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OVER THE COUNTER PLAN B AND DECISIONAL AUTONOMY FOR ADOLESCENTS

Jared Pickell

INTRODUCTION

College students at Shippensburg University can get Plan B emergency contraception from a vending machine for \$25.¹ New York City public schools distributed free Plan B to 567 high school students, without parental consent, during the 2011-2012 school year.² About one out of five pharmacies illegally denies emergency contraception to seventeen-year-old girls.³ An Indiana United States Senate candidate recently said he opposed abortion and emergency contraception “even when life begins in that horrible situation of rape, that it is something God intended to happen.”⁴ Wheaton College, an evangelical Christian liberal arts school in Illinois, requested an injunction against Obamacare’s emergency contraception insurance coverage, only to find out that the school itself had been inadvertently covering Plan B long before Obamacare went into effect.⁵

¹ Associated Press, *Morning-After Pills in Vending Machine*, POLITICO, Feb. 7, 2012, <http://www.politico.com/news/stories/0212/72592.html>.

² Ahemona Hartocollis, *More Access to Contraceptives in City Schools*, N.Y. TIMES, Sep. 23, 2012, <http://www.nytimes.com/2012/09/24/nyregion/resistance-low-to-school-contraceptives-effort-new-york-health-officials-say.html>. This was part of a pilot program for increasing the use and availability of contraceptives for high risk students who may not have easy access to healthcare regarding these matters. While parental consent is not necessary, the program does have a parental “opt out” feature. Only 1-2 % of parents chose to opt out.

³ Maia Szalavitz, *Plan B: 1 in 5 Pharmacists May Deny Eligible Teens Access to Emergency Contraception*, TIME, Mar. 26, 2012, <http://healthland.time.com/2012/03/26/plan-b-1-in-5-pharmacists-may-deny-eligible-teens-access-to-emergency-contraception/>.

⁴ Louise Radnofsky, *Indiana GOP Candidate Sparks New Fight Over Abortion*, WALL ST. J., Oct. 24, 2012, <http://online.wsj.com/article/SB10001424052970203937004578077122446378616.html> (the candidate is Richard Mourdock).

⁵ Laura Bassett, *Wheaton College “Inadvertently” Covered Emergency Contraception Before Birth Control Mandate*, HUFFINGTON POST, Aug. 2, 2012, http://www.huffingtonpost.com/2012/08/02/wheaton-college-birth-control_n_1734919.html.

The heavily politicized stories above help frame the debate over whether emergency contraception, namely, Plan B,⁶ should be available over the counter (OTC) to young women under the age of seventeen. This debate seems to be largely political, and it incites strong, sometimes visceral, reactions. There is no shortage of literature scolding the FDA and the Department of Health and Human Services⁷ and their officers for allowing political, and perhaps religious, inclinations to “win the day” in place of scientific and medical research. Scholars have also written extensively on First Amendment privacy issues and procreation decisions as a fundamental right, and how the legacy of *Griswold*,⁸ *Roe*,⁹ and *Casey*¹⁰ “obviously” mandates that all women should have access to OTC emergency contraception. The political bickering and the circularity of constitutional jurisprudence concerning Plan B and similar procreation issues obfuscates the importance of decisional autonomy for individuals, their medical care, and their bodily integrity.

This article checks the messy politics and the nebulous constitutional debates at the door and focuses on the decisional capacity of adolescent women to decide for themselves whether to use OTC Plan B. From the principle of individual autonomy, especially when it comes to making medical decisions, this article’s central thesis is that most adolescent women possess the cognitive and decision-making skills necessary to decide whether to use contraception, specifically, Plan B, free from red tape. This piece will use various law review articles, articles from medical, sociological, and psychological journals, as well as caselaw and examples by way

⁶ Plan B is “a backup plan that helps prevent pregnancy after unprotected sex or birth control failure.” PLAN B ONE-STEP, “What Plan B One-Step Is,” *available at* <http://www.planbonestep.com/what-is-plan-b.aspx>.

⁷ *See infra*, Part I.

⁸ *Griswold v. Connecticut*, 381 U.S. 479 (1966) (holding that the Constitution contains a right to privacy, and that the Connecticut law banning contraceptives violated this right and was therefore unconstitutional).

⁹ *Roe v. Wade*, 410 U.S. 113 (1973) (holding that the right to privacy found in the Due Process Clause of the Fourteenth Amendment extended to a woman’s decision to have an abortion, balanced by the state’s interest in both protecting the fetus and protecting the woman’s health).

¹⁰ *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992) (affirmed a woman’s right to have an abortion).

of comparison. From these sources, this piece argues that Plan B, approved for OTC use by seventeen-year-old women, should also be approved for OTC use by all adolescent women of reproductive age who possess the cognitive ability to make the autonomous decision to take Plan B.

Part I will provide background to the development of the OTC status of Plan B, its efficacy as a method of contraception, and the consensus of the medical community as to its safety, while emphasizing Plan B as a method of contraception and not an abortifacient.¹¹ Part II will set up the article's general framework and approach—the value of individual autonomy in making medical decisions—and highlight literature exploring adolescents' cognitive and emotional ability to make medical decisions, and other important decisions, generally. Part III will apply the framework of Part II to the debate over OTC Plan B for adolescent women.

Part IV will offer a solution to the debate regarding OTC Plan B for adolescent women—these women should decide whether to take Plan B for themselves because their decision-making faculties and the literature on Plan B's safety dictate that their decisional autonomy should be respected above all other considerations. It will highlight similar age-based regulations and restrictions (or lack thereof), and examine their justifications, offering a pause point for comparison with the OTC Plan B issue. These comparative examples include various types of tobacco regulation, and laws presuming that minors lack the capacity to make contracts. Part IV will also use its conclusions regarding the Plan B debate to offer broader instruction—in our policy-making and legislation we must defer more to the medical community and to the decisional autonomy of the individual to make medical decisions. And for medication and treatment approved for OTC use, this decisional autonomy should always extend to adolescents.

¹¹ Plan B “should not affect or terminate an existing pregnancy.” PLAN B ONE-STEP, “What Plan B One-Step Is,” available at <http://www.planbonestep.com/what-is-plan-b.aspx>.

I. HISTORY OF THE DEVELOPMENT OF PLAN B AND ITS OTC STATUS

In 1999, the Food and Drug Administration (FDA) approved the use of the synthetic hormone levonorgestrel¹² as a prescription-only emergency contraceptive that would be sold as Plan B.¹³ Plan B originally consisted of two tablets—the first pill should be ingested within seventy-two hours of unprotected sex, and the second pill twelve hours later.¹⁴ If taken properly, Plan B can prevent approximately 89 percent of unwanted pregnancies.¹⁵ It is important to remember that Plan B is not an abortion pill;¹⁶ Plan B works to prevent fertilization,¹⁷ or if fertilization does occur, to prevent implantation.¹⁸ When taken as directed, Plan B is safe¹⁹ and its “side effects are generally mild,” with some women experiencing “side effects similar to many birth control pills.”²⁰ These side effects include heavier or lighter periods, nausea, lower abdominal pain, fatigue, headaches, dizziness, and breast tenderness.²¹

Soon after, the lack of practicality of getting a prescription filled for a treatment that is only viable for less than seventy-two hours after unprotected sex became apparent.²² The fact that unprotected sex can often be a traumatic experience complicates the matter further.²³ Due to the exigency of taking Plan B within seventy-two hours after unprotected sex, and the difficulties

¹² Levonorgestrel is “a synthetic progestogen (any progesterone) that is used as a form of contraception in women.” ENCYCLOPEDIA BRITANNICA, “Levonorgestrel,” *available at* <http://www.britannica.com/EBchecked/topic/338040/levonorgestrel>.

¹³ Barbara Chevalier, *The Constitutionality of the FDA’s Age-Based Plan B Regulations: Why the FDA Made the Wrong Decision*, 22 WIS. WOMEN’S L.J. 235, 238 (2007).

¹⁴ *Id.* at 239.

¹⁵ Sydney Kokjohn, *The Imposition of an Age Restriction on Over-the-Counter Access to Plan B Emergency Contraception: Violating Constitutional Rights to Privacy and Exceeding Statutory Authority*, 9 MINN. J.L. SCI. & TECH. 369, 372 (2008).

