM), <http://www.suntimes.com/pulitzer/4903883-582/police-even-while-dying-teen-wont-talk.html> (many neighborhoods have the motto that: "[s]nitches get stitches[.]" and citizens fear retribution from community members more than police criminal investigations); Schaper, *supra* note 61.

64. Main, *supra* note 63.

65. Schaper, *supra* note 61. "It's that they don't trust police officers"—54 year-old Sherman Smith. *Id.* "Police patronize you, man. Police over here, they don't protect and serve. They patronize. . . The only thing I can really think of that would help the community really is if the police are more hands-on in serving and protection, you know what I'm saying? If they walk the streets and get to know people[.]"—21 year-old Joenathan Woods. *Id.*

Chicago's murder rate raises significant public health and safety concerns, and ideally these concerns could be alleviated by mandatory reporting requirements of gunshot wounds.⁶⁶ These ideal conditions are unattainable in the practical world and are not supported by quantitative crime reduction facts.⁶⁷ Advocates for mandatory reporting of gunshot wounds make the unsupported claim breach of patient confidentiality is justified because these laws protect general public safety.⁶⁸ They claim mandatory reporting of gunshot wounds can reduce crime by allowing police to quickly identify victims, mobilize investigation efforts, and establish a presence in endangered areas.⁶⁹

The problem is that this hypothetical scenario is not supported by anecdotal data from community members or hard police data in Chicago.⁷⁰ Mandatory reporting of gunshot wounds may be a misguided policy that harms the community more than it helps it due to the erosion of patient confidence.⁷¹ Police presence at emergency rooms without patient consent quickly turns a trustworthy and nurturing environment into an inquisitive and confrontational environment.⁷² If gunshot victims are wary of police investigation into the events, they may think twice before seeking medical treatment.⁷³ If a victim refuses to seek medical attention because of police exposure, the physician's goal of patient care and the police's goal of public safety are both negatively impacted.⁷⁴ Threatened minority communities

"The police are responsible for creating an atmosphere in a community that encourages residents to come forward and cooperate with them in solving crimes[.]"—Criminologist Art Lurigio.

66. See Owens, *supra* note 20.

67. See Davey, *supra* note 57; Levitt, *supra* note 58, at 172; Main, *supra* note 63; Schaper, *supra* note 61.

68. See Owens, *supra* note 20.

69. See *id.*

70. See Davey, *supra* note 57; Levitt, *supra* note 58, at 172; Main, *supra* note 63; Schaper, *supra* note 61.

71. See Pauls & Downie, *supra* note 32, at 1255-56.

72. See Hargarten & Waeckerle, *supra* note 4.

73. See Kipnis, *supra* note 27, at 16.

74. See generally *id.*

already have a general distrust of law enforcement due to their belief that they use abrasive tactics, and police involvement without patient consent may proliferate this feeling.⁷⁵ Law enforcement individuals may be better served by building trust organically through increased community involvement and fostering an atmosphere of cooperation.⁷⁶ Physicians breaching gunshot victims' confidentiality by giving such information to the police may also cause the general distrust of law enforcement.⁷⁷ Victims may view mandatory reporting as a partnership between police and physicians against impoverished minority communities.⁷⁸

If distrust of physicians is harbored within a community, it may have a chilling effect on patients seeking care for other sensitive issues such as drug use, sexual diseases, or violence not involving firearms.⁷⁹ The general public health of communities may be harmed if patients do not trust physicians enough to seek care when they need it or feel they must guard private information in a doctor-patient relationship to avoid police involvement.⁸⁰ Additionally, despite mandatory reporting of gunshot wounds being law for over twenty years, gunshot related crimes are being solved at historically low rates.⁸¹ These statistics indicate that mandatory reporting may not lead to significant amounts of arrests.⁸² Legislatures and the Chicago Police Department would be well-served to look for alternative methods to increase law enforcement effectiveness.⁸³ Physician-patient confidentiality is imperative to patient confidence and thus the success of medical treatments.⁸⁴ In an environment like Chicago where community members distrust police

75. See Schaper, *supra* note 61.

76. *Id.*

77. See Kottow, *supra* note 9.

78. See *id.*

79. See Pauls & Downie, *supra* note 32.

80. See Frampton, *supra* note 4.

81. See Schaper, *supra* note 61.

82. See *id.*

83. See Main, *supra* note 63.

84. See Kottow, *supra* note 9.

and their tactics, forcing physicians to act as an extension of the police through mandatory reporting of gunshot wounds is not ethically valid.⁸⁵ Based on poor results⁸⁶ and the potentially negative community effects that breaches of confidentiality bring,⁸⁷ mandatory reporting of gunshot wounds may not be a worthwhile policy.⁸⁸

V. CONCLUSION

Patient confidentiality and protection of public safety are both important goals that physicians value. Mandatory reporting of gunshot wounds that require physicians to breach patient confidentiality to protect the general public may be feasible in theory,⁸⁹ but when viewed in light of community dynamics in Chicago, where distrust of the police is deeply seeded in at-risk communities,⁹⁰ the law may do more harm than good.⁹¹

Respect for patient privacy should be paramount when dealing with gunshot wound patients.⁹² The ethical concerns raised by the Act that affect the patient directly are not outweighed by the potential societal benefits.⁹³ Historically low gun crime solving rates show that the Act has not proven effective, and different tactics should be implemented by Chicago police.⁹⁴ The Hippocratic Oath taken by physicians should be upheld without exception when dealing with gunshot victims.

85. *See id* at 117.

86. *See* Schaper, *supra* note 61.

87. *See* Pauls & Downie, *supra* note 32, at 1255-56.

88. *See* Kipnis, *supra* note 27.

89. *See* Ovens, *supra* note 20.

90. *See* Schaper, *supra* note 61.

91. *See* Kipnis, *supra* note 27.

92. *See* Kottow, *supra* note 9.

93. *See* Kipnis, *supra* note 27.

94. *See* Shaper, *supra* note 61.

Trading One Epidemic for Another: Child
Immunization Waivers and the Fight Against
Evading Stricter Waiver Requirements

Annette Wojciechowski*

I. INTRODUCTION

The Centers for Disease Control and Prevention (CDC) deems immunizations a successful public health intervention in preventing morbidity, mortality, and healthcare costs.¹ One of the methods used to control the number of vaccine-preventable diseases is mandating immunizations for children entering the school system.² Instead of being federally mandated, all laws requiring vaccinations are made at a state or local level.³ All fifty states allow for exemptions to vaccinations for medical reasons,⁴ and forty-eight states allow exemptions to vaccinations for religious reasons.⁵ As of

* Juris Doctor Candidate, Loyola University Chicago School of Law, Class of 2015. Ms. Wojciechowski is a staff member of *Annals of Health Law*.

1. See Ctrs. for Disease Control and Prevention, *Ten Great Public Health Initiatives*, 60 MORBIDITY AND MORTALITY WEEKLY REPORT 605, at 619 (2011), available at <http://www.cdc.gov/mmwr/pdf/wk/mm6019.pdf>; Daniel A Salmon, PhD, MRH, *Mandatory Immunization Laws and the Role of Medical, Religious and Philosophical Exemptions* (Oct. 2003), <http://www.vaccinesafety.edu/exemptreview101503.pdf>.

2. Salmon, *supra* note 1.

3. *Id.*

4. Proof of a medical exemption requires a form of a signed statement by a Medical Doctor or Doctor of Osteopathy (D.O.) which explains that the administration of one or more vaccines would be detrimental to the health of the individual. *Vaccine Laws*, NAT'L VACCINE INFO. CTR. (2013), <http://www.nvic.org/vaccine-laws.aspx#> (last visited Mar. 30, 2014) [hereinafter NAT'L VACCINE]. Most doctors use forms provided by The American Academy of Pediatrics or the CDC or similar forms. *Id.* Most states do not allow a D.O. to write medical exemptions to immunizations. *Id.* Additionally, some states allow for a private physician's written exemption and often review the doctor's exemption and revoke it if health department officials do not believe the exemption is justified. *Id.*

5. *States with Religious and Philosophical Exemptions from School Immunization Requirements*, NAT'L CONF. OF STATE LEGISLATURES (2012), <http://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx> [hereinafter NAT'L

December 2012, nineteen states allow exemptions to children whose parents have philosophical or personal belief objections to immunizations.⁶

In states like California that have looser vaccination requirements, a rise in outbreaks of vaccine-preventable infections and diseases, such as whooping cough and measles, is occurring.⁷ To combat the increasing numbers of unimmunized children in the state, states such as California have passed legislation to make it more difficult for a parent or guardian to receive a personal belief vaccination exemption for their child.⁸ However, the rise in retail clinics offering the ability to sign immunization waivers diminishes the effort toward creating tighter vaccination exemption laws.⁹

Ultimately, the increase in unvaccinated individuals in the United States poses a public health concern that is more important than a parent's person-

CONF., *States*]. Mississippi and West Virginia are the two states that do not allow exemptions to vaccinations for religious reasons. *Id.*

6. NAT'L CONF., *States*, *supra* note 5. Philosophical exemptions are more commonly known as personal belief exemptions. Ben Kleifgen & Justin Silpe, *Vaccination Requirements and Exemptions*, THE GREENWALL FOUND., http://www.vaccineethics.org/issue_briefs/requirements.php (last updated July 2010). These nineteen states which allow personal belief exemptions are Arkansas, Arizona, California, Colorado, Idaho, Louisiana, Maine, Michigan, Minnesota, Missouri, North Dakota, Ohio, Oklahoma, Pennsylvania, Texas, Utah, Vermont, Washington, and Wisconsin. NAT'L CONF., *States*, *supra* note 5. The Missouri philosophical or personal exemption applies only to daycare, preschool and nursery school. *Id.* In addition, some states will allow exemptions to vaccinations for certain diseases if proof of immunity can be shown to exist. NAT'L VACCINE, *supra* note 4. Immunity can be proven if the parent or the child has had the natural disease or has been vaccinated for it, or if a blood test proves that there is a high enough level of antibodies in the blood. *Id.*

7. See Gabriela Quirós, *Health Officials to Consider Tightening Vaccine Exemption*, KQED (Oct. 13, 2010), <http://science.kqed.org/quest/2010/10/13/health-officials-to-consider-tightening-vaccine-exemptions/>. In 2013, 189 people in the U.S. were reported to have measles, compared to the average of sixty cases per year. CENTERS FOR DISEASE CONTROL AND PREVENTION, *Measles Outbreaks*, <http://www.cdc.gov/measles/outbreaks.html> (last updated Jan. 14, 2014) [hereinafter CDC]. This represented the second largest number of cases in the U.S. since measles was eliminated in 2000. *Id.* About twenty-eight percent of these individuals unvaccinated for measles contracted the disease from travelling abroad, infecting others back in the U.S. *Id.*

8. Amy Norton, *States May Be Getting Stricter on Child Vaccine Exemptions*, HEALTHDAY (Feb. 11, 2014), <http://consumer.healthday.com/caregiving-information-6/infant-and-child-care-health-news-410/states-may-be-getting-stricter-on-vaccine-exemptions-684784.html>.

9. See Diana Lambert, *Clinic opens for parents who oppose vaccinating children*, THE SACRAMENTO BEE (Dec. 18, 2013), available at <http://www.sacbee.com/2013/12/18/6012620/clinic-opens-for-parents-who-oppose.html>.

al belief against vaccinating his or her child.¹⁰ However, there should be an exemption to the general rule mandating all children to get vaccinated if there is a medical or religious reason against doing so, as long as parents are properly educated on the risks of not vaccinating their children. California's attempt to pass laws to decrease personal exemptions from vaccinations serves as an example of good intentions that nevertheless fall short.¹¹ This article argues that there is a disconnect between states' general push toward vaccinating children versus the infringement upon a parent's autonomy to make personal decisions on behalf of his or her own child. This article also argues that the lack of regulation amongst retail clinics may begin to obstruct state resolutions to combat vaccine-preventable diseases amongst its population. Section II will analyze how the rise in personal belief exemption waivers contributes to the recent whooping cough epidemic in California, and it will analyze how a general mistrust in the government and safety concerns regarding vaccinations led to the increase in exemptions in California and across the country. Section III will explore state governments' response to the higher rate of vaccine-preventable diseases within their population and assess the likelihood of success of such measures. Section IV will illustrate the increase in the number and willingness of retail clinics to provide services for signing immunization waiver exemptions, and it will analyze how these services may conflict with the government's push for increasing the number of vaccinated children.

II. SKEPTICISM TOWARDS VACCINATIONS AND INCREASE IN EXEMPTIONS

In 2010, California was swept with the worst outbreak of whooping cough since 1947, sickening 9,120 people and killing ten infants, most of

10. See EMILY OSHIMA LEE ET AL., CTR. FOR AM. PROGRESS, THE EFFECT OF CHILDHOOD VACCINE EXEMPTIONS ON DISEASE OUTBREAKS 1 (Nov. 14, 2013), available at <http://www.americanprogress.org/wp-content/uploads/2013/10/VaccinesBrief-1.pdf>.

11. See Nancy Shute, *How A California Law to Encourage Vaccination Could Backfire*, NPR (Nov. 9, 2013), <http://www.npr.org/blogs/health/2013/11/09/243937869/how-a-california-law-to-encourage-vaccination-could-backfire> [hereinafter Shute, *California Law*].

whom were too young to be vaccinated.¹² This highly contagious disease continues to circulate throughout California.¹³ In response, researchers of John Hopkins Bloomberg School of Public Health analyzed the number and location of whooping cough incidents in 2010¹⁴ and compared them with the number and location of parents who obtained personal belief exemptions for their children.¹⁵ They discovered that the increased number of vaccine refusals indeed contributed to the increase in whooping cough cases.¹⁶ Researchers found that people who lived in areas with high rates of personal belief exemptions were two and a half times more likely to live in an area with a prevalence of whooping cough cases.¹⁷

California continues to house high rates of personal belief exemptions, with the number of Sacramento-area starting kindergarteners without vaccines soaring by thirty percent between September 2012 and September 2013.¹⁸ Health experts say that Sacramento's large immigrant population is

12. Nancy Shute, *Vaccine Refusals Fueled California's Whooping Cough Epidemic*, NPR (Sept. 30, 2013), <http://www.npr.org/blogs/health/2013/09/25/226147147/vaccine-refusals-fueled-californias-whooping-cough-epidemic> [hereinafter Shute, *Vaccine Refusals*].

13. *Pertussis (Whooping Cough)*, CAL. DEPT. OF PUB. HEALTH, <http://www.cdph.ca.gov/healthinfo/discond/pages/pertussis.aspx> (last modified Feb. 7, 2014, 8:40AM).

14. See generally Jessica E. Atwell ET AL., Nonmedical Vaccine Exemptions and Pertussis in California, 2010, 132 AM. ACAD. OF PEDIATRICS 624 (Sept. 30, 2013), available at <http://pediatrics.aappublications.org/content/early/2013/09/24/peds.2013-0878.full.pdf> (discussing original study, identifying that the nonmedical vaccination exemptions were clustered spatially and were associated with the clusters of whooping cough cases, and that both exemptions and clusters of whooping cough cases tended to be in neighborhoods with higher levels of education and income).

15. Shute, *Vaccine Refusals*, *supra* note 12.

16. *Id.* When the number of vaccinated individuals in a community drops below ninety-five percent, the community loses herd immunity to highly contagious germs, leaving babies and unvaccinated individuals prone to the contagion. *Id.* In 2010, ninety-one percent of kindergarteners were up to date on their shots in California. *Id.*

17. *Id.*

18. Diana Lambert & Phillip Reese, *Local schools lead state in personal belief vaccination exemptions*, THE SACRAMENTO BEE (Sept. 16, 2013), <http://www.sacbee.com/2013/09/16/5742274/local-schools-lead-state-in-personal.html>. In the Sacramento region, the number of children entering kindergarten with a personal belief exemption from vaccinations was one in twenty—double the statewide rate. Lambert, *supra* note 9. In contrast, New York has actively taken a role to diminishing illnesses by requiring children five years old and younger to obtain a vaccine for influenza who attend licensed pre-school or day care. Celeste Katz & Jennifer Fermino, *Mayor Bloomberg: Mandatory Flu Shots For NYC Pre-Schoolers Will Save Lives*, DAILY NEWS (Dec. 13, 2013), <http://www.nydailynews.com/blogs/>

one of the factors behind the growing number of exemptions.¹⁹ Because immigrants are new to the country and its laws, they are likely unfamiliar with their state's vaccination requirements, which are at times different from their homeland.²⁰ Specifically, about fifty-eight percent of kindergarteners at Community Outreach Academy, a Sacramento charter school that caters to families from the former Soviet Union, have personal belief exemptions on file.²¹ Parents from this school state that they do not remember receiving as many vaccines when they were children in their home country and know that immunizations are one way for a doctor to make money.²²

The fear that vaccinations are not safe also deters parents from allowing their children to be vaccinated.²³ This fear was triggered in 1998 when a small study connected the measles-mumps-rubella vaccine to autism.²⁴ However, the CDC concluded from several studies examining the trends in vaccine use and the changes in autism frequency that there was not a meaningful association between thimerosal, a preservative in vaccines, and autism.²⁵ Despite this discovery, the question of vaccine safety ensues, and celebrity activists such as Jenny McCarthy still maintain presence in the public eye to speak out against the current vaccine schedule and insist that

dailypolitics.com/2013/12/mayor-bloomberg-mandatory-flu-shots-for-nyc-pre-schoolers-will-save-lives.

19. Lambert & Reese, *supra* note 18. During the 2012-2013 school year, Sacramento beat the fifteen largest counties in the state with the highest number of philosophical or personal belief exemptions among kindergarteners. *Id.*

20. *See id.*

21. *Id.*

22. *Id.*

23. Norton, *supra* note 8.

24. *Id.*

25. *Concerns about Autism*, CTRS. FOR DISEASE CONTROL AND PREVENTION, <http://www.cdc.gov/vaccinesafety/concerns/autism/>, (last updated Feb. 3, 2014) [hereinafter CDC, *Autism*]. Thimerosal, previously used as a preservative in many recommended childhood vaccines, is the vaccine ingredient that has been specifically studied. *Id.* Since 2001, it has been removed or reduced to trace amounts in all childhood vaccines except for one type of flu vaccine, and there are thimerosal-free alternatives available for influenza vaccines. *Id.* Despite the change in the use of this ingredient, the CDC supports the Institute of Medicine's conclusion that there is no relationship between vaccines containing thimerosal and autism rates in children. *Id.*

more research be done on the safety of vaccine ingredients.²⁶ In response to some of these public concerns, the Institute of Medicine (IOM) conducted a thorough review of the current scientific evidence on vaccines and certain health events that may be observed after vaccination.²⁷ In August 2011, the IOM released a report on eight vaccines given to children and adults, deeming them to be generally safe and stating that serious side effects following these vaccinations are rare.²⁸ With the CDC and the IOM's approval of the safety of vaccines, state legislatures should encourage vaccination by proposing new legislation to minimize the amount of individuals who can exempt their children from vaccination.²⁹

III. NEW STATE LAWS ON IMMUNIZATION WAIVERS AND THE LIKELIHOOD OF THEIR SUCCESS

The fear of outbreaks of vaccine-preventable diseases and the increase in vaccination exemptions, combined with concerns regarding the safety and necessity of vaccinations, results in a mixed response from legislators.³⁰ Between 2009 and 2012, eighteen states introduced at least one bill on vaccine exemptions.³¹ Most of the bills, thirty-one in total, were aimed at launching or expanding personal belief exemptions, but none passed.³² While some states like California try to pass legislation to demand stricter requirements for parents to obtain vaccination exemptions for their children, they pose

26. *Jenny McCarthy: Report of new stance on autism, vaccines 'irresponsible and inaccurate,'* CTV NEWS (Jan. 4 2012), <http://www.ctvnews.ca/entertainment/jenny-mccarthy-report-of-new-stance-on-autism-vaccines-irresponsible-and-inaccurate-1.1617795>. TV personality star Jenny McCarthy has been known for her stance that her son's autism was caused by vaccines, and claimed that the current vaccine schedule for babies is "too bloated." *Id.* Health experts in the U.S. and Canada state that her views may be influencing parents not to vaccinate their children, which could lead to problematic consequences. *Id.*

27. CDC, *Autism*, *supra* note 25.

28. *Id.*

29. *See id.*

30. *See* NAT'L CONF., *States*, *supra* note 5. For example, Illinois allows personal belief exemptions, while California does not. *Id.*

31. Norton, *supra* note 8.

32. *Id.*

problems or fall short of being as effective as likely intended.³³

Due to the unsteady rise in vaccination exemptions for children beginning kindergarten in California, the state legislature passed a law to make it more difficult for families to obtain immunization waivers.³⁴ Effective January 1, 2014, this law requires parents seeking personal belief vaccination exemptions to first learn about the risks and benefits of vaccines from a healthcare practitioner.³⁵ There is a mandated California immunization waiver form that includes a box for a healthcare provider to sign, indicating that a conversation has taken place.³⁶ However, when the governor of California signed the bill into law, he issued an executive order directing the Department of Public Health to add a separate religious exemption on the form.³⁷ This new religious exemption effectively allows people whose religion precludes vaccinations to not be required to seek a healthcare practitioner's signature.³⁸ This form allows individuals to check a box which states that they are a member of a religion that prohibits them from seeking medical advice.³⁹ By checking this box, the individual does not have to seek a signature from a healthcare provider, and thus would circumvent the opportunity to be educated on the signs, symptoms, and importance of vaccines.⁴⁰ Researchers say that this new religious exemption option could fatally weaken the law and encourage parents to lie by checking the exemption box because it is easier than taking their children in to the doctor

33. See Shute, *California Law*, *supra* note 11.

34. See *id.* Vermont and Washington are also states which have recently passed stricter laws on allowing personal belief exemptions. Norton, *supra* note 8.

35. See *id.*

36. Shute, *California Law*, *supra* note 11.

37. Letter from Edmund G. Brown Jr., Governor of Cal., to Members of the Cal. State Assembly (Sept. 30 2012) (on file with California State Assembly), *available at* http://gov.ca.gov/docs/AB_2109_Signing_Message.pdf.

38. *Id.*

39. CAL. DEP'T OF PUB. HEALTH, *Personal Beliefs Exemption to Required Immunizations*, *available at* <http://media.npr.org/documents/2013/nov/vaccine-exemption.pdf> (last visited Mar. 31, 2014).

40. *Id.*

for shots.⁴¹ This new legislation intended to tighten the requirements for parents seeking personal belief exemptions, in reality allows these individuals to circumvent the important education of disease prevention and symptom-recognition from a healthcare practitioner.⁴²

California's government needs to hold medical providers and the parents who seek exemptions to higher standards. Medical providers need to properly educate parents about how their children may become ill and may spread diseases and infections to other non-vaccinated children.⁴³ Additionally, parents who are exempting their children for religious reasons should be required to prove their religious identity in some way instead of simply checking a box on a waiver form.⁴⁴ If states refuse to abolish personal belief vaccination exemptions, then parents need to be personally informed of the dangers and risks of not vaccinating their children by qualified medical authorities, in a regulated matter.⁴⁵

41. Shute, *California Law*, *supra* note 11.

42. *See id.* The other issue that researchers see is that the governor may not have the authority to unilaterally change the bill, and state agencies and parents may not know whether they need a doctor sign-off because the forms say they do not, while the law says they do. *Id.*

43. *See LEE*, *supra* note 10, at 5-6.

44. *See* NAT'L VACCINE, *supra* note 4. One way a parent could prove their religious identity is through a signed affidavit by a pastor or spiritual advisor. *See id.*

45. *See LEE*, *supra* note 10, at 5-6. Oregon, a state with the highest rate of nonmedical exemptions from immunizations for kindergarteners in 2012 is another that needs stricter personal exemption laws. *Oregon's 2013 Rate of Vaccine-Exempted Kindergarteners Increases Statewide Over 2012*, THE LUND REP. (May 7, 2013), http://www.thelundreport.org/resource/oregons_2013_rate_of_vaccine_exempted_kindergarteners_increases_statewide_over_2012. Oregon's current law requires parents to either talk to a healthcare practitioner who will sign a Vaccine Education Certificate or view an online vaccine education module during which parents must print a Vaccine Education Certificate. *School Law Nonmedical Exemptions: New Process Begins on March 1, 2014*, OREGON HEALTH AUTHORITY (2014), available at <http://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/GettingImmunized/Documents/SchNonmedExmptQApartners.pdf>. This law broadens the definition of religious exemption to the more-encompassing term, nonmedical exemption, allowing for a wider range exemptions." *Id.* As the law stands, parents who have religious beliefs against vaccinating their children must now choose whether to speak with a healthcare provider or view the online video. *Id.* However, individuals seeking to obtain nonmedical exemptions will choose the video option due to convenience instead of setting an appointment to see a healthcare provider. *Id.* If a parent only needs to print a Vaccine Education Certificate, there is no guarantee that these parents will be held accountable to viewing the video in its entirety, or viewing it at all. *See id.* Creating a con-

IV. RISE IN RETAIL CLINICS AND THE ACCESSIBILITY TO IMMUNIZATION WAIVERS

In response to the new California legislation that curbs the ability for parents to receive personal belief vaccination exemptions, a new retail clinic opened in California in January 2014.⁴⁶ The clinic opened for the primary purpose to aid parents without a primary care provider or those who have a healthcare practitioner who refuses to sign an immunization waiver for their child.⁴⁷ This clinic allows families to meet with a medical practitioner in the hospital's pediatric outpatient clinic to receive the signature required to allow them to enroll their children in school without immunizing them.⁴⁸ Although this clinic provides consultation to parents seeking to exempt their children from vaccinations,⁴⁹ the lack of state licensure of California clinics raises the question of how these clinics are educating parents on the benefits of vaccines.⁵⁰

This new California business is the beginning of a rise in retail clinics that will provide services to sign immunization waivers so children can be exempt from vaccinations. With the implementation of the Patient Protection and Affordable Care Act (PPACA),⁵¹ tens of millions of previously un-

venience for parents to view a video to obtain a nonmedical immunization waiver instead of receiving an education in person about the risks of not immunizing their children is not the way to lower the alarming rate of vaccination exemptions. See THE LUND REPORT, *supra* note 45.

46. *New clinic provides immunization information to Sacramento area parents*, UC DAVIS HEALTH SYSTEM (Jan. 14, 2014), <http://www.ucdmc.ucdavis.edu/publish/news/newsroom/8572>. University of California, Davis (UC) Medical Center physician Dean Blumberg, M.D. initiated the new clinic, stating that he is pro-immunization, but pro-parental rights. Lambert, *supra* note 9. Dean Blumberg originally supported the California law that makes personal belief vaccination exemptions more difficult to obtain. *Id.*

47. UC DAVIS HEALTH SYSTEM, *supra* note 46.

48. Lambert *supra* note 9.

49. UC DAVIS HEALTH SYS., *supra* note 46.

50. See MARY TAKACH & KATHY WITGERT, ANALYSIS OF STATE REGULATIONS AND POLICIES GOVERNING THE OPERATION AND LICENSURE OF RETAIL CLINICS 16 (Feb. 2009), available at <http://nashp.org/sites/default/files/RetailClinics.pdf?q=files/RetailClinics.pdf>.

51. See generally Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), available at <http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf>.

insured will gain access to health care,⁵² thus increasing the demand for primary care.⁵³ Such a demand will likely result in a decrease to access to primary care physicians, allowing for an increased demand for retail clinics.⁵⁴ While retail clinics often offer vaccinations services amongst others,⁵⁵ as the newly insured individuals flood the healthcare market, the retail clinic business will expand and progress, providing more services for more people.⁵⁶ It is quite foreseeable that as the retail clinic business will grow, the number of clinics that will offer immunization waivers will grow to accommodate newly insured individuals and increase profits.⁵⁷ Although these clinics can provide education about vaccinations to parents, the lack of regulation amongst retail clinics in states like California poses a threat to the consistency between what is said to each parent regarding the risks and benefits of vaccines.⁵⁸ This lack of regulation jeopardizes the effectiveness of these clinics' abilities to deter vaccination exemptions and to encourage vaccinations in the future.⁵⁹

California's legislatures, as well as legislatures in other states, need to encourage child vaccination by passing legislation to limit the number of

52. *Study: Number of Retail Health Clinics to Rise Sharply in Wake of ACA*, CAL. HEALTHLINE (June 13, 2013), <http://www.californiahealthline.org/articles/2013/6/13/study-number-of-retail-health-clinics-to-rise-sharply-in-wake-of-aca>.

53. *Special Feature: Retail Clinics Play Growing Role in Health Care Marketplace*, RAND HEALTH, <http://www.rand.org/health/feature/retail-clinics.html> (last visited Mar. 31, 2014).

54. *Id.*

55. Approximately ninety percent of retail clinics visits are for the following ten acute conditions and preventative care: upper respiratory infection, sinusitis (sinus inflammation), bronchitis, sore throat, immunizations, inner ear infections, swimmer's ear, conjunctivitis, urinary tract infections, and screen blood tests. *Id.*

56. *See* CAL. HEALTHLINE, *supra* note 52.

57. *See id.*

58. *See* Takach, *supra* note 50. As of February 2009, California had 90 clinics open, operating under different models. *Id.* States such as Illinois require a permit to operate a retail clinic issued by the Department of Public Health, while states such as Massachusetts regulate what medical conditions can be treated, medical record keeping procedures, what age groups can be treated, the treatment of repeat patients, and tobacco sale regulations. *Retail Health Clinics: State Legislation and Laws*, NAT'L CONF. OF STATE LEGISLATURES, <http://www.ncsl.org/research/health/retail-health-clinics-state-legislation-and-laws.aspx> (last updated Sept. 2012) [hereinafter NAT'L CONF.].

59. *See* Takach, *supra* note 50.

parents to receive immunization waivers for their children.⁶⁰ The government should mandate medical providers to educate the parents of exempt children on the signs and symptoms of vaccine-preventable diseases to encourage vaccination and seek medical care immediately if their child shows warning signs of such diseases. State governments should ensure that parents whose children are exempt from vaccinations due to religious beliefs can recognize the warning signs and symptoms of vaccine-preventable diseases.⁶¹ These individuals should also be required to sign an affidavit to prove their religion, have a witness testify to their religious beliefs, or submit any documents or certificates that would prove an affiliation to a certain religion.⁶²

Additionally, states such as California need to pass legislation to regulate retail clinics to provide the same high level of education about the benefits of vaccination to parents who wish to obtain personal exemptions for their children.⁶³ Since the CDC and IOM have proven the safety and effectiveness of vaccines,⁶⁴ these groups can work with school officials to provide information on state and country-wide immunization rates to make the data more transparent and to encourage parents to vaccinate their children.⁶⁵ Educating parents about the benefits of immunizations may encourage them to understand the importance of vaccinating their children.⁶⁶

60. See Norton, *supra* note 8.

61. See LEE, *supra* note 10, at 6.

62. See NAT'L VACCINE, *supra* note 4. Certain laws require a signed affidavit from a pastor or spiritual survivor of the parent who wishes to have their child religiously exempt from vaccines. *Id.* Other laws allow a parent exercising religious exemption to sign a notarized waiver on behalf of their child. *Id.*

63. See NAT'L CONF., *supra* note 58.

64. See CDC, *Autism*, *supra* note 25.

65. See LEE, *supra* note 10, at 6.

66. See *Id.*

V. CONCLUSION

The new retail clinics that sign vaccination waivers for schoolchildren and the states that are passing ineffective laws designed to decrease vaccination exemptions are participating in the re-emergence of diseases and infections that were once deemed cured in the United States.⁶⁷ It is unethical for the state legislature and the healthcare industry to loosen its requirements for child vaccination exemptions.⁶⁸ It is in the best interest of society to reduce the number of allowed personal belief exemptions.⁶⁹ If legislators decline to reduce the number of waivers, then they should require parents and qualified healthcare practitioners to have an in-person conversation about the dangers of their unvaccinated children contracting and spreading preventable diseases and infections.⁷⁰ Overall, the greater well-being of society at times outweighs the interest of a parent's individual autonomy over their child, and every effort must be made to lower the number of immunization waivers in the United States.⁷¹

67. In 2000, measles was declared eliminated from the United States' population. CDC, *supra* note 7.

68. See CAL. DEP'T OF PUB. HEALTH, *supra* note 39.

69. See LEE, *supra* note 10, at 5-6.

70. See Shute, *California Law*, *supra* note 11.

71. See LEE, *supra* note 10, at 5-6.

Legal & Ethical Ramifications Outweigh Potential
Benefits of Expedited Partner Therapy (EPT):
Michigan Should Not Authorize Health
Professionals to Provide EPT

*Sheila Geraghty**

I. INTRODUCTION

The Centers for Disease Control and Prevention (CDC) estimates that there are approximately nineteen million new occurrences of contracted sexually transmitted disease (STD) infections yearly in the United States.¹ Chlamydia and gonorrhea infections are the two most commonly reported STDs.² There are various options to either treat or prevent chlamydia and gonorrhea infections, including abstaining from sex, being in a long-term, mutually monogamous relationship, using condoms, and taking antibiotics.³ Traditional practices to inform, evaluate, and treat sex partners of infected persons rely upon patients or healthcare providers to notify those partners.⁴ As an alternative approach, expedited partner therapy (EPT) is a practice of authorizing medical practitioners to treat the sex partners of persons with STDs without an intervening medical evaluation or professional prevention

*J.D. Candidate, Loyola University Chicago School of Law

1. *Chlamydia and Gonorrhea – Two Most Commonly Reported Infectious Diseases in the United States*, CDC, <http://www.cdc.gov/features/dsstddata/> (last updated April 22, 2011) [hereinafter *Chlamydia and Gonorrhea*].

2. *Id.*

3. *Id.*; *Gonorrhea Treatment Guidelines: Revised Guidelines to Preserve Last Effective Treatment Option*, CDC (July 2013), available at “Media Fact Sheet” at <http://www.cdc.gov/std/gonorrhea/treatment.htm>.

