2009

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Recommended Citation

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Keywords
Oral contraceptives, The Deficit Reduction Act of 2005, Department of Health and Human Services, Women’s healthcare

This article is available in The Modern American: http://digitalcommons.wcl.american.edu/tma/vol5/iss1/5
Cutting Funds for Oral Contraceptives: Violation of Equal Protection Rights and the Disparate Impact on Women’s Healthcare

By
Rachel V. Rose*

Introduction
Cutting funding for oral contraceptives has far reaching implications for women, including adverse impacts on women’s health, negative economic impacts on society, and constitutional violations. In a country whose governmental health plans (Medicare and Medicaid) reimburse men’s costs for Viagra,1 it is hardly appropriate to deny women access to prescribed oral contraceptives that have traditionally been defined as supplementary services falling under the umbrella of primary care.2 Due to the wording of a provision within the Deficit Reduction Act of 2005, some contend that non-profit clinics and campus health centers can no longer offer oral contraceptives at reduced rates.3 This article will show how decreasing funding for oral contraceptives violates equal protection and embodies a disparate impact in relation to women’s health for Medicaid and Title X beneficiaries—low-income Americans who would benefit from access to contraceptives and other preventative health-care services.

Part I of this article addresses the history, uses, and economics of oral contraceptives. Part II highlights the government’s role and policies in funding oral contraceptives over the past 35 years. Part III discusses the present regulatory landscape, including The Deficit Reduction Act of 2005 (“DRA”), the Department of Health and Human Services (“DHHS”) proposed regulations, Prevention Through Affordable Access Act, and Title X. Finally, Part IV shows how the history, politics, and regulations culminate in a violation of the Constitutional right to equal protection.

I. Oral Contraceptives: History, Uses, Economics

A. History
Oral contraceptives are relatively recent forms of contraception.4 Between 1950 and 1954, Gregory Pincos, a scientist, and John Rock, a renowned Harvard obstetrician and gynecologist, developed a chemical contraceptive and performed the first human clinical trial.5 The “Pill” regime that they established (21 days on progesterone to inhibit ovulation, 7 days to menstruate) is still in use today.6 The “Pill,” called Enovid, was approved by the United States Food and Drug Administration (“FDA”) for the treatment of severe menstrual disorders.7

In the 1960’s, the FDA approved the first oral birth control pill.8 The FDA required Searle pharmaceutical company to complete field trials for all doses of its oral contraceptive, Enovid.9 Ortho Pharmaceutical introduced its first oral contraceptive in 1963. By 1965 the “Pill” became the leading method of pre-conceptual and reversible contraception in the United States.10

During the 1970’s, United States Senator Gaylord Nelson convened Senate hearings on the safety of the “Pill.”11 The FDA ordered that all oral contraceptive packages contain information detailing possible side effects.12 By 1988, the FDA recognized additional potential benefits of oral contraceptives, including decreased incidence of the following: ovarian cancer, endometrial cancer, pelvic inflammatory disease, ovarian cysts, and benign breast disease.13

In the twenty years since the FDA recognized additional potential benefits of oral contraceptives, manufacturers have received FDA approval to use oral contraceptives for the treatment of acne and for the severe condition of premenstrual dysmorphic disorder (“PMDD”).14 Oral contraceptives have been used to treat a variety of conditions and are proven to positively affect many aspects of women’s health, including preserving fertility.

B. Uses and Benefits of Birth Control Pills

Over the past 50 years, the FDA has recognized potential benefits in the area of women’s health, such as decreased incidence of the following: ovarian cancer, endometrial cancer, pelvic inflammatory disease, ovarian cysts, mid-cycle pain (dysmenorea), heavy bleeding and benign breast disease.15 Manufacturers have also received FDA approval to distribute oral contraceptives for the treatment of acne and for PMDD.16 Physicians regularly prescribe oral contraceptives for other debilitating conditions such as polycystic ovarian syndrome (“PCOS”), and endometriosis.17 These conditions, as well as PMDD, may cause irregular menstrual cycles, increased risk of high blood pressure, diabetes, high cholesterol, and infertility. These physical and emotional conditions may be mitigated by taking oral contraceptives, which are proven to preserve fertility.