¹⁶ There is an abortion pill, mifepristone, commonly known as RU-486. It has been available by prescription in the United States, but it is different from Plan B. Chevalier, *supra note* 13, at 240.

¹⁷ Fertilization is the union of sperm and egg.

¹⁸ Implantation is when the fertilized egg, or embryo, attaches to the uterus.

¹⁹ The FDA’s Center for Drug Evaluation and Research (CDER) ensures that drugs, before their approval for the market, “work correctly and that their health benefits outweigh their known risks.” FDA, “Development & Approval Process (Drugs),” *available at* <http://www.fda.gov/drugs/developmentapprovalprocess/default.htm>.

²⁰ PLAN B ONE-STEP, “FAQs,” *available at* <http://www.planbonestep.com/plan-b-faq.aspx>.

²¹ *Id.*

²² Kokjohn, *supra note* 15, at 374.

²³ *Id.*

of getting a prescription filled under those circumstances, Plan B's manufacturer filed an OTC petition with the FDA in 2003.²⁴ This type of petition is known as an "over-the-counter switch" and is the method through which the FDA allows drugs to be sold without a prescription.²⁵ Plan B's manufacturer revised its petition in 2004 after the FDA told it that there was not enough data to prove that adolescents fifteen and younger could use Plan B safely without a doctor's oversight.²⁶ This revised petition requested that only women age sixteen and older have access to OTC Plan B.²⁷ After numerous delays by the FDA,²⁸ and serious political involvement,²⁹ on August 23, 2006 the FDA approved OTC use of Plan B, but only for women over the age of eighteen.³⁰ To enforce the ban on the sale of OTC Plan B for adolescents under eighteen, the FDA required that only pharmacies or other facilities with a healthcare professional sell Plan B.³¹ The FDA also required that Plan B be kept behind the counter, and that women seeking to purchase it present proof of age.³²

In 2009, the FDA approved the sale of Plan B One-Step,³³ a one-pill version of the emergency contraception, to seventeen-year-olds without a prescription.³⁴ But this was only

²⁴ Rob Stein, *Obama Administration Refuses to Relax Plan B Restrictions*, WASH. POST, Dec. 7, 2011, http://www.washingtonpost.com/national/health-science/obama-administration-refuses-to-relax-plan-b-restrictions/2011/12/07/gIQAF5HicO_story.html.

²⁵ 21 C.F.R. § 310.200(b). Before an OTC switch takes place, the drug must meet certain FDA criteria. These include: (1) an acceptable safety profile based on prescription use and experience; (2) a low potential for abuse; (3) an appropriate safety and therapeutic index; (4) a positive benefit-to-risk assessment; and (5) it is needed for a condition that is self-recognizable, self-limiting, and requires minimal intervention by a healthcare practitioner for treatment. *Id.*

²⁶ Kokjohn, *supra* note 15, at 375.

²⁷ *Id.* at 376.

²⁸ For example, the FDA missed its statutory deadline for ruling on the application. *Id.*

²⁹ For example, then Senator Hillary Rodham Clinton promised to "prevent the Senate from voting on Lester Crawford's nomination to be the new Commissioner of the FDA until the agency ruled on Plan B's pending application." *Id.*

³⁰ *Id.* at 377.

³¹ *Id.*

³² *Id.*

³³ The FDA approved the safety and use of Plan B One-Step on July 13, 2009. See Drug Information Online, *FDA Approves Plan B One-Step*, July 13, 2009, available at <http://www.drugs.com/newdrugs/fda-approves-plan-b-one-step-new-one-pill-emergency-contraceptive-1486.html>.

after a federal judge ruled³⁵ on the issue, holding that “the agency’s 2006 decision to limit availability of the controversial contraception to women 18 and older was invalid and politically motivated.”³⁶ While this paper is not concerned with the political and religious undertones of the debate over OTC Plan B, these considerations cannot be ignored because they drove the next stage in the history of OTC Plan B. This stage saw results that seemed to disregard scientific evidence and to trump politics over considered advice from the medical community.

The political and implicit religious inclinations regarding whether Plan B should be available OTC to all females came to a head in 2011.³⁷ At this time, the FDA was ready to approve OTC access to Plan B for women and girls of all ages.³⁸ In a lengthy statement, FDA Commissioner Dr. Margaret Hamburg wrote that the agencies’ scientists “determined that the product [Plan B] was safe and effective in adolescent females, that adolescent females understood that the product was not for routine use, and that the product would not protect them against sexually transmitted disease.”³⁹ But flouting the scientific evidence, and with no precedent on the books,⁴⁰ the Department of Health and Human Services secretary, Kathleen Sebelius, publicly overruled the FDA’s decision.⁴¹ Secretary Sebelius based her decision on

³⁴ Rob Stein, *17-Year-Olds Gain Access to Plan B Pill*, WASH. POST, Apr. 23, 2009, <http://www.washingtonpost.com/wp-dyn/content/article/2009/04/22/AR2009042202248.html>.

³⁵ *Tummino v. Torti*, 603 F. Supp. 2d 519, 524 (E.D.N.Y. 2009) (“Indeed, the record is clear that the FDA’s course of conduct regarding Plan B departed in significant ways from the agency’s normal procedures regarding similar applications to switch a drug product from prescription to non-prescription use, referred to as a ‘switch application’ or an ‘over-the-counter switch.’”).

³⁶ Stein, *supra* note 34.

³⁷ See, e.g., Editorial, *Politics and the Morning-After Pill*, N.Y. TIMES, Dec. 7, 2011, <http://www.nytimes.com/2011/12/08/opinion/politics-and-the-morning-after-pill.html?ref=policy&gwh=95631044E0EFEE5D87DD57F1A07DC42C> (This editorial states that “once again, the politics of birth control have trumped science and sound public policy,” while mentioning that “social and religious conservatives have lobbied for years to restrict access to the pill”);

³⁸ Gardiner Harris, *Plan to Widen Availability of Morning-After Pill is Rejected*, N.Y. TIMES, Dec. 7, 2011, http://www.nytimes.com/2011/12/08/health/policy/sebelius-overrules-fda-on-freer-sale-of-emergency-contraceptives.html?_r=0&gwh=EB01D02592AC9885A36D38052B5F33BB.

³⁹ *Id.*

⁴⁰ Though it is legal for the secretary of the Department of Health and Human Services to overrule the FDA.

⁴¹ *Id.*

insufficient data: “the data provided as part of the actual use study and the label comprehension study are not sufficient to support making Plan B One-Step available to all girls 16 and younger, without talking to a health care professional.”⁴²

Interestingly, for purposes of this piece, Secretary Sebelius, in noting that approximately ten percent of girls at age eleven can become pregnant, mentioned that “there are significant cognitive and behavioral differences between older adolescent girls and the youngest girls of reproductive age.”⁴³ Perhaps, then, whether or not to place an “age floor” for OTC Plan B, when taking into account cognitive decisional capacity, is a legitimate scientific question. This piece will now explore scientific sources regarding an adolescent’s cognitive ability to make medical decisions, and the extent to which this cognitive ability should grant such an adolescent the power to make autonomous healthcare decisions.

II. INDIVIDUAL AUTONOMY, MEDICAL DECISIONS, AND ADOLESCENTS’ COGNITIVE ABILITY

Respect for autonomy is “a central value in Western medicine and medical ethics.”⁴⁴ But pinning down an exact definition of this concept, in any context, is difficult. Various distinctions of terminology exist, including moral autonomy,⁴⁵ personal autonomy,⁴⁶ and basic autonomy.⁴⁷ Conceptual and philosophical distinctions abound, and are, as expected, extremely complex and subject to scholarly debate. This piece, however, focuses on a distinct version of autonomy: autonomy in the bioethical sense, utilized in making personal healthcare decisions. And it is this

⁴² Department of Health & Human Services, *Statement by Kathleen Sebelius*, Dec. 7, 2011, available at <http://www.hhs.gov/news/press/2011pres/12/20111207a.html>.

⁴³ *Id.*

⁴⁴ Jukka Varelius, *The Value of Autonomy in Medical Ethics*, 9 MED. HEALTH CARE PHILOS. 3, 3 (2006).

⁴⁵ Moral autonomy, in the Kantian sense, is “the capacity to impose the (objective) moral law on oneself, and . . . is claimed as a fundamental organizing principle of all morality.” Stanford Encyclopedia of Philosophy, “Autonomy in Moral and Political Philosophy,” available at <http://plato.stanford.edu/entries/autonomy-moral/#AutRelationalAut>.