4. *Legal Status of Expedited Partner Therapy*, CDC, <http://www.cdc.gov/std/ept/legal/default.htm> (last updated September 27, 2013) [hereinafter *Legal Status*].

counseling.⁵ In this practice, medical practitioners provide their patients with sufficient medications directly or via prescription for the patients and their partners—without any prior evaluation of those partners.⁶ Throughout discussions of EPT, the legal status of the practice remains uncertain, but in 2008, the American Bar Association (ABA) issued a recommendation urging states, territories and tribes to support the removal of legal barriers to the appropriate use of EPT, in accordance with CDC recommendations.⁷

According to the CDC, current legal frameworks allow the practice of EPT in thirty-five states, potentially allow the practice of EPT in nine states, and prohibit EPT in six states.⁸ Implementation issues such as uncertain legal status, adverse effects of drug use, potential effects of drug use, privacy, providers' and health agencies' attitudes and beliefs, and administrative barriers may account for the hesitancy in some states.⁹ Michigan is one of six states that currently prohibits EPT, but there is a bill pending in Michigan's Senate Committee on Health Policy that, if passed, would legally allow Michigan healthcare providers to practice EPT.¹⁰ In light of the legal and ethical ramifications of EPT, Michigan should not authorize medical practitioners to practice EPT, as various legal uncertainties outweigh the potential benefits in decreasing STDs.¹¹ This article will discuss general provisions of Michigan's pending bill in Part II and will assess the legal en-

5. *Expedited Partner Therapy in the Management of Sexually Transmitted Diseases*, U.S. DEPT. OF HEALTH & HUMAN SERVS. 4 (2006) [hereinafter *Expedited Partner Therapy 2006*], available at <http://www.cdc.gov/std/treatment/eptfinalreport2006.pdf>.

6. *Legal Status*, *supra* note 4.

7. *Id.*; HEALTH L. SEC. AM. BAR. ASS'N, REPORT TO THE HOUSE OF DELEGATES 1 (2008), available at http://www.americanbar.org/content/dam/aba/migrated/health/04_government_sub/media/116A_EPT_Final.authcheckdam.pdf.

8. *Legal Status*, *supra* note 4.

9. HEALTH L. SEC. AM. BAR. ASS'N, *supra* note 7, at 8.

10. *Legal Status*, *supra* note 4; H.B. 4736, 97 Leg., 1st Reg. Sess. (Mich. 2013).

11. See Burstein, et al., *Expedited Partner Therapy for Adolescents Diagnosed with Chlamydia or Gonorrhea: A Position Paper of the Society for Adolescent Medicine*, 45 J. of Adolescent Health 303, 305 (2009) (Although EPT is an effective and acceptable technique to decrease gonorrhea or chlamydia reinfection rates, its use in routine clinical practice is limited by complex barriers).

vironment and reasons why the bill should not be passed in Part III, highlighting the absence of physician-patient relationships, lack of potential civil recovery for non-patients, potential abuse problems, and the need for education surrounding EPT's legality.

II. MICHIGAN'S PENDING BILL

Michigan's pending bill, House Bill 4736, would amend Michigan's Public Health Code by amending various sections and adding various sections relating to EPT.¹² The proposed bill would authorize EPT in order to protect and promote Michigan residents' public health by allowing health professionals to distribute or prescribe therapy to partners, even if the partner's identity is unknown.¹³ The bill would require health professionals to distribute an information pamphlet and to convey to the patient that partner notification is important in order for that non-patient partner to obtain medical care and a complete evaluation.¹⁴ However, the bill makes all health professionals who provide EPT not liable for damages in a civil action or subject to administrative action for personal injury, death, or other consequences arising from or related in any way to the provision of EPT.¹⁵ By passing House Bill 4736, Michigan would allow hazardous legal and ethical ramifications to surface, including the absence of physician-patient relationships, lack of potential civil recovery for non-patients, and potential abuse problems, which diminish the potential benefits that EPT may have in decreasing the prevalence of STDs.¹⁶

12. H.B. 4736, 97 Leg., 1st Reg. Sess. (Mich. 2013).

13. *Id.*

14. *Id.*

15. *Id.*

16. See *Expedited Partner Therapy 2006*, *supra* note 5, at 6.

III. LEGAL ETHICAL RAMIFICATIONS

A. Absence of Physician-Patient Relationships

The physician-patient relationship remains a foundation of care in which a patient's data is collected, diagnoses are made, and healing and support are provided.¹⁷ The physician-patient relationship can guide decision-making in healthcare plans, and the relationship allows for patient education and proper implementation of treatment plans.¹⁸ Sustaining physician-patient relationships allows for trust between physicians and patients, permitting physicians to retain professional standards to nurture and support their patients' health.¹⁹ However, health professionals who practice EPT do not maintain doctor-patient relationships with their patients' sex partners if they prescribe medicine to a non-patient.²⁰ In these cases, no clinical assessment of the patient's sex partner is required.²¹ This lack of clinical assessment diminishes the value of physician-patient relationships, and EPT's potential legal and ethical ramifications outweigh the benefits that it may have in limiting the number of STD infections.²²

Despite the endorsement of EPT by the ABA and CDC, there are valid reasons why some states still have not expressly authorized EPT.²³ Before passing the pending bill, Michigan should consider the potential slippery slope effect in allowing this new type of distant doctor-patient relationship. Medical practitioners experience ethical tension because providing any prescription without a prior evaluation or physician-patient relationship is im-

17. Susan D. Goold & Mack Lipkin, Jr., *The Doctor-Patient Relationship*, 14 J. GEN. INTERN. MED. S26, S26 (1999).

18. *Id.*

19. *Id.*

20. James G. Hodge, Jr. et al., *Expedited Partner Therapies for Sexually Transmitted Diseases: Legal and Policy Approaches*, 5 J. HEALTH & BIOMEDICAL L. 1, 2-3 (2008) [hereinafter *Legal and Policy Approaches*].

21. *Id.*

22. *See id.* at 3 ("After evaluating multiple studies demonstrating the efficacy of EPT as a public health measure in specific settings, CDC recommended national use of EPT. . . for certain populations with chlamydia and gonorrhea.").

23. *Legal Status*, *supra* note 4; HEALTH L. SEC. AM. BAR. ASS'N, *supra* note 7, at 2-3.

permissible²⁴, yet EPT in limited circumstances is permissible.²⁵ The incredibly valuable aspects of the physician-patient relationship will not survive when states authorize medical practitioners to prescribe some medication to non-patients.²⁶ If Michigan legalizes EPT, it seems conceivable that in the future other medications may be available through a similar process.²⁷

Patients' trust in their healthcare providers is fundamental to effective clinical encounters.²⁸ If Michigan were to legalize medical practitioners to practice EPT, current doctor-patient relationships would be affected when patients are diagnosed with STDs, as the patient would either be forced to tell the doctor the confidential name(s) of the person(s) to whom he or she could have spread the STD, or the unnamed individual(s) would be labeled "Expedited Partner Therapy" on the prescription.²⁹ If the patient were forced to expose confidential information of a non-patient, the vital characteristic of trust in the physician-patient relationship would be violated.³⁰ Further, even if the prescription was labeled "Expedited Partner Therapy,"

24. Brian M. Aboff et al., *Residents' Prescription Writing for Nonpatients*, 288(3) J. AM. MED. ASS'N 381, 384 (2002) ("Federal law in the area of prescription writing is limited to controlled substances. These laws requires that the prescriber have a bona fide patient-physician relationship with any person for whom he or she prescribes controlled substances.").

25. James G. Hodge, Jr. et al., *Expedited Partner Therapy for Sexually Transmitted Diseases: Assessing the Legal Environment*, 98 AM. J. PUB. HEALTH 238, 238 (2008) [hereinafter *Assessing the Legal Environment*].

26. See Goold & Lipkin, Jr., *supra* note 17 ("[The relationship] is the major influence on practitioner and patient satisfaction. . . Increasing data suggest that patients activated in the medical encounter to ask questions and to participate in their care do better biologically, in quality of life, and have higher satisfaction.").

27. *Before the Senate Comm. on Health & Education*, 1999 Leg., 75th Sess. 20 (Nv. 1999) ("Not every STD has proven to be effective with [EPT], and we would not want to open that slippery slope to those who are not proven for efficacy through [EPT].").

28. See Joanne E. Croker et al., *Factors affect patients' trust and confidence in GPs: evidence from the English national GP patient survey*, BMJ OPEN 2 (2013), <http://bmjopen.bmj.com/content/3/5/e002762.full.pdf+html> ("Numerous benefits may accrue from a trusting, confident doctor-patient relationship. These include the open communication of information between the doctor and the patient, with subsequent encouragement of the patient's enablement and improved adherence to medical advice. . . and the improvement of health outcomes and better patient perceptions of healthcare.").

29. H.B. 4736, 97 Leg., 1st Reg. Sess. (Mich. 2013).

30. See Goold & Lipkin, Jr., *supra* note 17, at S27 (trust is an essential and moral feature of the doctor-patient relationship).

allowing the patient to keep confidential information private, the absence of a proper physician-patient relationship still weighs against the practice. As EPT is only one method of decreasing the prevalence of STDs³¹, it should not be practiced at the expense of existing physician-patient relationships.

Michigan's proposed bill, as well as other states' already adopted bills, suggest that providing an information pamphlet about STD testing to the patient to give to the non-patient would be sufficient to substitute for a physician-patient relationship.³² Information pamphlets contain warnings about administering EPT to pregnant partners, information about STDs, their treatment and prevention, statements advising a person with questions about the information to contact his or her physician, pharmacist, or local health department, and more.³³ However, this information is simply not enough to make up for the absence of doctor-patient relationships, especially in light of the fact that the information pamphlets clearly indicate the need for the non-patient to direct questions to their own physician.³⁴ It seems that if states were not concerned with the non-patient's well-being, this element would not be included in any information pamphlet. Its mere presence appears to reveal that the absence of physician-patient relationships could create more problems than the benefits EPT may ultimately provide.

31. *Expedited Partner Therapy for Chlamydia trachomatis Infection, Neisseria gonorrhoeae Infection and Trichomoniasis: Guidance for Health Care Professionals in Wisconsin*, WIS. DEP'T. OF HEALTH SERVS. 3 (2013), http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&sqi=2&ved=0CCkQFjAA&url=http%3A%2F%2Fwww.dhs.wisconsin.gov%2Fpublications%2FP0%2FP00253.pdf&ei=dCU3U5-aGuGC2QXcqIH0Bg&usg=AFQjCNFhEWNz32b-bETZCX9Ps5wZ_DDwoQ&sig2=6uVrADg6JIDVVfn-GMQwtw&bvm=bv.63808443,d.cWc [hereinafter WIS. DEP'T. OF HEALTH SERVS.] ("While standard care for treating STDs includes testing, clinical evaluation and counseling by a clinician, EPT is an alternative when a partner is unable or unlikely to seek care.").

32. *Id.* at 4 ("A treatment information sheet must accompany each medicine or prescription. . ."); H.B. 4736, 97 Leg., 1st Reg. Sess. (Mich. 2013).

33. WIS. DEP'T. OF HEALTH SERVS., *supra* note 31, at 4.

34. *Id.*

B. Lack of Potential Civil Recovery for Non-Patients

If passed, Michigan's bill would effectively eliminate all civil liability for damages for personal injury, death, or other consequences arising from or related in any way to a health professional providing EPT.³⁵ A basic tenet of healthcare services is to help ensure that individuals do not gain access to medications they do not need or that could be dangerous to their health.³⁶ It seems that EPT goes directly against this fundamental tenet. Still, some argue that providing EPT is an exception to the basic tenet similar to the existing exceptions that allow physicians to routinely give prescription medications to children or elderly patients through parents or caregivers and to people with mental disabilities through court-appointed guardians.³⁷ However, this argument is flawed. Caregivers, court-appointed guardians, and parents giving their dependents medicine is not the same as a patient infected with a STD giving medication to all of his or her sexual partners because the aforementioned are legally consenting to the dependents' medical treatments.³⁸ Conversely, non-patients are not consenting to medical treatment, as they're only receiving extra medication from the patient.³⁹ Consequently, if a non-patient takes the medication and problems arise, a non-patient partner has no ability to recover from the health practitioner through a civil lawsuit, as the health practitioner would be relieved of all liability.⁴⁰

Inherent in all medications, the risks of allergic reactions and other adverse drug effects for individuals are present when a person takes medication to treat an STD.⁴¹ Without direct medical supervision, this risk increas-

35. H.B. 4736, 97 Leg., 1st Reg. Sess. (Mich. 2013).

36. *Assessing the Legal Environment*, *supra* note 25, at 238-39.

37. *Id.* at 239.

38. REBECCA GUDEMAN, NAT'L CTR. FOR YOUTH L., CONSENT TO MEDICAL TREATMENT FOR FOSTER CHILDREN: CALIFORNIA LAW 1 (December 2008).

39. *Legal and Policy Approaches*, *supra* note 20, at 3. Health care practitioners provide patients with sufficient medications either directly or via prescription for the patients and their partners. *Id.*

40. H.B. 4736, 97 Leg., 1st Reg. Sess. (Mich. 2013).

41. *Expedited Partner Therapy 2006*, *supra* note 5, at 6.

es, including medical problems such as: transient gastrointestinal intolerance, drug intolerance, fetal and pregnancy-related morbidity, allergic reactions, and disulfiram-like⁴² reactions in association with alcohol ingestion.⁴³ If Michigan's pending bill passes through the Senate and becomes law, a non-patient who suffers any of the negative side effects of EPT listed above will be left without any availability for recovery against the health practitioner.⁴⁴ This lack of recovery is a large legal ramification because any negatively affected non-patients cannot seek justice, which outweighs potential benefits that may come from EPT in decreasing the prevalence of STDs.

C. Potential Abuse Problems

Potential abuse problems also create legal and ethical concerns that weigh against Michigan's proposed legislation.⁴⁵ Some physicians are concerned that with EPT the medication will not be delivered to their patients' sex partners.⁴⁶ Physicians would not know whether or not their patients will be willing or even able to contact one or more of their past partners for treatment.⁴⁷ By dispensing an extra dose of the medication, Michigan physicians would be escaping liability for medical mishaps that occur to essentially anyone.⁴⁸ For example, a patient could take his or her extra dose of medicine and give it to one of his or her friends who only believe they have a STD. This action would not only be a missed opportunity to counsel part-

42. See *Antabuse (disulfiram)*, NETDOCTOR, <http://www.netdoctor.co.uk/alcohol-abuse/medicines/antabuse.html> (last updated Nov. 18, 2013) ("causing flushing, a racing heartbeat. . . a drop in blood pressure that causes dizziness. . . throbbing headache, shortness of breath, palpitations, nausea and vomiting").

43. *Expedited Partner Therapy 2006*, *supra* note 5, at 20.

44. H.B. 4736, 97 Leg., 1st Reg. Sess. (Mich. 2013).

45. HEALTH L. SEC. AM. BAR. ASS'N, *supra* note 7, at 7.

46. *Id.*

47. See *Partner Services Frequently Asked Questions for Patients Diagnosed with HIV/STD*, NEW YORK STATE DEPT. OF HEALTH, http://www.health.ny.gov/diseases/communicable/std/partner_services/faqs_for_patients.htm (last updated January 2011) (New York's Partner Services Specialists acknowledge that there are reasons why patients may not want to notify their partner(s) themselves).

48. H.B. 4736, 97 Leg., 1st Reg. Sess. (Mich. 2013).

ners, which physicians currently worry about⁴⁹, but it would also be a missed opportunity to counsel the potentially great number of individuals that could have access to their patient's extra dose of medication.

Further, the issue of funding creates a potential of abuse for patients, physicians and their practice, insurance companies, pharmacies, and health departments.⁵⁰ Funding medication given to an unknown individual who may or may not have contracted a STD from a patient is an abuse of resources allocated to the state, and therefore Michigan should not allow the proposed bill to pass in the Senate.⁵¹ In fact, some argue that funding is the greatest single impediment to EPT use because access to the medication requires insurance companies to routinely pay for it or for public health agencies to provide the medication through a separate program.⁵² States' public health agencies should not spend their resources on funding EPT when that money could be spent elsewhere.⁵³ The importance of the funding obstacle will vary in a wide variety of settings, but comprehensive programs by public health departments, health maintenance organizations, or other agencies will incur additional costs.⁵⁴ Admittedly, expenses of EPT may be modest in relation to the total costs incurred in diagnosis and management of patients with treatable STDs⁵⁵; however, even small incremental costs of EPT

49. HEALTH L. SEC, AM. BAR. ASS'N, *supra* note 7, at 7.

50. *Expedited Partner Therapy 2006*, *supra* note 5, at 21.

51. See Albert R. Jonsen & Kelly A. Edwards, *Ethics in Medicine: Resource Allocation*, UNIV. OF WASH. (1998), <https://depts.washington.edu/bioethx/topics/resall.html> ("Often scarcity of resources, such as equipment, beds, drugs, time or excessive numbers of persons in need make it difficult, if not impossible, to provide 'the full measure of service and devotion.'").

52. See, e.g., Matthew R. Golden & Claudia S. Estcourt, *Barriers to the implementation of expedited partner therapy*, 87 SEXUALLY TRANSMITTED INFECTIONS ii37, ii37 (2011) (A Washington state program treats approximately 12,000 partners per year at a cost of approximately \$105,000).

53. *Id.*

54. See *Expedited Partner Therapy 2006*, *supra* note 5, at 21. Expenses will be incurred in counseling index patients, purchasing drugs, development of educational literature, packaging drugs and counseling aids, administrative expenses incurred by arrangements with pharmacies, personnel time when medications are delivered to patients by public health workers, among others. *Id.*

55. *Expedited Partner Therapy 2006*, *supra* note 5, at 21.

may cause difficulties for underfunded public health departments.⁵⁶

D. Lack of Education Surrounding EPT's Legality

Finally, even if Michigan were to pass the proposed legislation, studies in states that legally allow EPT show that healthcare providers still perceive the process as illegal, thus limiting the potential benefits of EPT.⁵⁷ In those surveys, medical practitioners expressed uncertainty about the legality of EPT and further expounded that even if it were legal, the physicians had not been informed of the procedures or policies.⁵⁸ Even in EPT-supported legal environments, issues such as awareness, education, reimbursement, or funding may inhibit EPT use.⁵⁹ If Michigan were to pass the proposed bill, it is unlikely that many potential benefits from EPT would come to fruition⁶⁰, especially because states where EPT is legal lack education surrounding the process.⁶¹

IV. CONCLUSION

In conclusion, Michigan's proposed bill, House Bill 4736, legalizing the practice of EPT in the state, would create more legal and ethical ramifications than the potential benefits that EPT may have in decreasing the prevalence of STDs.⁶² As mentioned in the above analysis, EPT diminishes the value of physician-patient relationships, which allow for patient education and proper implementation of any treatment plans.⁶³ Further, the process

56. *Id.*

57. *Id.* at 20.

58. *Id.* at 21.

59. Ryan Cramer et al., *The Legal Aspects of Expedited Partner Therapy Practice: Do State Laws and Policies Really Matter?*, 40 SEXUALLY TRANSMITTED DISEASES 657, 662 (2013); See Hodge et al., *Assessing the Legal Environment*, *supra* note 25, at 239 ("Still, health care practitioners may be concerned that they will be subject to sanctions (e.g., censure, fines, suspension, or license revocation) by state licensing boards or civil claims for malpractice for providing prescriptions to nonpatients.").

60. *Expedited Partner Therapy 2006*, *supra* note 5, at 22.

61. *Id.* at 21.

62. See Burstein, et al., *supra* note 11, at 305.

63. See Goold & Lipkin, Jr., *supra* note 17, at S26 (one of the functions of a medical

leaves any non-patients negatively affected by receiving EPT without the ability for civil recovery against healthcare practitioners, as they are completely relieved of any liability.⁶⁴

If Michigan's proposed bill is passed, potential abuse problems will arise because of the opportunity for patients to give the medication to any of their friends or family, not only to their potentially affected partner. Additionally, funding medication to unknown individuals is an abuse of Michigan's resources.⁶⁵ Finally, the lack of education surrounding EPT's legality, process, and procedures undoubtedly limits any potential benefits of EPT.⁶⁶ Therefore, Michigan's proposed bill, House Bill 4736 should not be passed by the Senate.

interview is to carry out patient education and implementation of treatment plans).

64. H.B. 4736, 97 Leg., 1st Reg. Sess. (Mich. 2013).

65. See Jonsen & Edwards, *supra* note 51.

66. *Expedited Partner Therapy 2006*, *supra* note 5, at 21; Cramer et al., *supra* note 58, at 662 ("Among providers, awareness of EPT and reimbursement issues may inhibit EPT use even in supportive legal environments.").

Examining Patient Integrity and Autonomy: Is
Assisted Death a Viable Option for Adolescents in
the United States?

*Anne Compton-Brown**

I. INTRODUCTION

The right to die has always been a contentious issue in the United States.¹ Currently, only three states have a right to die statute and only two more have legalized assisted death through court ruling.² These statutes apply exclusively to adults aged eighteen years or older, and do not afford adolescents the right to die under any circumstance.³ Alternatively, the recent decision by the Belgian Parliament to lift the age restriction on requests for assisted death made the entire world question what it means to grant someone the freedom to die and what safeguards must be in place to prevent abuse of this right.⁴ This article will argue that the United States should

* Juris Doctor Candidate, Loyola University Chicago School of Law, Class of 2015. Ms. Compton-Brown is a staff member of *Annals of Health Law*.

1. Kate Pickert, *A Brief History of Assisted Suicide*, TIME (Mar. 3, 2009), <http://content.time.com/time/nation/article/0,8599,1882684,00.html>.

2. *Death with Dignity Acts*, DEATH WITH DIGNITY NATIONAL CTR. (2012), <http://www.deathwithdignity.org/acts> (last visited Apr. 6, 2014); see also Erik Eckholm, *New Mexico Judge Affirms Right to 'Aid in Dying'*, N.Y. TIMES, Jan. 14, 2014, at A16, available at www.nytimes.com/2014/01/14/us/new-mexico-judge-affirms-right-to-aid-in-dying.html.

3. *State by State Guide to Physician-Assisted Suicide*, PROCON.ORG, <http://euthanasia.procon.org/view.resource.php?resourceID=000132> (last updated Dec. 13, 2013) [hereinafter ProCon State by State].

4. See *Belgium debates giving children the right to die*, EUROPEAN AFFAIRS (Feb. 20, 2013, 16:45 CET), <http://www.euronews.com/2013/02/20/belgium-debates-giving-children-the-right-to-die/>; Diana Magnay, *Parents Plead to be able to help terminally ill children die*, CNN (Nov. 27, 2013, 3:39PM), <http://www.cnn.com/2013/11/27/world/europe/belgium-euthanasia-for-children-debate/>; Umberto Bacci, *Belgium Closer to Extending Right to Die to Minors*, INT'L BUS. TIMES (June 12, 2013, 12:54 GMT), <http://www.ibtimes.co.uk/belgium-euthanasia-minors-477764>.

mirror the efforts of Belgium and the Netherlands and that states should introduce bills allowing assisted death for terminally ill adolescents.

Part II of this article will define common terms associated with assisted death and the death with dignity movement. Part III will discuss the history of the right to die movement in the United States and the states that currently allow assisted death. Part IV will explore existing United States laws regarding the constitutionality of an individual's right to die, the impact of the reduced age requirement for assisted death in the Netherlands, and Belgium's recent move toward increasing access to assisted death for adolescents. Part V will argue that the United States should reevaluate the decision-making power of the adolescent individual as it relates to his or her autonomy in making health and medical treatment decisions, including the right to die.

II. RELEVANT TERMS AND DEFINITIONS

One of the most confusing aspects of discussions surrounding assisted death involves the misapplication of the terms assisted suicide and euthanasia.⁵ As such, several definitions and distinctions must be clarified.⁶ First, assisted suicide refers to a patient's decision to intentionally and willfully end his or her own life in a manner that requires the assistance of a third-party.⁷ On the other hand, voluntary active euthanasia refers to a patient's decision to receive a lethal dose of a medicine or substance through direct administration by a third party with compassionate intent.⁸ This term is most closely related to physician-assisted suicide, which is defined as a pa-

5. Barbara Supanich, *Ethical Issues Concerning Physician-Assisted Death*, in *HEALTH CARE ETHICS: CRITICAL ISSUES FOR THE 21ST CENTURY* 195, 195 (Eileen E. Morrison & Beth Furlong eds., 3d ed. 2014).

6. *Id.*

7. *Id.* See also *Assisted Suicide*, MERRIAM WEBSTER, <http://www.merriam-webster.com/dictionary/assisted%20suicide> (last visited Apr. 6, 2014) (defining assisted suicide as, "suicide by an individual facilitated by means or information (as a gun or indication of the lethal dosage of a drug) provided by someone else aware of the individual's intent").

8. Supanich, *supra* note 5, at 196.

tient's decision to end his or her life through the use of a prescription, or information regarding a lethal dose of a drug, provided by a physician who is aware of the patient's intent at the time that the prescription is given or the dosage information is disseminated.⁹ The term right to die includes not only the decision of the individual to end his or her life, but also the means by which the end will occur: by application of a lethal agent, by self or a third party, or through withholding or withdrawing a specific potentially life-extending medical therapy.¹⁰ Finally, in order to fall within the classification of right to die, it is imperative that the intent behind these acts be to end life rather than the mere decision to refuse or discontinue what may be life extending therapy; the decision to stop or ignore specific therapies does not carry the necessary intent.¹¹ This article will use the term assisted death to encompass the nuances associated with these terms and to imply that the decision made by a terminally ill individual to receive assistance with death could potentially stand within any of the defined terms associated with carrying out that choice.

III. ASSISTED DEATH IN THE UNITED STATES: PAST AND PRESENT

Historically, ethical guidelines and religious organizations have opposed assisted death.¹² Interestingly, public opinion polls show that while Americans are divided on this issue, two-thirds support assisted death in some form when evaluated on a case-by-case basis.¹³ Support for assisted death

9. See *Assisted Suicide*, MERRIAM WEBSTER, <http://www.merriam-webster.com/medical/physician-assisted+suicide?show=0&t=1393527099> (last visited Apr. 6, 2014).

10. Lara L. Manzione, *Is There a Right to Die?: A Comparative Study of Three Societies (Australia, Netherlands, United States)*, 30 GA. J. INT'L & COMP. L. 443, 445–46 (2002); see also Supanich *supra* note 5, at 196 (explaining that withdrawing or withholding treatment does not qualify as physician assisted death).

11. Supanich, *supra* note 5, at 196 (Explaining that the term assisted death does not encompass the decision not to initiate medical therapies, withdraw medical therapies, or to use high doses of pain-relieving medication for the purpose of palliative care).

12. Supanich, *supra* note 5, at 195.

13. *Id.*

has increased by thirty-three percent since 1948.¹⁴ However, the support is limited based on the terminology used to define the act of assisting death.¹⁵

In recent years, the terms right to die and assisted suicide have somewhat blended to allow the conversation surrounding an individual's decision to end his or her life to focus on the question of whether human beings should have a right to control when they die.¹⁶ When all efforts to reduce pain or alleviate symptoms are exhausted by physicians, supporters argue that even the best palliative care methods are often insufficient to effectively end a patient's suffering.¹⁷ For this reason, supporters of assisted death argue that in order to protect patient autonomy, states must recognize that only an individual knows what constitutes harm to himself and that it should be left to the patient to determine whether a life with severe, unrelenting suffering causes more harm than assisted death.¹⁸

Opponents of assisted death do not recognize patient autonomy as either appropriate or a moral justification for choosing assisted death.¹⁹ While opponents recognize that autonomy plays a significant moral role in determining a course of medical treatment, they maintain that the moral value of the choice does not and should not entitle an individual to require assistance from a third party in ending his or her life.²⁰ Disappointingly, this view fails to take into account that terminally ill individuals are often unable to

14. Lydia Saad, *U.S. Support for Euthanasia Hinges on How It's Described: Support is at low ebb on the basis of wording that mentions "suicide"*, GALLUP (May 29, 2013), <http://www.gallup.com/poll/162815/support-euthanasia-hinges-described.aspx>; see also, Erik Eckholm, *'Aid in Dying' Movement Takes Hold in Some States*, NY TIMES (Feb. 7, 2014), available at http://www.nytimes.com/2014/02/08/us/easing-terminal-patients-path-to-death-legally.html?_r=0 (further explaining the recent trend in assisted death approval and describing the history of the Death with Dignity movement in the U.S.).

15. Eckholm, *supra* note 14; see also Saad, *supra* note 14 (Detailing that 70% of persons polled supported assisted death when described as a painless way to end the patient's life versus only 51% supporting assisted death when described as assisting the patient with committing suicide).

16. Pickert, *supra* note 1.

17. Supanich, *supra* note 5, at 197.

18. *Id.*

19. *Id.*

20. *Id.*

perform the required actions to end their own lives and for that reason, must request the help of another.²¹

Due in part to the division between proponents and opponents to assisted death, only four states in the United States have enacted Death with Dignity Laws: Oregon, Washington, Montana, Vermont.²² Also, a judge for the Second District in New Mexico recently held that the choice of a terminally ill patient to request and receive assistance in dying is a fundamental right under the New Mexico Constitution.²³ In 1997, Oregon was the first state to enact a Death with Dignity law.²⁴ Data from Oregon demonstrates that since this law was adopted, its implementation is safe, carried out with the appropriate compassionate intent, and protects its vulnerable citizens by preventing abuse of the law.²⁵ Legislatures look to the results of Oregon's statute for reassurance in passage of their own death with dignity acts.²⁶ In 2008, Washington became the second state to pass its Death with Dignity Act, and even though it took eleven years to progress through the legislature, it was implemented within one year and no credible legal challenges were made against it.²⁷ In 2009, the Montana Supreme Court held that

21. *Id.* (discussing patient integrity and autonomy in regards to the interplay between a supportive environment where patients feel comfortable discussing all options related to their current status and assurance of patient integrity).

22. *Death with Dignity Acts*, *supra* note 2.

23. *See* Eckholm, *supra* note 2 (explaining that assisted death was banned everywhere in the U.S. save Oregon until 2008 and now it is legal in five states including, most recently, New Mexico); *see also* Findings of Fact and Conclusions of Law at 12-13, *Morris v. Brandenburg*, No. D-202-CV 2012-02909 (Jan. 13, 2014), *available at* <https://newmexico.tylerhost.net/ServeDocument.ashx?SID=0730da82-c2ce-4331-9d34-98fe74190124&RID=001664dd-e045-4d6c-b5ce-1294189b0a7a>.

24. DEATH WITH DIGNITY NAT'L CTR, *Death with Dignity Around the U.S.*, <http://www.deathwithdignity.org/advocates/national> (last updated Apr. 6, 2014) [hereinafter *Dignity Around the U.S.*]; *see also* ProCon State by State *supra* note 3 (explaining that a capable, adult resident of Oregon suffering from a terminal illness may make a voluntary written request for medication from a physician for the purpose of committing suicide and that the Controlled Substances Act does not empower the United States Attorney General to prohibit physicians from writing prescriptions for terminally ill patients which are related to physician-assisted suicide).

25. *Dignity Around the U.S.*, *supra* note 24; ProCon State by State *supra* note 3.

26. *Id.*

27. *Death with Dignity: the Laws & How to Access Them*, DEATH WITH DIGNITY NAT'L

Montana's Terminally Ill Act provides terminally ill patients with the right to involve direct physician participation in carrying out their end of life wishes, effectively permitting physician-assisted death in the state.²⁸ Four years later, in 2013, Vermont passed its assisted death statute into law.²⁹

Not surprisingly, many more death with dignity-related bills are drafted each term.³⁰ Currently, Connecticut, Hawaii, Kansas, Massachusetts, New Hampshire, New Jersey, and Pennsylvania have all proposed legislation related to aid in dying.³¹ Generally these bills are based on the existing death with dignity laws in Oregon, Washington, and Vermont.³² One unfortunate consequence of this new wave of legislation, drawing its basis from the original death with dignity acts, is the provision that only persons over the age of eighteen are permitted access to the relief granted by these laws.³³ Adolescents with terminal illnesses, aged fourteen to seventeen years, are precluded from accessing or even requesting assistance with death under the current laws because they are presumed unable to process the weight of the information required to make any medical decisions, let alone the choice to

CTR <http://www.deathwithdignity.org/access-acts> (last visited Apr. 6, 2014) [hereinafter Death with Dignity Access Acts].

28. *Baxter v. State*, 224 P.3d 1211, 1222 (Mont. 2009); *see also Montana*, PATIENTS RIGHTS COUNCIL, <http://www.patientsrightscouncil.org/site/montana/> (last visited Apr. 6, 2014) (describing the path of Assisted Death legislation in Montana and concluding that while no law has been enacted granting the citizens of Montana the right to assisted death, it is permitted under the current Terminally Ill Act); Rita L. Marker, *Montana Supreme Court: Physician Assisted Suicide Is and End-of-Life Option*, STATE COURT DOCKET WATCH 4, 5, 12 (2010), http://www.fed-soc.org/doclib/20100407_SCDWSpring10.pdf (explaining the Montana Supreme Court decision and providing relevant portions of the Terminally Ill Act); MONT. CODE ANN. § 50-9-204 (West 2013).

29. VT. STAT. ANN. tit. 18, § 5289 (2013) (provision regarding the protection of patient choice at end of life).

30. *Id.*; *See also* Rita L. Marker, *Assisted Suicide: Not for Adults Only?*, PATIENTS RIGHTS COUNCIL, <http://www.patientsrightscouncil.org/site/not-for-adults-only/> (last visited Apr. 6, 2014) (Discussing the failure of Right to Die legislation in Wisconsin and Illinois and the lack of support for Iowa's model Aid-in-dying Act).

31. Dignity Around the U.S., *supra* note 24.

32. *Id.* (providing a summary of current assisted death-related legislation throughout the U.S.).