One of the most threatening conditions to a woman’s fertility is endometriosis, a condition in which deposits of endometrium (uterine lining) are found outside the uterus.18 It is a common disorder, yet it is one of the most enigmatic gynecologic diseases.19 Endometriosis occurs when endometrial tissue outside the uterus responds to changes in hormones,20 breaking down and bleeding like the lining of the uterus does during the menstrual cycle.21 This breakdown of tissue often creates adhesions (scar tissue), which causes tremendous pain and binds surrounding organs together.22 Aside from surgery, the most common way to control symptoms of endometriosis and shrink existing implants is through the use of oral contraceptives.23

As indicated, the uses of oral contraceptives extend far beyond the indication for contraception. Ironically, PMDD, PCOS, and endometriosis have been shown to cause infertility.24 Oral contraceptives, however, have been shown to temper these conditions enabling a woman to retain her reproductive abilities.25
C. The Economics of Birth Control

The present cost of oral contraceptives is high.26 The cost to society, however, of preventing college students and low-income women from purchasing them at a reduced rate is even higher.27 In 2004, researchers estimated a net public savings of $4.3 billion by clinics through averting 1.4 million unintended pregnancies.28 This number does not include the costs of infertility treatments or the cost to treat the escalation of other diseases (Type 2 diabetes and cardiovascular disease) not associated with PMDD, PCOS, and endometriosis.29

Funding from Medicaid programs and Title X of the Public Health Service Act has helped millions of women maintain a healthy reproductive life.30 In fact, almost seventeen million women in the United States utilized these publicly subsidized services in 2002.31 The federal and state governments spent a combined $1.26 billion on reversible contraceptive services.32 Yet, despite these health benefits and substantial savings, the government enacted a provision that has forced pharmaceutical companies to stop providing oral contraceptives at reduced rates.33

At a time when demand for subsidized contraceptives has increased, public funding for family planning clinics has stagnated.34 Exacerbating this situation is the unwillingness of many pharmaceutical companies to continue to provide oral contraceptives to the public system funded by Title X at a relatively low cost.35 This appears to be the result of the 2005 DRA revamping the average manufacturer price (“AMP”) formula and altering the 340B drug-pricing program. The Omnibus Reconciliation Act of 1990 established AMP and Best Price for use in the Medicaid program.36 Thereby, sales by a manufacturer of covered outpatient drugs below ten percent of AMP were generally excluded from Best Price.37 In 1992, the 340B program that was created when the Public Health Services Act (“PHSA”) was amended to require pharmaceutical manufacturers to provide prescription drugs at reduced prices to “covered entities.”38

Calculating pharmaceutical costs for a 340B program is a semi-complex formula based on the AMP that is provided to the Center for Medicare/Medicaid Services (“CMS”).39 AMP is defined as “[t]he average price paid to manufacturers by wholesalers for drugs distributed to the retail pharmacy class of trade.”40 The lowest price available from “the manufacturer to any wholesaler, retailer, provider, health maintenance organization, or nonprofit or government entity, with some exceptions” is considered the Best Price.41 Although Best Price is required to be reduced to account for price adjustments such as rebates and discounts, it does not include prices charged to certain federal purchasers.42 The two factors involved in calculating 340B price are the AMP and a “rebate percentage” (consideration of both the AMP and the Best Price reported to CMS).43 This calculation is the “ceiling price” formula for brand name pharmaceuticals (AMP for the previous month—15.1% discount off the AMP) considered by CMS.44

Beginning in 2007, seemingly small language changes in the DRA impacted the calculation of AMP, Best Price, and limited the number of facilities that qualify for discounted prices on birth control.45 The concerns over that the AMP, which pharmaceutical companies providing covered outpatient drugs are required to calculate and submit to CMS, is not affected by the increase in customary portion of the new formula were directed at how pharmacies would be reimbursed.46 The Office of the Inspector General (“OIG”) and the General Accounting Office (“GAO”) found that this new formula may “result in reimbursements to pharmacies that are below pharmacy acquisition costs.” Specifically, the DRA of 2005 requires manufacturers to report AMP and Best Price to CMS on a monthly basis compared to the previous quarterly basis and imposes several important changes regarding AMP and Best Price calculations.47 However, the act has a provision that extends the “exclusion of customary prompt pay discounts [to wholesalers].”48 This means that the AMP is not affected by the increase in customary prompt pay wholesaler discounts.49 Therefore, the language should have no effect on pharmaceutical manufacturers’ ability to continue providing oral contraceptives to public health and campus health clinics, because the prices these facilities pay are not included in the AMP, Best Price, or ceiling price calculations.