⁴⁶ Personal autonomy “celebrates creative self-authorship and encourages the development of those virtues (such as integrity and authenticity) that support it.” Robert S. Taylor, *Kantian Personal Autonomy*, 33 POL. THEORY 5, 602 (2005).

⁴⁷ Basic autonomy is “the minimal status of being responsible, independent and able to speak for oneself.” Stanford Encyclopedia of Philosophy, “Autonomy in Moral and Political Philosophy,” available at <http://plato.stanford.edu/entries/autonomy-moral/#AutRelationalAut>.

sense of autonomy through which this piece analyzes the degree to which adolescents should be responsible for their healthcare decisions, specifically, whether to use Plan B.

Decisional autonomy in the healthcare realm—a complex and even philosophical issue—“is predicated on decision-making capacity.”⁴⁸ In bioethical discourse, autonomy is the principle out of which grew the doctrine of informed consent, which, generally, is the process “by which a fully informed patient can participate in choices about her health care.”⁴⁹ People should have a say in decisions about their medical care, and as rational actors, must be properly informed by their physicians to make such decisions.⁵⁰ From a philosophical perspective, we justify the principle of decisional autonomy in medical decisions—and define decision-making capacity—using different subsets of perhaps elusive variables. For example, one scholar has said such variables include “an ability to understand information, to deliberate about it, and to communicate a choice with clarity.”⁵¹

Bioethics scholars trying to provide clarity to the doctrine of informed consent have borrowed language from the law’s attempt to define “consent.”⁵² This includes an individual’s ability to give “voluntary, knowing, and intelligent” consent.⁵³ While perhaps never definitive, legal and bioethical scholars have tried to pin down definitions of these modifiers. For example, one bioethics scholar has defined “voluntary” as a patient’s ability “to provide consent that is not

⁴⁸ Rhonda Gay Hartman, *Adolescent Decisional Autonomy for Medical Care: Physician Perceptions and Practices*, 8 U. Chi. L. Sch. Roundtable 87, 87 (2001).

⁴⁹ Univ. Washington School of Medicine, “Ethics in Medicine: Informed Consent,” *available at* <http://depts.washington.edu/bioethx/topics/consent.html>.

⁵⁰ *Id.*

⁵¹ Hartman, *supra note* 48, at 87.

⁵² See Thomas Grisso & Linda Vierling, *Minors’ Consent to Treatment: a Developmental Perspective*, 9 PROF. PSYCHOL. 3 (1978).

⁵³ See, e.g., *Brady v. United States*, 397 U.S. 742, 748 (1970) (“Waivers of constitutional rights not only must be voluntary, but must be knowing, intelligent acts done with sufficient awareness of the relevant circumstances and likely consequences”).

merely an acquiescent or deferent response to authority.”⁵⁴ She defined “knowing” as “the match between the information given to the patient and the patient’s own paraphrase of that information,” and “intelligent” as “the competence of the patient to arrive at the consent decision rationally, not upon others’ opinions concerning the advisability of the patient’s decision itself.”⁵⁵ Informed consent, then, “is a primary means of respecting the autonomy of patients because one cannot act autonomously when denied access to information that is pertinent to the decision at hand.”⁵⁶

The law incorporates bioethical ideas of autonomy, informed consent, and decisional capacity in its decree that adults,⁵⁷ but not adolescents,⁵⁸ are presumed capable of making their own healthcare decisions.⁵⁹ Thus, the law presumes that adolescents are not capable of making their own medical decisions. This presumption is subject to numerous exceptions, including medical care for emergencies, treatment of sexually transmitted diseases, drug or alcohol dependency, mental health treatment, and abortion.⁶⁰ These exceptions are grounded in both practical and ethical concerns.⁶¹ The practical concerns include the public health goals of preventing the spread of disease, preventing drug abuse, and allowing access to stigmatized treatments for which adolescents might fear telling their parents.⁶² The ethical concerns highlight the value and benefit that autonomous decision-making brings to individuals.⁶³

Anomalously, the law presumes that adolescents do not possess the cognitive and emotional

⁵⁴ Kimberly M. Mutcherson, *Whose Body is it Anyway? An Updated Model of Healthcare Decision-Making Rights for Adolescents*, 14 CORNELL J.L. & PUB. POL’Y 251, 284–85 (2005).

⁵⁵ *Id.*

⁵⁶ *Id.* at 294.

⁵⁷ Those individuals eighteen years of age—the age of majority—and older.

⁵⁸ Generally those ranging from age fourteen to seventeen.

⁵⁹ Hartman, *supra* note 48, at 88.

⁶⁰ *Id.* at 90.

⁶¹ See Mutcherson, *supra* note 54, at 270.

⁶² *Id.* at 270–72.

⁶³ *Id.* at 272–78.

maturity to make their own health care decisions—unless the healthcare decisions are for “adult problems.”⁶⁴

The presumption that adolescents are incapable of making healthcare decisions derived from late nineteenth- and early twentieth-century notions of society that have not kept pace with developmental psychology.⁶⁵ In fact, vast quantities of medical research suggest that adolescents are capable of making autonomous healthcare decisions, at the very least beyond the level presently presumed by law.⁶⁶ One study found “little evidence that minors of age fifteen and above as a group are any less competent to provide consent [for medical decisions] than are adults.”⁶⁷ Another study showed that as early as age fourteen, minors are as competent as adults to make autonomous healthcare decisions.⁶⁸ A study on decision-making during pregnancy found that fourteen through seventeen year olds were similar to adults in cognitive ability and volition, and “remain competent decision makers when facing an emotionally challenging real world decision.”⁶⁹ In our society—which puts a high value on autonomy and individual freedoms—if an adolescent possesses the same level of cognitive ability as an adult, then it

⁶⁴ For example, a seventeen-year-old can seek STD treatment without parental consent, but would need parental consent to treat a complication arising from the STD treatment. Even more incongruous are the following examples: “a teenage mother must give consent before her baby may be treated, but, by and large, is not permitted to consent to her own health care. An adolescent boy can be tested and treated for HIV without parental involvement, but his parents must consent to setting his broken leg.” Michelle Oberman, *Minor Rights and Wrongs*, 24 J.L. MED. & ETHICS 127, 127 (1996).

⁶⁵ See Hartman, *supra* note 48, at 90; see also *Bellotti v. Baird*, 443 U.S. 622, 638 (1979) (“Deeply rooted in our Nation’s history and tradition, is the belief that the parental role implies a substantial measure of authority over one’s children.”).

⁶⁶ *Id.* at 96.

⁶⁷ Grisso & Vierling, *supra* note 52, at 423.

⁶⁸ Lois A. Weithorn & Susan B. Campbell, *The Competency of Children and Adolescents to Make Informed Treatment Decisions*, 53 *Child Dev.* 1589, 1595 (1982). “The age of 18 or 21 as the ‘cutoffs’ below which individuals are presumed to be incompetent to make determinations about their own welfare do not reflect psychological capacities of most adolescents.” *Id.* at 1595–96.

⁶⁹ Bruce Ambuel & Julian Rappaport, *Developmental Trends in Adolescents’ Psychological and Legal Competence to Consent to Abortion*, 16 *LAW & HUM. BEHAV.* 129, 147 (1992).

logically follows that she “should play a significant role in determining the course of her medical treatment.”⁷⁰

Courts have used two main justifications regarding the presumption that adolescents are incapable of making autonomous medical decisions: “(1) adolescents are not capable of making important life decisions; and (2) courts assume that parents, after being informed by the physicians, will make decisions in the best interests of the child.”⁷¹ The above discussion regarding developmental psychology dispels the first justification.⁷² As for the second justification, while (we hope) most parents will make medical and other decisions in the best interests of their children, for a variety of reasons,⁷³ not all do.⁷⁴ Cases of child abuse aside, “for some parents, despite best intentions and grave concern, their instincts may not always serve the best interests of a child.”⁷⁵ This evidence calls for a reexamination of the assumptions underlying the jurisprudence of adolescents and their capacity as autonomous decision-makers.