33. Death with Dignity Access Acts, *supra* note 27 (describing the eligibility requirements for accessing assisted death in Oregon, Washington, and Vermont); *See also* OR. REV. STAT. 127.800 §1.01 et seq. (2013); WASH. REV. CODE. § 70.245.010 (2013); VT. STAT. ANN. tit. 18 §§ 5283, 5289 (2013).

end their own lives.³⁴ While the increasing number of death with dignity bills introduced each term encourages proponents of assisted death, they fail to recognize that the current laws also need to be reevaluated to incorporate the adolescent right to assisted death.³⁵ However, social norms and political climates are changing in a way that may ultimately lead to acceptance of such a right.³⁶

IV. CONSTITUTIONALITY OF THE RIGHT TO DIE IN THE UNITED STATES AND THE IMPACT OF INTERNATIONAL LEGISLATION THAT INCREASES ACCESS

On June 26, 1997, the United States Supreme Court held that an individual does not have a fundamental Constitutional right to end his or her life.³⁷ However, four months later, Oregon enacted its Death with Dignity Act, the first law of its kind in the United States, which allows terminally ill adult residents of Oregon to receive assistance in death from a physician by means of a lethal prescription.³⁸ Seventeen years later on February 13, 2014, Belgium's Parliament passed a bill making it legal for terminally ill

34. Rhonda Gay Hartman, *Adolescent Decisional Autonomy for Medical Care: Physician Perceptions and Practices*, 8 U. CHI. L. SCH. ROUNDTABLE 87, 88 (2001) (comparing adult decision-making capability with that of the adolescent).

35. *Death with Dignity Access Acts*, *supra* note 2 (describing the eligibility requirements for accessing assisted death in Oregon, Washington, and Vermont); *See also* OR. REV. STAT., *supra* note 33; WASH. REV. CODE, *supra* note 33; VT. STAT. ANN. *supra* note 33.

36. *See* Dignity Around the U.S., *supra* note 24 (explaining that the Death with Dignity movement is gaining strength and that public opinion seems to be shifting toward acceptance of assisted death).

37. *Washington v. Glucksberg*, 521 U.S. 702, 702-703 (1997) (rejecting a substantive due process challenge to a Washington state law which prohibited assisted death by a group of terminally ill plaintiffs who alleged that they were denied liberty without due process when prohibited by the statute to seek or receive assistance with death. The Court held that the Washington statute on its face did not violate due process); *accord* *Vacco v. Quill*, 521 U.S. 793, 793-794 (1997) (Plaintiff challenged the constitutionality of the New York State's ban on physician-assisted suicide which permitted patients to refuse lifesaving treatment on their own, but made it a crime for physicians to provide terminally ill patients with assistance in death.); *see also* JOHN E. NOWAK AND RONALD D. ROTUNDA, *PRINCIPLES OF CONSTITUTIONAL LAW* 519 (3d ed. 2007) (explaining the evolution of right to die cases in the Supreme Court).

38. OR. REV. STAT., *supra* note 33; *See also* *Death with Dignity Act*, OREGON DEPT. OF PUB. HEALTH, *available at* <https://public.health.oregon.gov/ProviderPartnerResources/EvaluationResearch/DeathwithDignityAct/Pages/index.aspx> (last visited Apr. 6, 2014).

children and adolescents to request and receive assistance with death.³⁹ This recent decision by the Belgian Parliament to remove existing age restrictions on assisted death and expand adolescent autonomy to end-of-life decision-making has sparked a conversation surrounding the rights and capacity of terminally ill adolescents in deciding to end their lives.⁴⁰

In two concurrently published decisions, the United States Supreme Court placed the decision of whether to allow terminally ill citizens to seek assisted death firmly with the states.⁴¹ Under the rulings, a patient's right to refuse or withdraw medical treatment must be balanced against relevant state interests.⁴² Those relevant state interests include ensuring the integrity of the medical profession, protecting vulnerable citizens, and maintaining and preserving life, which includes the prevention of suicide.⁴³ Only five of fifty states have decided that the individual's interest in prevention of harm by means of assisted death outweighs the state's interest in preservation of life.⁴⁴ However, these states fail to address the issue of extending the protected interests of the patient to include the prevention of harm to adoles-

39. Duncan Crawford, *Belgium's parliament votes through child euthanasia*, BBC NEWS EUROPE (Feb. 13, 2014), <http://www.bbc.com/news/world-europe-26181615>.

40. Meghan Daum, *Belgium's humane stance on dying kids*, L.A. TIMES (Feb. 20, 2014), <http://www.latimes.com/opinion/commentary/la-oe-0220-daum-belgium-euthanasia-children-20140220,0,6107150.column#axzz2uT0ZO7Ge> (detailing the international headlines surrounding Belgium's decision to enact the law including "Belgium on Verge of OK to Kill Sick Children" and accusations that this law would be akin to the initiative in Nazi Germany that systematically euthanized severely disabled children in order to promote racial purification).

41. *Washington*, 521 U.S. at 735; *Vacco*, 521 U.S. at 808-809 (explaining that there is no fundamental right to commit suicide and therefore, the statutory distinction between allowing a patient to refuse or withdraw medical therapy/treatment and prohibiting a patient from receiving assistance in death is subject only to the rational basis test); accord JOHN E. NOWAK AND RONALD D. ROTUNDA, *supra* note 37, at 519.

42. *Cruzan v. Director, Mo. Dept. of Health*, 497 U.S. 261, 283-284 (1990) (holding that the state's interest must be considered and balanced in any decision to withdraw life-sustaining medical treatment); accord JOHN E. NOWAK AND RONALD D. ROTUNDA, *supra* note 37, at 519.

43. *In re Fiori*, 673 A.2d 905, 910 (Pa. Super. Ct. 1996); see also Michele M. Hughes, *State Interests*, 77 C.J.S. *Right to Die* § 7 (Dec. 2013), available at WestlawNext.

44. *Death with Dignity Acts*, *supra* note 2; see also Eckholm, *supra* note 2 (explaining that assisted death was banned everywhere in the U.S. save Oregon until 2008 and now it is legal in five states including, most recently, New Mexico); see also Findings of Fact and Conclusions of Law at 12-13, *Morris v. Brandenburg*, *supra* note 23.

cents.⁴⁵

In 2002, the Netherlands enacted the Termination of Life on Request and Assisted Suicide (Review Procedures) Act.⁴⁶ This act codified the practice of physician-assisted death which, up to that point, had been tolerated by the public and the law for the past three decades, and provided an exception for minors over the age of twelve.⁴⁷ This exception allows terminally ill minors experiencing both lasting and unbearable suffering to voluntarily request assistance in death.⁴⁸ Minors older than twelve but younger than sixteen must have consent from a parent or guardian and their decision must be informed.⁴⁹ The decision to seek assisted death by minors aged sixteen or seventeen years old does not require parental consent, but parents are required to be involved in the adolescent's decision-making process.⁵⁰

Similar to current United States laws regarding assisted death, Belgium passed a law in 2002 that decriminalized euthanasia for terminally ill adults over the age of eighteen.⁵¹ However, Belgium's Parliament recently voted to lift the age restriction on requests for assisted death and extend the right

45. See *Death with Dignity Access Acts*, *supra* note 27 (describing the eligibility requirements for accessing assisted death in Oregon, Washington, and Vermont); see also OR. REV. STAT. 127.800 § 1.01 et seq. (2013); WASH. REV. CODE. § 70.245.010 (2013); VT. STAT. ANN. tit. 18, §§ 5283, 5289 (2013).

46. GOV'T OF THE NETHERLANDS, *Euthanasia*, <http://www.government.nl/issues/euthanasia/euthanasia-assisted-suicide-and-non-resuscitation-on-request> (last visited Apr. 6, 2014); see also RIGHT TO DIE-NL, *About NVVE*, <http://www.nvve.nl/about-nvve> (last visited Apr. 6, 2014).

47. GOV'T OF THE NETHERLANDS, *supra* note 46; see also CARE, *Euthanasia: Country Comparison*, <http://www.care.org.uk/advocacy/end-of-life/euthanasia-country-comparison> (2010).

48. GOV'T OF THE NETHERLANDS *supra* note 46; see also David Jolly, *Push for the Right to Die Grows in the Netherlands*, N.Y. TIMES (Apr. 2, 2012), available at http://www.nytimes.com/2012/04/03/health/push-for-the-right-to-die-grows-in-the-netherlands.html?_r=0; see also PATIENTS RIGHTS COUNCIL, *Background about Euthanasia in the Netherlands*, <http://www.patientsrightscouncil.org/site/holland-background/>.

49. GOV'T OF THE NETHERLANDS, *supra* note 46; see also CARE *supra* note 47 (stating that each case under consideration for euthanasia must have a second medical opinion.); see also PATIENT RIGHTS COUNCIL, *supra* note 48 (explaining that a patient who requests euthanasia must be given alternatives and adequate time to consider the alternative courses of treatment or non-treatment).

50. GOV'T OF THE NETHERLANDS, *supra* note 46.

51. Crawford, *supra* note 39.

to terminally ill children and adolescents who (1) make a voluntary and deliberate decision which demonstrates consciousness of the choice being made; (2) have approval from both parents or guardians and the adolescent's medical team; and (3) are in unrelenting pain and suffering due to the unavailability of treatment to combat their suffering.⁵² These procedural measures provide strict guidelines for the practice of assisted death that help prevent abuse of the practice and provide terminally ill adolescents the opportunity to exercise much needed autonomy when it comes to medical decision-making.⁵³

Unfortunately, the image securely planted in the minds of the American public is that assisted death only occurs in terminally ill elderly patients who, after many good years, are allowed to peacefully slip away by their voluntary decision to seek assisted death.⁵⁴ Any discussion surrounding extending end-of-life decision-making autonomy to adolescents causes alarm, discomfort, and often outrage.⁵⁵ This scenario is precisely what makes the newly minted Belgian law so important; while its impact on the number of children choosing to terminate their lives rather than spend their last days suffering excruciating pain may be minimal due to the procedural safeguards in place, it has effectively removed the muzzle from the unthinkable subject of extending the right to assisted death to adolescents and placed it

52. *Id.*; see also Daum, *supra* note 40 (explaining that, due to the new law, in order for children and adolescents in Belgium to qualify for assisted death they must be suffering from unmanageable pain as determined by a physician, receive approval from parents and the medical team, undergo psychological evaluation, be close to death, and must repeatedly make voluntarily requests to demonstrate their ability to understand what they are requesting).

53. See Daum, *supra* note 40; see also Hartman, *supra* note 34, at 88.

54. Marker, *supra* note 30, at 1.

55. Daum, *supra* note 40 (discussing that the public outrage over Belgium's decision to lift age restrictions on assisted death has brought to the forefront arguments comparing Belgian physicians and lawmakers to Nazis); see also Marker, *supra* note 30, at 1 (stating that the mere question of extension of assisted death eligibility to adolescents might brand the questioner a vehement opponent using 'emotionally charged fear tactics' but neglecting to mention that the questioner could conversely be accused of advocating for infanticide and other less than flattering ideals).

at the forefront of the American consciousness.⁵⁶

V. ADOLESCENT AUTONOMY AND END-OF-LIFE DECISION-MAKING – TIME FOR A CHANGE

Proponents of assisted death advocate for a competency exception to the general rule against assisted death.⁵⁷ This exception requires that a patient be at the end of his or her life, experiencing relentless suffering, having undergone all possible palliative treatment measures, and voluntarily and repeatedly requested aid from a physician or loved ones in assisting or hastening his or her death.⁵⁸ So long as these factors are in place, the patient should be permitted to receive such assistance.⁵⁹ If appropriate procedural safeguards similar to those within Belgium's assisted death statute are implemented, it seems that there is no valid reason why this exception should not be applied to adolescents in the United States.⁶⁰

American adolescents are traditionally regarded as minors by law and are thereby considered legally disabled.⁶¹ Under this designation, individuals suffering from terminal illnesses presumptively lack the capacity for medical decision-making.⁶² The current legal presumption is that adolescents lack the capacity to make medical decisions regarding treatment at the end

56. See Daum, *supra* note 40 (stating that Belgium's new law is procedurally safe, well-reasoned, supported by a majority of the Belgium citizenry, and an important catalyst to conversations regarding adolescent right to assisted death in the U.S. and elsewhere).

57. Supanich, *supra* note 5, at 199.

58. See Daum, *supra* note 40 (describing the requirements for adolescents to qualify for consideration of assisted death);

59. See also Hartman, *supra* note 34, at 88 (stating that adolescent decisional autonomy needs to be further examined, that the discussion surrounding the capacity of an adolescent to consent should be supported by empirical evidence, and providing examples of instances where the adolescent's capacity for autonomy shifts from one extreme to another simply based on the context of the issue or action being addressed).

60. Hartman, *supra* note 34, at 88; see also Daum, *supra* note 40 (explaining the procedural safeguards in place for the provision of child or adolescent assisted death in Belgium).

61. Rhonda Gay Hartman, *Coming of Age: Devising Legislation for Adolescent Medical Decision-Making*, 28 AM. J.L. & MED. 409, 409 (2002).

62. *Id.* (stating that the "Supreme Court has observed that vulnerability impairs minors decision-making capability" and observing that the law regulates decision-making by minors more comprehensively than adults).

of life.⁶³ This presumption disregards the current social norms and laws that provide adolescents with decisional autonomy and allow them to bear the consequences of their choices.⁶⁴ Current developmental research demonstrates that adolescents are capable of taking on the same level of autonomy legally provided to them in family court proceedings and similarly apply it to medical decision-making.⁶⁵ The lack of compelling research in support of the limited autonomy provided to adolescents stems not from any scientific determination, but rather from the outdated notion that the state should act through care and concern to protect adolescents from themselves.⁶⁶ This notion fails to acknowledge the ability of adolescents, especially those suffering from terminal illnesses, to combine their own decision-making abilities with the advice and consent of their parents and physicians, and conclude that the harm of staying alive far outweighs the harm that would be done by requesting or receiving assistance in death.

The procedural safeguards put in place by Belgium and the Netherlands, which provide adolescents with access to assisted death, should be a catalyst to a discussion amongst state legislatures in the United States. For instance, the legalization of assisted suicide for individuals over the age of twelve in the Netherlands in 2002 is instructive, since then only five children have actually received assistance in death because the requirements for approval of such a request are stringent and require the input of parties outside of the child.⁶⁷ In order for a physician to avoid prosecution for committing assisted suicide or euthanasia, all of the requirements in the Dutch

63. Hartman, *supra* note 34, at 89.

64. *Id.* (providing the example of juvenile delinquency and family court proceedings where adolescents are granted decision-making autonomy and stating that “legal recognition of adolescent waiver for fundamental constitutional rights and adolescents’ legal ability to bring personal injury suits against their parents stand in contradistinction to the lack of autonomy afforded adolescents for medical decision making . . . which rests on scant scientific and social evidence”).

65. Hartman, *supra* note 34, at 89.

66. *Id.* at 91 (describing how the state’s decision to act as *parens patriae* dictates that the state act through care and concern to protect adolescents from themselves).

67. Daum, *supra* note 40.

Termination of Life on Request and Assisted Suicide (Review Procedures) Act must be satisfied.⁶⁸ The argument for extending the right to die to its citizens and providing legal protection for physicians who engage in these practices arises out of the need for more patient autonomy – patients should have the right to make decisions about how they die.⁶⁹

Most people in the Netherlands support the practice of assisted death as demonstrated by poll results that show an overwhelming majority believes in patient autonomy and that assisted death should be available to those who want it.⁷⁰ The most controlling procedural safeguard to prevent abuse of assisted death is the requirement that physicians report the cause of death to the municipal coroner and that physicians voluntarily report acts of assisted death to the Euthanasia Commission for review.⁷¹ The Commission, composed of a lawyer, physician, and ethicist, examines each reported case to determine whether the physician complied with the strict requirements of the Dutch Termination of Life on Request and Assisted Suicide (Review Procedures) Act sufficiently to secure immunity from criminal prosecution.⁷² These requirements heighten the accountability of the physician in order to protect the patient while he or she is in a vulnerable state.

While assisted death for adolescents in the Netherlands has been legal within the constraints of the law for twelve years, the Belgian law that removes all age restrictions from access to assisted death is quite recent.⁷³ The requirements that must be met before an adolescent may seek assisted death in Belgium function as procedural safeguards that operate to reduce

68. GOV'T OF THE NETHERLANDS, *supra* note 46.

69. PATIENT RIGHTS COUNCIL, *supra* note 45.

70. Jolly, *supra* note 48.

71. FAQ – Euthanasia in the Netherlands, RADIO NETHERLANDS WORLDWIDE (Sept. 29, 2009, 11:14AM), <http://www.rnw.nl/english/article/faq—euthanasia-netherlands> (last visited Apr. 6, 2014).

72. *Id.*

73. *Id.*; see also Crawford *supra* note 39.

instances of abuse.⁷⁴ According to Belgian polls, seventy-five percent of the public supports expansion of the law that permits assistance in death to persons of any age including children who can prove a capacity for discernment through a series of requests and psychological evaluation.⁷⁵ The psychological evaluation, in addition to the existing requirement that the request for assistance in death be a voluntary, informed decision that is approved by multiple physicians and the parents of the child, serves to shield the child from possible abuse by preventing coercion or uninformed decision-making.

The laws in states that permit assisted death in the United States should be amended to mirror not only the lowered age restrictions of the law in the Netherlands, but also the safeguards within that law. There is seemingly no rationale, aside from the refusal to provide adolescents with decisional autonomy in regards to medical decisions, which would preclude the United States from lifting the current age restriction of eighteen years old for requesting assistance with death.⁷⁶ The distinction drawn in the United States between the ages of seventeen and eighteen dissolves into nothing more than a legal fiction when procedural standards that require a patient, cognizant of his or her voluntary decision to end his or her own life, to be suffering unbearably from a terminal illness are rigorously enforced. The implementation of a committee similar to the Netherlands' Euthanasia Committee that would review the physician's determination that assisted death is per-

74. See Daum, *supra* note 40 (explaining the strict requirements for receiving assistance in death in Belgium that preclude abuse).

75. Daum, *supra* note 40.

76. Cf. *States That Allow Same-Sex Marriage*, NAT'L CONF. OF STATE LEGISLATURES, <http://www.ncsl.org/research/human-services/same-sex-marriage-laws.aspx> (last updated Mar. 6, 2014); *State Medical Marijuana Laws*, NAT'L CONF. OF STATE LEGISLATURES, <http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx> (last updated Mar. 27, 2014) (In light of recent progressive legislation involving same-sex marriage and legalization of marijuana it is time to encourage a change in the legislative opinions surrounding assisted death and extend the right to a controlled, death with dignity to adolescents).

missible would serve to further protect citizens.⁷⁷ If the current procedural safeguards remain intact and states are willing to include a review committee, there is no reason why the right to access assisted death could not be expanded to include adolescents in the United States.

VI. CONCLUSION

While the number of states that permit assisted death is still in the single digits, it should not remain that way for long. The right to die movement in the United States has steadily gained traction in the past few years, including recent victories in New Mexico and Montana state courts that allow patients to receive aid in dying according to strict procedures and protocols in place to prevent abuse. The decision made by the Netherlands to provide assistance in death to patients over the age of twelve and the recent decision of Belgium to remove any age restrictions from access to assisted death provide a guide for adolescent medical autonomy in the United States. So long as procedural guidelines are strictly adhered to, there is no reason why the United States should not expand access to assisted death to terminally ill adolescents.

The procedural safeguards surrounding the right to die in the United States continue to prove sufficient to protect patients from abuse of assisted death laws. For this reason, the current age restriction seems to be based on a fictional distinction drawn between one year of life and another. Therefore, the United States should mirror the efforts of Belgium and the Netherlands and that states should introduce bills allowing assisted death for terminally ill adolescents.

77. See *Death with Dignity Access Acts*, *supra* note 2 (explaining that current state laws that allow for assisted death protect the public by allowing the patient to rescind his or her request at any time, which allows the patient to be in full control of the process. The process for procuring a lethal prescription for use in assisted death includes the requirement that the patient make a verbal request for the lethal prescription on two separate occasions, with fifteen days elapsing between the requests, a written request that is witnessed by parties who are not directly affected by the patient's choice, and the patient is able to self-administer the prescribed lethal medication).

United States' Blood Donor Policy on Gay Men:
Adopting an Italian Individual Risk Assessment
Policy

*Melissa Kong**

I. INTRODUCTION

An estimated thirty-seven percent of the United States' population is eligible to donate blood, but less than ten percent of those eligible actually donate each year.¹ The small eligibility pool is due in part to restrictions placed upon potential donors.² One such restriction is a permanent ban from donating blood against men who had sexual contact with other men (MSM) at least once since 1977.³ According to the United States Food & Drug Administration (FDA), MSM who donate blood pose an increased risk for the human immunodeficiency virus (HIV) and other infections to be transmitted by a blood transfusion.⁴ Not all countries, however, prevent MSM from donating blood.⁵ Italy does not prohibit blood donations from individuals

* Melissa Kong is a second-year student at Loyola University of Chicago School of Law who is pursuing a public interest certificate and a health certificate.

1. Vianca Diaz, *A Time for Change: Why the MSM Lifetime Deferral Policy Should be Amended*, 13 U. MD. L.J. RACE, RELIGION, GENDER & CLASS 134, 146 (2013); *Facts & Figures*, AM.'S BLOOD CTRS., <http://www.americasblood.org/about-blood/facts-figures.aspx> (last visited Mar. 7, 2014).

2. Diaz, *supra* note 1, at 146 (indicating one reason for the blood shortage is that only 37% of Americans are eligible to donate blood; if the United States amends its deferral policies then more willing and healthy citizens can donate).

3. Dwayne J. Bensing, *Science or Stigma: Potential Challenges to the FDA's Ban on Gay Blood*, 14 U. PA. J. CONST. L. 485, 486 (2011).

4. *Blood Donations from Men Who Have Sex with Other Men Questions and Answers*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/biologicsbloodvaccines/bloodbloodproducts/questionsaboutblood/ucm108186.htm> (last updated Aug. 19, 2013) [hereinafter FDA FAQ].

5. See Meredith Ciufo, *Drawing Blood: Towards an EU Remedy for Blood Donation Rights*, 31 B.U. INT'L L.J. 341, 344 (2013) (stating Spain and Italy do not have MSM restrictions in their blood donation qualifications).

based on their sexual orientation;⁶ instead, Italy uses a process called an individual risk assessment (IRA).⁷ If a person is deemed under an IRA to have high-risk behavior, he or she is not allowed to donate blood.⁸

This article argues the United States should emulate Italy's blood donation policy where an individual is assessed according to his or her own behavior, regardless of sexual orientation. Part II outlines the United States' MSM permanent deferral policy and Italy's IRA policy. Part III discusses the significant increase in the availability of scientific data in regards to HIV, which supports the fact that it is time to adopt an IRA policy in the United States. Part IV demonstrates other donors, outside of MSM donors, have the potential to be HIV-positive, further invalidating the United States' ban on MSM. Part V examines the advancements in technology that enables Italy to detect HIV-antibodies and that leads to virtually zero such infections entering the blood supply. Part VI will discuss the FDA's resistance to an IRA policy.

II. BLOOD DONOR POLICIES

A. United States' Blood Donor Policy

In the United States, the FDA requires that a blood donor is healthy, at least seventeen years old, and weighs a minimum of 110 pounds.⁹ Moreover, a donor cannot fall into a deferral category.¹⁰ A donor may receive a deferral for various reasons, including if an individual lived in certain coun-

6. See *id.* (indicating Italy's blood donation qualifications are based on an individual analysis of high-risk behavior and MSM are not explicitly mentioned).

7. Barbara Suligoi et al., *Changing Blood Donor Screening Criteria from Permanent Deferral for Men Who Have Sex With Men to Individual Sexual Risk Assessment: No Evidence of a Significant Impact on the Human Immunodeficiency Virus Epidemic in Italy*, 11 BLOOD TRANSFUSION 441, 442 (2013), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3729137/>.

8. *Id.*

9. Whitney Larkin, *Discriminatory Policy: Denying Gay Men the Opportunity to Donate Blood*, 11 HOUS. J. HEALTH L. & POL'Y 121, 125 (2011) (stating in some states a blood donor may be 16 years old with parental consent).

10. *Id.*

tries, previously engaged in high-risk behavior, or possesses signs and symptoms of HIV.¹¹ There are two types of deferrals: temporary and permanent.¹² If a donor is issued a temporary deferral, a donor must wait for a specified period of time before giving blood.¹³ If a donor is issued a permanent deferral, that individual is indefinitely banned from donating blood and subsequently placed on a national deferral registry.¹⁴ The United States' current policy permanently defers MSM from donating blood.¹⁵

B. Italy's Blood Donor Policy

Comparatively, Italy does not have a specific MSM deferral policy.¹⁶ In 2001, Italy modified its blood-donor eligibility from a permanent deferral for MSM to an IRA, analyzing individuals based on his or her own at-risk behavior.¹⁷ Instead, both males and females, heterosexuals and homosexuals, are permanently deferred if they engage in high-risk behavior.¹⁸ A permanent deferral is issued if an individual engages in sex with more than one partner whose sexual behavior is unknown, participates in prostitution, injects drugs, or engages in sex with a partner who is known to have a communicable disease.¹⁹ Sexual orientation, by itself, is not grounds for a permanent deferral.²⁰

III. INCREASED AWARENESS OF HIV

A. Scientific Knowledge Prior to the MSM Policy

The FDA issued its MSM blood donation policy in 1985, at a time of un-

11. *Id.*

12. *See id.* at 126 (discussing temporary and permanent deferrals).

13. *Id.*

14. *Id.*

15. Bensing, *supra* note 3, at 486.

16. *See* Ciufo, *supra* note 5, at 344 (indicating that there is no mention of MSM in Italy's policy to qualify as a donor).

17. Suligoi et al., *supra* note 7, at 442.

18. *Id.*

19. *Id.*

20. *Id.*

certainty when tests could not accurately detect HIV-antibodies in blood and the cause of the virus was unknown.²¹ In mid-1981, the first case of acquired immunodeficiency syndrome (AIDS) was characterized in homosexual men, but referred to as a rare lung disease.²² Toward the end of the year, at least 270 homosexual men were diagnosed with what is now known as AIDS.²³ In response to this outbreak, in 1983, the FDA issued non-mandatory guidelines suggesting that at-risk groups refrain from donating blood.²⁴ One year later, scientists discovered HIV triggered the AIDS virus.²⁵ Throughout this time, HIV was most prevalent in sexually active MSM, and there was a general lack of scientific knowledge regarding the transmission of HIV.²⁶

The AIDS outbreak transpired worldwide.²⁷ In Italy, the HIV epidemic began in 1982 and peaked in 1987.²⁸ Similar to the United States, there was a general lack of knowledge as to the cause of the AIDS outbreak.²⁹ Subsequently, Italy implemented a permanent deferral to MSM.³⁰ The FDA fur-

21. See Larkin, *supra* note 9, at 121, 132.

22. See Kumanan Wilson et al., *Three Decades of MSM Donor Deferral policies. What Have we Learned?*, 18 INT'L J. OF INFECTIOUS DISEASES 1, 1 (2014), available at <http://download.journals.elsevierhealth.com/pdfs/journals/1201-9712/PIIS1201971213003081.pdf> (indicating in mid-1981 AIDS was characterized in homosexual men); Diaz, *supra* note 1, at 136 (indicating that on June 5, 1981, five gay men were found to have what is now known as AIDS; the United States Centers for Disease Control and Prevention published a report detailing the men with a rare lung infection).

23. Diaz, *supra* note 1, at 136.

24. See Bensing, *supra* note 3, at 491-92 (stating the Office of Biologics issued non-mandatory guidelines suggesting individuals that had an increased risk for AIDS should refrain from donating blood); *Vaccines, Blood, & Biologics*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/ucm331317.htm> (last updated March 31, 2014) (indicating the Office of Compliance and Biologics is a division of the U.S. Food & Drug Administration).

25. Wilson, *supra* note 22, at 2.

26. See Larkin, *supra* note 9, at 121-22 (indicating at the time, AIDS was most prevalent in the MSM community and there was no test to accurately detect HIV antibodies).

27. See Wilson, *supra* note 22, at 1 (“In the early 1980s, several countries were confronted with the tragedy of HIV-contaminated blood”).

28. Suligoi et al., *supra* note 7, at 441.

29. See Wilson, *supra* note 22, at 1-2 (indicating in mid-1982, AIDS was primarily diagnosed in MSM and in response, blood operators worldwide issued blood donor deferrals from MSM; at the time, no blood test could detect the AIDS-causing agent).

30. Suligoi et al., *supra* note 7, at 442 (“[A]ny male who declared having ever had sex

ther revised its policy in 1985 to exclude MSM entirely and include language for a lifetime deferral, creating the United States' policy as it is today.³¹ As scientific research improved, Italy adopted a new approach and the United States decided to stand by its MSM policy.³²

B. Scientific Knowledge Post MSM Policy

Increased awareness of HIV and its causes lead to policy changes worldwide.³³ In particular, Italy changed its policy to accept blood donations from healthy gay and bisexual individuals so long as they posed no high-risk behavior and their blood tested as safe.³⁴ The global community now knows that AIDS is a blood-borne disease and can be transferred through blood contact from one individual to another.³⁵ In the United States, in the time period after the FDA implemented the MSM policy, individuals began to practice safer sex, tests were developed to detect HIV antibodies, and the population better understood the disease.³⁶ Statistically, from the 1990s to the early 2000s, HIV rates decreased among gay men and increased among other groups.³⁷ However, the United States fails to react to

with other men was systematically permanently deferred”).

31. See Larkin, *supra* note 9, at 134 (stating the FDA initially recommended to blood banks not to accept MSM blood but eventually MSMs were permanently barred from donating blood in 1985).

32. See Suligoi et al., *supra* note 7, at 442 (stating Italy adopted its new IRA policy in 2001); Larkin, *supra* note 9, at 121 (indicating scientists developed tests concluding sexual orientation has nothing to do with HIV); David Crary, *Gay Blood Donors Ban Endures In the U.S., Despite Lacking ‘Sound Science’*, HUFFINGTON POST (Sept. 15, 2013, 11:25 AM), http://www.huffingtonpost.com/2013/09/15/gay-blood-donors-ban_n_3932001.html (indicating U.S. should adopt measures similar to Spain and Italy, where a ban on blood donations by MSM has been replaced by policies that ban donations to anyone who recently had unsafe sex).

33. See Ciufu, *supra* note 5, at 352 (indicating Australia abandoned its five-year deferral for MSM and adopted a one-year deferral period); Ferbus Walsh, *Gay Men Blood Donor Ban Lifted*, BBC NEWS (Sept. 8, 2011), <http://www.bbc.co.uk/news/health-14844413?print=true> (indicating the U.K. lifted its permanent deferral on MSM in 2011).

34. Crary, *supra* note 32.

35. Larkin, *supra* note 9, at 121.

36. See *id.*

37. *Id.* at 139 (adding in 1999, blacks were twenty-five times more likely than whites to acquire HIV and women had a high likelihood of contracting HIV; among HIV-positive individuals between twenty and twenty-four years old, forty-four percent were women).

this new knowledge of information.³⁸

The MSM policy unethically prohibits individuals from donating blood because of their sexual orientation, even though many of them are potential healthy donors.³⁹ The policy also sends a false message that MSM naturally participate in inherently risky activities, consequently undermining education that an individual can decrease the likelihood of contracting a sexually transmitted disease through protected sexual activity or involvement in a monogamous relationship.⁴⁰ It is an unjust system because heterosexual individuals engaging in risky behavior are only issued a temporary ban, whereas MSM are indefinitely banned.⁴¹ Not only is the policy unjust to MSM, it is also inefficient in protecting the donated blood supply from infection.⁴²

The policy is over-inclusive in permanently banning healthy MSM donors and under-inclusive in admitting risky non-MSM donors.⁴³ Given the new span of information regarding the causes of HIV, it would be reasonable to adopt Italy's IRA policy to ensure those engaging in the same level of risky behavior are treated fairly.

IV. AN ITALIAN STUDY: EXAMINING HIV-POSITIVE BLOOD DONORS

Italy's IRA policy demonstrates that MSM HIV-positive individuals do not outnumber HIV-positive individuals from other groups; rather, heterosexuals substantially contribute to new HIV diagnoses, which further indi-

38. See *id.* at 127 (indicating blood drive questionnaires focus on a person's sexual orientation, asking, "From 1977 to present, have you [male donors] had sexual contact with another male, even once?").

39. See Diaz, *supra* note 1, at 135 (indicating the lifetime deferral policy prohibits those who are healthy and fit to donate).

40. Bensing, *supra* note 3, at 499.

41. See Larkin, *supra* note 9, at 129 (indicating the ban that applies to MSM does not apply to heterosexuals; heterosexuals who engage in similar risky sexual behavior have a temporary deferral for up to twelve-months).

42. See *id.* (indicating there is a flaw in a system that tolerates a wide range of risks associated with heterosexual sex but not MSM, even if MSM pose no risk through their individual behavior).

43. Bensing, *supra* note 3, at 501.

cates that the United States' permanent ban on MSM is unwarranted.⁴⁴ One study obtained data from the Italian blood donor surveillance system in order to compare data from 1999, when Italy had a permanent deferral on MSM, to data from 2009 and 2010, when Italy applied its IRA policy.⁴⁵ The study established that Italy did not see a significant impact from the IRA policy on the number of HIV-positive MSM donors.⁴⁶ Instead, the study found the number of HIV-positive MSM donors increased at a similar rate to the incidence of HIV-positive heterosexual donors.⁴⁷

The study demonstrates there are other risks, besides allowing MSM to donate blood, that lead to an increase in HIV-positive blood donors.⁴⁸ Although the study did conclude that overall, Italy had a higher percentage of HIV-positive blood donors compared to other Western European countries,⁴⁹ there is no indication that there is a higher percentage of HIV-positive MSM donors.⁵⁰ In 2011, the World Health Organization found that 55.4% of HIV infections in Italy occurred through heterosexual contact, 38.1% occurred through MSM sexual contact, and 5.5% occurred through intravenous drug use.⁵¹ These statistics suggest the greatest risk to donors is not the risk of allowing MSM donors, as the United States seems to think.⁵²

44. See Suligoi et al., *supra* note 7, at 445 (“[I]n 2010, MSM accounted for 40.3% and heterosexuals for 46.8% of new HIV diagnoses”).