Equally important is the limitation that certain entities will be excluded from the calculation of the AMP and the “rebate percentage” on which pharmaceutical companies base their profits.50 These entities include those defined in section 340B(a)(4) of the Public Health Service Act; intermediate facilities for the mentally retarded; a State-owned or operated nursing facility; and any other entity determined by the Secretary of DHHS to be a safety net provider.51 The Office of Pharmacy Affairs oversees the 340B pricing program and its administration.52 Entities that have been identified as qualifying 340B organizations under the Social Security Act and the Public Health Services Act (“PHSA”) include: federally-qualified health centers; a family planning project receiving a grant or contract under Section 1001 of the PHSA; and any entity receiving assistance under section 318 (42 USC § 247c) (relating to the treatment of sexually transmitted diseases).53

Even if campus health centers do not qualify as 340B organizations, the Secretary of DHHS has the discretion to determine what facilities qualify as safety net providers to which the sales of drugs at nominal prices would be appropriate based upon four factors.54 The factors are: 1) facility or entity type; 2) the nature of the services provided; 3) the patient population served; and 4) the number of other facilities or entities eligible to purchase at nominal prices in the same service area.55 Based upon these criteria, it is reasonable for the Secretary to include campus health centers as qualifying entities.

By interpreting the language to mean a 340B qualifying facility does not include community health and college health centers as an exclusion when calculating the AMP and the “rebate percentage,” and interpreting the language that exempts certain “safety net providers” to exclude family planning clinics; pharmaceutical manufacturers, including Organon, the maker of Cyclessa® and Desogen® oral contraceptives, made an economic decision not to provide drugs at a discounted rate.56 Despite the company being unhappy about increasing the prices for colleges, “Nick Hart, Organon’s executive director of contraception, says they were forced to make ‘a business decision’ after the law went
they needed to preserve their reproductive health. As a result, women who were paying between $3–$10 per month for oral contraceptives are now paying nearly 900% more for the same prescription.58

Sadly, this price increase was unnecessary. The decision of pharmaceutical companies to stop offering low-priced oral contraceptives to health centers and clinics was an independent decision that the DRA of 2005 did not mandate.59 On the contrary, four types of entities, including 340B qualifying facilities and certain safety net providers determined by the Secretary of DHHS, were excluded from the best price determination (meaning that pharmaceuticals offered at reduced rates to these four types of entities would not be included in the price determination).60 Additionally, Congress passed a provision to delay the application of new payment limits for multiple source drugs under Medicaid until September 30, 2009.61 Therefore, the AMP or the “ceiling price” is not impacted by the DRA.62

Pharmaceutical companies’ interpretations of the DRA of 2005 have affected over three million college and low-income women.63 Many hard-working women can no longer access FDA approved methods of birth control, including oral contraceptives.64 The only entities benefiting are manufacturers and savvy entrepreneurs through higher prices and arbitrage opportunities.65 Overall, there is no logical explanation for repealing access to low price oral contraceptives based on the statutory language of the DRA of 2005.

II. GOVERNMENT FUNDING AND POLICIES RELATED TO ORAL CONTRACEPTIVES

It is hard to fathom that President Dwight Eisenhower stated in 1959 that birth control “is not a proper political or government activity or function or responsibility” and emphatically added that it is “not our business.”66 Only five years later, President Lyndon B. Johnson pushed legislation for federal support of birth control for the poor.67 During the Nixon administration, this trend continued.68 Title X of the Public Health Services Act (“Family Planning Services and Population Research Act of 1970”) authorized the Secretary to make grants to public and nonprofit private entities for projects to plan and develop community health centers which will serve medically underserved populations.69

Without publicly funded clinics providing contraceptive services, there would be 1.4 million more unintended pregnancies and 49% more abortions annually in the United States.84 Moreover, for every $1.00 spent to provide services in the nationwide network of publicly funded clinics, $4.02 is saved in Medicaid birth costs.85

Unfortunately, the pharmaceutical companies’ unwillingness to offer oral contraceptives at nominal prices to publicly funded clinics has created a birth control crisis.86 Now, millions of women are paying up to nine or ten times what they were paying before, if they can afford it.87 The companies’ decisions undermine the benefits under Title X and are detrimental individually on women’s reproductive health and collectively on our nation’s economic welfare.88

A. Title X v. DRA

Statutes or provisions relating to the same individual or class of individuals, or to a closely allied subject or object may be regarded under the rule of in pari materia,89 to ascertain and effectuate Congressional intent by proceeding upon the supposition that several statutes were governed by one spirit and policy and were intended to be consistent and harmonious.90 In the present case, Title X and section 6001 of the DRA, both
provisions related to funding, should be read together for the intent of providing funding so all women could have access to reproductive healthcare, family planning, and preconceptional birth control.91