Presumptive decisional incapacity for adolescents contravenes social norms and trends in other areas—these include juvenile delinquency and family court, “where adolescents are afforded decisional autonomy and accompanying accountability.”⁷⁶ In family law, the older a child gets, the more say he or she has in matters concerning, for example, custody, visitation rights, and adoption.⁷⁷ Tort law provides no immunity based solely upon the age of an accused tortfeasor; rather, the tort duty is phrased in language like “how a reasonable fourteen year old

⁷⁰ Anthony W. Austin, *Medical Decisions and Children: How Much Voice Should Children Have in their Medical Care?*, 49 ARIZ. L. REV. 143, 149 (2007).

⁷¹ *Id.* at 151–52.

⁷² See text accompanying notes 22–27.

⁷³ For example, some parents might physically and emotionally abuse their children, and then refuse to seek treatment for their children to avoid legal and criminal ramifications.

⁷⁴ See Mutcherson, *supra* note 54, at 282.

⁷⁵ *Id.* For example, a parent might attempt to prevent his child from receiving a life-saving blood transfusion for religious reasons.

⁷⁶ Hartman, *supra* note 48, at 89.

⁷⁷ *Id.*

(or fifteen or sixteen year old, etc.) would act in a given situation.”⁷⁸ These examples show the exception to the rule: as children develop cognitively and gradually attain decisional maturity, they become increasingly able to become more involved in making autonomous decisions and otherwise participating in society in general. But “in choosing the chronological age marker of eighteen, the law denies rights to fourteen to seventeen-year-old adolescents who are generally capable of exercising such rights in a thoughtful fashion.”⁷⁹

Given the increasing cognitive ability and competency of adolescents with each successive year, the purported presumptions do not represent reality with respect to adolescents.⁸⁰ Adolescents approach medical decisions “with a quality of intentionality that is not seen in the decisions made by children,”⁸¹ which suggests that recognizing adolescent autonomous decision-making for healthcare “may improve their response to treatment and encourage the development of self-efficacy.”⁸² While a few states have recognized the “mature minor”⁸³ doctrine, and in the abortion context the Supreme Court allows for “judicial bypass”⁸⁴ of the parents’ wishes, the law does not contain the requisite flexibility to deal with adolescent decision-making.

The proposed autonomy analysis of this piece requires one to “reject the formulation that the adolescent is being protected [and i]nstead . . . view the [traditional] insistence on parental

⁷⁸ Mutcherson, *supra* note 54, at 290.

⁷⁹ *Id.* at 254.

⁸⁰ See Jessie Hill, *Medical Decision Making by and on Behalf of Adolescents: Reconsidering First Principles*, 15 J. HEALTH CARE L. & POL’Y 37, 39 (2012).

⁸¹ David G. Scherer, *The Capacities of Minors to Exercise Voluntariness in Medical Treatment Decisions*, 15 LAW & HUM. BEHAV. 431, 446 (1991).

⁸² *Id.*

⁸³ The “mature minor” doctrine “allows minors who can understand the nature and consequences of the medical treatment being offered the legal power to consent or refuse treatment in situations in which parental consent would be difficult to obtain or would cause family conflict.” Austin, *supra* note 70, at 159.

⁸⁴ See *Baird* 443 U.S., at 643–44 (holding that a minor who wished to avoid parental-consent requirements for abortion must be given the opportunity to bypass the requirement by proving to a judge that either she is mature enough to make the abortion decision on her own, or that abortion would be in her best interests).

consent as a denial of the adolescent's rights as a person, separate from his parents."⁸⁵ For those who believe that it is sacrilege to put autonomous medical decisions in the hands of minors, all autonomous actors, adults and children alike, do not always act rationally, or with compassion, or according to everyone's competing ideals. In the words of one scholar:

it is false to suggest that young people lack autonomy because they may make decisions that appear irrational, cruel, or otherwise deficient. Autonomy need not rest on an assessment of the decision that might have been made by another, but instead is premised upon the *process* by which an actor reaches a decision.⁸⁶

Thus, when the cognitive ability of an adolescent enables her to reach decisions based on a similar process to that of adults, she should be able to make autonomous medical decisions. This does not mean that the adolescent should not have input from her parents or other concerned individuals; dependence and an autonomous existence are not mutually exclusive.⁸⁷ For "in the continuous development of the relative-adult out of the relative-child there is no point before which the child himself has no part in his own shaping, and after which he is the sole responsible maker of his own character and life plan."⁸⁸

Thus, this article puts forth the following framework: once reaching the age of fourteen, the adolescent, based on her maturity and cognitive development, should be allowed to make certain autonomous healthcare decisions. As the adolescent reaches the age of seventeen she should be given more autonomy to make such decisions, again, qualified by her developmental ability to make such decisions. To the extent that the maturity level of an adolescent would preclude her from making a completely autonomous medical decision, the parent should decide, with the adolescent having substantial input. Healthcare providers and courts should take this

⁸⁵ Thomas J. Silber, *Ethical Considerations in Caring for Adolescents*, 10 PEDIATRIC ANNALS 408, 409 (1981).

⁸⁶ Mutcherson, *supra note* 54, at 277.

⁸⁷ *Id.* at 273.

⁸⁸ Joel Feinberg, "Autonomy," THE INNER CITADEL: ESSAYS ON INDIVIDUAL AUTONOMY 27, 34 (John Christman, ed. 1989).

input seriously, in the same vein as the family law context mentioned above. And the law should apply this framework for all medical decisions, including the OTC Plan B controversy.

III. WHY THE INDIVIDUAL AUTONOMY FRAMEWORK SHOULD BE APPLIED TO ADOLESCENTS' DECISIONS REGARDING OTC PLAN B

This article has advocated for the principal of autonomy in medical decision-making.⁸⁹ When feasible, we should put the ball in the patient's court to make her own medical decisions, based on sound medical advice as well as advice from friends and family. This framework faces the least resistance when a fully capable adult makes the healthcare decision—indeed the law presumes that adults over the age of majority have decisional capacity.⁹⁰ But when an adolescent, under the age of eighteen, is faced with the same medical decision, the law and society in general push back.⁹¹ In many cases, the law presumes that adolescents do not possess the cognitive and emotional maturity to make their own health care decisions.⁹² And the societal opposition is especially acute when the medical decision involves reproductive rights⁹³ and reproductive health.⁹⁴ This piece will now argue for the application of the cognitive development framework set out in Part II to OTC Plan B specifically, and then advocate the use of that approach to solve the Plan B debates.

A recent New York City pilot program⁹⁵ that provides high school students with Plan B and other contraceptives without parental consent has received considerable media attention.⁹⁶ Interestingly, the pilot program appears to have received very little resistance from the parents of

⁸⁹ See *supra*, Part II.

⁹⁰ See Hartman, *supra* note 5, at 88.

⁹¹ *Id.*

⁹² See Oberman, *supra* note 63, at 127.

⁹³ For example, the rights to contraception and to abortion.

⁹⁴ See Alicia Munday, *Election Night with Abortion-Rights and Anti-Abortion Groups*, WALL ST. J., Nov. 7, 2012, <http://blogs.wsj.com/washwire/2012/11/07/election-night-with-abortion-rights-and-anti-abortion-groups>.

⁹⁵ See Hartocollis, *supra* note 2. The program was designed to deal with the fact that “in New York City, over 7,000 young women become pregnant by age 17 – 90 percent of which are unplanned.” Its “new approach” was designed to “improve a situation that can have lifelong consequences.” *Id.*

⁹⁶ *Id.*

the adolescents receiving the contraceptives.⁹⁷ In the 2011-2012 school year, 567 young women received Plan B emergency contraception from the program, while only 1-2 percent of parents chose the “opt-out option,” which would prevent their children from receiving any contraceptives through the program.⁹⁸ Given the 180-day school year, that means that an average of 3.15 Plan B regiments were distributed to high school students daily.

Presumably a large number of the adolescents receiving Plan B through the New York City public high school pilot program are under age 17, and thus circumvent the current requirement that girls under 17 get a prescription before they can receive Plan B.⁹⁹ But, as mentioned above, the parents of these adolescents amendable to the program did *not* opt out.¹⁰⁰ Thus, in certain areas of New York City, a vast majority of parents implicitly believe that their adolescent daughters can make the decision whether to use Plan B on their own. Even assuming that New York is more progressive toward reproductive rights generally, and might be a potential outlier from a national perspective, a key distinction to keep in mind is that the parents allowed their children to make their own decision regarding Plan B.¹⁰¹

Perhaps then, in the event that other localities enact programs similar to that in New York, the resistance that some people would feel toward such a program would be based on an aversion toward birth control, Plan B, or abortion generally, and would have nothing to do with questions of decisional autonomy and cognitive development in adolescents.¹⁰² Also, the

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ Even assuming some of the parents had no idea about the program, which is not likely to have been the case in large numbers, the underwhelming 1-2 percent opt-out rate shows a large degree of parental acquiescence to the program.