45. *Id.* at 442-43.

46. *Id.* at 445.

47. *Id.*

48. See *id.* (demonstrating an increase in the number of new HIV-diagnoses in heterosexuals from 16% in 1999 to 46.8% in 2010 in comparison to MSM from 38.4% in 1999 to 40.3% in 2010; 2010 data reflects a lower percentage of new MSM HIV-diagnoses in comparison to new heterosexual HIV-diagnoses, MSM are not the sole cause of HIV-diagnoses and other factors may come into play).

49. *Id.*

50. See *id.* at 447 (indicating the IRA policy “did not significantly affect either the incidence or prevalence of HIV infection among blood donors or the distribution of MSM and heterosexuals among HIV antibody-positive blood donors”).

51. WORLD HEALTH ORG., KEY FACTS ON HIV EPIDEMIC IN ITALY AND PROGRESS IN 2011 (2013), available at http://www.euro.who.int/__data/assets/pdf_file/0019/191080/Italy-HIVAIDS-Country-Profile-2011-revision-2012-final.pdf.

52. See *id.* (indicating heterosexuals have contracted HIV infections at a higher rate in comparison to MSM).

The United States is concerned that if we allow MSM to donate blood, there will be an increase in the number of MSM HIV-positive blood donors who will contaminate the blood bank, but this concern is not valid.⁵³ Even during the period that Italy's permanent deferral was in effect, Italy saw an increased prevalence of HIV-positive donors, indicating that other factors might be responsible for contaminating blood banks with HIV.⁵⁴ One factor may be the perceived low risk of acquiring HIV, a belief particularly prevalent among heterosexuals who have unprotected sex.⁵⁵ Moreover, a study conducted in Lombardy, Italy concluded that despite the increase in HIV-positive donors before and after Italy's 2001 change of policy, there was no significant increase in MSM HIV-positive donors.⁵⁶ In general, if the United States implements an IRA policy, it does not mean the number of MSM HIV-positive donors will increase.⁵⁷

V. ADVANCEMENTS IN BLOOD TESTING METHODS

A. Nucleic Acid Testing in Italy

By adopting an IRA policy, Italy gives greater confidence to its donor screening procedures and its blood testing capabilities.⁵⁸ Shortly after implementation of the IRA policy, on June 28, 2002, Italy mandated nucleic acid testing (NAT) technology to screen blood donations.⁵⁹ This method en-

53. See *id.* (indicating stating in 2011, Italy saw a higher percentage of heterosexual HIV infections than MSM HIV infections); FDA FAQ, *supra* note 4 (stating MSM have an increased risk for HIV); see also Suligoi et al., *supra* note 7, at 445 (stating in 2010, Italy had a higher percentage of new heterosexual HIV diagnoses in comparison to new MSM HIV diagnoses).

54. Barbara Suligoi et al., *Epidemiology of Human Immunodeficiency Virus Infection in Blood Donations in Europe and Italy*, 8 BLOOD TRANSFUSION 178, 183 (2010), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2906188/>.

55. *Id.*

56. *Id.*

57. See *id.* (stating in Italy there was "no significant increase in the prevalence of HIV in blood donations from MSM before and after 2001").

58. Ciufo, *supra* note 5, at 356.

59. C. Velati et al., *Impact of Nucleic Acid Amplification Technology (NAT) in Italy in the Three Years Following Implementation (2001-2003)*, 10 EUROSURVEILLANCE 12, 12 (2005), available at <http://www.eurosurveillance.org/images/dynamic/EQ/v05n01/v05n01>.

sure detection of HIV-antibodies and helps improve detection of viral infections that are not detectable under other blood testing measures.⁶⁰ After an individual is infected with the HIV virus, he or she may not develop the antibodies for several months, so there may be a gap in time when the virus goes undetected by a blood test.⁶¹ This gap in time, also known as the window period, is narrowed due to NAT.⁶² NAT can detect infections at an early stage, approximately in four to seven days from when the donor was infected.⁶³ Although there is little data on the effectiveness of this type of blood testing in Italy, its effectiveness is proven to be very successful in other parts of the world.⁶⁴

B. Nucleic Acid Testing in the United States

With the advancements in today's technologies to detect infection, the blood testing process in the United States has virtually eliminated the possibility of infected blood entering the donated blood supply.⁶⁵ Today the risk of transmitting HIV through a blood transfusion is 1 in 2,000,000 in the United States.⁶⁶ The FDA invested many of its resources to test blood for HIV antibodies through NAT.⁶⁷ The technological advancement with NAT and its high level of accuracy calls into question the MSM lifetime deferral policies of the United States.⁶⁸ MSM should not be permanently deferred

pdf.

60. See Syria Laperche, *Blood Safety and Nucleic Acid Testing in Europe*, 10 *EUROSURVEILLANCE* 3, 3 (2005), available at <http://www.eurosurveillance.org/images/dynamic/EQ/v05n01/v05n01.pdf> (indicating NAT detects viral infections not detected by the serological screening methods).

61. Bensing, *supra* note 3, at 493.

62. See Larkin, *supra* note 9, at 137 (indicating that NAT can trim a few days off of the "window period").

63. Diaz, *supra* note 1, at 145-46.

64. Ciufo, *supra* note 5, at 356 (indicating effective blood tests have shown donors that they are HIV-positive when they were otherwise unaware).

65. Larkin, *supra* note 9, at 132.

66. *Blood Testing*, AM. RED CROSS, <http://www.redcrossblood.org/learn-about-blood/what-happens-donated-blood/blood-testing> (last visited Apr. 4, 2014).

67. Larkin, *supra* note 9, at 137.

68. Bensing, *supra* note 3, at 493.

when testing methods have drastically improved to detect viruses.⁶⁹

VI. FDA'S RESISTANCE TO AN INDIVIDUAL RISK ASSESSMENT

Despite the success rate of NAT, the FDA still calls into question the small time frame in which HIV-antibodies cannot be detected.⁷⁰ The FDA argues individuals are less likely to unknowingly donate blood during the window period of infection if there is a permanent deferral in place on MSM.⁷¹ This window period, however, applies to all high-risk groups; MSM do not pose a higher risk.⁷² According to the FDA, there is not sufficient information to lift the ban, and there is a need for further evaluation.⁷³ The FDA emphasizes MSM have a higher risk than the general population of transmitting HIV and other infectious diseases.⁷⁴ The MSM policy ignores other groups that have a high prevalence of HIV.⁷⁵ Without justification, there is no reason to exclude one high-risk group and not the other.⁷⁶ Under the FDA's reasoning, it would make more sense to issue a permanent ban for all high-risk groups and include heterosexual donors who engage in unprotected, multiple-partner sex.⁷⁷ The FDA's policy is not in line with its stated goal to protect the donor pool.⁷⁸

Moreover, the FDA argues there is a possibility once blood is stored for someone to accidentally give a patient untested blood or even blood that has

69. *Id.*

70. FDA FAQ, *supra* note 4 (indicating the "window period" exists very early after infection and blood tests are unable to detect all infections).

71. Bensing, *supra* note 3, at 500.

72. *Id.* at 501.

73. See FDA FAQ, *supra* note 4 (stating that the highest increase in HIV-positive MSM was in ages 13 to 24 years, increasing twenty-two percent from 2008 to 2010 and that there needs to be further research because the younger generation is more likely to donate blood).

74. *Id.*

75. Bensing, *supra* note 3, at 501.

76. See *id.* (indicating the FDA does not provide a justifiable distinction between other groups with a high prevalence of HIV, such as African American females, and MSM).

77. *Id.*

78. *Id.*

tested positive for an infectious disease.⁷⁹ The FDA suggests even though medical errors are rare, they can occur due to the large number of donations, amounting to about 17 million each year.⁸⁰ The possibility that blood may be misplaced is an ever-present issue.⁸¹ The sexual orientation of the donor does not matter; there is always the slight possibility of an accident occurring.⁸² Regardless, the FDA intends to uphold its MSM policy until there is more scientific data validating that a change in policy would not present a significant risk to blood recipients.⁸³

VII. CONCLUSION

At the time the FDA implemented the United States' MSM policy, the nation took a precautionary approach to ensure the blood supply was free from pathogens;⁸⁴ however, with the evolution of science and the introduction of new technologies, it is time to lift the ban on MSM. Specifically, the United States should emulate Italy's IRA policy. By adopting Italy's IRA policy, the United States would ensure all high-risk behavior is deferred, regardless of one's sexual orientation.⁸⁵ Scientists uncovered the causes of HIV and determined it is not based on sexual orientation, but rather the transmission of blood or other bodily fluids, further indicating that it is time for a change.⁸⁶ Studies suggest there are several contributing factors that can account for high level of HIV-positive blood donors outside of MSM

79. FDA FAQ, *supra* note 4.

80. *Id.*

81. Bensing, *supra* note 3, at 501.

82. *See id.* (indicating that the risk of blood accidentally being given to a patient in error is a threat that is always present).

83. FDA FAQ, *supra* note 4.

84. *See* Larkin, *supra* note 9, at 121 (indicating a permanent ban was issued against MSM donors in the absence of tests to detect HIV antibodies in blood and because of the past high prevalence of HIV in their community).

85. Suligoi et al., *supra* note 7, at 442 (stating Italy's IRA policy is applied to "all blood donors, both males and females, heterosexuals and MSM").

86. Larkin, *supra* note 9, at 121.

blood donations,⁸⁷ and this weakens the FDA's ban on MSM.⁸⁸ Advancements in technology virtually eliminate infected blood from entering the blood supply, undermining the United States' permanent deferral on MSM.⁸⁹ It is unethical for the United States to implement a permanent ban on MSM while only issuing a temporary ban on heterosexuals who engage in high-risk behavior.⁹⁰ The United States needs to take into account the fact that other groups, outside of MSM donors, pose a risk to the blood donor pool.⁹¹ There is not a valid reason why one group should be permanently deferred over the other. It is time for the United States to adopt Italy's individual risk assessment blood donation policy.

87. See Suligoi et al., *supra* note 7, at 446 (indicating Italian studies found no significant changes in the distribution of MSM and heterosexual HIV-positive blood donors before or after the country's IRA policy was implemented).

88. FDA FAQ, *supra* note 4.

89. Bensing, *supra* note 3, at 492.

90. Larkin, *supra* note 9, at 129.

91. See Diaz, *supra* note 1, at 140 (indicating the U.S. blood donation policy has several oversights including allowing donations from persons who had sex with a prostitute or women who had sex with HIV-positive males).

Acting in the Best Interest of Vulnerable Patients:
The Role of Independent Parties in Off-Label
Antipsychotic Prescribing for the Elderly in Nursing
Homes and Children in Foster Care

Jena Grady*

I. INTRODUCTION

Medical ethicists agree that physicians have an ethical obligation to place patients' welfare above their own self-interest and above obligations to other stakeholders in order to be proper advocates for their patients' well-being.¹ One of the biggest obstacles to patients receiving the best care from their physicians is the powerful and controversial relationship physicians have with pharmaceutical companies,² especially regarding off-label drugs.³ Off-label use of drugs are those that are prescribed for a particular use that have not been formally approved by the Food and Drug Administration (FDA) and therefore, has not been tested for safety and efficacy for that use.⁴ Off-label prescribing is a common practice in the medical industry.⁵

* J.D. Candidate, May 2015, Loyola University Chicago School of Law.

1. COUNCIL ON ETHICAL & JUD. AFF., AM. MED. ASS'N, CEJA REP. 1-A-01, THE PATIENT-PHYSICIAN RELATIONSHIP, 3-4 (2001).

2. Victor E. Schwartz et. al., *Marketing Pharmaceutical Products in the Twenty-First Century: An Analysis of the Continued Viability of Traditional Principles of Law in the Age of Direct-to-Consumer Advertising*, 32 HARV. J.L. & PUB. POL'Y 333, 336 (2009) (discussing that pharmaceutical companies have the sole power to disseminate the information necessary for the FDA to decide what products should be available to the market and what information is necessary to provide physicians to make an "educated treatment decision").

3. See generally Gregory Conko, *Hidden Truth: The Perils and Protection of Off-Label Drug and Medical Device Promotion*, 21 HEALTH MATRIX 149, 150 (2011) (stating that "[t]he agency bars nearly all speech promoting an off-label use regardless of its veracity, and vigorously enforces this restriction even when the information is not being broadcast to lay audiences but is provided directly to physicians with sophisticated medical training.").

4. Philip M. Rosoff & Doriane Lambelet Coleman, *The Case for Legal Regulation of Physicians' Off-Label Prescribing*, 86 NOTRE DAME L. REV. 649, 649-650 (2011).

While prescribing off-label drugs is not prohibited by law, there are substantial concerns for geriatric and pediatric populations because physicians are exercising excessive off-label prescribing of antipsychotic drugs without adequate scientific evidence of their efficacy.⁶

This article argues that independent parties need to be used as an appropriate safeguard to ensure that any off-label antipsychotic prescriptions are truly for the best interest of the patients. First, this article will briefly examine the general off-label practice and its prevalence among children in foster care and the elderly in nursing homes. Next, this article will address how caregivers' concerns can lead to off-label antipsychotic prescriptions, even with the knowledge of several concerns associated with prescribing. Lastly, this article will argue that an additional party, who is independent, should be used to act in the best interest of the patient instead of relying on physicians.

II. GENERAL OFF-LABEL PRACTICE AND ITS PREVALENCE AMONG CHILDREN IN FOSTER CARE AND THE ELDERLY IN NURSING HOMES

Federal and state governments, as well as the United States Supreme Court, have all determined that physicians should have the freedom to pre-

5. See Tim Mackey & Bryan A. Liang, *Off-Label Promotion Reform: A Legislative Proposal Addressing Vulnerable Patient Drug Access and Limiting Inappropriate Pharmaceutical Marketing*, 45 U. MICH. J.L. REFORM 1, 1-2 (2011) (finding that the prevalence of off-label prescribing has been estimated to be as high as 83 percent for certain kinds of drugs).

6. Rebecca Dresser & Joel Frader, *Off-Label Prescribing: A Call for Heightened Professional and Government Oversight*, 37 J.L. MED. & ETHICS 476, 476 (2009) (finding that a study examining prescribing practices for 169 commonly prescribed drugs found high rates of off-label use with little or no scientific support). However, even without proper scientific evidence there are times where physicians prescribing off-label antipsychotic drugs can be within the best interest of their patients. See generally O.I.G., OVERPRESCRIBED: THE HUMAN AND TAXPAYERS' COSTS OF ANTIPSYCHOTICS IN NURSING HOMES (2011) (statement of Daniel R. Levinson, Inspector General Department of Health & Human Services). Furthermore, David R. Levinson points out that most physicians have nursing home patients' best interest in mind when prescribing off-label antipsychotic drugs. *Id.* See also Scott Tillet, *Off-Label Prescribing of SSRIs to Children: Should Pediatric Testing Be Required, Or Are There Other Means to A Safer End for Children?*, 19 S. CAL. REV. L. & SOC. JUST. 447, 448 (2010) (finding that the American Academy of Pediatrics supports off-label prescribing because it can be the best available therapy for the pediatric patient).

scribe off-label with the belief that physicians will exercise this freedom responsibly.⁷ For example, the Food, Drug, and Cosmetic Act (FDCA) specifically prohibits the FDA from interfering with a healthcare practitioner's ability to prescribe any legally marketed drug FDA approved drug for any condition or disease.⁸ The notion behind this prohibition being that the FDA does not have the authority to interfere with a genuine healthcare practitioner-patient relationship.⁹

With the lack of federal restrictions to off-label prescribing, there is the belief that the FDCA has unintentionally made off-label prescribing a common practice for physicians finding that physicians no longer rely on the FDA for guidance on their prescription practices.¹⁰ Off-label prescribing has especially been prevalent with the amount of antipsychotic drugs being prescribed by psychiatrist and non-psychiatrists greatly increasing in the last few years.¹¹ Antipsychotic drugs are FDA approved for patients with serious mental illnesses, but are increasingly being prescribed off-label to other populations and for other uses besides alleviating hallucinations and other severe behavioral symptoms.¹² As of 2010, one-quarter of nurs-

7. See Dresser & Frader, *supra* note 6, at 476.

8. Sandra H. Johnson, *Polluting Medical Judgment? False Assumptions in the Pursuit of False Claims Regarding Off-Label Prescribing*, 9 MINN. J.L. SCI. & TECH. 61, 69 (2008).

9. *Id.*

10. See, e.g., *id.* at 69-70 (determining that the "operation of the FDCA encourages the proliferation of off-label uses" and that "[t]he frequency and breadth of off-label prescribing. . . provide strong inferential evidence that doctors do not regard FDA approval as a necessary indicator of effectiveness. . . and perhaps even safety").

11. See Sandra G. Boodman, *Off-Label Use of Risky Antipsychotic Drugs Raises Concerns*, KAISER HEALTH NEWS, (Mar. 13, 2012), <http://www.kaiserhealthnews.org/Stories/2012/March/13/off-label-use-of-risky-antipsychotic-drugs.aspx> (finding that antipsychotic prescriptions doubled between 1995 and 2008, from 4.4 million to 9 million).

12. Duff Wilson, *Side Effects May Include Lawsuits*, N.Y. TIMES (Oct. 2, 2010), <http://www.nytimes.com/2010/10/03/business/03psych.html>. Important to note that the FDA has only approved antipsychotics for youth that have schizophrenia, bipolar disorder, or irritability associated with autism. Mehmet Burcu et al., *Atypical Antipsychotic Use Among Medicaid-Insured Children and Adolescents: Duration, Safety, and Monitoring Implications*, 24 J. OF CHILD & ADOLESCENT PSYCHOPHARMACOLOGY 112 (2014). Furthermore, some antipsychotics that are approved for schizophrenia and bipolar purposes have not been approved for children and therefore are considered off-label prescriptions for any child regardless of his or her medical condition. Lara Salahi, *Antipsychotics for Foster Kids: Most*

ing home residents take antipsychotic drugs.¹³ Furthermore, in 2012, a study by Rutgers University found that twelve to thirteen percent of children in foster care are prescribed antipsychotic drugs.¹⁴

Forty-two to sixty percent children in foster care determined to have emotional and behavioral problems,¹⁵ and these problems are likely caused by awful family settings, the trauma from being placed into foster care, and separation from the biological parent.¹⁶ Off-label antipsychotics may appear to be the only option in the current foster care system that needs to quickly control children with disruptive and violent behavior.¹⁷ For elderly patients in nursing homes, a common reason that antipsychotic drugs are prescribed is for the treatment of dementia, specifically treatment of Alzheimer's disease.¹⁸ There are many psychological symptoms that are associated with dementia, including but not limited to, delusions and hallucinations.¹⁹ A list of behaviors, such as screaming, hitting agitation, and wandering, frequently coincide with these psychotic features.²⁰

Commonly Prescribed Meds, ABC NEWS (Dec. 1, 2011), <http://abcnews.go.com/Health/Wellness/foster-children-commonly-prescribed-antipsychotics/story?id=15056937>.

13. Wilson, *supra* note 12.

14. Lucette Lagnado, *Foster Kids Drugged Against Their Will Speak Out*, WALL ST. J. (FEB. 23, 2014), <http://online.wsj.com/news/articles/SB10001424052702303442704579361333470749104>.

15. Rick Naeurt, *Mental Health Needs of Foster Children*, PSYCH CENTRAL (Feb. 28, 2014), <http://psychcentral.com/news/2009/01/14/mental-health-needs-of-foster-children/3634.html>.

16. Michelle L. Mello, *Psychotropic Medication and Foster Care Children: A Prescription for State Oversight*, 85 S. CAL. L. REV. 395, 401 (2012).

17. Laurie E. Scudder, *Prescribing Antipsychotics in Children: Proceed With Caution*, MEDSCAPE (Apr 10, 2012), <http://www.medscape.com/viewarticle/761411>.

18. Artie Berns, *Dementia and Antipsychotics: A Prescription for Problems*, 33 J. LEGAL MED. 553, 555 (2012).

19. Kenneth Brummel-Smith, *It's Time To Require Written Informed Consent When Using Antipsychotics in Dementia*, 2 BRIT. J. MED. PRAC. 4, 4 (2008).

20. *Id.*

III. CAREGIVER INFLUENCE THAT LEADS TO PRESCRIBING OFF-LABEL ANTIPSYCHOTIC DRUGS

Given the popularity of off-label antipsychotic prescriptions for vulnerable populations, supporters of this practice claim that the ethical justification for prescribing off-label drugs is that it provides the best available therapy for a particular patient.²¹ As previously mentioned, the notion is that a physician will be able to prescribe for therapeutic purposes and for the best interest of a patient.²² However, prescribing antipsychotic drugs to the elderly in nursing homes and children in foster care tend to be beneficial to the caretakers and fail to account for what should be done in the best interest of the patients.²³

A. Elderly in Nursing Homes

For the elderly, nursing homes are the usual provider of care for those who no longer have the physical or mental abilities to care for themselves.²⁴ There are often disputes concerning what constitutes adequate care in this type of long-term care setting, especially in regards to patients with dementia.²⁵ In order to reduce the discomfort nursing home caregivers face, one of physicians' first reactions is to prescribe antipsychotic drugs that can possibly minimize the upsetting behaviors caused by dementia.²⁶ Further-

21. Dresser & Frader, *supra* note 6, at 478-479.

22. *See Id.* at 478-479 (noting that guides for professional practice by a few medical organizations regarding policies on off-label prescribing for the patient's best interest).

23. *See* Edward Opton, *Can Antipsychotic Medications for Foster Children Be Better Regulated*, 31 YOUTH LAW NEWS, Apr. – Jun. 2012, available at http://www.youthlaw.org/publications/yln/2012/apr_jun_2012/can_antipsychotic_medications_for_foster_children_be_better_regulated/ (finding that “[c]oncern that antipsychotic drugs in the foster care context often benefit caretakers at the expense of their foster children...”). *See* CAL. ADVOCS. FOR NURSING HOME REFORM, IN A STUPOR: WHAT CALIFORNIA'S ANTIPSYCHOTIC DRUG COLLABORATIVE REVEALS ABOUT ILLEGAL NURSING HOME DRUGGING 2 (2012), available at http://www.canhr.org/reports/In_a_Stupor.pdf (finding the misuse of antipsychotic drugs as a chemical restraint).

24. *See* David S. Douglas, David Feinberg, Robin Jacobsohn & Alice B. Stock, *Rx for the Elderly: Legal Rights (and Wrongs) Within the Health Care System*, 20 HARV. C.R.-C.L. L. REV. 425, 426 (1985).

25. *Id.*

26. *See* Brummel-Smith, *supra* note 19, at 4.

more, nursing homes have minimal staff with specialized training in psychology or behavior management to help understand and manage these types of behaviors.²⁷

Nursing homes are prohibited from using physical restraints since the late 1990s, which has resulted in a significant decrease in their utilization.²⁸ Nursing home staff must attempt to manage difficult patients without physical restraints and therefore see medication as an effective alternative to decrease operation disruptions caused by behaviors associated with dementia.²⁹ This type of modern restraint is considered a chemical restraint in order to make patients' behavior more manageable.³⁰ The Centers for Medicaid and Medicare Services (CMS) attempted to mitigate unnecessary antipsychotic prescribing, such as when it used as a restraint, by establishing regulations.³¹ However, these regulations do not specifically prohibit the use of antipsychotic medications for dementia patients, nor do they precisely define the unacceptable prescriptions for nursing home patients.³²

B. Children in Foster Care

For children in foster care, child welfare state agencies are accountable for supporting the health and mental health needs of children who are brought into their custody.³³ While a child is in foster care, the agency as-

27. AM. SOC'Y OF CONSULTANT PHARMACISTS, USE OF ANTIPSYCHOTIC MEDICATIONS IN NURSING FACILITY RESIDENTS 3 (2001), <https://www.ascp.com/sites/default/files/ASCP-antipsychotics-statement.pdf>.

28. See Krista Maier, *Chemical Restraints and Off-Label Drug Use in Nursing Homes*, 16 MICH. ST. U. J. MED. & L. 243, 255 (2012) (stating that nursing homes only have to resort to using physical restraints 1.2% of the time).

29. *Id.* at 257. There is also no current drug that is actually available to inhibit behaviors caused by dementia. *Id.*

30. CAL. ADVOCS. FOR NURSING HOME REFORM, *supra* note 23, at 2. California has defined chemical restrict in its regulations as "a drug used to control behavior and used in a manner not required to treat the patient's medical symptoms." *Id.*

31. Maier, *supra* note 28, at 259-260.

32. *Id.* at 259-260.

33. Mello, *supra* note 16, at 398. For a majority of children, physicians can assume that parents will act in the best interest of the child. Anthony W. Austin, *Medical Decisions and Children: How Much Voice Should Children Have in Their Medical Care?*, 49 ARIZ. L. REV.

sumes the role of guardian over his health and wellness.³⁴ Although there are federal guidelines in place for the administration of health care to children in foster care, states usually have discretion in developing their programs and policies.³⁵

Children with mental health conditions such as attention deficit hyperactivity disorder (ADHD) or depression can receive psychosocial therapy that assists in reducing symptoms and helping the child improve his or her functioning.³⁶ However, children in foster care fail to actually find this therapy available anywhere near them.³⁷ While state Medicaid programs are generally required to cover services and treatment outside of antipsychotic prescriptions, such as mental health screenings and treatment for identified conditions, state Medicaid administrators concede that it is difficult for foster children's physicians to find mental health specialists for appropriate referrals.³⁸ Instead, they resort to an easier and quicker solution – prescribing antipsychotic drugs.³⁹

Critics have argued that off-labeling antipsychotic prescriptions are helping foster parents, schools, therapists, and caseworkers manage children that have serious behavioral issues but have not been diagnosed with a seri-

143, 152 (2007).

34. Mello, *supra* note 16, at 398.

35. *Id.* Nearly all the children in foster care are enrolled in Medicaid health care coverage. *Id.*

36. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-13-15, CHILDREN'S MENTAL HEALTH: CONCERNS REMAIN ABOUT APPROPRIATE SERVICES FOR CHILDREN IN MEDICAID AND FOSTER CARE (2012).

37. *Id.* Furthermore, here is a story of one foster child, "Giovan Bazan was only six-years-old when he was first treated with medication for hyperactivity. Years later, while taking Ritalin at a double dosage, he was prescribed an antidepressant after another physician saw him "so mellowed out that he barely reacted." Twenty-year-old Bazan is now free of all medications and recognizes that "[t]hey start you on one thing for a problem, then the side effects mean you need a new medicine . . . [a]s a foster kid, I'd go between all these doctors, caseworkers, therapists, a[nd] it seemed like every time there was a new drug to try me on." Mello, *supra* note 16, at 397.

38. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 36.

39. Tovin Lapan, *Legislation aims to curb over-medicated odyssey many foster children face*, LAS VEGAS SUN (Jun. 18, 2012), <http://www.lasvegassun.com/news/2012/jun/18/experts-worry-foster-kids-are-being-overmedicated/>.

ous mental illness.⁴⁰ This idea is supported by research that demonstrates that the largest group receiving these drugs in foster care are those with a disruptive-behavioral disorders and ADHD disorders.⁴¹ When children in foster care are given antipsychotic drugs, the side effects can lead the children to be very passive and lethargic, leading children easier to manage than perhaps children not on antipsychotic medication who are very active and rebellious without any therapy treatment options.⁴² While Congress enacted the Fostering Innovations and Improvement in Child Welfare Act in 2011 in order to require states to develop policies for oversight for all antipsychotic prescriptions for children in foster care, there is concern that state government cannot implement enough change by simply reviewing prescribing practices.⁴³

IV. KNOWN RISKS OF PRESCRIBING OFF-LABEL ANTIPSYCHOTIC DRUGS

There are specific concerns that should lead physicians to contemplate if these drugs are in the best interest of vulnerable patients due to the lack of research and the possible safety risks.⁴⁴ Most clinical research protocol typically excludes children and the elderly.⁴⁵ These potential research subjects are more vulnerable to adverse drug reactions and therefore will respond differently than typical patients, resulting in their omission from the re-

40. Jennifer Brown and Christopher Osher, *Colorado responds slowly to psychotropic drug use among foster kids*, DENVERPOST.COM, http://www.denverpost.com/fostercare/ci_25555472/colorado-responds-slowly-psychotropic-drug-use-among-foster (last visited May 4, 2014). About half of children enrolled in state and federal funded health insurance programs that take antipsychotics in Colorado have not been diagnosed with a serious mental illness that would lead to an FDA approved prescription of antipsychotics. *Id.*

41. Lagnado, *supra* note 14. Dr. Christoph Correll states that “the drugs generally work fast, which is often desired when kids are at risk of being suspended from school for their behaviors. . .having to wait for an appointment is not an option.” *Id.* See also Burcu, *supra* note 12 (finding that “Medicaid-insured youth diagnosed with externalizing behavioral disorders by far represented the largest group of youth receiving antipsychotic medications”).

42. Opton, *supra* note 23.

43. See Opton, *supra* note 23.

44. Mackley, *supra* note 5 at 22.

45. Marc A. Rodwin, *Rooting Out Institutional Corruption to Manage Inappropriate Off-Label Drug Use*, 41 J.L. MED. & ETHICS 654, 655 (2013).

search pool.⁴⁶ Furthermore, once the FDA approves a drug, there is limited motivation for pharmaceutical companies to continue doing costly research to determine how their drugs affect vulnerable populations.⁴⁷

Without clinical research for these populations, off-label antipsychotic prescriptions require significant monitoring and dosage adjustments by physicians.⁴⁸ This necessity is promoted through the issuance of the black box warning on labels for antipsychotic drugs, and it is the most serious labeling available for prescription medication.⁴⁹ Pharmaceutical companies are required to impose a black box warning to the label due to the potential severe adverse effects that have occurred with off-label antipsychotic prescribing for these populations.⁵⁰ However, the warning is not sufficient because evidence shows that it has not deterred physicians from off-label prescribing.⁵¹

Around 15,000 elderly people in nursing homes die each year from off-label use of antipsychotic medications.⁵² Furthermore, children who are prescribed off-label antipsychotic medication have increased risk of suicidal ideation.⁵³ Off-label antipsychotic drugs are usually meant to treat severe mental illnesses such as bipolar and schizophrenia and are known to cause

46. *Id.*

47. Johnson, *supra* note 8, at 81-82.

48. See Tillett, *supra* note 6, at 448 (finding also that these types of drugs also have serious restrictions for advertisements).

49. *Id.*

50. See Boodman, *supra* note 11 (finding that the black-box warning because the drugs increase the risk of death). See Salahi, *supra* note 12 (finding that Abilify received a black box warning label for inducing suicidal feelings in children).

51. See Mackley, *supra* note 5 at 23 (finding that Zyprexa black box warning specifically stated that research had shown an increase in mortality of elderly patients with dementia but physicians still inappropriately prescribed the drug). See also Tillett, *supra* note 6 at 447-448 (concluding that although the FDA determined in a study that certain antidepressants lead to increased suicidal behavior physicians continued to off-label prescribe these drugs).

52. Maier, *supra* note 28, at 243.

53. Tillett, *supra* note 6 at 447. A study consisted of a thorough review of published and unpublished controlled clinical trials of antidepressants, and involved nearly 4,400 children and adolescents. *Id.* The results of the study suggested that suicidal behavior and ideation was twice as likely in children with Major Depressive Disorder (“MDD”) who were prescribed off-label antidepressants. *Id.*

severe side effects.⁵⁴ Children that receive improper dosages can experience severe side effects including, but not limited to, significant increases in cholesterol, rapid weight gain, development of diabetes, and irreversible movement disorders.⁵⁵ Nursing home patients have similar negative side effects, as well as possible life-threatening nervous system problems, neuroleptic malignant syndrome, diabetes, movement problems, seizures, and strokes.⁵⁶

V. ENSURING ANTIPSYCHOTIC DRUG PRESCRIPTIONS ARE IN THE BEST INTEREST OF VULNERABLE PATIENTS

Most physicians want what is best for their patients.⁵⁷ However, based on the availability of reimbursement and caregivers directly benefiting from off-label antipsychotic drugs being prescribed, there should be an independent party involved in physicians' decisions to prescribe off-label drugs to ensure these vulnerable patients' needs and interests are properly met. These independent parties can be implemented as a consultant pharmacist in nursing homes and state court appointed individuals responsible for the psychiatric care of children in foster care.

A. Consultant Pharmacists in Nursing Homes

While nursing homes are already required to have a license pharmacist as a consultant, nursing homes should be required to employ consultant pharmacists that are independent from any incentives to promote off-label antipsychotic prescriptions for elderly patients.⁵⁸ Consultant pharmacists' main

54. Boodman, *supra* note 11.

55. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 36.

56. O.I.G., *supra* note 6.

57. See generally Douglas Mossman, M.D. & Jill L. Steinberg, *Promoting, Prescribing, and Pushing Pills: Understanding the Lessons of Antipsychotic Drug Litigation*, 13 MICH. ST. U. J. MED. & L. 263, 266 (2009) ("[A] few doctors may be amoral, evil, or corrupt, but the vast majority—including the many physicians who have accepted meals, lecture fees, and other favors from drug companies—want to better the lives and health of their patients.").