1. **TITLE X: SETTLED POLICY**

Since 1970, the purpose of Title X has been to assist in making voluntary family planning services available to all persons by enabling public and non-profit private entities to plan and develop comprehensive programs. Understanding the need for a high standard for ethical delivery of services, Title X required that clients be offered a broad range of contraceptive methods.92 Today, Title X supports approximately 4,400 out of 7,700 family planning clinics, serving nearly five million women.93 The current guidelines were developed in conjunction with the American College of Obstetricians and Gynecologist (“ACOG”) and require a complete physical exam (including Pap test) and education about the importance of preventive care.94 Title X is indicative of settled policy that women should have access to reproductive healthcare, family planning, and preconceptional birth control.

2. **2005 DRA – EFFECTIVE JANUARY 2007**

An unintended consequence of the DRA, specifically Section 6001, is that health centers no longer receive prescription contraceptives at a nominal or base price. Because there is a provision in the DRA that insulated publicly funded health clinics from paying a higher premium and in turn exempted these prices from the AMP calculations, there is no acceptable explanation for this consequence. The only explanation proffered by the pharmaceutical companies is that they made a “business decision” to no longer follow established legislative precedent. Furthermore, Congress has done nothing since the implementation of the DRA to rectify the situation. The result is that the objective of Title X and Medicaid is being undermined while pharmaceutical manufacturers are realizing higher profit margins.

The provisions in section 6001 of the DRA should be construed to mean that because of the “safe harbor” exempting nominal sales pricing to certain entities from being included in the calculation, Congress intended to preserve the Title X objective, while not adversely impacting the reimbursement of pharmaceuticals through Medicaid. It is imperative that Congress continue to uphold the original legislative intent of providing access to high quality contraceptive services and preventive care to young and low-income citizens.95

**B. DHHS INITIATIVES TO UNDERMINE WOMEN'S REPRODUCTIVE HEALTHCARE FUNDING**

In the summer of 2008, the Bush Administration called on DHHS to draft new rules that would severely restrict women’s healthcare options by defining “abortion” so broadly that it would encompass many types of birth control, including oral contraceptives.96 The DHHS proposal defined abortion as “any of the various procedures—including the prescription, dispensing and administration of any drug or the performance of any procedure or any other action—that results in the termination of the life of a human being in utero between conception and natural birth, whether before or after implantation.”97 This definition defies Congressional intent and the Supreme Court’s interpretation of abortion.98

In addition to posing serious threats to the reproductive health of millions of uninsured and low-income Americans, the language could prevent health facilities from guaranteeing their patients access to the full range of comprehensive reproductive healthcare.99 On July 15, 2008, several Senators signed a letter addressed to the Secretary of DHHS urging reconsideration of the regulations.100 One argument was that the proposed definition would allow common forms of contraception such as the birth control pill to be classified as abortion, thereby denying contraception to women who need it.”101 In a follow-up letter, they emphasized the medical definition of pregnancy,102 specifically that a pregnancy does not begin until a fertilized egg implants itself to the uterine wall,103 and most modern forms of birth control work by blocking implantation.104 Calling a pre-implanted fertilized egg a “human being in utero” is incorrect.105 Ultimately, confusing the definitions of contraception and abortion would wreak havoc on law, regulations, and policy.106

**C. PREVENTION THROUGH AFFORDABLE ACCESS ACT**

The Prevention Through Affordable Access Act was introduced in the House of Representatives107 to clarify any ambiguity in the DRA language and protect student health centers and public or nonprofit private entities providing health services.108 It received bipartisan support and aimed to “rectify an allegedly flawed condition in the DRA, which caused national pharmaceutical companies to stop selling birth control to college clinics [and publicly funded health clinics] at discounted prices.”109 Both the House and the Senate versions of the bill were introduced and referred to Committees nearly a year ago.110 No other action has been taken since the initial introduction.111

**IV. THE 2005 DRA – VIOLATION OF EQUAL PROTECTION**

In December 1961, it was still a crime to use birth control in Connecticut.112 Boldly, C. Lee Buxton, M.D. and Estelle Griswold opened four Planned Parenthood Clinics.113 Their arrest brought national attention to anachronistic state laws, which culminated in a 7–2 ruling by the United State Supreme Court that Connecticut’s law prohibiting the use of birth control was unconstitutional, violating a couple’s right to privacy.114 *Eisenstadt v. Baird* made it clear that a state cannot impede the distribution of birth control to an unmarried person, thus striking down a Massachusetts law.115 Less than a year later, the Supreme Court ruled on one of the most controversial issues of our time—abortion.116 These judicial precedents not only set the tone for the adoption of Title X, but also laid the foundation for recognizing women as a protected class.