¹⁰¹ Hartocollis, *supra note 2*.

¹⁰² We would then have a clash between parents, who do not approve of Plan B for their daughters, and the daughters’ individual autonomy in making such a decision. This article takes the position that autonomous decision-making should always trump having decisions made for you. Thus, the parents are free to refrain from using Plan B and other contraceptives themselves, but the parents should not be able to prevent their daughters from accessing

aversion potentially would have nothing to do with scientific research and sound medicine. As mentioned above, the FDA “determined that the product [Plan B] was safe and effective in adolescent females, [and] that adolescent females understood that the product was not for routine use.”¹⁰³ Secretary Sebelius and the Department of Health & Human Services, however, disagreed with the FDA and overruled the FDA’s decision to approve OTC Plan B for all ages.¹⁰⁴ Sebelius based this decision on her finding that there was insufficient data to support OTC Plan B for adolescents under seventeen.¹⁰⁵

The disagreement here between the FDA and the Department of Health & Human Services has been criticized as largely, if not completely, political.¹⁰⁶ Also, the way the disagreement has played out among the citizenry is not only political, but often ignores valid scientific and medical research, and neglects to take into account decisional capacity with a processed-based approach.¹⁰⁷ In the context of medicine, political inclinations should take a

OTC Plan B, assuming the young women possess the cognitive ability to decide for themselves. The spirit of such a conclusion in this piece finds a parallel in this piece’s approach to abortion. Specifically, that approach stands for the idea that one can disapprove of abortion for herself, but cannot force another woman to forego obtaining a legal abortion. In general terms, everyone is free to *not* take advantage of a positive right for herself, and at the same time, no one may force *another* to not take advantage of that positive right. The same is true, albeit conversely, for a “negative right,” like the right not to believe in a certain religion.

¹⁰³ Gardiner Harris, *Plan to Widen Availability of Morning-After Pill is Rejected*, N.Y. TIMES, Dec. 7, 2011, http://www.nytimes.com/2011/12/08/health/policy/sebelius-overrules-fda-on-freer-sale-of-emergency-contraceptives.html?_r=0&gwh=EB01D02592AC9885A36D38052B5F33BB.

¹⁰⁴ Department of Health & Human Services, *Statement by Kathleen Sebelius*, Dec. 7, 2011, *available at* <http://www.hhs.gov/news/press/2011pres/12/20111207a.html>.

¹⁰⁵ *Id.*

¹⁰⁶ See Harris, *supra note* 103 (“The decision ensures that Plan B will continue to be far more important as a political issue than for public health.”); see also Laura Meckler & Jennifer Corbett Doorren, *Obama Backs Plan B Move*, WALL ST. J., Dec. 9, 2011, *available at* <http://online.wsj.com/article/SB10001424052970203413304577086472287736982.html> (“The politics of the decision could have cut two ways for Mr. Obama. Had his administration allowed unrestricted sales of the drug, critics were sure to attack him from the political right. Some social conservatives view the use of the “morning after” drug as akin to abortion, and they were likely to accuse the president of affording young girls the ability to end a pregnancy on their own. But blocking the drug opens him up to criticism from the political left.”).

¹⁰⁷ See Mutcherson, *supra note* 54, at 277 (advocating for an approach for measuring cognitive ability that prioritizes the *process* by which adolescents make decisions, and not confusing the importance of a processed-based approach with a results-based approach whereby decisions are demonized in hindsight).

backseat because medicine, at its core, is not a political question, but a scientific one.¹⁰⁸ Too much political bickering on issues that people hold close to heart not only prevents peaceable solutions, but also potentially stalls novel approaches to resolve such disputes. The vitriol between the two camps¹⁰⁹ regarding the right to an abortion, for example, is still going strong despite the fact that the Supreme Court definitively ruled to give women such a right almost forty years ago.¹¹⁰ Rather than facilitate the implementation of the law, or perhaps more constructively, to figure out ways to help prevent the need for an abortion, many are content to advocate abolishing the right to an abortion.¹¹¹ This is extremely unlikely to happen, in large part because the scientific community has essentially come to a consensus on the safety of regulated abortions.¹¹²

¹⁰⁸ Doctors and scientists should drive the policy on medicine and healthcare treatments. How these treatments and drugs should be paid for, and other health insurance questions, are beyond the scope of this article and have no bearing on this piece's argument regarding decisional autonomy in the healthcare context. The thesis can be understood as follows: once the medical community puts forth valid medical research supporting a certain treatment, here Plan B, an adolescent, assuming she possesses the cognitive ability to appreciate such a decision, should be able to decide whether to utilize that treatment.

¹⁰⁹ Pro-choice, those that support a woman's right to make the abortion decision on her own; and pro-life, those who believe that abortion is always morally wrong and should be illegal, with the possible exception of cases of rape or incest. Recent studies, however, are asking "whether these binary, politicized labels accurately capture Americans' nuanced views on abortion," while pointing out that "support for legal abortion has remained steady even as Americans' identification with the politicized "pro-choice" or "pro-life" labels has fluctuated." Robert B. Jones, *Pro-Choice and Pro-Life? On Abortion, Americans It's Complicated*, WASH. POST, May 29, 2012, available at http://www.washingtonpost.com/blogs/figuring-faith/post/pro-choice-and-pro-life-on-abortion-americans-say-its-complicated/2012/05/29/gJQAjj0qyU_blog.html.

¹¹⁰ See *Roe v. Wade*, 410 U.S. 113 (1973) (holding that the right to privacy found in the Due Process Clause of the Fourteenth Amendment extended to a woman's decision to have an abortion).

¹¹¹ See Jennifer Steinhauer, *Akin Controversy Stirs up Abortion Issues in Campaign*, N. Y. TIMES, Aug. 21, 2012, <http://www.nytimes.com/2012/08/22/us/politics/todd-akin-controversy-may-hurt-republican-chances.html?pagewanted=all> (describing the comments of Missouri Representative Todd Akin, who claimed that victims of something he calls "legitimate rape" have a mechanism in their bodies that somehow prevent pregnancy; this novel idea was used to combat the so-called "rape exception" found in proposed anti-abortion legislation).

¹¹² Indeed the only changes in the constitutional jurisprudence on abortion since *Roe* have revolved around new scientific information coming to light, especially regarding viability of a fetus. See *Casey*, 505 U.S. 833 (affirmed a woman's right to have an abortion, and incorporated new scientific evidence regarding viability in fashioning a new abortion framework).

Although debates continue to rage over reproductive health and reproductive rights, people usually do not take issue with drugs that become available OTC.¹¹³ For example, ibuprofen, originally a prescription-only NSAID,¹¹⁴ was approved by the FDA for OTC use, as Advil, in 1984.¹¹⁵ Today people take Advil to help relieve pain and headaches without much thought.¹¹⁶ People feel the pain, want to alleviate it, know Advil works to do so, and then ingest the Advil if they decide it is a proper course of action given the circumstances—adults and children age 12 and over are directed to take the same dose and are susceptible to the same side effects.¹¹⁷ And people throughout the world have Advil in medicine cabinets.¹¹⁸ It would not be remiss to claim that once medical treatment is deemed safe, then society generally believes that people should be able to decide for themselves whether to use such a treatment.

Most people will concede that one may decide for herself whether to take an Advil, safeguarded by the fact that the FDA approved that drug for OTC use—an approval process that requires a rigorous scientific process.¹¹⁹ Further, but for Secretary Sebelius’s political rejection of the FDA’s recommendation, Plan B would be available to all adolescent women OTC based on sound scientific evidence.¹²⁰ Yet, even though those FDA safeguards are present in the Plan B “OTC switch,” large swaths of American society might cringe at the idea of a minor deciding for herself whether to use Plan B. And it is this “cringing,” and its accompanying backlash, that

¹¹³ In fact, consumers generally benefit from OTC drugs because once drugs are OTC, they foster competition, which drives down prices. Harlan Levine, *Room for Debate: Getting your Prescription without a Prescription - Let Competition Cut Costs*, N. Y. TIMES, Sept. 12, 2012, <http://www.nytimes.com/roomfordebate/2012/09/16/getting-your-prescriptions-without-a-prescription/consumers-benefit-from-over-the-counter-competition>.