58. See generally Dana Shilling, *Typically Atypical: Do Nursing Homes Misuse Atypi-*

purpose in nursing homes is to ensure that all medications are properly given and to protect the elderly from inappropriate use of antipsychotics.⁵⁹ These pharmacists review all residents' drug records on a monthly basis and educate nursing home staff and prescribing physicians on any concerns they have regarding unnecessary use, duration, or dosage amount of antipsychotic medication.⁶⁰ If truly independent, these consultant pharmacists are a valuable tool in ensuring medication is prescribed only in the best interest of the patient.⁶¹

Unfortunately, there have been many findings that consultant pharmacists currently do not have independence.⁶² Therefore in 2011, CMS issued a Notice of Proposed Regulation, which would require nursing homes to only use consultant pharmacists who are unaffiliated with a long-term care pharmacy, pharmaceutical manufacturers, or distributors.⁶³ If such a proposed regulation was enacted, consultant pharmacists will have the ability to ensure that antipsychotic drugs are prescribed properly without any conflict of interest.⁶⁴ Unfortunately, in 2012, CMS released the final rule and

cal Antipsychotic Drugs?, 251 Elder Law Advisory 1, 1 (Feb. 2012) (finding that nursing homes already are required to employ an consultant but the financial incentives of these consultants have been questioned).

59. See AM. SOC'Y OF CONSULTANT PHARMACISTS, *supra* note 27 at 3-4.

60. CAL. ADVOCS. FOR NURSING HOME REFORM, *supra* note 23 at 5.

61. *Antipsychotic Drugs*, CTR. FOR MEDICARE ADVOC., <http://www.medicareadvocacy.org/medicare-info/skilled-nursing-facility-snf-services/antipsychotic-drugs/> (last visited Mar. 31, 2014). See also CALIFORNIA ADVOCATES FOR NURSING HOME REFORM, *supra* note 23 at 5 (finding "[i]ndependence is critical to the effectiveness of consultant pharmacists").

62. See Wilson, *supra* note 12 (finding that Johnson & Johnson paid large kickbacks to Omnicare, the nation's largest long-term care pharmacy provider-Omnicare for Risperdal – an antipsychotic drug). Omnicare consultant pharmacists then made recommendations to nursing home physicians regarding which antipsychotic drugs to prescribe to those in long-term care. Maier, *supra* note 28, at 258.

63. Medicare Program; Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2013 and Other Proposed Changes; Considering Changes to the Conditions of Participation for Long Term Care Facilities, 76 FR 63018-01 (proposed Oct. 11, 2011) (to be codified at 42 C.F.R. pt. 417, 422, 423, 483).

64. Stephen Barlas, *Medicare Wants Only 'Independent' Consultant Pharmacists in Nursing Homes*, 37 PHARMACY AND THERAPEUTICS (Jan. 2012), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278190/>.

removed any obligation for consultants to be independent.⁶⁵ Therefore until CMS again proposes mandatory pharmacy consultant independence, states should collaborate with American Society of Consultant Pharmacists to establish regulations that effectively promote pharmacy consultant independence for proper oversight of off-label antipsychotic prescriptions with a nursing.⁶⁶

B. Court Appointed Individual Responsible for Psychiatric Care of a Foster Child

Because children in foster care are considered a state based issue, states should follow the lead of Nevada's recent law, enacted in 2011, that enables the state district court to appoint an individual who is legally responsible for all the decisions regarding a child's psychiatric care.⁶⁷ This legislation supports the idea that another party, besides the physician, should promote a child in foster care's best interest.⁶⁸ Pursuant to the law, a person who is legally responsible for the psychiatric care of a child will have the ability to approve or deny any physician recommendation for a foster child's prescription of antipsychotic drugs.⁶⁹ This appointed person must consider if

65. Press Release, CMS, CMS Approves Program Changes for Medicare Advantage and Prescription Drug Benefit Programs for Contract Year 2013 (Apr. 4, 2012) (on file with author), available at <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-Sheets/2012-Fact-Sheets-Items/2012-04-02.html>.

66. See AM. SOC'Y OF CONSULTANT PHARMACISTS, STATEMENT ON SEPARATION OF CONSULTANT PHARMACISTS AND LONG-TERM CARE PHARMACY PROVIDERS (2001), <https://www.ascp.com/sites/default/files/ASCP-separation-statement.pdf> (finding that "because of the potential for conflicts of interest. . . recommends that consultant pharmacists who serve long-term care facilities should be independent of the long-term care pharmacy that provides medications to residents of the facility"). New Jersey already requires separation consulting pharmacist and any other party with ties to pharmaceutical companies. N.J. Admin. Code 8:39-29.1 (2014).

67. Lapan, *supra* note 39. See also Placement Resources, NEVADA DIVISION OF CHILD & FAM. SERVICES, http://www.dcfs.state.nv.us/DCFS_PlaceRes.htm (last visited May 5, 2014).

68. See *Id.* (Author of the legislation stated "Instead of regulating doctors or pharmaceutical, we wanted to bring it to a personal level and have someone act in the role as parent for every foster kid.").

69. NEV. REV. STAT. § 432B.4687 (2013). Only in exceptional circumstances will a child be prescribed such drugs without consent from the legal representative. *Id.* at § 432B.4689. This includes when a physician or psychiatrist has determined that an emergen-

the benefits of each recommended antipsychotic drug for the child and the exact purpose of the drug, such as to control violent outbursts, outweigh any possible risks or likely side effects.⁷⁰ Furthermore, in order to fully safeguard against the unnecessary use of off-label antipsychotic drugs for children in foster care, an appointed person must have specific knowledge that the requested use of the drug has not been tested or approved by the FDA before authorizing the prescription for a child in foster care.⁷¹

VI. CONCLUSION

A physician can act in the best interest of his or her patients when off-label prescribing antipsychotic drugs.⁷² However, this ability to act in the best interest of the patient is questioned when drug benefits seems to only directly benefit the caregiver rather than the individual.⁷³ Even though these drugs are not approved for behavior modification purposes, these drugs are used as chemical restraints to control the upsetting behaviors of patients with dementia⁷⁴ or manage children that have serious behavioral issues but have not been diagnosed with a serious mental illness.⁷⁵ Any external benefit to the caregiver must be carefully weighed against the possibility of severe side effects to the patient. However, this evaluation of benefits to side effects has not occurred properly even with black box labels now on most antipsychotic medication that is prescribed to vulnerable populations.⁷⁶

With little federal effective guidance on off-label antipsychotic prescriptions⁷⁷, state government should instead enact independent parties to evaluate antipsychotic drug prescriptions for the elderly in nursing homes and

cy situation exists. *Id.*

70. NEV. REV. STAT. § 432B.4687 (2013).

71. *Id.*

72. *See supra* note 22.

73. *See supra* Part III.

74. *See supra* note 19.

75. *See supra* note 40.

76. *See supra* note 51.

77. *See supra* note 7.

children in foster care. These individuals can be properly trained in clearly understand the purpose of the drugs as well as the possible side effects and complications.⁷⁸ Independent pharmacy consultants for elderly in nursing homes and court appointed individuals for children in foster care can be used as appropriate safeguards for ensuring that any off-label antipsychotic prescription are indeed prescribed in the best interest of the patient.

78. See *supra* note 58 and 69.

Predicate Creep: The Danger of Multiple Predicate
Devices

Arianne Freeman*

I. INTRODUCTION

Before a company can begin marketing a new medical device in the United States, the device must first be approved by the Federal Drug Administration (FDA).¹ Device manufacturers must submit a Premarket Approval (PMA) application or a §510(k) premarket notification to gain FDA approval.² A PMA application is the most stringent FDA review, requiring manufacturers to use clinical trials and scientific evidence to establish a device's safety and efficacy for its intended use.³ Conversely, a manufacturer seeking clearance through §510(k) is only required to show that the device is substantially equivalent to a predicate device, a device already legally marketed in the United States.⁴ The FDA can approve a new medical device as substantially equivalent even if the device combines different functional

*Juris Doctor Candidate, Loyola University Chicago School of Law, Class of 2010. Ms. Freeman is a staff member of Annals of Health Law.

1. See *Overview of Device Regulation*, FDA (Mar. 5, 2013), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm>; *Premarket Notification (510k)*, FDA (Jan. 3, 2014), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm>; *Medical Device Exemptions 510(k) and GMP Requirements*, FDA (Mar. 31, 2014), <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/315.cfm>. Low risk medical devices, such as Class I devices, may be exempt from a formal review process so long as the manufacturer register with the FDA and comply with good manufacturing practices. *Id.*

2. *Overview of Device Regulation*, *supra* note 1.

3. *Premarket Approval (PMA)*, FDA (Jan. 24, 2012), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm>.

4. *Premarket Notification (510k)*, FDA (Jan. 3, 2014), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm>.

components of multiple predicate devices.⁵ The use of multiple predicates is now scrutinized because of the recent DePuy metal-on-metal hip implant litigation.⁶

Using multiple predicate devices in the §510(k) pathway creates a potential danger called the Predicate Creep. The predicate creep emerges from the repeated cycle of slight component changes from predicate device to predicate device, which leads to uncertainty in the clinical risks and benefits of the device.⁷ The danger is most severe in high-risk, life-saving medical devices.⁸ Allowing such devices to bypass the PMA application process shifts device testing from the clinical trial setting to the public marketplace, thus unethically veering potential risks to patients.⁹ This paper advocates for legislative reform to minimize the use of multiple predicate devices. Part II examines the federal landscape of medical device regulation. Part III illustrates the flaws of the §510(k) program in light of the recalled DePuy ASR XL Metal-on-Metal Hip Replacements.¹⁰ Part IV provides recommen-

5. CTR. FOR DEVICES AND RADIOLOGICAL HEALTH, U.S. FOOD AND DRUG ADMIN., MEDICAL DEVICE REPORTING (MDR) RATE IN 510(K) CLEARED DEVICES USING MULTIPLE PREDICATES (Oct. 14, 2011), available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM275631.pdf> [hereinafter MDR RATE IN 510(K) DEVICES].

6. See Complaint at ¶17, *Kransky v. DePuy Orthopaedics, Inc.*, No. BC456086, 2013 WL 1193838 (Cal. Super. Feb. 25, 2011).

7. FDA & HHS, REVIEW OF THE REGEN MENAFLEX®: DEPARTURES FROM PROCESSES, PROCEDURES, AND PRACTICES LEAVE THE BASIS FOR A REVIEW DECISION IN QUESTION 1, 3 (Sept. 2009), <http://www.fda.gov/downloads/newsevents/publichealthfocus/ucm183642.pdf>

8. See *Classify Your Medical Device*, FDA (Dec. 3, 2012), <http://www.fda.gov/%20MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm>

9. See Deborah Cohen, *How safe are metal-on-metal hip implants?*, BRIT. MED. J. 1, 4 (Feb. 28, 2012), <http://www.bmj.com/content/344/bmj.e1410.pdf%2Bhtml> [hereinafter *How safe are metal-on-metal hip implants?*].

10. The DePuy ASR XL litigation was based in the design flaws of a metal-on-metal hip implant cleared through the §510(k) process. See generally Complaint at ¶17, *Kransky v. DePuy, Inc.*, No. BC456086, 2013 WL 1193838 (Cal. Super. Feb. 25, 2011). DePuy lawfully received clearance by citing to multiple predicate devices to prove substantial equivalence. *The 510(k) Ancestry of a Metal-on-Metal Hip Implant*, 368 N. ENGL. J. MED. 97-98 (2013) [hereinafter *510(k) Ancestry*], available at <http://www.nejm.org/doi/full/10.1056/NEJMp1211581>. Without clinical testing to establish safety and effectiveness, the DePuy entered the market despite having a significantly higher rate of revision, four times the average 5-year revision rate. *Id.*

dations to encourage both innovative and safe medical devices.

II. DEVELOPMENT OF MEDICAL DEVICE REGULATION & §510(K) CLEARANCE

For most of the twentieth century, medical devices were largely unregulated and not required to undergo a premarket review.¹¹ The massive Dalkon Shield failure demonstrated the American tort system's inability to manage the dangers arising from defective devices.¹² The Dalkon Shield Intrauterine Device entered the market without any federal oversight or premarket testing and was linked with serious complications such as pelvic inflammatory disease, ectopic pregnancies, sterility, and in some cases, death.¹³ In response, Congress passed the Medical Device Amendments of 1976 (MDA) to provide additional protection to patients and enacted a regime of detailed federal oversight by the FDA.¹⁴ The MDA imposed different safeguards depending on the device's classification,¹⁵ determined by a risk-based approach and the type of controls required to ensure its safety and effectiveness.¹⁶ Class I devices present the least risk of illness or injury,

11. See Jordan Bauman, *The "Déjà Vu Effect:" Evaluation of United States Medical Device Legislation, Regulation, and the Food and Drug Administration's Contentious 510(k) Program*, 67 FOOD & DRUG L.J. 337, 340-41 (2012) (Noting the significant premarket reviews for new drugs and the obvious lack of specific premarket requirements for medical devices).

12. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008) (noting that the IUD litigation showcased the inability of the tort system); See generally, John M. Van Dyke, *THE DALKON SHIELD: A "Primer" in IUD Liability*, 40 W. St. U. L. Rev. 1, 7 (2012); Gina Kolata, *The Sad Legacy of the Dalkon Shield*, N.Y. TIMES, (May 2, 2013). The IUD was attached to a multi-filament string that created a pathway for bacteria to travel from the vagina to the uterus. *Id.* Over 200,000 claimed injuries and years of litigation concluded with a 2.4 billion dollar compensation fund and the bankruptcy of the manufacturer. *Id.*

13. *Id.*

14. See *Riegel*, 552 U.S. at 316.

15. See 21 U.S.C. § 360c (2014); *Classify Your Medical Device*, FDA (Dec. 3, 2012), <http://www.fda.gov/%20MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm>.

16. *Regulatory Controls*, FDA (April 11, 2013) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm2005378.htm>. Class I devices are required to comply with general controls such as registering the device with the FDA and conforming with good manufacturing practices. 21 U.S.C. § 360c (2014). In addition to general controls, Class II devices must also comport with special controls such as creating patient registries, conducting post-market surveillance,

Class II devices are intermediary risk devices, and Class III devices support or sustain human life, thus presenting the highest risk of illness and injury.¹⁷

Today, manufacturers are required to submit either a PMA application or §510(k) premarket notification submission.¹⁸ A PMA review is rigorous, requiring all clinical study reports and investigative documents of the device's safety and effectiveness, FDA facility inspections, manufacturing controls, labeling proposals, and a full description of the investigational methods.¹⁹ The FDA spends an average of 1,200 hours²⁰ reviewing each PMA application, granting PMA approval only when a device demonstrates a reasonable assurance of safety and effectiveness.²¹

Devices that satisfy substantial equivalence to a predicate device enjoy significantly easier FDA clearance²² through the §510(k) premarket notifi-

and meeting FDA promulgated performance standards. *Id.* Because Class III devices may present a potential unreasonable risk of illness or injury, more than general and special controls are required to provide a reasonable assurance of safety and effectiveness. *Regulatory Controls*, FDA (April 11, 2013) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm2005378.htm>. Therefore, devices used in supporting or sustaining human life are classified under Class III and must submit a PMA application. *Id.*

17. *Regulatory Controls*, supra note 15.

18. *Overview of Device Regulations*, supra note 1. Some devices are also exempt from all review so long as they comply with good manufacturing practices such as quality inspection of materials, meeting specific requirements for the building which houses the manufacturing, and labeling specifications. *See Class I/II Exemptions*, FDA (Dec. 12, 2012), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051549.htm>; *Quality System Regulation Labeling Requirements*, FDA (Dec. 6, 2012) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/QualitySystemRegulationLabelingRequirements/default.htm>.

19. MARK HERMANN & DAVID B. ALDEN, *DRUG AND DEVICE PRODUCT LIABILITY LITIGATION STRATEGY* 13 (2012).

20. *Riegel*, 552 U.S. at 315.

21. 21 U.S.C. § 360c (2014). *See also* 21 C.F.R. § 860.7(d)(1) (2014) ("There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks."); 21 C.F.R. § 860.7(e)(1) (There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.).

22. *See* Chris Schorre, *How long does it take for a 510(k) submission to be cleared by the US FDA?*, EMERGO GROUP, <http://www.emergogroup.com/research/fda-510k-review->

cation.²³ A manufacturer need only show that the new device is substantially equivalent to predicate devices legally marketed in the United States.²⁴ In stark contrast to the average FDA approval time spent reviewing a PMA application, the FDA spends an average of twenty hours reviewing a 510(k) application.²⁵

While Class III devices are statutorily required to be approved through the PMA pathway, most new Class III medical devices reach the market through a loophole in §510(k) clearance.²⁶ The purpose of §510(k) was to prevent long-standing manufacturers from enjoying a monopoly by allowing competitors of Grandfathered Devices to bypass the PMA application process and market new devices through the §510(k) program.²⁷ The FDA was tasked with reviewing the different grandfathered Class III devices and deciding whether (1) a PMA application would be required or (2) if the de-

times-research (last visited April 2, 2012); see also *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 492-494 (1996) (discussing that a determination of substantial equivalence is not considered to be approval and how §510(k) clearance is only considered a green light to market the product); The term “clearance”, instead of “approval”, is used for medical devices that satisfy the §510(k) process because only medical devices that have undergone the “gauntlet of the PMA process” is deemed to be FDA approved. *Id.* While this may seem like a minute difference in semantics, a device that has been approved by the FDA through the PMA process enjoys an almost unfettered preemption of state tort litigation. See generally MICHAEL K. BROWN ET AL., REED SMITH, MEDICAL DEVICE PREEMPTION—IS THERE LIFE FOR PLAINTIFFS’ CLAIMS AFTER RIEGEL V. MEDTRONIC, INC.?, 337(May 2012), available at www.dri.org/DRI/course-materials/2012-DMD/pdfs/12_Brown.pdf (discussing key supreme court cases and the high bar plaintiffs must surpass to overcome federal preemption).

23. See Daniel R. Levinson, *FDA’s Clearance of Medical Devices Through the 510(k) Process*, DEPT. OF HEALTH AND HUMAN SERVS. (Sept. 2013), <https://oig.hhs.gov/oei/reports/oei-04-10-00480.pdf>. A device qualifies for §510(k) clearance if a manufacturer can establish that the new device is substantially equivalent to a legally marketed device. *Premarket Notification (510k)*, *supra* note 4. Unlike a PMA application, a §510(k) is a limited review. 21 U.S.C. § 360c (2014).

24. *Premarket Notification (510k)*, *supra* note 4. A new device is substantially equivalent to a predicate device if it has the same intended use and (1) the same technological characteristics or (2) different technological characteristics that (a) does not raise new questions of safety and effectiveness and (b) is at least as safe and effective as the legally marketed device. *Id.*

25. *Lohr*, 518 U.S. at 479.

26. See Michael VanBuren, Note, *Closing The Loopholes In The Regulation Of Medical Devices: The Need For Congress To Reevaluate Medical Device Regulation*, 17 HEALTH MATRIX 441, 449 (2007).

27. *Lohr*, 518 U.S. at 494; 515 Program Initiative, FDA (Mar. 22, 2013), <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm240310.htm>

vice could be reclassified to Class I or II.²⁸

Unfortunately, reclassification was never finished leaving the door open for fourteen types of Class III devices to enter the market through §510(k) clearance.²⁹ This is disconcerting as new devices that fall under these 14 devices are all used in supporting or sustaining human life and may be used on patients without ample assurance of safety and effectiveness.³⁰ Combining different functional components of predicates allows the erection of new devices comprised of different materials and clinical indications for different anatomical parts than their predicates.³¹ Using multiple predicates further the uncertainty of the new device's safety and effectiveness.³² Additionally, the FDA is bound to approve a new device based on a predicate device that has been voluntarily recalled for safety design flaws if the new device is deemed to be substantially equivalent.³³ A device is eligible to be a predicate device so long as the recall was not initiated by the FDA or mandated by court order.³⁴ This process allows new devices with known safety design characteristics to enter the market.³⁵

28. *515 Program Initiative supra* note 28.

29. *See 515 Project Status*, FDA (Feb. 21, 2014), <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm240318.htm>. The FDA launched the 515 program initiative in an effort to reclassify the remaining Class III devices in need of review. *Id.*

30. *See 510(k) Ancestry, supra* note 10 at 97.

31. *Id.*

32. *See, e.g., REVIEW OF THE REGEN MENAFLEX, supra* note 7, at 3.at 3.

33. Alex Nussbaum, *Medical Device Loophole Needs Closing by Congress, FDA Device Chief Says*, BLOOMBERG NEWS (Feb. 28, 2012), <http://www.bloomberg.com/news/2012-02-28/fda-device-chief-says-approval-loophole-needs-closing.html> ("By law, the FDA has to approve devices that cite an eligible predicate unless the older device has been ordered off the market by the agency or a court order. [. . .] Because most companies opt for voluntary recalls before they reach that point, the devices can continue to serve as a basis for future products, Shuren [director of the FDA's CDRH] said).

34. *Id.*

35. *Id.*

III. POTENTIAL RISKS OF § 510(K) CLEARANCE

The DePuy ASR XL hip replacement system illustrates the potential danger of using multiple predicates in the §510(k) premarket notification.³⁶ A class action suit was filed on behalf of over 8,000 ASR XL patients and is projected to cost the company \$4 billion dollars in patient settlement costs.³⁷ The device's alleged safety design defects coupled with the unsound approval through the §510(k) process resulted in patients suffering from a lack of mobility, high levels of toxic metal in the blood stream, and the necessity for revision surgery to replace the ASR XL.³⁸

While a conventional artificial hip is made of metal and plastic, the DePuy ASR XL used the designs of multiple predicates to create a metal-on-metal ball and socket design, resulting in metallic debris to be released into the body.³⁹ DePuy produced two models of the ASR Systems: the ASR XL Acetabular Hip System (ASR XL) and the ASR Hip Resurfacing system (ASR Resurfacing).⁴⁰ Both models had similar metal-on-metal components but required different surgical methods of replacement.⁴¹ The ASR

36. See *The 510(k) Ancestry*, *supra* note 10, at 98..

37. Lisa Parker, *Plaintiffs Face Agonizing Decision In Hip Implant Settlement*, NBC CHICAGO (Mar. 11, 2014), <http://www.nbcchicago.com/investigations/Plaintiffs-Face-Agonizing-Decision-In-Hip-Implant-Settlement-249671721.html#ixzz2xhVCqGZT>.

38. See generally Deborah Cohen, *Out of joint: The story of the ASR*, BRIT. MED. J. (May 14, 2011), <http://www.bmj.com/content/342/bmj.d2905> [hereinafter *Out of Joint*]; Complaint at ¶17, *Kransky v. DePuy Orthopaedics, Inc.*, No. BC456086, 2013 WL 1193838 (Cal. Super. Feb. 25, 2011).

39. See Barry Meier, *Johnson & Johnson in Deal to Settle Hip Implant Lawsuits*, N.Y. TIMES (Nov. 19, 2013), <http://www.nytimes.com/2013/11/20/business/johnson-johnson-to-offer-2-5-billion-hip-device-settlement.html>.

40. Jef Feeley & David Voreacos, *J&J Said to Reach \$4 Billion Deal to Settle Hip Lawsuits*, BLOOMBERG (Nov. 13, 2013), <http://www.bloomberg.com/news/print/2013-11-12/j-j-said-to-reach-4-billion-deal-to-settle-hip-lawsuits.html>; *Important Information About the ASR Hip System Recall*, DEPUY SYNTHES (2013), <http://asrrecall.depuy.com/depuy-asr-recall-usen>.

41. *Hip Replacement vs. Hip Resurfacing*, N.Y. TIMES (Feb. 26, 2010, 10:37 AM), <http://consults.blogs.nytimes.com/2010/02/26/hip-replacement-vs-hip-resurfacing>. *How safe are metal-on-metal hip implants?* *supra* note 9, at 4; The ASR XL was used for traditional hip replacements where the neck of the femur, the ball, is surgically removed, and the implant is inserted deep inside the bone. *Id.* In contrast, the ASR Resurfacing only required replacing the joint surfaces with the ASR resurfacing implant. *Id.* While the PMA requirements may have prevented the ASR resurfacing device to be used, later studies would prove

Systems were designed so that the metal surfaces would trap a layer of naturally occurring fluid and prevent the metal surfaces from touching.⁴² In theory, the naturally occurring fluid would have become thicker and result in less wear and tear of the implants.⁴³ However, test would should that the all metal implant would become more likely to strike each other and release metallic debris inside the patient.⁴⁴

Because of the ASR Resurfacing device's cutting edge surgical technique, the FDA required a full clinical trial to prove safety and effectiveness.⁴⁵ While the ASR Resurfacing device was never approved because of safety and effectiveness concerns,⁴⁶ the FDA cleared the ASR XL due to the use of multiple predicates.⁴⁷ Upon approval, the ASR XL was marketed to young, active patients as a superior alternative to the traditional hip devices with lower revision rates.⁴⁸

DePuy cited six predicate devices to establish substantial equivalence and gain §510(k) clearance for the ASR XL.⁴⁹ In determining substantial equivalence, the FDA seemed to incorrectly determine that the device was either (1) the same intended use as the predicate and the same technological characteristics or (2) that the different technological characteristics did not

that the ASR resurfacing device had twice the revision rate when compared to conventional hip implants. *Id.*

42. See *How safe are metal-on-metal hip implants?* *supra* note 9 at 2.

43. See *Out of Joint*, *supra* note 39, at 2.

44. See Barry Meier, *Implant Risk Was Assessed Inadequately, Court Is Told*, N.Y. TIMES (Jan. 31, 2013), http://www.nytimes.com/2013/02/01/business/hip-implants-risks-inadequately-assessed-depuy-report-found-in-2010.html?_r=0.

45. See *Out of Joint*, *supra* note 39, at 2.

46. To receive approval, the ASR resurfacing device was required to undergo clinical testing to prove safety and effectiveness for the intended use. See Deborah Cohen, *Out of joint: The story of the ASR*, BRIT. MED. J. (May 14, 2011) [hereinafter *Out of Joint*], <http://www.bmj.com/content/342/bmj.d2905>. Because of the clinical test requirement, the FDA was apprised of the high rate of femoral knee fractures. *Id.*

47. See *510(k) Ancestry*, *supra* note 10, at 98; Cohen, *supra* note 48, at 2.

48. See *How safe are metal-on-metal hip implants?* *supra* note 9 at 4;

49. *510(k) Ancestry*, *supra* note 10, at 98. FDA approval focused on three characteristics of the ASR XL: the porous bone ingrowth surface, metal-on-metal articulation, and large femoral head sizes. *Id.* Substantial equivalence was determined by comparing each characteristic to six different predicate devices. *Id.*

raise new questions of safety and effectiveness and that the device is as safe and effective as the marketed device.⁵⁰ The use of multiple predicates to determine substantial equivalence is flawed because it only compares the device's subparts to a respective predicate instead of comparing the entire device to a predicate. Substantial equivalence was not determined by comparing the ASR XL device to the six predicates, but instead compared each individual characteristic to the respective predicate device.⁵¹

If the FDA used the first prong of substantial equivalence, it was based on a piecemeal analysis of each functional characteristic to a different corresponding predicate device.⁵² None of the predicates cited by the ASR XL contained all three functional characteristics.⁵³ The FDA defends the §510(k) review process by arguing that the new device is merely combining the functionality of two predicates, but this logic fails where the combination of predicates gives rise to a significantly different, new device with uncertain consequences.⁵⁴ The ASR XL metal-on-metal implant, as well as the 14 unclassified Class III medical devices, should not be able to bypass a meaningful clinical trial and unethically shift the potential risks to patients.⁵⁵

In the alternative, it was still improper for the FDA to clear the ASR XL based on a finding that the device did not raise new concerns for safety because of the device's higher than average failure rates for metal-on-metal hip systems should have raised safety and effectiveness concerns.⁵⁶ Addi-

50. *Premarket Notification (510k)*, *supra* note 4.

51. *510(k) Ancestry*, *supra* note 10, at 98.

52. *See* MDR RATE IN 510(K) DEVICES, *supra* note 5, at 3.

53. *See 510(k) Ancestry*, *supra* note 10, at 98; Heather Thompson, *Researchers Say DePuy Hip Ancestry Shows 510(k) Flaws*, (Feb. 19, 2013) <http://www.mddionline.com/article/researchers-say-depuy-hip-ancestry-shows-510k-flaws>; *Ancestry list available* at <http://www.nejm.org/doi/full/10.1056/NEJMp1211581>. In fact, none of the ninety-five devices in the ASR XL ancestry device list had the same combination of characteristics. *Id.*

54. MDR RATE IN 510(K) DEVICES, *supra* note 5, at 3.

55. *See How safe are metal-on-metal hip implants?* *supra* note 9 at 4;

56. *See Premarket Notification*, *supra* note 24; Deborah Cohen, *Revision rates for metal on metal hip joints are double that of other materials*, BRIT. MED. J. (2011).

tionally, the ancestry for the predicate devices used for the ASR XL dated back more than five decades, including three devices that are no longer in use due to the device's high revision rates.⁵⁷

The current statutory landscape does not distinctly provide for the FDA to reject the use of predicates that were voluntarily recalled by the manufacturer for safety design defects.⁵⁸ No obligation is placed on the manufacturer to establish that the defect was considered or fixed in the new device.⁵⁹ In fact, a medical device is five times as likely to undergo a recall if its predicate was recalled for safety design issues.⁶⁰ The law must be changed to reduce the risk that new devices have the same flawed characteristic as defective devices.⁶¹

IV. RECOMMENDATIONS TO STRENGTHEN THE §510(K) PROCESS

While the DePuy product liability litigation sheds some light on the §510(k) premarket notification, the scrutiny of this pathway is not new.⁶² In 2009, the FDA turned to the Institute of Medicine (IOM) to review the §510(k) process.⁶³ The study concluded that the §510(k) pathway was not

57. *510(k) Ancestry*, *supra* note 10, at 98.

58. Gergana Koleva, *Loophole in FDA's Approval Process for Medical Devices Prompts Letter from Congress*, FORBES (Aug. 17, 2002, 3:13 PM), <http://www.forbes.com/sites/gerganakoleva/2012/08/17/loophole-in-fdas-approval-process-for-medical-devices-prompts-letter-from-congress>.

59. *Medical Device Loophole Leaves Patients At Risk – Consumers Union Responds to Medical Device Industry on Recalled Predicates*, CONSUMERS UNION (May 20, 2012, 6:14PM), <http://safepatientproject.org/document/medical-device-loophole-leaves-patients-at-risk>.

60. Nussbaum, *supra* note 33.

61. *See Medical Device Loophole Leaves Patients At Risk – Consumers Union Responds to Medical Device Industry on Recalled Predicates*, CONSUMERS UNION (May 20, 2012, 6:14PM), <http://safepatientproject.org/document/medical-device-loophole-leaves-patients-at-risk>.

62. *See generally*, COMMITTEE ON THE PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS & INST. OF MED., MEDICAL DEVICES AND THE PUBLIC'S HEALTH 4-8 (The Nat'l Academies Press, 2011) [*hereinafter* MEDICAL DEVICES AND THE PUBLIC'S HEALTH], available at http://www.nap.edu/catalog.php?record_id=13150 (criticizing the flaws of the §510(k) process).

63. *Id.* at 4. Specifically, the Institute was asked to determine 2 questions: (1) Was the current §510(k) clearance process protect patients optimally and promote innovation in support of public health? (2) If not, what legislative, regulatory, or administrative changes are

designed to evaluate safety and effectiveness of new devices and that the FDA's liberal interpretation of substantial equivalence is being used to avoid requiring PMAs for new and novel Class III devices.⁶⁴ It recommended that the FDA abandon the §510(k) process for an integrated premarket and post-market regulatory framework.⁶⁵ Even though the IOM's comprehensive regulatory framework is a commendable goal, it does not address present concerns regarding the §510(k) process.⁶⁶ To prohibit the §510(k) from being used as a regulatory loophole, it is important to restrict the use of multiple predicates and empower the FDA to reject new devices based on defective predicates.⁶⁷

First, the §510(k) pathway application should be restricted only to Class I and II devices.⁶⁸ The fact that a majority of Class III devices are cleared through the §510(k) pathway defies Congressional intent.⁶⁹ The FDA should make it a priority to reclassify the remaining fourteen remaining Class III pre-amendment devices and ensure that Class III devices undergo PMA review to provide reasonable assurance of safety and effectiveness.⁷⁰

Second, new devices using more than five different predicate devices should be required to clinically establish that combining the different functional components do not create uncertainty in safety and effectiveness.⁷¹ §510(k) devices that cite six to ten predicates are associated with an in-

recommended to achieve the goals of the §510(k) clearance process optimally. *Id.*

64. *Id.* at 5. 87

65. *Id.* at 7-8.

66. *Id.* at 8.

67. Nussbaum, *supra* note 33.

68. Research conducted by the IOM found an association between devices that cited 6-10 predicates and an increased §510(k) recall rate. See Theresa Wisemann, *Public Health Effectiveness of the FDA 510(k) Clearance Process*, INST. OF MED., 87 (2011), <http://www.iom.edu/Reports/2010/Public-Health-Effectiveness-of-the-FDA-510k-Clearance-Process-Measuring-Postmarket-Performance-and-Other-Select-Topics.aspx>; See also Nussbaum, *supra* note 33. The research also found that Class III devices were 3 times as likely to be recalled under §510(k). *Id.*

69. See MEDICAL DEVICES AND THE PUBLIC'S HEALTH, *supra* note 62, at 92.

70. See *Medical Device Loophole Leaves Patients At Risk* *supra* note 61.

71. IOM research also found that Class III devices were 3 times as likely to be recalled under §510(k). See Wisemann, *supra* note 68 at 91.

creased recall rate when compared to §510(k) devices that cited one to five predicates.⁷² The ASR XL is an example of the hazards in comparing singular characteristics of the new devices to multiple predicates.⁷³ By requiring scientific evidence of safety and effectiveness, the manufacturer bears the burden to prove that the device is free from unreasonable risk of injury before it can be marketed.⁷⁴

The FDA should have the flexibility to reject new devices based on defective predicates unless the new device was designed to improve upon the recalled device's defect.⁷⁵ In 2012, Massachusetts Representative Edward Markey introduced H.R. 3847 for the purpose of ensuring that medical devices were not marketed based on a finding of substantial equivalence to a recalled or removed predicate device.⁷⁶ The bill called for clear statutory authority to deny predicates resulting from a recalled device to be denied.⁷⁷ Although H.R. 3847 was never enacted, the sound principles of the bill should be reconsidered and adopted by Congress.⁷⁸

V. CONCLUSION

The need for innovative, lifesaving devices to reach the market and patients must be balanced with an assurance that the device will be safe and effective.⁷⁹ The use of multiple predicates to find a §510(k) substantial equivalence does not adequately review the actual risks for Class III devices.⁸⁰ Regardless of whether the FDA or a manufacturer initiates a design re-

72. *Id.*

73. *See generally* *How safe are metal-on-metal hip implants?* *supra* note 9.