**A. EQUAL PROTECTION ANALYSIS**

The fundamental question under consideration is whether there is something in the DRA requiring pharmaceutical companies to no longer offer nominal pricing on oral contraceptives to public, non-profit, and campus health clinics. The Equal Protection Clause of the United States Constitution provides
that no person shall be denied the equal protection of the law.\textsuperscript{117} Fundamentally, equal protection deals with “governmental classifications that deprive a certain class of persons of benefits that persons in other classes are entitled to receive, or that subject a certain class of persons to burdens that are not imposed on persons in other classes.”\textsuperscript{118} By making oral contraceptives unavailable because of the exorbitant cost, women are the class of persons being deprived of benefits of reproductive healthcare and family planning they are entitled to under Medicaid and Title X.\textsuperscript{119} Although men also use the same federally funded centers, they do not carry the burden of paying more for prescriptions under the DRA.

On its face, the DRA does not discriminate because it contains no explicit gender classification language.\textsuperscript{120} However, just because it is facially neutral does not mean it is free from discrimination. The difference is that courts will not merely assume that the DRA is intentionally discriminatory; instead, evidence of discrimination must be found through its administration and purpose or effect.\textsuperscript{121} In \textit{Yick Wo v. Hopkins}, the Supreme Court held that even if a law “be fair on its face and impartial in its appearance, [equal protection will still be violated] if it is applied and administered by public authority with an evil eye and an unequal hand.”\textsuperscript{122} There, equal protection was denied when the discrimination and public administration of the law was found to be illegal.

\textit{Personnel Administrator of Massachusetts v. Feeney} dealt with discriminatory intent in the purpose and effect of a law giving preferential treatment to veterans.\textsuperscript{123} There, the Supreme Court asserted that proof of discriminatory “impact provides ‘an important starting point,’ but purposeful discrimination is the condition that offends the Constitution.”\textsuperscript{124}

The DRA must be considered \textit{in pari materia} with Title X and Medicaid when considering the administration and purpose and effect of the law. The situation of women being denied access to affordable oral contraceptives because of the AMP calculation is akin to the situation in \textit{Yick Wo} and distinguishable from \textit{Feeney}. In fiscal year 2006, the Medicaid program spent $1.3 billion for family planning services, and Title X funds contributed $215 million to approximately 7,683 clinics.\textsuperscript{125} Each year, approximately seven million women received contraceptives.\textsuperscript{126} Of the total number of patients treated, men accounted for only 5% of the overall caseload.\textsuperscript{127} Here, Congressional intent points toward the “evil eye and unequal hand” and “purposeful discrimination” because Congress knew the DRA AMP formula was being applied in a way that denied women access to oral contraceptives to which they were entitled under federal programs.\textsuperscript{128} Congress also knew of executive initiatives to equate oral contraceptives to a surgical abortion.\textsuperscript{129} Therefore, the discrimination against women, public administration, and purpose and effect of the DRA should be violations of equal protection.

For purposes of the DRA, the classifying factor distinguishing between two similarly situated classes is gender, which receives intermediate scrutiny. Men’s access to prescriptions related to reproductive health has not been rendered inaccessible due to cost while women’s prescriptions for oral contraceptives have been affected by the DRA.

\textbf{As a matter of public policy, we, as a nation, want women to have affordable access to oral contraceptives.}

When assessing a statute under an intermediate scrutiny level of review, two operative parts must be considered—the “means” and the “ends.”\textsuperscript{130} The “ends” or the objective the government seeks to achieve must be actual and important. The “means” or the classification the government has used must be “substantially related” to the ends. Here, the means (the gender-based reproductive health access exclusion) and the ends (presumably, reducing Medicaid spending by $4.7 billion between 2006–2010) can be compared to \textit{United States v. Virginia}, where the Supreme Court subjected Virginia Military Institute’s (“VMI”) male-only admissions policy to intermediate scrutiny.\textsuperscript{131}