¹¹⁴ Non-steroidal anti-inflammatory drug.

¹¹⁵ See Advil, FAQs, available at <http://www.advil.com/faqs>.

¹¹⁶ Although some people object to taking these types of drugs, and any drugs, for religious and other reasons.

¹¹⁷ See Advil, FAQs, available at <http://www.advil.com/faqs> (side effects include ulcers, if the medicine is not taken properly).

¹¹⁸ See The Branding Blog, *The Law of Leadership*, BRANDING STRATEGY INSIDER, Apr. 11, 2009, <http://www.brandingstrategyinsider.com/2009/04/the-law-of-leadership.html> (Advil has 51 percent of global market share for ibuprofen).

¹¹⁹ See FDA, “Development & Approval Process (Drugs),” available at <http://www.fda.gov/drugs/developmentapprovalprocess/default.htm>.

¹²⁰ Harris, *supra* note 38.

call for the application of the decisional autonomy framework from Part II to the OTC Plan B controversy.

Decisional autonomy on personal and sensitive healthcare decisions like abortion and Plan B, which have been sanctioned by medical science, should be *the* fundamental principle grounding any policy discussions thereon. Once a treatment is deemed safe, the person seeking such treatment should be able to decide for herself whether to take advantage of such a treatment, regardless of her age. If a woman's personal values caution her against the use of Plan B, and she elects not to use Plan B in a relevant situation, then decisional autonomy has won the day, and the integrity of that individual remains intact. But when that same woman cannot decide on her own—either because someone forced her to take Plan B or because someone prevented her from taking Plan B—then the woman has lost the ability to control her own life, and perhaps has lost a bit of herself. For these reasons, and for those discussed in Part II and in this part, above, adolescents who possess the cognitive ability to make healthcare decisions should decide for themselves whether to use Plan B. This application of the principle of autonomy in medical decision-making calls for Plan B to be available to all decisionally capable adolescents, regardless of age. The next section of this piece will use the aforementioned framework to put forth a solution to the OTC Plan B debate, and will open up its analysis to include a broader policy discussion.

IV. A SOLUTION TO THE DEBATE REGARDING OTC PLAN B FOR ADOLESCENT WOMEN

This article has argued that Plan B, approved for OTC use by seventeen-year-old women, should also be approved for OTC use by all adolescent women who possess the cognitive ability to make autonomous decisions. In the case of Plan B, the scientific and medical research shows two crucial factors: (1) Plan B is safe; and (2) adolescents younger than seventeen understand

and appreciate the decision-making process to take Plan B.¹²¹ After balancing public health against individual liberty, and because their decision-making faculties and the literature on Plan B's safety dictate that their decisional autonomy should be respected, these adolescents should decide whether to take Plan B for themselves whenever possible.

This Part of the article first focuses on the rights of parents versus the rights of their children to choose to use Plan B. It concludes that, based on the principles of decisional autonomy and cognitive ability, in the case of Plan B, the rights of the adolescent trump those of the parents. Part IV-B then discusses some comparative cases of age-based regulation, including the right to buy and use tobacco products and the contractual doctrine of minority incapacity. This article hopes to use the similarities and differences between these other age-based regulations and the OTC Plan B debate to both bolster its central thesis and to suggest that age-based regulations are oversimplifications of more complex issues. This section will then open up its central thesis to address broader considerations and suggest how the principles of decisional autonomy and cognitive ability can be a better approach than purely age-based regulations in various areas.

A. Dealing with the Purported Rights of Parents

Two long-standing presumptions have influenced the jurisprudence surrounding the balancing of interests between parents and their minor children regarding medical decision-making.¹²² The first presumption is that, unless an exception applies,¹²³ “minors lack the legal authority to consent to medical treatment on their own.”¹²⁴ The second presumption holds that

¹²¹ See *supra*, Part I.

¹²² See Hill, *supra* note 80, at 38 (The thesis of Hill's article is to question these two presumptions and show that after reconsidering them, the law should give more discretion to minors, especially adolescents, in making medical decisions).

¹²³ See Part II, *supra*, text accompanying notes 56-60.

¹²⁴ Hill, *supra* note 80, at 38.

“parents have a legal entitlement to make medical decisions for the minor child.”¹²⁵ The validity of these presumptions are *legally* true, as they undergird much of the positive law in the United States surrounding healthcare decisions for and by minors.¹²⁶ But the medical research mentioned above¹²⁷ shows that, with adolescents, the validity of these presumptions *in practice* is questionable at best. Furthermore, there is a sort of cognitive dissonance with how the rights of the parent versus the rights of the child play out in this area.¹²⁸

The constitutional rights of the parents and those of the adolescent regarding medical decision-making, especially in the reproductive rights context, are in conflict. Parents possess the right to direct the upbringing of their children, free from state interference.¹²⁹ Yet adolescents also possess a constitutional right to bodily integrity.¹³⁰ Professor Anne Dailey eloquently lays out the crux of the dilemma regarding the balance of the rights of the child against those of the parent:

Any allotment of liberty to the parents necessarily diminishes the liberty of the child; conversely, any enhancement of the child’s liberty curtails that of the parents. Unlike the right of individual privacy—which entitles the individual to rights against the state and over herself—parental rights entitle parents to rights against the state, but over another person.¹³¹

In keeping with the principle of autonomy and the framework of respecting adolescents’ cognitive ability to make healthcare decisions, the adolescent’s right to bodily integrity should

¹²⁵ *Id.*

¹²⁶ *Id.* at 39–40.

¹²⁷ See Part II, *supra* (citing numerous studies regarding the cognitive ability of adolescents to make their own medical decisions).

¹²⁸ Hill, *supra* note 80, at 56.

¹²⁹ See *Pierce v. Soc’y of Sisters*, 269 U.S. 510 (1925) (parents have a constitutional right to raise their children without state interference).

¹³⁰ See *Planned Parenthood v. Danforth*, 428 U.S. 52 (1976) (states cannot give a parent an absolute veto over a minor’s decision to have an abortion); see also *Baird*, 443 U.S. at 643 (judicial bypass procedures allowing minor to circumvent parental consent regarding abortion decisions).

¹³¹ Anne C. Dailey, *Constitutional Privacy and the Just Family*, 67 TUL. L. REV. 955, 986–87 (1993) (cited in Hill, *supra* note 80, at 62–63).

outweigh the paternalistic rights of parents whenever feasible. This is feasible whenever adolescents possess the maturity and cognitive ability, from a process-based approach, to make their own medical decisions.¹³² Looking toward the future, our laws, especially those surrounding such personal decisions as whether to take OTC Plan B, should incorporate these policies.

Refusing to provide Plan B OTC to adolescents under the age of seventeen is implicitly letting the parent's interest outweigh that of the adolescent.¹³³ This not only goes against the constitutional arguments for bodily integrity of adolescents—it also ignores recent developments in scientific research regarding an adolescent's cognitive ability to make autonomous healthcare decisions.¹³⁴ We should prioritize the bioethical principle of autonomy as much as possible, especially when dealing with the decision to utilize safe medical treatments like Plan B.¹³⁵ Furthermore, the fact that the FDA approved Plan B for OTC use by seventeen-year-olds shows that the FDA believes Plan B to be safe for that demographic, as well as that people of that age group are able to appropriately decide whether to utilize that treatment.¹³⁶

Yet Plan B is only available OTC for women 17 and older. Besides de-prioritizing the principle of autonomy, this policy also undermines confidentiality in the medical context, another critical element of how people approach healthcare.¹³⁷ Indeed, adolescents are often “reluctant to seek certain types of medical treatment if their parents have access to information

¹³² See Part II, *supra*.

¹³³ It would be quite difficult, if not impossible, for teens aged 14-16 to go to a doctor and get a prescription for Plan B without their parents finding out, and then preventing the acquisition of the Plan B treatment. And this is without regard to the time constraints surrounding the ineffectiveness of Plan B after seventy-two hours.