74. *See* *How safe are metal-on-metal hip implants?* *supra* note 9 at 4;

75. Nussbaum, *supra* note 33.

76. H.R. 3847, 112th Cong. § 2 (2012).

77. *Id.* (amending the Federal Food, Drug and Cosmetic Act to allow the rejection of new devices based on defective predicate devices).

78. H.R. 3847..

79. Doug Schoen, *Medical Innovation and Safety: A delicate balance*, *Forbes* (Mar. 5, 2012), <http://www.forbes.com/sites/dougschoen/2012/03/05/medical-innovation-and-safety-a-delicate-balance/>

80. *See* Nussbaum, *supra* note 33 (noting that Class III devices were 3 times as likely to

call, future devices relying on recalled device(s) should have to prove that they addressed the design defect and the new device is free from unreasonable risk. The unknown risks that Class III devices pose when they are cleared with inadequate predicates is an unethical burden that patients should not have to bear.⁸¹

be recalled under §510(k).

81. See Barry Meier, *Implant Risk Was Assessed Inadequately, Court Is Told*, N.Y. TIMES (Jan. 31, 2013), http://www.nytimes.com/2013/02/01/business/hip-implants-risks-inadequately-assessed-depuy-report-found-in-2010.html?_r=0.

Physician Marketing on Groupon: How Healthcare Providers Can Ethically Leverage This Technology and Why States Should Allow Them to Do So

*Miriam Neems**

I. INTRODUCTION

Technological innovations disrupt the paradigm under which the medical profession operates,¹ and healthcare providers are shifting the practice of medicine to accommodate digital processes.² An important element of this transition is the development and implementation of digital marketing plans in the medical field.³ Healthcare providers increasingly look to leverage online technology to brand and market their services in order to be competitive and match the way in which society consumes, shares, and responds to

*Juris Doctor Candidate, Loyola University Chicago School of Law, Class of 2015.

1. See generally Bertalan Meskó, *Rx Disruption: Technology Trends in Medicine and Health Care*, 48 THE FUTURIST (2014) (discussing the impact that technology has on the healthcare sector).

2. See CHUN-JU HSIAO & ESTHER HING, USE AND CHARACTERISTICS OF ELECTRONIC HEALTH RECORD SYSTEMS AMONG OFFICE-BASED PHYSICIAN PRACTICES: UNITED STATES, 2001-2013 (2014), available at <http://www.cdc.gov/nchs/data/databriefs/db143.pdf> (finding that 78% of office-based physicians used an electronic health record (EHR) system in 2013); Brian Eastwood, *Healthcare Finally Warming to Cloud Technology*, CIO.COM (Nov. 18, 2013), http://www.cio.com/article/743379/Healthcare_Finally_Warming_to_Cloud_Technology (noting that healthcare providers are beginning to utilize cloud computing in the storage of personal health information); SHERYL COUGHLIN, ET AL., DELOITTE CTR. FOR HEALTH SOLUTIONS, PHYSICIAN ADOPTION OF HEALTH INFORMATION TECHNOLOGY (2013), available at [http://www.deloitte.com/assets/Dcom-UnitedStates/Local%20Assets/Documents/Health%20Care%20Provider/us_dchs_2013PhysicianSurveyHIT_051313%20\(2\).pdf](http://www.deloitte.com/assets/Dcom-UnitedStates/Local%20Assets/Documents/Health%20Care%20Provider/us_dchs_2013PhysicianSurveyHIT_051313%20(2).pdf) (finding that a growing number of physicians – approximately 4 in 10 – use mobile health technology for clinical purposes).

3. See generally Marketo, *How to Leverage Digital Marketing in the Healthcare Industry*, http://www.marketo.com/_assets/uploads/How-to-Leverage-Digital-Marketing-in-the-Healthcare-Industry.pdf (last visited Mar. 29, 2014) (explaining the importance of digital marketing in healthcare).

information.⁴ In the process of doing so, a number of medical professionals seek the services of daily deal advertising platforms, made popular by Groupon.⁵ These platforms offer daily deal advertising across a number of industries,⁶ but the expansion into health care poses unique legal and ethical challenges.⁷ Healthcare providers frequently question whether such marketing arrangements violate fee splitting⁸ prohibitions under the American Medical Association (AMA) Code of Medical Ethics and state statutes.⁹ Their questions, however, remain largely unanswered.¹⁰

This article argues that the AMA and state licensing boards should pro-

4. Anna M. Grizzle & Lori S. Richardson Pelliccioni, *A Marketing Compliance Primer for Healthcare Providers*, AM. HEALTH LAWYERS ASS'N, http://www.healthlawyers.org/Events/Programs/Materials/Documents/PHY13/A_grizzle_pelliccioni.pdf (last visited Mar. 28, 2014); see also Thomas Daschle & Bill Frist, *Technology and the Changing Business of Health Care*, HEALTHAFFAIRS BLOG (Aug. 14, 2013), <http://healthaffairs.org/blog/2013/08/14/technology-and-the-changing-business-of-health-care/> (describing how consumers expect information technology to shape their interactions with healthcare providers).

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5. See Suzanne D. Nolan, Mercedes Varasteh Dordeski & Frank Haron Weiner, *Health Care Marketing: A Tricky Operation*, 25 HEALTH LAW. 34, 36 (2012).

6. See *id.* (explaining that consumers commonly purchase daily deal promotions for discounts at restaurants, health clubs, clothing retailers and spas).

7. *Id.*

8. Fee splitting occurs when a physician makes or accepts payment solely for the referral of a patient. AM. MED. ASS'N COUNCIL ON ETHICAL AND JUD. AFFS., CODE OF MEDICAL ETHICS (2013), available at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion602.page>.

9. See Bob LaMendola, *Are Groupon Discounts for Medical Treatments Illegal?*, SUNSENTINAL, (Sep. 25, 2011), http://articles.sun-sentinel.com/2011-09-25/news/fl-hk-groupon-medical-20110925_1_websites-discounts-medical-professionals.

10. *Id.* (commenting on the lack of clarity provided to healthcare providers on the issue). Only three states have taken a position on the legality of daily deal advertisements in the medical field. See THE STATE MED. BD. OF OHIO, GRAND ROUNDS: PHYSICIAN PARTICIPATION IN "DEAL OF THE DAY" OFFERS 13 (2012), available at <http://www.med.ohio.gov/pdf/Newsletters/Spring2012.pdf>; Referral Fees and Fee Splitting, N.C. MED. BD., REFERRAL FEES AND FEE SPLITTING, http://www.ncmedboard.org/position_statements/detail/referral_fees_and_fee_splitting (last updated Jan. 2013); THE ILL. DEPT. OF FIN. AND PROF'L REG., VOUCHER ADVERTISING AND FEE-SPLITTING (2013), available at <http://www.idfpr.com/News/newsrsls/VoucherAdvertisingStatement04102013.pdf>.

vide healthcare providers with guidance and adopt a framework that makes it ethically and legally permissible for healthcare providers to advertise medical services on daily deal platforms, as done by the Illinois Department of Professional Regulation (IDPR). Section II details how daily deal platforms work and explores the benefits realized from these marketing arrangements.¹¹ Section III discusses the legal and ethical implications that healthcare providers encounter under the AMA Code of Ethics and state statutes when they market on daily deal websites.¹² Lastly, Section IV explains why the IDPR takes a sensible approach to the issue by allowing healthcare providers to legally market their services on daily deal platforms and why the AMA and other state licensing boards should adopt this framework.¹³

II. HOW DAILY DEAL ADVERTISING WORKS AND ITS BENEFITS

Groupon and similar daily deal platforms¹⁴ are online platforms where a business offers a subscriber the opportunity to purchase advertised goods and services at deep discounts.¹⁵ A subscriber provides Groupon with an

11. See *infra* Section II.

12. See *infra* Section III.

13. See *infra* Section IV.

14. Although Groupon claimed nearly 60% of the United States market for daily deal platforms in 2013, there are several other notable competitors sharing the market, including Living Social, Google Offers, Amazon Local, and BuyWithMe. See *Groupon Owns Nearly 60% of the U.S. Daily-Deals Market in 2013, Industry to See Slowed Growth*, DMCONFIDENTIAL (Sept. 3, 2013), <http://www.dmconfidential.com/report-groupon-owns-nearly-60-of-the-daily-deals-market-in-2013/>.

15. See *Social Networking Advertising-Marketing and the Medical Practice – Coupons and Daily Deals*, AM. HEALTH LAWYERS ASS'N (Aug. 6, 2013, 4:19 PM), www.healthlawyers.org/hlresources/Health%20Law%20Wiki/Social%20Networking%20Advertising-Marketing%20and%20the%20Medical%20Practice%20-%20Coupons%20and%20Daily%20Deals.aspx; see also Ryan Spoon, *10 Fun Groupon Statistics, from Geography to Sushi to NBA*, BUS. INSIDER (Mar. 20, 2011), <http://www.businessinsider.com/10-fun-groupon-statistics-from-geography-to-sushi-to-nba-2011-3> (noting that the average Groupon offers consumers a 56% discount on the advertised good or service).

email address and zip code to sign up.¹⁶ Once a subscriber, the consumer begins receiving advertisements to purchase various online coupons from merchants.¹⁷ The coupons are often limited in quantity or the amount of time that they are made available to the subscriber.¹⁸ If a subscriber decides to purchase an online coupon, the subscriber pays Groupon the value of the online coupon, and Groupon keeps fifty percent of the payment.¹⁹ Groupon then remits the remaining fifty percent of the payment to the merchant.²⁰

The public immediately took to Groupon's offerings.²¹ Generating \$2.6 billion in revenue in 2013, Groupon experiences impressive success in the daily deal industry.²² The tremendous popularity of daily deal advertising platforms draws physicians to consider their applicability and value in medical advertising.²³ Physicians seek to leverage Groupon and similar platforms as a tool to build and grow their practice.²⁴ With over 200 million subscribers in forty-eight countries, Groupon prides itself on its broad reach

16. *Social Networking Advertising-Marketing and the Medical Practice – Coupons and Daily Deals*, *supra* note 15.

17. *Id.*

18. *Id.*

19. *Id.*

20. *Id.*

21. Christopher Steiner, *Meet the Fastest Growing Company Ever*, FORBES (Aug. 12, 2010), <http://www.forbes.com/forbes/2010/0830/entrepreneurs-groupon-facebook-twitter-next-web-phenom.html>.

22. Alex Wilhelm, *Groupon Skyrockets After Hours on Q4 Beat With Revenue of \$768.4M, EPS of \$0.04*, TECHCRUNCH (Feb. 20, 2014), <http://techcrunch.com/2014/02/20/groupon-skyrockets-after-hours-on-q4-beat-with-revenue-of-768-4m-eps-of-0-04/>.

23. Claudia Ahiabor, *There's a Coupon for That: How Coupons for Medical Services on Daily Deal Websites Violate the Federal Anti-Kickback Statute*, 7 HEALTH L. AND POLICY BRIEF 67, 67, available at <http://digitalcommons.wcl.american.edu/hlp/vol7/iss1/6>.

24. See Nolan et al., *supra* note 5; see generally Benjamin Edelman, et al., *To Groupon or Not to Groupon: The Profitability of Deep Discounts*, HARVARD BUSINESS SCHOOL (Feb. 3, 2014), http://www.hbs.edu/faculty/Publication%20Files/11-063_42425cdb-81ee-4d66-9420-4ebdb809358f.pdf (discussing how Groupon can benefit businesses by offering advertising).

and ability to generate business.²⁵ Physicians that decide to utilize Groupon's marketing services may be motivated by the opportunity to attract new business with the use of coupons, which will potentially lead to repeat business.²⁶ By virtue of such marketing tactics, physicians also seek to enjoy heightened exposure of their practice in the local community.²⁷ Groupon's success within the mobile market may be another compelling reason that physicians would integrate its services into their marketing plan.²⁸ The host of benefits offered to healthcare providers by Groupon causes these providers to reevaluate their traditional reluctance to engage in online marketing and employ more innovative solutions.²⁹ It is estimated that marketing arrangements between daily deal platforms and healthcare providers amount to five to ten percent of the online coupon industry.³⁰

Healthcare consumers recognize the substantial benefit of using daily deal advertisements.³¹ Medical costs exceeded the inflation rate by threefold

25. See GrouponWORKS, <http://works.groupon.sg/en/> (last visited Feb. 28, 2014).

26. See *Groupon Q3 2013 Public Fact Summary*, GrouponWORKS.COM, <http://files.shareholder.com/downloads/AMDA-E2NTR/2832382440x0x710981/E9EEB68D-05DB-4C99-9BF4-0D04B326C698/2013> (last visited Feb. 28, 2014) (stating that, based on internal data, "82% of merchants agree that their Groupon deal brought in new customers" and that "93% of recent Groupon customers plan to purchase from Groupon again in the next 50 days").

27. See *Id.* (stating that, based on internal data, "81% of merchants felt the Groupon deal increased awareness of their business within the community" and that "81% of customers have referred someone to the business").

28. See Tara Clarke, *Groupon (Nasdaq: GRPN) Earnings Update: Record-Breaking Quarter, and Promising Future on these Two Numbers*, MONEY MORNING (Feb. 20, 2014), <http://moneymorning.com/2014/02/20/groupon-nasdaq-grpn-earnings-preview-two-numbers-watch/> (stating that nearly 70 million people have downloaded Groupon's mobile application and that 50% of Groupon's transactions take place on a mobile device).

29. See, e.g., Ankita Rao, *Doctors And Dentists Lure Patients With Money – Saving Deals Online*, KAISER HEALTH NEWS (Jan. 8, 2013), <http://www.kaiserhealthnews.org/Stories/2013/January/09/groupon-living-social-health-care-deals.aspx> (describing how AMG Medical Group used Groupon to bring in more than 1,000 new patients over the course of a year).

30. *Id.*

31. See *id.*

over the past few decades, and online vouchers for medical services provide consumers with an alternative way to meet the rising costs of health care.³² In addition, such arrangements may effectively combat the inaccessibility of health care in underserved populations.³³ Millions of Americans are currently uninsured or have gaps in their coverage, and these individuals can turn to Groupon as a way to access affordable health care.³⁴ While Groupon is more commonly known to advertise elective procedures such as Botox, liposuction, or Lasik eye surgery, at times physicians utilize daily deal websites to offer general medical care, such as full checkups and eye exams.³⁵

III. ETHICAL AND LEGAL IMPLICATIONS OF DAILY DEAL WEBSITES

The use of daily deal platforms to connect healthcare providers and consumers generates controversy in the field of medicine over the extent to which such conduct is legal and ethical.³⁶ While other concerns exist,³⁷ this article specifically addresses the issues of fee splitting violations under the AMA Code of Medical Ethics and state statutes and the increased risk of

32. DEVON M. HERRICK, NAT'L CTR. FOR POL'Y ANALYSIS, *THE MARKET FOR MEDICAL CARE SHOULD WORK LIKE COSMETIC SURGERY* (2013), *available at* <http://www.ncpa.org/pdfs/st349.pdf> (noting that the price of medical care has increased by 2,700 percent since 1950 whereas inflation has increased by only 800 percent).

33. See Catherine Hoffman & Julia Paradise, *Health Insurance and Access to Health Care in the United States*, 1136 ANNALS N.Y. ACAD. SCI. 149, 152-53 (2008), (explaining that "[m]ore than 90% of the uninsured cite cost as the main barrier to getting care (as do more than half the insured)" and that "uninsured adults are significantly more likely to delay or forgo care and to have unmet needs than their insured counterparts"); see also Associated Press, *Uninsured turn to Groupon for Health Care*, CBSNEWS (Dec. 30, 2011 3:28 PM), <http://www.cbsnews.com/news/uninsured-turn-to-groupon-for-health-care/>.

34. Associated Press, *supra* note 33; see also Ankita Rao, *supra* note 29 (describing how the majority of patients brought into AMG's medical practice through Groupon were low-income, uninsured or on high deductible plans).

35. Associated Press, *supra* note 33.

36. Bob LaMendola, *supra* note 9.

37. Additional issues are posed in the analysis of a daily deal marketing agreement if a government-funded program covers any amount of the services that the patient receives. In this circumstance, all federal and state anti-kickback statutes should be carefully considered. See, e.g., 42 U.S.C. § 1320a-7b.

patients receiving unnecessary and inappropriate medical services.

A. Prohibitions on Fee-Splitting

Since 1847, the AMA Code of Medical Ethics provides the authoritative ethics guide for practicing physicians.³⁸ The Code establishes that it is unethical for a physician to engage in the practice of fee splitting.³⁹ The Code defines fee splitting as a physician paying or receiving payment for the referral of a patient,⁴⁰ and almost all state licensing entities have enacted similar statutes prohibiting fee splitting by healthcare providers.⁴¹

As described in Section II, in the typical scenario where a patient purchases an online voucher for medical services on a daily deal platform, the patient pays the daily deal company the full amount of the discount coupon and the daily deal company then charges the physician fifty percent of that amount by retaining fifty percent of the patient's payment and remitting the remaining balance to the healthcare provider.⁴² In this scenario, ethical violations arise when the dollars retained by the daily deal company represent part of the healthcare provider's fee for providing the patient with medical

38. *History of AMA Ethics*, AM. MED. ASS'N, <http://www.ama-assn.org/ama/pub/about-ama/our-history/history-ama-ethics.page> (last visited Feb. 27, 2014) (providing a general history of the Code of Medical Ethics). While not laws, the AMA Council of Ethical and Judicial Affairs' (CEJA) ethical guidelines are "standards of conduct which define the essentials of honorable behavior for the physician." Frank A. Riddick, *The Code of Medical Ethics of the American Medical Association*, 5 OCHSNER J. 6, 6-10 (2003), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3399321/>. Members voluntarily agree to abide by the applicable code as a condition of membership and may be subject to AMA sanctions for failure to comply with its guidelines. *Id.*

39. AM. MED. ASS'N COUNCIL ON ETHICAL AND JUD. AFFS, *supra* note 8.

40. *Id.*

41. See, e.g., COLO. REV. STAT. § 12-36-125(1) (2014); HAW. REV. STAT. § 431:10C-308.7(b) (2013); IDAHO CODE ANN. § 54-1814(8) (1994); NEB. REV. STAT. § 38-179 (2013); WIS. STAT. § 448.08(1) (2008); N.C. GEN. STAT. § 90-401 (1994); N.M. STAT. ANN. § 61-6-15(16) (2013); OHIO REV. CODE § 4731.22(B)(4),(17) (2013); TENN. CODE ANN. § 63-6-225(a) (1995); N.Y. EDUC. LAW § 6509-a; FLA. STAT. ANN. § 458.331(1)(i) (2013); 225 ILL COMP. STAT. 60/22.2(a) (2010).

42. Nolan et al., *supra* note 5.

services.⁴³ With this assumption in place, the healthcare provider's conduct may be interpreted as fee splitting.⁴⁴

As it stands today, there is little uniformity and clarity surrounding the issue of whether a medical professional's decision to participate in daily deal advertising violates fee-splitting prohibitions.⁴⁵ The AMA and most state licensing boards have not addressed the issue of fee splitting within the context of medical promotions on daily deal platforms.⁴⁶ Only three state medical licensing boards have taken a position on the legality of these promotions: Illinois, Ohio, and North Carolina.⁴⁷ In these three instances, the states concluded that daily deal advertising as it applies to medical practice is not a *per se* violation of state fee splitting statutes and, under certain circumstances, is permissible.⁴⁸ Without a change in or comment on the majority of existing state policies, however, healthcare providers proceed with caution in arranging daily deal promotions because such arrangements can be considered violations of the ethical and legal rules governing healthcare providers.⁴⁹ It is imperative that the AMA and state licensing boards weigh in on the specific issue of daily deal medical promotions to provide guidance and certainty to those healthcare providers seeking to leverage this

43. *Id.*

44. *Id.*

45. See, e.g., THE STATE MED. BD. OF OHIO, *supra* note 10; N.C. MED. BD., *supra* note 10; ILL. DEPT. OF FIN. AND PROF'L REG, *supra* note 10; but see, e.g., Francis J. Serbaroli, *Internet Discounts on Health Care Services: Strictly Illegal*, 247 N.Y.L.J. (2012), available at <http://www.gtlaw.com/News-Events/Publications/Published-Articles/155511/Internet-Discounts-on-Health-Care-Services-Strictly-Illegal> (discussing the strict illegality of daily deal advertisements).

46. Wailin Wong, *Illinois agency OKs daily deal for medical services*, CHICAGO TRIBUNE BUSINESS (Apr. 16, 2013), http://articles.chicagotribune.com/2013-04-16/business/ct-biz-0416-tech-notebook-20130416_1_daily-deals-lightbank-paul-taaffe (stating that the AMA has not undertaken a legal review of daily deals).

47. THE STATE MED. BD. OF OHIO, *supra* note 10; N.C. MED. BD., *supra* note 10; ILL. DEPT. OF FIN. AND PROF'L REG, *supra* note 10.

48. THE STATE MED. BD. OF OHIO, *supra* note 10; N.C. MED. BD., *supra* note 10; ILL. DEPT. OF FIN. AND PROF'L REG, *supra* note 10.

49. See Francis J. Serbaroli, *supra* note 45.

technology.⁵⁰

B. Increased Risk of Unnecessary or Inappropriate Treatment

Another expressed concern over medical marketing on daily deal platforms where the patient prepays for medical services is the increased risk that the healthcare provider will provide medically unnecessary services or services that the patient is not a suitable candidate to receive.⁵¹ Upon paying for the medical service on the daily deal platform, a patient forms expectations about the eventual receipt of medical services, regardless of whether that patient is suitable for or needs the medical services.⁵² Although the Office of Inspector General (OIG) has not directly addressed the issue of daily deal healthcare marketing, it has expressed concern that healthcare providers in a pre-paid online marketing arrangement will feel unduly pressured to provide the medical services even if unnecessary or inappropriate.⁵³

50. The need for clarity for healthcare providers is what prompted the IDPR to address the issue. The IDPR stated that it issued a policy statement in response to an influx of questions and concerns from healthcare providers on whether daily deal advertisement would subject them to legal scrutiny. *See* Wailin Wong, *supra* note 46; *see also* Michael J. Sacopolos, *The Price is Right: Are group discounts really fee splitting in disguise?*, PLASTIC SURGERY PRACTICE (Sep. 26, 2013), <http://www.plasticsurgerypractice.com/2013/09/the-price-is-right-are-group-discounts-really-fee-splitting-in-disguise/> (explaining that the varying models of daily deal advertising and lack of direction on how to use these arrangements without engaging in fee splitting prompted North Carolina to issue a statement on the issue).

51. Claudia Ahiabor, *supra* note 23 at 72 (Mar. 27, 2012) (citing OFFICE OF INSP. GEN., DEP'T HEALTH & HUMAN SERVS., NO. 12-02 at 8 (2012)), *available at* <https://oig.hhs.gov/fraud/docs/advisoryopinions/2012/AdvOpn12-02.pdf>).

52. *Id.*

53. Nolan, et al, *supra* note 5 (citing OFFICE OF INSP. GEN., DEP'T HEALTH & HUMAN SERVS., NO. 12-02, 8 (2012)), *available at* <https://oig.hhs.gov/fraud/docs/advisoryopinions/2012/AdvOpn12-02.pdf>). The Office of Inspector General's concerns follow that "if a beneficiary bought a pre-paid coupon for Service X, when that beneficiary walks into the offering provider's office requesting Service X – already having paid for Service X – the offering provider might feel pressured to render Service X, even though it is not medically necessary." *Id.*

IV. THE IDPR FRAMEWORK AND WHY IT IS SENSIBLE

A blanket ban on daily deal marketing in the field of medicine due to fee splitting prohibitions is not justifiable on textual or policy grounds. Rather, it is sound policy to permit healthcare providers to leverage a daily deal marketing solution so long as the fundamental concerns at play with fee splitting arrangements are appropriately mitigated. The IDPR's opinion provides a sensible model for how to ethically realize the benefits of daily deal advertising while also ensuring built-in safeguards against fraudulent or abusive tactics.

A. The Requirements Under the Illinois Department of Professional Regulation

The IDPR concludes that daily deal marketing in medicine is permissible so long as four conditions are met.⁵⁴ First, the negotiated fee between the daily deal advertising company and the healthcare provider must be reasonable compensation for the cost of advertising.⁵⁵ Second, all advertisements must disclose a comparison in price between the actual service and the discounted service.⁵⁶ Third, all advertisements must disclose that decisions about health care are made on an individual basis, should not be made in haste, and that all patients may not be eligible for the advertised service.⁵⁷ Fourth, all advertisements must provide a mechanism whereby the patient is entitled to a full refund in the event that the patient is not a candidate for the medical service.⁵⁸

B. The IDPR Framework Does Not Violate the Letter of the Law

As a threshold matter, fee splitting precludes a physician from making or

54. THE ILL. DEPT. OF FIN. AND PROF'L REG., *supra* note 10.

55. *Id.* While the IDPR states that the advertising fee must be reasonable, it does not define what constitutes a reasonable fee. *Id.*

56. *Id.*

57. *Id.*

58. *Id.*

accepting a payment solely for a referral.⁵⁹ The IDPR, however, recognizes that the portion of a consumer's payment that Groupon retains represents the cost of advertising and not a referral fee.⁶⁰ Groupon is merely an advertising channel.⁶¹ It does not make any recommendations, but merely provides a platform where healthcare providers can promote their services.⁶² Therefore, a blanket ban on daily deal medical marketing cannot be justified on the face of the fee-splitting statutes, as Groupon's advertising fees do not fall within the purview of the statute.⁶³

C. The IDPR Framework Does Not Violate the Spirit of the Law

Daily deal advertisements for medical services do not threaten the policy reasons that drove fee splitting statutes into existence in the first place. Careful examination of such statutes reveals that their fundamental concern is the best interests of patients and to ensure that a referral for health care is based on competencies and talent, rather than any financial considerations.⁶⁴ To this effect, the Code emphasizes that patients rely on the physician's advice regarding referrals and that fee splitting constitutes a failure to deal honestly with patients.⁶⁵ The fundamental principle, however, that referrals should be based on skill, rather than financial incentive, does not hold true because Groupon is not a referring entity.⁶⁶ Moreover, the risk that a refer-

59. AM. MED. ASS'N COUNCIL ON ETHICAL AND JUD. AFFS, *supra* note 8.

60. THE ILL. DEPT. OF FIN. AND PROF'L REG., *supra* note 10 (providing that daily deal marketing is permissible when the daily deal company retains payments for reasonable compensation for the cost of advertising).

61. Similar ethical and legal implications of daily deal advertising platforms arise in the legal context. Krista Umanos, *Ethics, Groupon's Deal-of-the-Day, and the "McLawyer"*, 81 U. CIN. L. REV. 1169, 1184-85 (2013), available at <http://scholarship.law.uc.edu/uclr/vol81/iss3/12/>. Please refer to this article for an interesting discussion on how Groupon functions as a mere advertising platform and not as a referral agency.

62. *Id.*

63. *See id.*

64. Francis J. Serbaroli, *supra* note 45.

65. AM. MED. ASS'N COUNCIL ON ETHICAL AND JUD. AFFS., *supra* note 8.

66. *See* Krista Umanos, *supra* note 61.

ring physician will breach a patient's trust does not exist, as Groupon is not a physician.⁶⁷ Fee-splitting statutes are designed to combat white coat marketing,⁶⁸ and the policy justifications for its prohibition subside when the patient is not being directed to a physician from another physician.⁶⁹ Because Groupon discloses to the public that it is in the business of marketing goods and services for a fee,⁷⁰ and does not exclusively market healthcare goods and services,⁷¹ there is a low risk that patients will construe Groupon as a referring entity and make a healthcare decision based on misplaced trust.

D. The IDPR Framework Guards Against the Increased Risk of Unnecessary or Inappropriate Treatment

The IDPR's framework for regulating medical marketing on daily deal platforms sufficiently guards against the risk that physicians will provide unnecessary or inappropriate treatment. A disclosure on the discount voucher that the patient is not necessarily a suitable candidate for the medical service mitigates the risk that patients will form inappropriate expecta-

67. See Nolan et al., *supra* note 5 (noting that the OIG, in advisory opinion 12-02, found a low risk of fraud in an advertising agreement between a website that hosted online coupons for healthcare services and healthcare providers where the coupon website was not a healthcare provider).

68. "White coat marketing" occurs where the marketer is a healthcare professional. Claudia Ahiabor, *supra* note 23 at 71.

69. *Id.* (explaining that daily deal websites do not fit into the white coat marketing scheme that is subject to higher scrutiny); see also Anna M. Grizzle & Lori S. Richardson Pelliccioni, *supra* note 4 at 6 (listing advisory opinions issued by the OIG that raises the issue of white coat marketing).

70. See *Groupon FAQs*, GROUPONWORKS, <https://www.grouponworks.com/merchant-resources/FAQs> (last visited Mar. 30, 2014) (disclosing that Groupon charges businesses a marketing fee for advertising and promoting their offers).

71. Claudia Ahiabor, *supra* note 23 at 72 (noting that the distribution of non-health related coupons further shows that a daily deal website is not a healthcare provider or affiliated solely with the healthcare industry).

tions about receiving the service.⁷² An additional disclosure on the discount voucher that the healthcare provider's decision to deliver the particular service is made on a case-by-case basis and depends on the individual patient helps ensure that the provider makes decisions based on the best interests of the individual patient.⁷³ Further, the requirement that a full refund be made available to the patient if the patient is not eligible for the medical service mitigates the risk that healthcare providers will feel undue pressure to deliver the service regardless of need or suitability.⁷⁴

V. CONCLUSION

Healthcare providers who turn to Groupon and similar daily deal platforms to promote their medical services need guidance on how to leverage this technology without running afoul the law.⁷⁵ The AMA and state licensing boards should provide healthcare providers with such guidance and issue a policy statement that adopts the framework set forth by the IDPR.

This framework properly recognizes that daily deal advertisements can be structured so as to comply with fee splitting statutes and guard against any increased risk of unnecessary or inappropriate treatment.⁷⁶ Also, this framework empowers healthcare providers to broaden their patient base, increase access to health care, and evolve with society.⁷⁷

72. See *id.* (discussing the concern that patients develop improper expectations about the receipt of medical services when they purchase medical discount vouchers).

73. See Francis J. Serbaroli, *supra* note 45 (explaining that fee splitting statutes are designed to ensure that health care decision making is based on the best interests of the patient).

74. See Nolan, et al, *supra* note 5 (noting that the OIG is concerned with the undue pressure placed on healthcare providers to provide medical services when payment is fixed in full prior to consultation with the provider).

75. See, e.g., Wailin Wong, *supra* note 46 (recognizing the level of uncertainty that existed in Illinois regarding the use of daily deal platforms for medical advertising prior to the issuance of a statement by the IDPR).

76. See *infra* Section IV.

77. See *infra* Section II.

Ready or Not, Here They Come: A Discussion of
the Legal and Ethical Considerations for the
Implementation of Electronic Medical Records

Ashley R. Huntington *

I. INTRODUCTION

Perhaps the oldest known principle in medical ethics is “do no harm.”¹ While short and sweet, this axiom is loaded with difficult questions, especially in an era of great medical innovation.² Despite the momentous innovation and evolution of health care, many medical providers must approach patients who have untreatable and terminal illnesses and give them options that are experimental and may ultimately cause harm, or choose to do nothing, which results in certain harm.³ Because of this array of choices, medicine has moved away from the simplicity of “do no harm,” and moved into a more nuanced idea of choosing one care plan that is no more harmful than any other care plan.⁴ However, many medical providers do not take into consideration the idea that “do no harm” applies much more broadly—this axiom should be followed when using, accessing, and disclosing a patient’s personal health information (PHI). Attention to the security of a patient’s PHI is more important than ever, especially as an increasing number of medical providers are making the transition from paper medical records to

* Juris Doctor Candidate, Loyola University Chicago School of Law, Class of 2015. Ms. Huntington is a staff member of *Annals of Health Law*.

1. Scott Groudine & Philip D. Lumb, *First, Do No Harm*, 23 J. MED. ETHICS 377, 377 (1997).

2. *Id.*

3. *Id.*

4. *Id.*

electronic medical records (EMRs).⁵ Although significant concerns surround the implementation of EMRs, especially with regard to data security, this article will argue that the implementation and effective use of EMRs allows medical providers to facilitate the best care for their patients as long as proper safeguards for data security are in place first. Part I of this article will explore the advantages of EMRs and how they allow medical providers to give the best care to their patients. Part II will delve into the criticisms and concerns about EMRs, specifically about data security. Part III will show that through a successful and well-planned pre-implementation phase, EMRs that have the required safeguards, technical support, and other factors will allow the system to produce more beneficial and ethical care.