The Court determined that Virginia’s male-only admissions policy to VMI was not “substantially related” to the state’s objective of maintaining the adversative method, and the objective of educating “citizen soldiers” was not “substantially advanced by women’s categorical exclusion, in total disregard of their individual merit.”\textsuperscript{132} Likewise, the federal government’s gender-based reproductive health access exclusion in the DRA is not “substantially related” to the objective of spending reduction. For every tax dollar spent on contraceptive services, $3.00 in Medicaid costs for pregnancy-related healthcare and medical care of newborns is saved, 1.3 million unplanned pregnancies are avoided, and without publicly supported services, there would be an annual increase of 40% more abortions.\textsuperscript{133} Furthermore, the DRA defies the purpose of other statutes, Title X and Medicaid, which have ensured women’s affordable access to oral contraceptives in relation to reproductive health and family planning for over a quarter of a century. When a heightened level of scrutiny is applied, economic reasons are not enough to uphold a statute as unconstitutional. Therefore, in terms of the DRA, the government has failed to demonstrate the requisite “exceedingly persuasive justification” for denying women access to affordable oral contraceptives to which they are entitled under federal law.\textsuperscript{134}

A final step in the “means/ends” analysis is the assessment of the concepts of over-inclusiveness and under-inclusiveness. A law is over-inclusive when it applies to some situations that do not serve its objectives.\textsuperscript{135} Conversely, a law is under-inclusive when it “does not apply to some situations that do serve its objectives.”\textsuperscript{136} The DRA, although it contains no express language regarding gender differentiation and denial of access to oral contraceptives, can be seen as over-inclusive because it affects all women procuring oral contraceptives from federally funded or campus health clinics, including those individuals not traditionally covered under the umbrella of Title X or Medicaid. There is a strong likelihood that the classification will meet the applicable means test.

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to the public good. Therefore, as a matter of public policy, it is imperative that access to oral contraceptives at pre-DRA prices be reinstated.

B. Remedies

The Supreme Court has held that 42 U.S.C. § 1983 broadly construes a private federal right of action for damages and injunctive relief to redress violations by state officials of rights created by the United States Constitution as well as federal statutes. For example, a reading of the Public Health Service Act does not “reveal a precise or elaborate remedial scheme that would be obfuscated by allowing enforcement through a § 1983 action.” Also, the statutory language and legislative history indicate an intent to improve and expand all aspects of family planning services by providing grants to public or nonprofit private entities or state health authorities. Therefore, the Court in Planned Parenthood of Billings v. Montana concluded that the Public Health Services Act created federally enforceable rights in the plaintiffs and since no Congressional intent to preclude private enforcement existed, § 1983 provided a cause of action to remedy an alleged violation of the Act.

Relying on Supreme Court decisions, a U.S. District Court recently held in Children’s Hosp. of Philadelphia v. Horizon NJ Health that a hospital’s claims against an insurance provider for deprivation of constitutional rights in violation of 42 U.S.C. § 1983 could proceed. The court noted that a symbiotic relationship was present because approximately 50% of funding received was federal and that the insurance company derived a substantial benefit. Additionally, the doctrine of third party standing and in turn associational standing was upheld because “the hospital had alleged facts sufficient to establish the third-party standing of its doctors to bring their patients’ claims.”

Similarly, the DRA, because it is read in pari materia with Title X and Medicaid, creates federally enforceable rights in women who utilize clinics that qualify for federal funding and since no Congressional intent is presently precluding private enforcement, § 1983 should be applicable. As in Children’s Hosp. of Philadelphia, a symbiotic relationship exists between the government and the pharmaceutical companies because the drug manufacturers derive a substantial benefit from the billions of dollars the government expends annually on prescriptions. In addition, Congress knew of the denial of access to oral contraceptives and has not passed any legislation or enforced correct application of the AMP formula.

The pharmaceutical companies’ interpretations of Section 6001 of the DRA to no longer offer oral contraceptives to federally funded and campus health clinics based on the AMP formula is also possibly unconstitutional. Federal courts have held that private corporations that contract with the government may not be entitled to qualified immunity under § 1983. The Supreme Court, applying the nexus approach, held the appropriate inquiry is “whether there is a sufficiently close nexus between the State and the challenged action of the regulated entity so that the action of the latter may be fairly treated as that of the State itself.”

Moose Lodge No. 107 v. Irvis is an instructive example of the application of the inquiry. Focusing on the state’s involvement, the challenged action was the lodge’s racial discrimination against private guests. The Supreme Court emphasized that a nexus would exist and state action would be present, if the state had “fostered or encouraged” the allegedly unconstitutional action. Applying this reasoning to the DRA and the “business decisions” made by pharmaceutical companies, it could be found that a “sufficiently close nexus” between the State, the pharmaceutical companies and the potentially challenged action exists to impose liability on both the State and the private companies under § 1983.