¹³⁴ See Part II, *supra*.

¹³⁵ See Scherer, *supra* note 81, at 446 (this is especially true when people, including adolescents, possess the cognitive ability to make their own healthcare decisions).

¹³⁶ See Kohkjohn, *supra* note 15, at 375 (generally, an “OTC switch” would not occur but for those conditions being in place; also, the FDA's scientists concluded that Plan B was safe and effective for females of all ages).

¹³⁷ See Melissa Prober, *Please Don't Tell My Parents: The Validity of School Policies Mandating Parental Notification of a Student's Pregnancy*, 71 BROOK. L. REV. 557, 574 (2005) (describing the importance of confidentiality in healthcare, specifically, in building trust between patients and doctors, and between patients and the healthcare system as a whole).

about their medical treatment.”¹³⁸ These types of treatment include abortion, contraception, Plan B, and other treatments of a delicate and deeply personal nature.¹³⁹

Ultimately, the young woman facing the need to use Plan B is in the best position to decide whether to disclose that fact to her parents. If she wants to inform her parents and ask for help, that is her prerogative, and she is free to do so. The problem is that the adolescent under age 17 does not have the power to make such a decision, in practice.¹⁴⁰ Adolescents should not have to fear making otherwise legal decisions because those decisions must be channeled through a parent, who might subject the adolescent to unnecessary contempt, social stigma, or punishment. Plan B is safe and effective, and adolescents possess the cognitive ability to utilize a rational decision-making process regarding Plan B.¹⁴¹ Thus, any argument here that the “parent knows best” fails, and Plan B should be approved OTC for all those adolescents that possess the cognitive ability to choose whether to take Plan B. Comparative examples in other contexts can serve to bolster this analysis and its conclusion.

B. Comparative Cases: Smoking and Contracting

America places high value on individual rights and autonomous decision-making, with the aim of protecting the people from government intrusion.¹⁴² Therefore, any regulation, or “any interference with liberty, is presumptively invalid and must be justified.”¹⁴³ Such justifications, from the purview of ethics, almost always rely on one of two ideas: (1) the harm

¹³⁸ *Id.* at 574–75.

¹³⁹ *Id.*

¹⁴⁰ Again, this is because those 16 and under would need to get a prescription for Plan B before buying it from a pharmacy. It is hard to imagine a scenario where the parent would not either have to be informed about this, or would not find out.

¹⁴¹ See Harris, *supra* note 38 (quoting FDA Commissioner Dr. Hamburg, who reported that FDA scientists found Plan B to be safe and effective in adolescent females, and that they understood that Plan B was not intended for routine use).

¹⁴² Thaddues Mason Pope, *Balancing Public Health against Individual Liberty: The Ethics of Smoking Regulations*, 61 U. PITT. L. REV. 419, 426 (2000).

¹⁴³ *Id.* at 427. Depending on the type of regulation, the Constitution demands various levels of scrutiny of regulation, ranging from rational basis to strict scrutiny, where the regulation must be narrowly tailored to serve a specific government purpose. This constitutional analysis is being the scope of this paper.

principle¹⁴⁴; and (2) some type of paternalism.¹⁴⁵ While both of these theories influence laws pertaining to adolescents, the driving force justifying such laws is paternalism.¹⁴⁶ But the cognitive development framework espoused by this paper questions such an assumption, and would actually assert that the “harm principle” is a better rationalization than paternalism for laws treating adolescents different from adults.¹⁴⁷ Two examples of rules that effect adolescents, and are instructive for the OTC Plan B debates, are the tobacco ban for minors and the presumption that they lack the capacity to enter contracts. This piece will now examine the justifications behind such laws, and suggest that how they shed light on the OTC Plan B issue.

i. Smoking

The laws banning tobacco sales to, and advertising geared toward, minors are almost always justified using a paternalistic framework.¹⁴⁸ The framework is as follows: eye-opening statistics of tobacco-related illness and death are followed by an explanation of the addictive qualities of nicotine; then come statistics that claim the majority of people have their first cigarette under age eighteen, followed by the conclusion that preventing tobacco use among adolescents is critical.¹⁴⁹ Underlying that framework is the belief that people ages sixteen and seventeen are somehow more susceptible to tobacco advertising, as well as more likely to not understand the consequences of smoking, than those who are eighteen or nineteen years old.¹⁵⁰

¹⁴⁴ This idea originated with John Stuart Mill, who wrote “that the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others.” John Stuart Mill, *ON LIBERTY* 63 (Penguin ed., 1974). It has become the “primary philosophical, political, and legal rationale for interfering with individual autonomy.” Pope, *supra* note 142, at 435.

¹⁴⁵ See Pope, *supra* note 142, at 429. “Soft” paternalism justifies intervention where one has assumed risk with information asymmetries, or while lacking maturity (i.e. minors), or where coercion exists. “Hard” paternalism “constrains individuals’ decisions even though those decisions are informed and voluntary.” *Id.* at 430.

¹⁴⁶ *Id.*

¹⁴⁷ See Part II, *supra*.

¹⁴⁸ See Matthew R. Herington, *Tobacco Regulation in the United States: New Opportunities and Challenges*, 23 NO. 1 HEALTH LAW 13, 13 (2010) (laying out the framework of tobacco regulation generally, and of youth-related tobacco regulation).

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

Indeed in the most recent wide-sweeping piece of federal tobacco legislation,¹⁵¹ a primary justification was that “past efforts to restrict advertising and marketing of tobacco products have failed to adequately curb tobacco use *by adolescents*.”¹⁵²

The “harm principle” –based justifications, and all of smoking’s negative externalities, are only strongly put forward when the smoking laws at issue affect “adults”—implicitly, and naïvely, non-adults apparently cannot smoke because they cannot buy tobacco products.¹⁵³ For example, the harm principle is the primary justification for smoking bans in public places such as offices, restaurants, and libraries, with the emphasis on the dangers of “second-hand smoke” and smoking mortality rates.¹⁵⁴ And the negative externalities associated with smoking—added shared costs in the healthcare system, reduced productivity in the workplace—also comport with the utilitarian idea of the harm principle.¹⁵⁵ Yet somehow these “adult” concerns are presented as only tangentially related to the need to prevent adolescents from beginning to smoke.¹⁵⁶

This leaves us in a position where sixteen and seventeen year olds are supposed to be banned from smoking because they do not know any better, and where the rights of knowledgeable eighteen and nineteen year olds to smoke can be curtailed a bit because smoking causes illness and death, and raises social costs. The arbitrary line-drawing in the tobacco context is further baffling when considering that “on average 443,000 people in the United States die prematurely each year from exposure to cigarette smoke.”¹⁵⁷ Illness and death from smoking

¹⁵¹ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 2, 123 STAT. 1776 (2009).

¹⁵² *Id.* (emphasis added).

¹⁵³ Pope *supra note* 142, at 441.

¹⁵⁴ *Id.*

¹⁵⁵ *Id.* at 435.

¹⁵⁶ *Id.*

¹⁵⁷ Herington, *supra note* 148, at 13.

do not discriminate based on age—whether you start smoking at fifteen or at thirty, you become susceptible to all of the negative health consequences associated with tobacco use.¹⁵⁸

Just as in the healthcare decision-making context and in the law generally, there is a presumption that adolescents are incapable of making behavioral decisions regarding smoking.¹⁵⁹ As mentioned above, these presumptions do not comport with current developmental psychology, because adolescents as young as fourteen have the same process-based decisional capacity as adults.¹⁶⁰ With smoking, the balancing of individual autonomy against public health is essentially: someone eighteen and older can choose to smoke, and assumes the risk, but must do so in a private place, so as not to injure non-smokers; but no one under eighteen may smoke, because they do not understand the risk.

With Plan B, we can try to do a similar balancing of individual autonomy against public health, but we have to remove the notion of “risk” because medical research has deemed OTC Plan B safe for females of all ages.¹⁶¹ Plan B also does not pose a threat of injury to others.¹⁶² The only sound reason offered for why those under seventeen should not have OTC access to Plan B that is not overtly political or religious, is an alleged lack of adequate data supporting its safety for that demographic.¹⁶³ Thus, someone seventeen and older can choose to get Plan B OTC; but no one under seventeen may do so, because there is a lack of data, although the FDA disagrees, and claims that the data is sound. But as long as that data, insufficient or otherwise, is out there, and adolescents possess the cognitive ability to make their own healthcare decisions,

¹⁵⁸ *Id.*

¹⁵⁹ See Hartman, *supra* note 48, at 90.