II. A REVIEW OF THE LEGAL AND ETHICAL INCENTIVES OF EMR IMPLEMENTATION

Although the widespread implementation of EMRs across the healthcare field draws significant concerns from medical providers, as well as patients, using such records also has important legal, ethical, financial, and health benefits that justify their implementation.⁶ Even though the technology for EMRs dates back to the 1970s, the push for implementing such technology is a relatively recent trend.⁷ In 2004, former President Bush set the goal for a majority of Americans to have an EMR within ten years.⁸ Current statistics for implementation show that in 2012, seventy-two percent of office-

5. See CHUN-JU HSIAO & ESTHER HING, CTR. FOR DISEASE CONTROL AND PREVENTION, USE AND CHARACTERISTICS OF ELECTRONIC HEALTH RECORD SYSTEMS AMONG OFFICE-BASED PHYSICIAN PRACTICES: UNITED STATES, 2001-2012, at 1 (2012), available at <http://www.cdc.gov/nchs/data/databriefs/db111.pdf>. The percentage of office-based physicians using EMR systems increased from forty-eight percent in 2009, to seventy-two percent in 2012, with individual state implementation ranging from fifty-four percent in New Jersey to eighty-nine percent in Massachusetts. *Id.*

6. See generally Richard Hillestad et al., *Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, and Costs*, 24 HEALTH AFFAIRS 1103 (2005).

7. Karoline Kreuser, *The Adoption of Electronic Health Records*, 16 ANNALS HEALTH L. 317, 318 (2007).

8. *Id.*

based physicians used EMR systems,⁹ while a little over forty-four percent of hospitals used at least a basic EMR system in 2012.¹⁰

This dramatic increase in EMR implementation seems to be motivated at least partially by the Health Information Technology for Economic and Clinical Health Act (HITECH) and the American Recovery and Reinvestment Act (ARRA), which provide incentives to eligible professionals and eligible hospitals that participate in Medicare and Medicaid programs, and that are meaningful users of certified EMR technology.¹¹ Under the incentive programs, eligible professionals can receive up to \$44,000 through the Medicare incentive program, and up to \$63,750 through the Medicaid incentive program, with payments totaling up to an unprecedented \$27 billion over ten years.¹² Although these incentives may not be enough to cover the entire cost of an expensive EMR system implementation, the incentives can help to defray some of the cost, which will make implementation less burdensome for smaller practices.¹³ Central to the incentive programs is the demonstration of meaningful use of EMR systems, which is divided between a set of core objectives and a menu of ten additional tasks.¹⁴ Provid-

9. HSIAO & HING, *supra* note 5.

10. See OFF. OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., *Adoption of Electronic Health Record Systems Among U.S. Non-Federal Acute Care Hospitals, 2008-2012*, available at <http://www.healthit.gov/sites/default/files/oncdatabrief9final.pdf>.

Hospital adoption of EMR systems more than tripled since 2009, when only twelve percent of hospitals had and used a basic EMR system. *Id.*

11. *Electronic Health Record Medicaid Incentive Payment Program (eMIPP)*, ILLINOIS DEP'T OF HEALTHCARE AND FAM. SERVS., <http://www2.illinois.gov/hfs/MedicalProvider/eMIPP/Pages/default.aspx> (last visited

Apr. 5, 2014). The incentive program is designed to encourage eligible professionals and eligible hospitals to adopt, implement, or upgrade certified EMR technology and use it in a meaningful manner—the program is not designed to serve as a reimbursement. *Id.*

12. *EHR Incentive Programs*, CMS.GOV., <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/ehrincentiveprograms/> (last visited Apr. 5, 2014). Eligible hospitals are eligible to receive payments from both incentive programs, while eligible professionals are only able to receive payments through one incentive program of their choosing. *Id.* Differences between the programs include the time period over which payments are made, the agency running the program, payment adjustments, and the degree to which meaningful use must be demonstrated. *Id.*

13. *Id.*

14. David Blumenthal, *The "Meaningful Use" Regulation for Electronic Health Rec-*

ers can choose any five off this menu to implement, thus giving them autonomy in deciding their own path toward full EMR implementation.¹⁵ The meaningful use rule creates a balance between the importance of adopting EMRs while still recognizing the risks and challenges that are associated with such implementation.¹⁶

In addition to the legal incentives that accompany the implementation of an EMR system, it has a number of ethical advantages.¹⁷ EMRs are generally seen as a way to achieve quality and continuity in treatment while also being cost effective.¹⁸ At the most basic level, EMRs can provide medical providers with ready access to a patient's complete lifetime medical history.¹⁹ EMRs provide increased accessibility of a patient's medical history for medical providers and make it possible for medical providers to make the best choices for care after reviewing the more complete medical history provided by an EMR²⁰, thus allowing them to "do no harm."

The ability to review a complete medical history and make decisions based on that history is especially important if a medical provider is participating in an Accountable Care Organization (ACO). An ACO is a group of doctors, hospitals, and other healthcare providers who come together voluntarily to give coordinated, high-quality care to Medicare patients.²¹ Although participation in an ACO is completely voluntary for medical providers, incentives are available when providers keep costs down and meet specific benchmarks, focusing on prevention and carefully managing pa-

ords, 363 NEW ENG. J. MED. 501, (Aug. 5, 2010), available at <http://www.nejm.org/doi/full/10.1056/NEJMp1006114>.

15. *Id.*

16. *Id.*

17. See Wes Fisher, *Patient Safety and the Ethics of EMR Implementation*, MEDPAGE TODAY (Jan. 22, 2013), <http://www.medpagetoday.com/DrWes/36939>.

18. Kreuser, *supra* note 7, at 319.

19. *Id.*

20. *Id.*

21. *Accountable Care Organizations (ACO)*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ACO/> (last visited Apr. 5, 2014).

tients with chronic diseases.²² Thus, providers receive more compensation for ensuring that their patients remain healthy and out of the hospital.²³ EMRs can help facilitate this quality care.²⁴

EMRs have the capability to provide diagnostic and treatment advice while allowing the medical provider to make the final decision for course of care.²⁵ EMRs have the ability to track when a clinician ignores a warning or advice, especially for potentially dangerous medication interactions, thus providing enhanced accountability for care.²⁶ However, it should be noted that many medical decisions cannot be made on entirely scientific or computer-based grounds²⁷ because providers must consider all aspects of care, including the underlying goals and values of the individual patient.²⁸

III. DATA SECURITY AND OTHER CONCERNS SURROUNDING EMR IMPLEMENTATION

As previously noted, opponents of EMRs have a number of fears about the widespread implementation of EMRs, especially with regard to data security issues. This section will discuss the opposition to EMRs, but ultimately show that the main concern of data security can be taken into consideration and remedied before implementation takes place. A quick review of newspaper headlines from the past few years reveals an increasingly significant problem for consumers in the United States: data security. While credit card and identity information can be valuable to thieves and hackers, what many consumers and medical providers fail to realize is that health information is significantly more valuable, thus making it highly sought-

22. *Id.*

23. Jenny Gold, *Accountable Care Organizations, Explained*, NPR, (Jan. 18, 2011, 8:21 AM), <http://www.npr.org/2011/04/01/132937232/accountable-care-organizations-explained>.

24. *See generally* Hillestad, *supra* note 7, at 1106.

25. *See* Peter S. Winkelstein, *Ethical and Social Challenges of Electronic Health Information*, in *MED. INFORMATICS*, 139, 147 (Hsinchun Chen et al. eds., 2005).

26. *Id.*

27. *Id.*

28. *Id.*

after.²⁹ Because of PHI's value, cases involving hospital personnel selling PHI are occurring more than ever.³⁰ But as more medical providers transition to EMRs, the risks of data breaches and unauthorized PHI disclosures may seem greater because EMRs allow more individuals access to patient records.³¹ These risks make some patients resistant to having their PHI stored on EMRs.³² Among the most serious effects of a data breach are the patient's loss of health insurance or the patient being held financially accountable for medical expenses related to treatments they did not receive,³³ however some breaches ultimately have little consequence on the patients affected.³⁴

Though the value of electronic records is particularly worrisome for patients, medical providers should be concerned with ensuring the security of electronic records because of the serious legal consequences that come with lack of data security, specifically under the Health Insurance Portability and Accountability Act (HIPAA).³⁵ HIPAA provides both civil and criminal

29. See Jim Avila & Serena Marshall, *Your Medical Records May Not Be Private: ABC News Investigation*, ABC NEWS, <http://abcnews.go.com/Health/medical-records-private-abc-news-investigation/story?id=17228986&singlePage=true> (last visited Apr. 5, 2014). Thieves may approach medical staff and offer upward of \$500 per week for providing twenty to twenty-five insurance claim forms, medical records, or health financing records. *Id.*

30. See NITROSECURITY & FAIR WARNING, SECURITY AND PRIVACY OF ELECTRONIC MEDICAL RECORDS 4 (2011), available at <http://www.himss.org/files/HIMSSorg/content/files/SecurityandPrivacyofElectronicMedicalRecords.pdf>.

A Howard University hospital medical technician pleaded guilty to selling patient information, including names, birth dates, and Medicare numbers, for \$500 to \$800 per transaction for over a year. *Id.* An admissions clerk at the Baptist Health Medical Center in Little Rock, AR was recently accused of using stolen patient information to buy Wal-Mart gift cards. Approximately 1,800 patient records were exposed. *Id.*

31. See Judy Foreman, *At Risk of Exposure*, L.A. TIMES (June 26, 2006), <http://articles.latimes.com/2006/jun/26/health/he-privacy26>. One report estimates that at least 150 people, including nurses, x-ray technicians, and billing clerks have access to at least part of a patient's records during hospitalization. *Id.*

32. See Maranda Gibson, *EMRs Cause Concern Among Patients*, SIGNAL NEWS (Mar. 1, 2011), <http://signalnews.com/emrs-cause-concern-among-patients>.

33. Peter P. Yu, *Ethical Principles and the Use of Electronic Health Records*, ASCO DAILY NEWS (June 1, 2013), <http://am.asco.org/ethical-principles-and-use-electronic-health-records>.

34. *Id.*

35. See, *HIPAA Violations and Enforcement*, AMA, <http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/>

penalties based on the number of violations and degree of knowledge involved in a breach.³⁶ Aside from civil and criminal penalties, entities involved in a breach are also required to provide individual notices to those affected by the breach, and must notify the media if the breach impacts over 500 individuals.³⁷

Aside from the legal considerations involved with potential data breaches and the security of PHI, medical providers should consider the ethical implications that come with a transition to EMRs. These considerations include the continued obligation to keep their patients' information safe, while making the best decisions for their patients' care.³⁸ Because EMRs come with enhanced portability and accessibility, ethical questions are raised with regard to medical providers informing their patients of the potential for privacy breaches.³⁹ These questions include whether patients must be informed that EMR vendors sold, or have the rights to sell, de-identified copies of patient databases to pharmaceutical companies, medical devicemakers, and health services researchers.⁴⁰

Additionally, the technology of many EMR systems allows them to provide automatic alerts such as dangerous drug interactions and suggestions for treatment and diagnosis.⁴¹ While these warnings and suggestions can be viewed as merely advice, the availability of such technology raises ethical

hipaahealth-insurance-portability-accountability-act/hipaa-violations-enforcement.page (last visited Apr. 5, 2014). Under HIPAA's civil penalties, entities may be fined between \$100-\$50,000 per violation, or up to \$1.5 million in a calendar year. *Id.* Individuals may receive between one and ten years in prison if criminal liability is found under HIPAA. *Id.*

36. *Id.*

37. *Breach Notification Rule*, U.S. DEP'T OF HEALTH & HUM. SERVS., <http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/> (last visited Apr. 5, 2014).

38. Dean F. Sittig & Hardeep Singh, *Legal, Ethical, and Financial Dilemmas in Electronic Health Record Adoption and Use*, 127 PEDIATRICS e1042, e1044 (2011).

39. *Id.*

40. EMR vendors such as Cerner, GE, and Allscripts [formerly Eclipsys] have all sold de-identified patient information to a variety of health care companies. *Id.* EMRs may also be used for quality reviews, administrative reviews, and utilization studies to manage the business aspects of health care. Kreuser, *supra* note 7, at 320.

41. Winkelstein, *supra* note 26, at 146.

questions about whether the provider or the computer is ultimately making treatment decisions.⁴² Medical providers must remember that computer technology can be prone to errors, crashes, and other unavoidable accidents, and thus must exercise sound judgment aside from computer recommendations when engaging in clinical decision-making.⁴³ Further, by shifting to centralized record-keeping through EMRs, patients are able to receive periodic or on-demand reports of the audit trail of accesses to their records.⁴⁴ These reports can then lead to the assumption that the patient is responsible for monitoring their medical reports much like they are responsible for monitoring their credit card statements.⁴⁵

IV. COMBATING DATA SECURITY ISSUES THROUGH PRE-IMPLEMENTATION PLANNING AND POST-IMPLEMENTATION SUPPORT

Although concerns surrounding EMRs range from data security issues to allowing technology to take over the medical provider's role in making decisions for patient care, many of these issues can be avoided with proper EMR implementation.⁴⁶ At the center of successful implementation are three factors: people, process, and technology.⁴⁷ Generally, three main phases will occur during implementations: pre-implementation, implementation, and post-implementation.⁴⁸ It is important to note that the three main factors may exist in all stages of implementation, or many only exist in a single stage of implementation.⁴⁹ Perhaps most important to the successful

42. *Id.* at 146–47.

43. *Id.*

44. *Id.*

45. *Id.*

46. See Karim Keshavjee et al., *Best Practices in EMR Implementation: A Systematic Review* 1, 3 (2006), available at http://www.infoclin.ca/assets/7e474_best%20practices%20in%20emr%20implementation%20-%20july,%202006.pdf.

47. *Id.*

48. *Id.*

49. *Id.* For example, provider governance, EMR project leadership, and project stakeholders will be involved in all stages of implementation, though tasks such as choosing software and work-flow redesign will only be involved in the pre-implementation and implementation phases, respectively. *Id.* at 4.

implementation of an EMR system is the pre-implementation phase, where project managers decide the mission and vision for the system, where software is chosen, and where project managers sell the benefits of the system to personnel.⁵⁰ During the actual implementation of the EMR, it is critical that the EMR functions and usability align with the workflow of physicians and staff.⁵¹ Further, training for the EMR system must take place during implementation and should be on-going so as to facilitate a smooth transition to paperless patient care.⁵² Finally, post-implementation technical support and incentives are important for maintaining the EMR system and ensuring that users are utilizing it properly.⁵³

In addition to ensuring strong pre-implementation planning and post-implementation support, biometric authentication offers another solution to the problem of data security of EMRs.⁵⁴ Biometric authentication is generally seen as more advantageous compared to token-based or knowledge-based systems.⁵⁵ It has been suggested that to allow the maximum availability of records to both patients and medical providers, a combination of signature and voice recognition should be implemented into EMR systems.⁵⁶

V. CONCLUSION

In an age of rapidly growing medical technology, it is inevitable that EMRs will be implemented, but the key to successful implementation in-

50. *Id.* at 4. Ensuring internal readiness for an EMR system has been shown to be important in the successful implementation of EMRs. *Id.* EMRs bring serious changes to an organization, so it become essential to demonstrate the benefits of the system to physicians, nurses, and staff while addressing possible obstacles and barriers. *Id.*

51. *Id.* at 7.

52. *Id.*

53. *See id.* at 8.

54. *See* Stephen Krawczyk & Anil Jain, *Securing Electronic Medical Records Using Biometric Authentication*, in AUDIO- AND VIDEO-BASED BIOMETRIC PERSON AUTHENTICATION, 1, 2 (Kanade et. al eds., 2005).

55. *Id.* at 2. Biometric authentication can include systems that use modalities such as fingerprints, iris scanning, signatures, or voice recognition while token-based authentication refers to the usage of identification cards, and knowledge-based authentication refers to password systems. *Id.*

56. *Id.* at 3.

volves three stages and many factors.⁵⁷ Critics of EMRs cite numerous concerns of data security, an increased likelihood for data breaches, and the possibility that EMRs may take over medical providers' job of diagnosing.⁵⁸ However, the benefits of EMRs outweigh the negatives.⁵⁹ Not only do medical providers have financial incentives through HITECH and ARRA, but using EMRs allows medical providers to provide better care and communicate more effectively with other clinicians, as well as patients. These benefits relate back to the central ethical goal in medicine of "do no harm." By utilizing the available EMR technology, medical providers put their patients' care first, and they are able to see a complete medical history before making any decisions about course of care.⁶⁰ The complete implementation of EMRs is no longer a possibility, but rather a process that is occurring rapidly in an effort to bring patient health records into the twenty-first century.⁶¹ While clinical alerting and decision-making systems can improve the quality of health care for patients, it is essential that these systems are implemented properly.⁶² By following the three stages of implementation, and paying special attention to the pre-implementation phase, EMRs have the possibility to make healthcare easier and more accessible.⁶³ Ongoing attention to EMR systems, which includes providing EMR users with training and education about the abilities and limitations of the system, as well as evaluating and maintaining systems, is critically important.⁶⁴ Using biometric authentication is another way to help combat the problem of data se-

57. See Keshavjee et al., *supra* note 47, at 3.

58. See Winkelstein, *supra* note 26, at 147.

59. *The Benefits of EHRs Drastically Outweigh the Risk*, EXSCRIBE (Oct. 14, 2013), <http://www.exscribe.com/orthopedic-e-news/ehremr/the-benefits-of-ehrs-drastically-outweigh-the-risks>.

60. Kreuser, *supra* note 7, at 319.

61. See David Blumenthal, *The Future of Health Care and Electronic Records*, HEALTH IT BUZZ (July 13, 2010, 4:11 PM), <http://www.healthit.gov/providers-professionals/benefits-electronic-health-records-ehrs>.

62. See Winkelstein, *supra* note 26, at 149.

63. See Keshavjee et al., *supra* note 47, at 3.

64. See *id.* at 7-8.

curity with EMRs.⁶⁵ Both voice recognition and signature verification can allow maximum access to both patients and medical providers while still being less invasive than fingerprint or iris scanning.⁶⁶ Further, medical providers must remember the ethics of their profession and strive to understand the advice produced by EMR systems while still choosing care actions based upon the patient's values and the goals of their health care.

65. See Krawczyk & Jain, *supra* note 55, at 3.

66. *Id.*

PPACA and the Moral Integrity of Corporations

*Robert Hogan**

I. INTRODUCTION

The Patient Protection and Affordable Care Act (PPACA) requires employers to provide contraceptive coverage to their employees at no additional cost.¹ This requirement is a subject of moral objection, and has been challenged² as violating the Religious Freedom Restoration Act (RFRA)³

* J.D. Candidate, Loyola University of Chicago School of Law, 2015.

1. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 19 (2010) (codified as amended throughout 42 U.S.C.). The PPACA requires group health plans and insurance issuers to offer certain preventative care and screenings with no cost sharing. Public Health Service Act, 42 U.S.C. § 300gg-13 (2010). The law delegates the task of enumerating the preventative care and screenings to the Health Resources and Services Administration (HRSA). *Id.* The HRSA, in turn, adopted the recommendations of the Institute of Medicine. *Women's Preventive Services Guidelines*, HEALTH RESS. AND SERVS. ADMIN., <http://www.hrsa.gov/womensguidelines/> (last visited March 31, 2014); *see also* Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 77 Fed. Reg. 8725 (February 15, 2012). This includes coverage of "[t]he full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity." *Clinical Preventive Services for Women (Report Brief)*, INST. OF MED. 3 (July 2011), available at http://www.iom.edu/~media/Files/Report%20Files/2011/Clinical-Preventive-Services-for-Women-Closing-the-Gaps/preventiveservicesforwomenreportbrief_updated2.pdf.

2. *See, e.g.* Complaint at 65, Roman Catholic Archbishop of Wash. v. Sebelius, No. CV 13-1441 (ABJ), 2013 WL 6729515 (D.D.C. Dec. 20, 2013); Complaint at 27-28, Priests for Life v. Sebelius, No. CV 13-1261 (EGS), 2013 WL 6672400 (D.D.C. Dec. 19, 2013). Although the Obama administration has administered an exception for religious employers, the exception is available only to nonprofit "religious employers" as narrowly defined by I.R.C. § 6033(a)(3)(A)(i), (iii). Coverage of Certain Preventative Services Under the Affordable Care Act, 78 Fed. Reg. 39874 (July 2, 2013) (to be codified at 45 C.F.R. pt. 147.131(a)) available at <http://www.gpo.gov/fdsys/pkg/FR-2013-07-02/pdf/2013-15866.pdf>. The exception itself has been the subject of challenge. *See, e.g.*, Complaint at 28, Little Sisters of Poor Home for Aged, Denver v. Sebelius, 134 S.Ct. 1022 (2014) (No. 1:13CV02611) (arguing that the required act of self-certification would entangle the organization in the very behavior objected to) [hereinafter Little Sisters]. Notably, the question of whether contraceptive use is moral or ethical is outside of the scope of this article. Moreover, "the resolution of that question is not to turn upon a judicial perception of the particular belief or practice in question; religious beliefs need not be acceptable, logical, consistent, or comprehensible to others in order to merit First Amendment protection." *Thomas v. Review Bd. of Ind. Sec. Div.*, 404

and Free Exercise Clause of the First Amendment.⁴ This challenge has given rise to a circuit split, which is typified by the Tenth Circuit's *en banc* opinion in *Hobby Lobby Stores, Inc. v. Sebelius*,⁵ and the Third Circuit's opinion in *Conestoga Wood Specialties v. Sec'y of U.S. Dep't of Health & Human Servs.*⁶ Both cases turned on the analysis of whether corporations are persons capable of religious exercise for the purposes of RFRA and the Free Exercise clause of the First Amendment.⁷ The court in *Hobby Lobby* ruled in favor of the corporations, finding that corporations are capable of religious beliefs.⁸ The court in *Conestoga*, in contrast, ruled in favor of the government, finding that corporations are not capable of religious beliefs, and that the religious beliefs of a corporation's owners cannot pass through to the corporation.⁹ These two cases have been consolidated and granted

U.S. 707,714 (1981).

3. Religious Freedom Restoration Act of 1993, 42 U.S.C. § 2000bb (2009) [hereinafter RFRA]. RFRA was enacted as a "super-statute" to bind the Federal Government. Michael Paulsen, *A RFRA Runs Through It: Religious Freedom and the U.S. Code*, 56 MONT. L. REV. 249, 253 (1995). RFRA superseded the decision of *Employment Division v. Smith*, in which the Supreme Court held that the government could burden religious exercise if the law was generally applicable, despite the Free Exercise Clause of the First Amendment. Jonathon Tan, *The HHS Mandate*, 47 U. RICH. L. REV. 1301, 1338 (2012-13); *Emp't Div. v. Smith*, 494 U.S. 872, 885 (1990), *superseded by* Religious Freedom Restoration Act (RFRA) of 1993, Pub. L. No. 103-141, 107 Stat. 1488.

4. U.S. CONST. amend. I. "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof. . . ." *Id.* (emphasis added).

5. *Hobby Lobby Stores, Inc. v. Sebelius*, 723 F.3d 1114 (10th Cir. 2013), *cert. granted*, 134 U.S. 678 (2013) (argued March 25, 2014) [hereinafter *Hobby Lobby*]. The Tenth Circuit opined that *Hobby Lobby* and *Mardel* (both closely held corporations) are "persons" for the purpose of the Religious Freedom Restoration Act, that the contraceptive-coverage requirement of the Affordable Care Act substantially burdens the corporations' religious practice, and that the government failed to articulate a compelling interest. *Id.* at 1136, 1141, 1143.

6. *Conestoga Wood Specialties Corp. v. Sec'y of U.S. Dep't of Health & Human Servs.*, 724 F.3d 377, 388-389 (3d Cir. 2013) *cert. granted*, U.S. 678 (2013) (argued March 25, 2014) [hereinafter *Conestoga*]. The Third Circuit opined that for profit corporations cannot assert claims under either the Free Exercise Clause of the First Amendment or the Religious Freedom Restoration Act, and that the owners of the closely held corporation *Conestoga Wood Specialties* likewise could not assert these claims. *Id.*

7. *Hobby Lobby*, *supra* note 5, at 1126 ("The Principal questions we must resolve here include: (1) whether [the corporations] are "persons" exercising religion for purposes of RFRA . . ."); *Conestoga*, *supra* note 6, at 388-89 (concluding directly after finding that the corporation could not engage in the exercise of religion, by extending this logic to likewise find that the owners of the corporation could not bring claims).

8. *Id.* at 1137, 1147.

9. *Conestoga*, *supra* note 6, at 388.

writ of *certiorari* to the Supreme Court of the United States.¹⁰

However, both courts overemphasized the applicability of religious freedom guarantees to corporations and overlooked the practical implications of the PPACA contraception mandate on the managers of corporations.¹¹ This article argues that the RFRA and Free Exercise Clause guarantees of religious freedom necessitate the opportunity for corporations to object to the contraception mandate, regardless of whether corporations are capable of religious exercise. Individual managers and owners of corporations are unquestionably persons capable of religious beliefs, the exercise of which can be substantially burdened by laws applicable to corporations.¹²

Part II of this article introduces the cases defining the circuit split. Part III critiques the opinions of both the Third and Tenth Circuits for analyzing the law in an overly idealistic manner that ignores practical implications of the PPACA on individual business owners. Part IV proposes that the threshold of whether a corporation is considered religious for purposes of RFRA and the Free Exercise Clause should depend on a majority vote of shares, and explains why such a threshold is sensible.

II. SCOPE, ISSUES, AND APPLICABLE LAW

While the contraception mandate has been challenged by an array of business entities,¹³ this article focuses only on the questions presented by

10. See generally *Sebelius v. Hobby Lobby Stores, Inc.*, 134 S.Ct. 678 (2013); *Conestoga Wood Specialties Corp. v. Sebelius*, 134 S.Ct. 678 (2013). Another case, *Autocam Corp. v. Sebelius* is pending petition. *Autocam Corp. v. Sebelius*, SCOTUSBLOG, <http://www.scotusblog.com/case-files/cases/autocam-corp-v-sebelius/> (last visited March 30, 2014).

11. See, e.g., *Conestoga*, *supra* note 6, at 381 (“As we conclude that for profit, secular corporations cannot engage in religious exercise, we will affirm the order of the District Court.”); *Hobby Lobby*, *supra* note 5, at 1126.

12. See, e.g., *Conestoga*, *supra* note 6, at 385 (referring to religious exercise as an “inherently ‘human’ right.”).

13. See, e.g., *Little Sisters*, *supra* note 2 (nonprofit religious corporation); *Legatus v. Sebelius*, 901 F.Supp.2d 980 (E.D.Mich. 2012) (nonprofit religious trade group); *Univ. of Notre Dame v. Sebelius*, 2014 WL 687134 (N.D.Ind. 2013) (nonprofit religious university); *Monaghan v. Sebelius*, 931 F.Supp.2d 794 (E.D. Mich. 2013) (secular for profit corporation). Courts have distinguished the religious rights of for profit versus nonprofit corpora-

secular, for-profit, closely held corporations.¹⁴ These corporations pose a peculiar question; certain religious and non-profit organizations, as opposed to secular for-profit ones, have been either excluded from some implications of the PPACA, or deemed protected by RFRA and the Free Exercise Clause guarantees.¹⁵ Sole proprietorships and partnerships enjoy religious protections coextensive with that of their owners,¹⁶ whereas corporations are distinct legal persons from their owners and managers.¹⁷ Also, courts often distinguish closely held corporations from those that are publicly traded.¹⁸

Businesses have challenged the contraception mandate under RFRA and the Free Exercise Clause, both of which are of similar and substantial import.¹⁹ Because the two authorities are so similar, they can be substantially collapsed into a single analysis.²⁰ The test under both authorities is that the

tions. *See, e.g., Hosanna-Tabor Evangelical Lutheran Church & Sch. v. EEOC*, 132 S. Ct. 694, 706 (2012). “[T]he text of the First Amendment . . . gives special solicitude to the rights of religious organizations.” *Id.* Nonetheless, as this article attempts to make clear, applicability of RFRA and the Free Exercise Clause of the First Amendment to natural persons (i.e. individuals) may render distinctions between certain entities useless for determining whether business entities can refrain from certain activities such as providing contraceptive coverage. *Id.*

14. 26 C.F.R. §1.170A-13 (2014); I.R.C. §542(a)(2). A closely held corporation is any corporation other than an S Corporation which, “[a]t any time during the last half of the taxable year[,] more than 50 percent in value of its outstanding stock is owned, directly or indirectly, by or for not more than 5 individuals.” *Id.*

15. Coverage of Certain Preventative Services Under the Affordable Care Act, *supra* note 2; *Hosanna-Tabor Evangelical Lutheran Church & Sch. v. EEOC*, *supra* note 13.

16. *See, e.g., Transcript of Oral Argument Sebelius v. Hobby Lobby, Inc.*, No. 13-354, 15 (argued March 25, 2014) (“the government concedes that sole proprietorships and partnerships and nonprofit corporations are all protected by RFRA”) [Hereinafter Transcript of Oral Argument].

17. WILLIAM MEADE FLETCHER ET AL., FLETCHER CYCLOPEDIA OF THE L. OF CORP. § 25 (“It is generally accepted that a corporation is an entity distinct from its shareholders . . . directors and officers . . .”) [hereinafter FLETCHER].

18. *See, e.g., Transcript of Oral Argument*, *supra* note 16, at 52 (“Whether it applies in the other situations is . . . a question that we’ll have to await another case when a large publicly-traded corporation comes in and says, we have religious principles . . .”).

19. *Hobby Lobby* *supra*, note 5, at 1133 (“Undoubtedly, Congress’s understanding of the First Amendment informed its drafting of RFRA . . .”); RFRA, *supra* note 3 (“The purposes of this chapter are (1) to restore the compelling interest test . . . and to guarantee its application in all cases where free exercise of religion is substantially burdened . . .”).

20. *See, e.g., Conestoga*, *supra* note 6, at 388 (“Our conclusion that a for profit, secular corporation cannot assert a claim under the Free Exercise Clause necessitates the conclusion

government may place a substantial burden on the exercise of religion only if the burden is the least restrictive means of furthering a compelling government interest.²¹ The underlying question of applicability concerns whether the law was intended to protect the religious beliefs of corporations.²²

The Third Circuit Court in *Conestoga* considered the case of Conestoga Wood Specialties Corporation, a for-profit, secular, closely held corporation owned entirely by the Hahns family.²³ The court distinguished the rights of for profit versus non-profit corporations, and focused on the distinct entity doctrine of corporate law.²⁴ Finding that for-profit, secular corporations are incapable of exercising religion, the court held that the corporation lacked standing.²⁵ Similarly, the court found that the individual owners could not bring a claim on behalf of the corporation.²⁶ Using this reasoning, the court

that a for profit, secular corporation cannot engage in the exercise of religion.”); Hobby Lobby, *supra* note 5, at 1133 (Noting, “Congress, through RFRA, intended to bring the Free Exercise jurisprudence back to the test established before *Smith*,” the court collapsed the Free Exercise analysis into the RFRA analysis.).

21. See RFRA *supra*, note 3. While the plain language of the statute invokes the language reserved for the highest constitutional standard – namely, the “least restrictive means of furthering a compelling governmental interest” – this standard was hotly contested in oral argument before the Supreme Court. *Id.*; See, e.g., Transcript of Oral Argument, *supra* note 16, at 13-14.

22. See, e.g., *Conestoga supra* note 6, at 381 (“Before we can even reach the merits . . . we must consider a threshold issue: whether a for profit, secular corporation is able to engage in religious exercise under the Free Exercise Clause of the First Amendment and the RFRA.”). This is the central question defining the current circuit split. Compare Hobby Lobby, *supra* note 5, at 1128 (finding that the corporations are “persons exercising religion” under RFRA), with *Conestoga, supra* note 6, at 388 (denying claim based on lack of standing since “for profit, secular corporation[s] cannot engage in the exercise of religion.”).

23. *Conestoga, supra* note 6, at 381, 388.

24. *Id.* at 386, 388. “That churches – as means by which individuals practice religion – have long enjoyed the protections of the Free Exercise Clause is not determinative of the question of whether for profit, secular corporations should be granted these same protections.” *Id.* at 386. “Since *Conestoga* is distinct from the Hahns, the [contraception m]andate does not actually require *the Hahns* to do anything. All responsibility for complying with the [contraception m]andate falls on *Conestoga*.” *Id.* at 388 (emphasis in original). The doctrine of distinct corporate entity recognizes the corporation as a distinct legal entity from the corporation’s shareholders, officers, and directors for many purposes. FLETCHER, *supra* note 17.

25. *Id.* at 388.

26. *Id.* at 389.

denied Conestoga the requested preliminary injunction.²⁷ The court's analysis, then, presented a paradigm whereby the corporation is the only entity impacted by the contraception mandate, yet lacks the standing to object to the mandate because the entity cannot exercise religious beliefs.²⁸ Meanwhile, the individual owners are capable of exercising religious beliefs, but lack standing to object to the contraception mandate since the mandate does not directly impact them.²⁹

The contrasting opinion of the Tenth Circuit in *Hobby Lobby* involves two corporate entities, Hobby Lobby and Mardel, both of which are closely held, for-profit corporations owned and managed by the Green family.³⁰ The Tenth Circuit Court, *en banc*, found that because the Dictionary Act³¹ generally includes corporations within the meaning of the term 'persons,' and because RFRA does not specifically exclude corporations from the law's application, corporations are persons protected under RFRA.³² Based on this reasoning, the court found that Hobby Lobby should be granted a preliminary injunction from the PPACA to protect its religious freedom.³³

27. *Id.*

28. *Id.* at 388-89.

29. *Id.* at 389 ("The [contraception m]andate does not impose any requirements on the Hahns. Rather, compliance is placed squarely on Conestoga.").

30. *Hobby Lobby*, *supra* note 5, at 1122. "The Greens operate Hobby Lobby and Mardel through a management trust (of which each Green is a trustee) . . ." *Id.*

31. 1 U.S.C. 1.