CONCLUSION

There is no comparable situation for men. Women’s overall healthcare is at issue and this type of funding reduction of medical treatment options promulgated by the DRA is constitutionally invalid. As shown, cutting funding for oral contraceptives has far reaching implications for women including the Deficit Reduction Act of 2005, which embodies the notion that what is not good policy is also not good politics.

ENDNOTES

1 Rachel V. Rose holds an MBA from Vanderbilt University – Owen Graduate School of Management and is a second year law student at Stetson University College of Law with an interest in healthcare policy and law. She would like to thank the following individuals for their support, guidance, and encouragement: Stetson University College of Law Professor Ann Piccard, JD, LLM, for advising and editing this paper; Pamela Burdett, Associate Director & Head of Public Services, Stetson University College of Law Library, for assistance with research; Stetson University College of Law Professors Michael Allen and William Kaplin for assistance with Constitutional issues.

2 See Viagra® [package insert]; NY(NY): Pfizer, Inc.; 2007 (listing a single indication under the “Indications and Usage” section, “VIAGRA® is indicated for the treatment of erectile dysfunction.”).

3 See Letter from Sally K. Richardson, Director, HCFA, to State Medicaid Directors (Nov. 30, 1998), available at www.coms.hhs.gov/smd/downloads/smd103098.pdf (requiring that a State’s Medicaid program cover Viagra as required by the Omnibus Budget Reconciliation Act of 1990); Medicare Prescription Benefit to Cover Viagra, Other ‘Lifestyle’ Drugs, (Feb. 21, 2005), available at www.NewsRx.com (reporting that sexual performance drugs like Viagra will be covered under Medicare’s new prescription drug benefit beginning in 2006); Patricia Anstett, Medicare Limits Coverage for Viagra, Seattle Times, Jan. 27, 2007, at A4 (limiting coverage of Viagra® through an amendment to the Social Security Act, to allow reimbursement if a man takes Viagra®, Cialis®, or Levitra® for a primary medical condition not labeled erectile dysfunction).


7 See id. (funding the large scale clinical trials, G.D. Searle and Co., on Oct. 29, 1959, filed an application with the FDA for approval of Enovid as a contraceptive).
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ENDNOTES CONTINUED