¹⁶⁰ See Weithorn & Campbell, *supra* note 68, at 1595–96 (age 18 as a “cutoff” does not reflect the cognitive and decisional capacities of most adolescents).

¹⁶¹ Harris, *supra* note 38.

¹⁶² This paper will not engage in the philosophical ruminations of when life begins. It does assert, however, that Plan B is *not* an abortifacient. See Chavlier, *supra* note 13, at 240.

¹⁶³ See Statement by Kathleen Sebelius, *supra* note 42; see also Editorial, *Politics and the Morning After Pill*, *supra* note 37 (“once again, the politics of birth control have trumped science and sound public policy”).

which they do, adolescents can use that data to make their own decision regarding OTC Plan B. And the line-drawing between the ages of seventeen and sixteen is purely arbitrary in the Plan B context, just as it is with the presumption that all minors do not possess the capacity to contract.

ii. Contracting

Throughout the history of Anglo-American jurisprudence, all minors have long been regarded as lacking the capacity to contract.¹⁶⁴ One eighteenth-century English judge proclaimed that “miserable must the condition of minors be; excluded from the society and commerce of the world.”¹⁶⁵ The consequence of this bright-line rule is that the contracts of minors are voidable, by the minors only, for a reasonable time after they reach the age of eighteen, subject to some exceptions.¹⁶⁶ These exceptions, codified in state laws, include contracts for items that are life necessities, contracts for insurance, and contracts for student loans, among others.¹⁶⁷ The justification behind the legal assumption of incapacity for minors to contract is that minors “lack the ability to understand and appreciate the consequences of their acts,” and are susceptible to overreaching and undue influence by adults.¹⁶⁸ This doctrine has often been framed in language comparing minors “to those laboring under mental incapacity,” but unlike the truly mentally incapacitated, the veil of incapacity is thrown from an adolescent’s face the moment she turns eighteen.¹⁶⁹ This leads to situations where adolescents are licensed to

¹⁶⁴ Juanda Lowder Daniel, *Virtually Mature: Examining the Policy of Minors’ Incapacity to Contract through Cyberspace*, 43 GONZ. L. REV. 239, 240 (2008).

¹⁶⁵ *Zouch v. Parsons*, (1765) 97 Eng. Rep. 1103, 1106-07 (K.B.).

¹⁶⁶ See Debra D. Burke & Angela J. Grube, *The NCAA Letter of Intent: A Voidable Agreement for Minors?*, 81 MISS. L.J. 265, 271 (2011) (providing an overview of the history of the infancy doctrine and its exceptions).

¹⁶⁷ *Id.* at 272–73.

¹⁶⁸ Daniel, *supra* note 164, at 240.

¹⁶⁹ Rhonda Gay Hartman, *Adolescent Autonomy: Clarifying an Ageless Conundrum*, 51 HASTINGS L.J. 1265, 1302 (2000).

drive by the state, but they cannot purchase a car on their own; and if an adolescent did buy a car, she could void that purchase agreement even after she turned eighteen.¹⁷⁰

The problem is that any attempt to determine whether a *particular* minor, even a seventeen year old, is competent to contract is conspicuously lacking with this longstanding bright-line rule.¹⁷¹ This is true even though recent research in developmental psychology regarding the decision-making ability of adolescents pokes large holes in the minority incapacity doctrine, making it look more and more like historical anachronism.¹⁷² As one scholar put it, “noticeably absent from the scheme governing rights and obligations of minors in the contract arena is a recognition of the developmental transition between childhood and adulthood commonly referred to as adolescence.”¹⁷³ It is in the recognition of this transition where the principle of decisional autonomy for adolescents, bound by their cognitive ability, has the greatest chance to impact these problems in our legal system, by providing a more nuanced solution.

The common law of contracts, as well as the OTC Plan B debates, present a scenario where “the threshold capacity issue is either overlooked entirely, or the pendulum of incapacity capriciously swings to capacity without examination and explication.”¹⁷⁴ Indeed in all areas of the law surrounding adolescence, “incongruity reigns supreme” and the discordant approach is confusing and bordering irrational.¹⁷⁵ Our lawmakers need to realize this and utilize what developmental psychology and other scientific research tell us about adolescents—that their

¹⁷⁰ See Kate Zernike, *Youth Driving Laws Limit Even the Double Date*, N.Y. TIMES, Aug. 13, 2012, <http://www.nytimes.com/2012/08/14/nyregion/teenage-driving-laws-stiffened-in-many-states.html?pagewanted=all>.

¹⁷¹ *Id.* at 249.

¹⁷² See Hartman, *supra note* 48, at 90.

¹⁷³ *Id.* at 241.

¹⁷⁴ Hartman, *supra note* 169, at 1287.

¹⁷⁵ *Id.*

process-based decisional capacity is no different than that of “adults.”¹⁷⁶ Respecting the decisional autonomy of adolescents, who possess the cognitive ability to make decisions whether to enter into certain contracts and to use Plan B, is a real solution. This approach is empirical, rational, nuanced, and subject to modification based on new information—in other words, it is scientific. It ignores political and religious considerations, especially in the case of reproductive rights, which quickly devolve into a quagmire of bickering.¹⁷⁷ And taking a more empirical and scientific approach to our lawmaking generally is also good public policy.

C. Broader Considerations

This piece’s conclusions regarding the Plan B debate can offer broader instruction—in our policy-making and legislation we must defer more to the medical community and to the decisional autonomy of individuals. It is especially important in the context of the laws governing adolescents, which need a complete overhaul because of “the lack of evidentiary foundation to sustain presumptive decisional inability” for adolescents.¹⁷⁸ The law also treats adolescents very inconsistently, and justifies these laws and their various exceptions in different ways, and comes close to incoherence.¹⁷⁹ One scholar has argued: “autonomous decisional ability should be the cornerstone for a coherent legal model governing issues of adolescence.”¹⁸⁰ This piece agrees with this notion, and holds that this legal model is especially crucial for the OTC Plan B issue, and for reproductive rights issues generally.

With complex medical issues that implicate bioethical examination, we should try to use reason, logic, empiricism, and scientific evidence in crafting legislation. Too often, this methodology becomes co-opted by the political process, which itself often devolves into a

¹⁷⁶ *Id.*

¹⁷⁷ See Stein, *supra* note 24.

¹⁷⁸ Hartman, *supra* note 169, at 1268.

¹⁷⁹ See Part II, *supra* notes 57–64 (highlighting the incongruousness of this area of the law).

¹⁸⁰ Hartman, *supra* note 169, at 1270–71.

partisan screaming match. This political pandering frequently incites visceral and emotional responses, especially at the fringes of both sides of the political spectrum. And while we want a robust debate in the “marketplace of ideas,” too often this debate becomes “white noise” and chills any rational and peaceable solution. Thus, the framework that this piece puts forth to solve the OTC Plan B debate, a debate which is heavily politicized and painted with religious and moral strokes, can be applied to other hot button issues subject to rigorous and invective debate. Deferring to decisional autonomy and to the scientific method, when applicable, will allow American society and American legislators to come to the best solutions for the various difficult problems that we face on a daily basis.

CONCLUSION

From the principle of individual autonomy in making medical decisions, this article’s central thesis is that most adolescent women possess the cognitive and decision-making skills necessary to decide whether to use Plan B. This piece has argued that Plan B, approved for OTC use by seventeen-year-old women, should also be approved for OTC use by all adolescent women of reproductive age who possess the cognitive ability to make the autonomous decision to take Plan B. The adolescents should decide for themselves whether to take Plan B because their decision-making faculties and the literature on Plan B’s safety dictate that their decisional autonomy should be respected above all other considerations. In cases involving reproductive rights, and in general, our policy-making and legislation must defer more to the medical community and to the decisional autonomy of the individual to make medical decisions.

The introduction to this piece outlined the political and religious debates surrounding the OTC Plan B for adolescents issue. While reasonable minds can disagree on a final solution to this issue, the fact remains that the two sides are arguing about the rights of a third party that

does not have any say in the matter. It is for precisely this reason that individual autonomy, wherever possible, should take primacy in our policymaking.