32. *Hobby Lobby*, *supra* note 5, at 1129, 1137. Notably, the court distinguished the applicability of statutes which specifically exclude for profit corporations from RFRA, such as the Americans with Disabilities Act and the National Labor Relations Act. *Id.* at 1129-30. The court found this precedent compelling, given that RFRA omitted such exemption, in contrast to these prior acts of Congress. *Id.* The court also suggested that the for profit versus nonprofit distinction may be arbitrary in this context, noting "[w]e are also troubled . . . by the notion that Free Exercise rights turn on Congress's definition of 'nonprofit.'" *Id.* at 1135. Even nonprofit entities that "exercise religion" do not "pray, worship, or observe sacraments . . ." *Id.* at 1136.

33. *Id.* at 1147. The court, finding that "all preliminary injunction factors tip in favor of Hobby Lobby and Mardel," remanded the case to the district court with instructions to enter a preliminary injunction. *Id.*

III. LIMITATION OF CORPORATE FORM

Applying the RFRA test to the corporation alone, as the Third and Tenth Circuits did, ignores a practical reality; government regulation of corporations can incidentally or directly affect individuals.³⁴ The contraception mandate, in effect, requires the owners and managers of closely held corporate employers to either 1) shop for, select, and enroll the corporation's employees into a qualified health plan, or 2) do nothing and subject their corporation to substantial taxes.³⁵ This effect of the PPACA cannot be ignored, and it must be analyzed under the scrutiny of RFRA and the Free Exercise Clause.

The outcome of *Conestoga* clearly illustrates the principle at issue. The court held that the contraception mandate applies only to corporations, and the Free Exercise guarantees apply only to individuals, such as the Hahns.³⁶ This analysis clearly and entirely separates the Hahns' religious rights from the corporation they own; it likewise separates the Hahns from the corporation's obligation under the mandate.³⁷ If this analysis is accurate, then there is no need for the Hahns' religious rights to apply to the corporation, or for the Hahns to assert their own religious rights.³⁸ Indeed, this analysis neatly

34. *E.g.* 42 U.S.C. § 300gg-13, *supra* note 1. The PPACA contraception mandate requires *employers* (many corporations fall into this category) to provide no-cost sharing coverage of contraceptive services to *employees* (individuals). *Id.* The direct effect, then, of the regulation of corporations here is to provide a benefit to individuals. *See id.*

35. Tax on Conversion of Qualified Plan Assets to Employer, I.R.C. § § 4980D(b)(1), 4980H(c)(1) (2012). Practically speaking, a corporation can only act by or through an individual. FLETCHER, *supra* note 17, at § 30 n. 1 *citing* Meyer Intellectual Properties Ltd. v. Bodum, Inc., 597 F. Supp. 2d 790, 796 (N.D.Ill. 2009) *rev'd*, 690 F.3d 1354 (Fed. Cir. 2012). It is this individual's behavior with which this article is concerned. The Tenth Circuit estimates that the fines faced by Hobby Lobby and Mardel (both owned by a single management trust) would be \$475 million per year for excluding contraceptive coverage from their health plan (13,000 employees at \$100 per employee per day), or \$26 million per year if they dropped health insurance benefits altogether (13,000 employees at \$2,000 per employee per year). Hobby Lobby, *supra* note 5, at 1125 *citing* I.R.C. § § 4980D(b)(1), 4980H(c)(1).

36. *Conestoga*, *supra* note 6, at 388, 389.

37. *Id.* ("For the same reasons that we concluded that the Hahns' claims cannot 'pass through' *Conestoga*, we hold that the Hahns do not have viable claims,").

38. *Contra, e.g.,* Legatus v. Sebelius, *supra* note 13, at 988 (finding that beliefs of the

separates the Hahns from the corporation they own and control.³⁹ This separation seems to reflect the fundamental doctrine that corporations are separate legal entities from their owners.⁴⁰ Indeed, the purpose of the Free Exercise Clause “is to secure religious liberty in the *individual* by prohibiting any invasions thereof by civil authority.”⁴¹

However, a more practical analysis dismantles this clear distinction; the ambitions, values, and volition of a corporation cannot be so neatly separated from those of its owners. The key is that the contraception mandate does not, in practice, only apply to the corporation, for the corporation cannot in fact act on its own behalf.⁴² The mandate depends in a real way on the volition of the individuals who manage a company, such as the Hahns.⁴³ Herein lies the problem, because the Hahns, as individuals, are entitled to the protection of the First Amendment, which “secure[s] religious liberty in the individual by prohibiting *any* invasions thereof by civil authority.”⁴⁴ The Hahns cannot simply isolate the act of managing their corporation from all other acts which are subject to their consciences, as if their consciences do not apply to business decisions.⁴⁵ Considered from the perspective of the Hahns, their options are to either compromise their religious beliefs by authorizing, and perhaps even selecting, contraceptive coverage, or subject

owners of a closely held, for profit corporation can pass through to the corporation, thus giving a “strong case for standing”).

39. Conestoga, *supra* note 6, at 389.

40. FLETCHER, *supra* note 17.

41. Sch. Dist. of Abington Twp., Pa. v. Schempp, 374 U.S. 203, 233 (1963) (emphasis added).

42. FLETCHER, *supra* note 17, at § 30 n. 1 *citing* Meyer Intellectual Properties Ltd. v. Bodum, Inc., 597 F. Supp. 2d 790, 796 (N.D.Ill. 2009) rev’d, 690 F.3d 1354 (Fed. Cir. 2012), (“Corporations can speak, act and have knowledge only through their human agents.”).

43. *Id.*; Conestoga, *supra* note 6, at 390 (Jordan, Circuit Justice dissenting). The Hahns are “hands-on owners” who “manage their business.” *Id.*

44. Sch. Dist. of Abington Twp., 233.

45. Conestoga, *supra* note 6, at 390 (Jordan, Circuit Justice dissenting) (“[W]here people try to live lives of integrity and purpose, that kind of division sounds as hollow as it truly is).

their business to substantial taxes implicated by the PPACA.⁴⁶ The substantial burden is apparent. While the corporation remains a distinct entity from the Hahns for many purposes,⁴⁷ such clear distinction does not carry into every aspect of relationship between the Hahns and their corporation.⁴⁸ The outcome of *Conestoga*, then, places the Hahns in a situation that substantially burdens their religious beliefs.⁴⁹

Hobby Lobby likewise jeopardizes the rights of the owners of Hobby Lobby and Mardel by oversimplifying the issue to only determine that Hobby Lobby and Mardel are persons capable of exercising religion.⁵⁰ This analysis similarly ignores the intermingling of the corporation and its owners and managers.⁵¹ The rights of individual owners and managers *qua* owners and managers are overshadowed by, and made contingent on, the rights of the corporation.⁵² While the outcome of *Hobby Lobby* enables the owners and managers to exercise their religious rights, it does so only incidentally, leaving this fundamental right dependent on the definition of corporations.⁵³

46. See Tax on Conversion of Qualified Plan Assets to Employer, *supra* note 35.

47. See generally FLETCHER, *supra* note 17, at §§ 29 – 40 (discussing the “distinctness of the corporate entity”).

48. Tax Treatment of S Corporations and Their Shareholders, I.R.C. §§ 1361, 1366 (2006). Conestoga is organized under Subchapter S of the Internal Revenue Code. Petitioner’s Reply Brief at 7, *Conestoga Wood Specialties Corp. v. Sebelius*, No. 13-356 (U.S. filed March 12, 2014). S Corporations and their owners are treated as one entity for tax liability. I.R.C. § 1366.

49. *Contra* Conestoga, *supra* note 6, at 389-90 (in concluding that the Hahns lacked standing, the court never considered the merits of the Hahns’ claim).

50. Hobby Lobby, *supra* note 5, at 1128.

51. *Id.* By concluding that the corporations are persons capable of exercising religion, the court never addresses the issue of whether the Greens’ religious rights would be protected if the corporations do not have religious rights. *Id.*

52. *Id.*

53. *Id.*

IV. AN EQUITABLE SOLUTION

Although corporations are generally distinct legal persons from their owners and managers, the corporate entity doctrine has limitations.⁵⁴ Corporate theory only makes sense inasmuch as it is useful and equitable.⁵⁵ In certain applications, equity requires the corporate personality to be disregarded or “pierced.”⁵⁶ The threshold issue that permits such disregard must be determined. There must be a middle ground between the positions adopted by the Third and Tenth Circuit courts that better conforms to reality and equity. The court in *Conestoga* rejected a Ninth Circuit precedent that beliefs of family owners of closely held corporations extend to the corporation, and that such corporations therefore have standing to assert the free exercise rights of their owners.⁵⁷ The dissent criticizes the opinion for tying religious sentiment to tax status.⁵⁸ Perhaps the threshold depends on the percentage of shareholders or officers who share a particular belief, or on the percentage of business that is religious in nature.⁵⁹ It seems clear that extension of the corporate form that results in *de facto* inequity – such as is demonstrated in Tenth Circuit’s reasoning in *Conestoga* – goes beyond the limits of corporate reality. Nonetheless, the Third Circuit opinion that corporations are capable of religious beliefs poses obvious epistemological problems.⁶⁰

54. George F. Canfield, *The Scope and Limits of Corporate Entity Theory*, 17 COL. L. REV. No. 2 128, 129 (1917) (“[The corporate entity] is not an arbitrary assumption without regard to fact, and does not involve a false deduction or conclusion.”).

55. FLETCHER, *supra* note 17. “The legal fiction of separate corporate entity was designed to serve convenience and justice. When it is invoked to subvert justice, it is ignored by the courts.” *Id.*

56. FLETCHER, *supra* note 17, at §41.20.

57. *Conestoga*, *supra* note 6, at 387.

58. *Conestoga*, *supra* note 6, at 390 (Jordan, Circuit Justice dissenting) (“The government takes us down a rabbit hole where religious rights are determined by the tax code, with nonprofit corporations able to express religious sentiments while for profit corporations and their owners are told that business is business and faith is irrelevant.”); *see also* Jonathon Tan, *supra* note 3, at 1357 (“The profit motive does not sufficiently distinguish a for profit corporation from a nonprofit corporation for RFRA purposes . . .”).

59. Transcript of Oral Argument, *supra* note 16, at 18-19 (Justice Sotomayor cynically suggests that a corporation’s beliefs may be dependent on these seemingly arbitrary thresholds).

60. *Hobby Lobby*, *supra* note 5, at 1128. It seems that only rational beings have the ca-

Perhaps the threshold to be considered for RFRA and Free Exercise Clause claims should be whether a controlling majority of voting shareholders would pose religious objection to a particular statute affecting a corporation.⁶¹ Because statutes affecting corporations can affect the individuals that control the corporations, a threshold that corresponds to ownership interest reflects the practical relations between the owners and the corporation while respecting the religious rights of individual owners.⁶²

Further, this threshold clarifies the culpability problem; if a controlling majority does not object to a statutory requirement, then the minority nonetheless has the opportunity to express their concern. Here, the minority does not act in furtherance of what they deem to be immoral. The minority would not thereby be complicit with immoral activity, because it is the majority who act towards the end, which is deemed immoral.⁶³ On the other hand, if the controlling majority objects, on religious grounds, to a statute that controls corporations, then the Religious Freedom Guarantees ought to apply.⁶⁴ Such objection can be trumped, just as those of individuals, if the statute in question is determined to be the least restrictive means of furthering a compelling government interest, or if a court determines that the individual religious beliefs are not sincerely held.⁶⁵

Such equitable limitations to the corporate form are nothing new; the

capacity to form beliefs. *See Id.* Because corporations are legal fictions and not rational beings, they therefore lack the capacity to engage in or form beliefs in the proper sense of the word. *See id.*

61. *See* FLETCHER, *supra* note 17, at §2020 (discussing differing voting requirements).

62. *See supra* Section III.

63. *Cf.*, Ill. Bus. Corp. Act of 1983, 805 ILCS 5/8.65(b). This principle is analogous to statutory clauses that exculpate directors who affirmatively dissent to improper director actions.

64. RFRA, *supra* note 3. In such instance, RFRA would apply to the individual shareholders holding the majority interest.

65. *Id.*; *see* United States v. Quaintance, 608 F.3d 717, 721 (10th Cir. 2010) (finding claim that defendant belongs to the church of marijuana was a factual matter); *Sourbeer v. Robinson*, 791 F.2d 1094, 1102 (3d Cir. 1986) (upholding lower court's finding of insincerity based on defendant's sparse attendance at religious services).

corporate shield of liability can be pierced to avoid fraud or injustice.⁶⁶ Procedurally, associational standing permits corporations to assert the rights of its owners under certain circumstances.⁶⁷ This procedural mechanism achieves the same outcome as does the proposed threshold, by combining the interest of the two parties into one.

V. CONCLUSION

In the pursuit of better health care, ethics cannot be forgotten. The PPACA has jeopardized the moral integrity of many business owners by requiring employers to provide contraceptive coverage for their employees.⁶⁸ The practical implication of this requirement causes individuals to act in furtherance of an end they deem to be immoral.⁶⁹ The Courts' interpretations make the religious freedom of these business owners contingent on whether corporations are protected by RFRA and the Free Exercise Clause of the First Amendment.⁷⁰ Focusing on ownership interest, rather than on application of these religious protections to corporations, both reflects the interrelations of individuals and corporations, and respects the religious rights of individual owners. Such an application of the religious freedom guarantees would in fact secure religious freedom for individual business owners in a way that respects the distinct entity of the corporation.

66. FLETCHER, *supra* note 17, at §41.20.

67. Warth v. Seldin, 422 U.S. 490, 511 (1975). Indeed, some courts considering corporations' rights under RFRA for purposes of the contraception mandate found association standing. Legatus, *supra* note 13, at 988; Tyndale House Publishers v. Sebelius, 904 F. Supp. 2d, 106, 116-17 (D.D.C. 2012); Geneva Coll. V. Sebelius, Op. No. 2:12-cv-00207, 2013 WL 838238, at *20 (W.D. Pa. Mar. 6, 2013)

68. See PPACA, *supra* note 1; see *supra* text accompanying note 2.

69. See *supra* section IV.

70. See *supra* section IV.

Stem Cell Therapy: The Athlete's Illegal
Destination

Greg Lamorena*

I. INTRODUCTION

What do Peyton Manning, Bartolo Colon, and Rick Perry all have in common?¹ They are medical tourists.² Medical tourism is when people travel outside their country for medical treatment.³ Stem cell therapy is not offered in the United States, so Americans must travel abroad in order to get the treatment.⁴ This article will focus on autologous stem cell transplants that allow individuals, such as athletes, to use their own stem cells to grow bigger and stronger muscles that improve the recovery time.⁵ This type of therapy is becoming an ethical concern because some view it as a perfor-

*Juris Doctor Candidate. Loyola University Chicago School of Law. Class of 2015. Mr. Lamorena is a staff member of *Annals of Health Law*.

1. Peyton Manning is a quarterback in the NFL. Bartolo Colon is a professional baseball player. Rick Perry is the governor of Texas.

2. Stacy Pyre, *Peyton Manning & Bartolo Colon: Stem Cell Therapy in Sports*, STEM CELL THERAPY REV. J., stemcelltherapyreviewjournal.com/peyton-manning-bartolo-colon-stem-cell-therapyinsports/ (last accessed Mar. 31 2014); Marilyn Marchione, *Doctors Question Perry's Stem Cell Back Treatment*, ASSOC. PRESS, (Aug. 19, 2011 10:21 AM), <http://news.yahoo.com/doctors-perrys-stem-cell-back-treatment-072921392.html>.

3. C. Virginia Lee and Victor Balaban, *Medical Tourism*, CTRS. FOR DISEASE CONTROL AND PREVENTION, <http://wwwnc.cdc.gov/travel/yellowbook/2014/chapter-2-the-pre-travel-consultation/medical-tourism> (last accessed May 6, 2014). In the United States, the term generally refers to people traveling to less-developed countries for medical care.

4. Rebecca Taylor, *Why do Peyton Manning, Americans Leave U.S. for Stem Cell Treatment?*, LIFE NEWS, Sept. 21, 2011, <http://www.lifenews.com/2011/09/21/why-do-peyton-manning-americans-leave-u-s-for-stem-cell-treatment/>. Rebecca Taylor is a clinical laboratory specialist in molecular biology. *Id.* Taylor has a B.S. in Biochemistry from the University of San Francisco with a national certification in clinical Molecular Biology MB. *Id.*

5. Helen Zachary, *Stem Cells, Sports Ethics, & Cheating Super-Athletes?*, HEALTH CARE ZONE (Mar. 05 2013), <http://healthcarenewsblog.com/stem-cells-sports-ethics-cheating-super-athletes/>.

mance enhancer,⁶ while others consider it a valid type of therapy.⁷

This article argues that there is no difference because stem cell therapy should be considered a form of genetic doping.⁸ Professional sports leagues should treat athletes who partake in medical tourism for stem cell therapy like those who use any other illegal performance enhancer.

Part II of this article discusses background information about stem cells and the procedures that athletes receive. Part III discusses the current laws regarding this type of therapy. Part IV examines the ethical issues of using stem cell therapy. Part V concludes that athletes should be punished for going abroad and receiving this treatment.

II. STEM CELL THERAPY

Stem cells are a type of cell that have the capability of creating new cells for an indefinite period of time.⁹ Stem cell therapy is used to regenerate or re-grow tissue in a person's body to its original state.¹⁰ Prior to stem cell therapy the only way doctors were able to treat torn cartilage in the knee required that doctors would have to cut tissue out arthroscopically, or temporary numb the area with cortisone injections.¹¹ However, stem cell therapy avoids major surgery and reduces the recovery time.¹² Stem cell harvesting

6. See Mark S. Frankel and Cristina J. Kapustij, *Enhancing Humans*, THE HASTINGS CTR., <http://www.thehastingscenter.org/Publications/BriefingBook/Detail.aspx?id=2162> (last accessed May 6, 2014). The President's council on Bioethics defines human enhancement as going "beyond therapy" rather than returning an individual to a normal state. *Id.* From this definition, a performance enhancer can be defined as artificially enabling a person to exceed a normal state. *See id.*

7. Pyre, *supra* note 2.

8. See Frankel and Kapustij, *supra* note 6. Gene doping is defined as the use of genetic interventions in a nontherapeutic manner. *Id.*

9. Kathleen Doody, *Comment: The Moral, Ethical, and Legal Controversy Surrounding Pluripotent Stem Cell Research*, 48 LOY. L. REV. 267, 270 (2002).

10. *Id.*

11. Taylor Bloom, *New Stem Cell Therapy Procedure Could Have a Major Impact on Sports Injuries*, SPORTTECHIE (Nov. 21, 2013), <http://www.sporttechie.com/2013/11/21/new-stem-cell-therapy-procedure-could-have-a-major-impact-on-sports-injuries/>. Dr. Rajagopalan is an orthopedic surgeon who specialized in sports and fitness procedures. He describes the

12. *Id.* The avoidance of surgery and long recovery times is valuable to athletes because it saves them time and money. *Id.*

is a type of stem cell therapy that many athletes undergo.¹³ In this therapy stem cells are harvested from the bone marrow.¹⁴ Next, the bone marrow is put in a centrifuge, which separates the mesenchymal stem cells from the platelets and blood.¹⁵ Finally, the stem cells are injected into the damaged joint tissue.¹⁶

Mesenchymal stem cells have can turn into cartilage, ligament, tendon, bone, nerve tissue, blood vessels, or muscle tissue.¹⁷ The cells find the damaged area, attach to the DNA, and read the code that tells them what to reproduce.¹⁸

III. CURRENT LAW AND REGULATIONS

Athletes must go abroad for this procedure because the United States lags behind the world in stem cell research and technology.¹⁹ In 2005, Congress passed the Stem Cell Therapeutic and Research Act.²⁰ However, President George W. Bush restricted the funding of stem cell research.²¹ Five years later, Congress passed the Stem Cell Therapeutic and Research Reauthorization Act.²² This act again created funding for stem cell research.²³ The delay in funding limited the amount of research.²⁴ Four years later, the research conducted in the United States is still in the early stages of devel-

13. *Id.* Many athletes choose to get this procedure because it is relatively quick and painless. *Id.*

14. *Id.*

15. *Id.*

16. *Id.*

17. *Id.*

18. *Id.* The human body's genetic code is preprogrammed. *Id.* Thus, when the stem cells attach they determine what is missing, and turn into that tissue. *Id.*

19. *Id.* The lack of funding made it difficult for the United States to keep up with other countries. *Id.*

20. *See* Stem Cell Therapeutic and Research Act of 2005, Pub. L. No. 109-29, § 119 Stat. 2550 (2005). This act created funding for stem cell research. *Id.*

21. *See* Bloom, *supra* note 11.

22. *See* Stem Cell Therapeutic and Research Reauthorization Act of 2010, Pub. L. No. 111-264, 124 Stat. 2789. President Obama granted funding in December 2010. *Id.* The act grants \$23,000,000 a year from 2011-2014 and \$20,000,000 for 2015. *Id.*

23. *Id.*

24. *See* Taylor, *supra* note 4.

opment.²⁵

The United States Food and Drug Administration (FDA) has not approved any treatment of orthopedic injuries using stem cells.²⁶ The FDA categorized stem cell transplant as it would a pharmaceutical drug, and stem cells transplants must go through the same phases of clinical trials that a new drug would before receiving approval.²⁷ Public Health Safety Act, Section 351, governs the use of stem cells, regulates the use of biologic products, and requires that they follow the new drug application to the FDA before being released to the public.²⁸ This type of stem cell therapy is not legal in the United States.²⁹ Thus, professional athletes become medical tourists.³⁰

The World Anti-Doping Agency prohibits stem cell injections.³¹ The International Olympic Committee also bans this type of therapy.³² However, professional sports leagues, including the National Football League (NFL), National Basketball Association (NBA), and Major League Baseball (MLB), do not ban stem cell therapy.³³ The discrepancy between United States and professional sports rules on stem cell therapy creates a grey area

25. See Nat'l Pub. Radio, *Can Stem Cell Treatments Help Athletes?*, HOSP. FOR SPECIAL SURGERY (June 17, 2011), <http://www.npr.org/2011/06/17/137250823/can-stem-cell-treatments-help-athletes>. Scott Rodeo is an orthopedic surgeon and co-chief of sports medicine and shoulder service at Hospital for Special Surgery. *Id.* This source is from a transcript from a radio interview. *Id.*

26. Pyre, *supra* note 2.

27. See Dina Gould Halme and David A. Kessler, *FDA Regulation of Stem Cell Based Therapies*, 355 N ENGL J MED, 1730, 1735 (2006).

28. *Id.*

29. See Eric Adelson, *Undetectable Stem Cell Treatment Could be the Wave of the Performance-Enhancement Future*, YAHOO SPORTS, (Aug. 24, 2012), <http://sports.yahoo.com/news/undetectable-stem-cell-treatment-could-be-the-wave-of-the-performance-enhancement-future.html>.

30. *Id.*

31. *Gene Doping Test for Athletes in the Works*, CBC NEWS (June 6, 2013), <http://www.cbc.ca/news/health/gene-doping-test-for-athletes-in-the-works-1.1410525>

32. *Id.*

33. See David Epstein, *Stem Cell Procedure Nothing New*, SPORTS ILLUSTRATED (May 12, 2011), http://sportsillustrated.cnn.com/2011/writers/david_epstein/05/12/colon.stem.cells/. Bartolo Colon and Grady Sizemore are professional baseball players that used stem cell therapy and were not reprimanded. *Id.* Professional football player Darren Sharper was not punished by the league for undergoing stem cell therapy. *Id.* Jason Kidd and Tracy McGrady are a few of the professional basketball players who received stem cell therapy. *Id.*

as to which law applies.³⁴ Therefore, to remove this grey area, professional sports leagues need to follow suit with the international sporting committees and properly classify this procedure as illegal.³⁵

IV. ETHICS

There are two main reasons that stem cell therapy should be banned in professional sports in the United States. First, the therapy can negatively affect an athlete's health.³⁶ Second, the use of stem cell therapy in this manner is a performance enhancer, and thus it is cheating.³⁷

A. Effects on Health

The stem cell therapy that many athletes receive is a relatively new treatment.³⁸ Although it has been tested on animals, there is little data with humans.³⁹ The FDA and the International Society for Stem Cell Research warn that no rigorous studies demonstrate that the treatments are safe and effective.⁴⁰ As stated above, the United States only researched stem cell therapy extensively for four years.⁴¹ This lack of experience raises serious concerns because in the United States' scientists are not yet able to suggest if the treatment is safe or effective.⁴²

34. See Andy Miah, *Rethinking Enhancement in Sport*, 1093 N.Y. ACAD. SCI. 201, 320 (2006). It is unclear whether professional athletes violate the law or regulations of their sports when they travel abroad to receive stem cell therapy. *Id.* Similar to steroids in baseball, the United States intervened to govern the issue. *Id.*

35. *Id.*

36. Deborah Franklin, *A Dangerous Game: Some Athletes Risk Untested Stem Cell Treatments*, SCI. AM. (Jan. 15, 2013), <http://www.scientificamerican.com/article/a-dangerous-game-athletes-risk-unttested-stem-cell-treatments/>.

37. See Frankel and Kapstij, *supra* note 6. Stem cell therapy should be considered a form of gene doping. *Id.*

38. Nat'l Pub. Radio, *supra* note 25. It is relatively new based off of research conducted in the United States. *Id.*

39. Franklin, *supra* note 36.

40. *Id.*

41. See Stem Cell Therapeutic and Research Reauthorization Act of 2010, Pub. L. No. 111-264, 124 Stat. 2789.

42. See James Fell, *Stem Cells May Aid in Sports Injuries*, CHICAGO TRIBUNE, (May 1, 2013), http://articles.chicagotribune.com/2013-05-01/health/sc-health-0501-fitness-stem-cells-20130501_1_stem-cells-sports-injuries-injections.

Even though the potential risks of stem cell therapy are unknown, some athletes are willing to undergo this treatment, which will allow them to slow down the effects of time.⁴³ For example, Bartolo Colon, a pitcher in Major League Baseball, won the Cy Young Award 2005.⁴⁴ He then suffered a string of injuries and in 2009 he was almost out of baseball.⁴⁵ Instead of retiring, Colon underwent this stem cell therapy, and in 2010, the thirty-seven year old was playing for the New York Yankees.⁴⁶ In 2013, and at the age of forty, Colon had one of his best seasons of his career.⁴⁷ Peyton Manning credits his return to the game to the stem cell therapy he received in Germany.⁴⁸ There is a lot of anecdotal evidence, such as Colon's story, but the fact whether this is safe, effective, and ethical procedure is still unknown.⁴⁹ The potential health effects that Colon and other athletes may suffer in the future is a mystery.⁵⁰

Stem cell therapy is not proven by scientists to work or to even be safe.⁵¹ Athletes willing to risk their own health to play a game is serious issue.⁵² They have always sought ways to enhance their performance.⁵³ One survey conducted in the 1980s asked elite athletes whether they would take an enhancement, which guaranteed them gold medals, but would eventually kill them within five years.⁵⁴ Surprisingly, the results revealed that more than

43. Frankel and Kapustij, *supra* note 6.

44. Franklin, *supra* note 36. The Cy Young award is an annual award given to the best pitcher in baseball in their respective league. *Id.*

45. Franklin, *supra* note 36.

46. *Id.*

47. Record was 18-6, with a 2.65 ERA.

48. Fell, *supra* note 42.

49. *Id.* David Hart, a professor of microbiology at the University of Calgary notes that there is a lot of anecdotal evidence, but very few controlled studies. *Id.*

50. *Id.*

51. *Id.*

52. See Kate Kelland, *Genetically Modified Olympians: Could Future Athletes Cheat Without Being Detected?*, REUTERS (Aug. 7, 2012), http://www.huffingtonpost.com/2012/08/07/genetically-modified-athletes-olympians_n_1751952.html.

53. See Frankel and Kapustij, *supra* note 6. Ancient Olympians ate mushrooms to improve their performance. *Id.*

54. Kelland, *supra* note 52. The study was conducted by Bob Goldman, a doctor and

half of the participants answered in the affirmative.⁵⁵ This survey was conducted every two years for the next decade, and the results were always the same: about half of the athletes were ready to die for gold.⁵⁶ The miracle stories of the athletes bolster the hype behind the treatment, while overshadowing the ethics behind the therapy.⁵⁷ Many athletes would do anything for success in their sport.⁵⁸ Professional sports leagues enact rules that safeguard players' safety and regulate the sport.⁵⁹ Therefore, these organizations must intervene and ban this therapy to protect players' health and guard the integrity of the respective sport.

Professional sports organizations reform the rules to increase player safety.⁶⁰ For example, the NFL implemented new rules about helmet-to-helmet contact to reduce concussions and other serious injuries.⁶¹ The new rules not only look out for the players' current health status, but they seek to protect them later in life.⁶² Likewise, stem cell therapy may be dangerous to athletes later down the road, so rules should be implemented now to protect athletes from potentially serious ailments caused by the therapy.⁶³ Until evidence is produced that shows the safety of stem cell therapy, professional sports should ban this type of therapy.

founder of the U.S. National Academy of Sports. *Id.*

55. *Id.*

56. *Id.*

57. See Franklin, *supra* note 36. Many people will see the success and undergo the surgery even with unknown risks. Also, the hype from the surgery may encourage people to follow suit. *Id.* This could be alarming if a teen wants to follow in their favorite athletes footsteps. *Id.*

58. See Kelland, *supra* note 52. Bob Goldman's study showed that athletes would be willing to die to be successful. *Id.*

59. See Mark Maske, *NFL Pushes Forward In Rule Changes Designed to Reduce Brain Injuries, Make Game Safer*, WASHINGTON POST (Mar. 24 2013), http://www.washingtonpost.com/sports/redskins/nfl-pushes-forward-in-rule-changes-designed-to-reduce-brain-injuries-make-game-safer/2013/03/24/8de37782-9309-11e2-8e33-9cc6c739d012_story.html.

60. *Id.*

61. *Id.* The NFL banned helmet-to-helmet contact which occurs when a player tackles another and the first point of contact is the players' helmets. *Id.*

62. *Id.*

63. Franklin, *supra* note 36.

B. Stem Cell Therapy is a Performance Enhancer

In addition, stem cell therapy could be used to unfairly enhance a player's performance.⁶⁴ Many athletes have used medical advances, such as pharmaceuticals, to gain an edge in competition.⁶⁵ Thus, athletes may be tempted to use stem cell therapy to accomplish the same result.⁶⁶ Stem cell therapy also raises the issue of fairness in sports.⁶⁷ Injuries are part of the game and threaten professional athletes' careers.⁶⁸ However, athletes can use stem cell therapy as a means to reverse or slow down the effects of time.⁶⁹ An athlete that uses stem cell therapy will recover much faster than normal.⁷⁰ This unfair advantage is what separates the use of stem cell therapy from medical use to performance.⁷¹ For instance, an individual who suffers from muscular dystrophy may use this procedure to increase their muscle-building hormones to improve his/her quality of life.⁷² Athletes without a muscle disorder could use the same procedure to increase their muscle mass and improve their performance. Similar to steroids or other performance enhancers, athletes can abuse stem cell therapy.⁷³

Furthermore, athletes who are relatively healthy individuals could use and potentially abuse stem cell therapy.⁷⁴ Allowing stem cell therapy can

64. See Frankel and Kapustij, *supra* note 6.

65. Garry R. Gaffney & Robin Parisotto, *Gene Doping: A Review of Performance-Enhancing Genetics*, 54 PEDIATRIC CLINICS OF N. AM. 807, 820 (2007).

66. *Id.*

67. See Zachary, *supra* note 5.

68. See Epstein, *supra* note 33. The athletes mentioned in the article used stem cell therapy to overcome injuries. *Id.*

69. See Frankel and Kapustij, *supra* note 6. The purpose of stem cell therapy is not to prolong an athlete's career. *Id.*

70. See Zachary, *supra* note 5. As people age, it takes longer for their body to recover. *Id.* Older athletes can use stem cell therapy to aid in recovery and make them still competitive. *Id.*

71. See Frankel and Kapustij, *supra* note 6. Athletes are relatively healthy and do not need stem cell therapy to survive. *Id.*

72. *Id.*

73. *Id.* Steroids are banned because they allow an athlete to augment their natural abilities with a performance enhancing drug. *Id.*

74. *Id.*

lead to a slippery slope of abuse.⁷⁵ Stem cell therapy can provide athletes with the capability of grow bigger and stronger muscles.⁷⁶ However, there is no regulation or laws guiding this in professional sports in the United States.⁷⁷ In other words, there is nothing stopping these athletes from receiving stem cell therapy.⁷⁸ They will essentially become genetically modified athletes.⁷⁹ Athletes that choose to do this therapy will have a significant competitive advantage from players who abstain from it.⁸⁰ Therefore, professional sports leagues should ban this therapy now to prevent this unfair advantage along with other unforeseen consequences.

V. CONCLUSION

There was a time when prescribed steroids were permissible for the rehabilitation of injuries.⁸¹ Now, their use is prohibited by all major sports because they were abused and their effects became well known.⁸² Likewise, stem cell therapy should be banned because it is a form of cheating and its health effects are unknown.⁸³ Professional sports leagues should implement the same penalties that punish those who are guilty of cheating or caught using performance enhancers. Regardless of its legality in other countries, professional sports leagues should ban its players from going overseas to receive it.

Athletes who get stem cell therapy overseas receive an unfair advantage, while putting their health at risk.⁸⁴ In order to protect the integrity of the

75. See Adelson, *supra* note 29. It is difficult to draw the line between restoration and enhancement or between healing and doping. *Id.*

76. Zachary, *supra* note 5.

77. See Epstein, *supra* note 33.

78. See Epstein, *supra* note 33.

79. Kelland, *supra* note 52.

80. See Frankel and Kapustij, *supra* note 6. As mentioned throughout the article, stem cell therapy can shorten recovery time, and allow athletes to become faster and stronger. *Id.*

81. See Gaffney, *supra* note 66.

82. *Id.* The use of these drugs posed significant health risks. *Id.*

83. *Id.*

84. Franklin, *supra* note 36.

sport and the health of players, professional sports leagues in the United States should ban this therapy. A few extra years of playing a sport is not worth taking a gamble on an athlete's life.