8 The Pill, supra note 5.
9 Id.
10 Id. (discussing how the birth control pill rendered Griswold v. Connecticut invalid, where the Supreme Court held that laws prohibiting birth control were unconstitutional).
11 Id.
12 Id.
13 Id.
15 History of Birth Control, supra note 4.
16 Id.
17 See Interview with Dr. Lisa Fish and Dr. Robert Jaffe (Dec. 4, 2003), available at http://womenshealth.about.com/cs/pcos (highlighting PCOS because it is the most common hormonal disorder in women and acknowledging the role of birth control pills in its treatment); R.L. Barbieri, Hormone Treatment of Endometriosis: The Estrogen Threshold Hypothesis, 166 AM. J. OBSTET-GRIV. (Feb. 1992) (hypothesizing that hormonal therapy with a gonadotropin-releasing hormone agonist is an effective alternative to the surgical treatment of endometriosis).
21 Id.
22 Id.
23 Id.; see also S. Ferrero, M.D., V. Remorgida, M.D., Endometriosis – Images in Clinical Medicine, NEW ENG. J. MED., 357 (Aug. 16, 2007) (showcasing pictures of endometriotic nodules in the diaphragm and indicating a follow-up regime of norethindrone [a type of birth control pill] enabled the patient to be pain free one year post-operative).
24 Deficit Reduction Act § 6001(d)(2).
25 Id.
26 Walgreen’s Pharmacy, LoEstrin® 24 FE Tablets (Retail price: $64.99, United Healthcare Student Resources Copay $50.00), Feb. 12, 2008; see also http://www.plannedparenthood.org/health-topics/birth-control/birth-control-pill-4228.htm (last visited Sept. 19, 2008) (indicating that family planning clinics often charge less than private health care providers for an exam and for the pill).
28 See Government Saves Money, supra note 27 (reaching this figure by “factoring only the public-sector costs for maternity care, delivery, and one year infant related care for those contraceptive clients who would be eligible for Medicaid maternity care in their state if they became pregnant”); see also, Mark Niesse, Hawaii Ending Universal Child Health Care, Associated Press, Oct. 17, 2008 (ending the only state universal child health care program in the country just seven months after its inception because of the 2011 projected $900 million general fund shortfall).
29 See Government Saves Money, supra note 27 (acknowledging that the savings reflects the increasing costs of health care services as well as an expansion for Medicaid. “By fiscal year 2001, Medicaid accounted for 61% of public dollars spent for contraceptive services, $770 million.”); see also, Kevin Freking, Strong Growth in Medicaid Anticipated, Associated Press (Oct. 17, 2008), available at http://www.examiner.com/a-1643483-Strong_growth_in_Medicaid_anticipated.html?cid=rss-Health (indicating Medicaid’s growing strain on state and federal budgets will grow at 7.9% while the overall economy is projected to grow at 4.8% over the next 10 years).
31 Id.
32 See id. (citing a survey of public agencies by The Alan Guttmacher Institute).
33 Deficit Reduction Act § 6001(d)(2).
35 Id.
37 See Medicaid Drug Pricing Regulation: A Summary, Centers for Medicare and Medicaid Services, (July 6, 2007), available at http://www.cms.hhs.gov/pdf (reviewing changes to AMP in light of the DRA of 2005 and recognizing that the final rule “continues to define nominal sales as those sales at less than ten percent of AMP, but limits the Best Price exemption.”).
38 340B, supra note 34; see also Deficit Reduction Act § 6001(d)(2).
40 See http://www.gao.gov/newitems/d0669.pdf (last visited Oct. 16, 2008) (“According to CMS, transactions used to calculate AMP are to reflect cash discounts and any adjustments that affect the price realized, but are not to include prices to direct federal purchasers based on the Federal Supply Schedule (FSS), prices from direct sales to hospitals or health maintenance organizations or prices to wholesalers when they re-label drugs they purchase under their own label. There is no definition in the statute for “retail pharmacy class of trade.”); see also Deficit Reduction Act § 6001(d)(2), 42 U.S.C. § 1396s-8.
41 See id. (noting that in the February 2005 report, considerable variation in the methods manufactures used to determine AMP and Best Price was found); see Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States, Pub. No. GAO-05-102, (Feb. 4, 2005), available at http://www.gpaccess.gov/gaoreports/index.html (last visited Oct. 2, 2008); see also 42 U.S.C. § 1396s-8(c)(1)(C) (stipulating “CMS has further defined Best Price as the lowest price at which the manufacturer sells the drug to any purchaser in any pricing structure, including capped payments, with some exceptions.”).
42 Deficit Reduction Act § 6001(d)(2).
43 340B, supra note 34.
44 Id. For example, if AMP equals $100.00 and the rebate percentage is 15.0%, then the ceiling price for this example would be $85.00.
46 See Press Release, US Federal News, Sens. Roberts, Lincoln, Salazar Offer Medicaid Pharmacy Reimbursement Amendment to SCHIP, (July 19, 2007) (highlighting the concerns and continuing efforts on behalf of pharmacists to oppose the way pharmacies would be reimbursed under the new AMP formula in the DRA of 2005) [hereinafter Roberts]; see also, Press Release, State News Service, Finance Committee Senators Introduce Legislation to Fix Unfair Medicaid Rules for Kansas Pharmacists, (Aug. 2, 2007) (reporting that in response to the DRA of 2005, The Fair Medicaid Drug Payment Act of 2007 was introduced to stave off some of the most severe cuts and enable pharmacies to continue serving Medicaid patients by increasing the Medicaid payment rate to pharmacies from 250% of AMP to 300% of AMP).
47 See Roberts, supra note 46 (emphasizing that the calculation of AMP for a covered outpatient drug will exclude customary prompt pay discounts extended to wholesalers and only certain sales of covered outpatient drugs will be excluded from the rebate percentage. Previously, the exclusion applied to all [emphasis added] sales at a nominal price, regardless of the purchaser.); see also, Pub. L. No. 109-171, § 6001(d)(2) (2006).
See id. (including specific examples of adverse implications: allowing health care institutions to claim “conscientious objection”; undermining important state laws which enable rape survivors access to emergency contraception; and conflicting with Medicaid and Title X which require contraceptive services to be provided).

See H.R. 4054 (proposing to amend Title XIX of the Social Security Act to restore and protect access to Medicaid discount drug prices for university-based and safety-net clinics).

Id. at §(2)(a)(2).

Recalde, supra note 63 (relying that the DRA was a direct result of changes in Medicaid reimbursement rules that limited the number of facilities that qualify for discounted prices.)

H.R. 4054; S. 2347.

H.R. 4054

The Pill, supra note 5.

Id. (Dr. Buxton was the chairman of the Department of Obstetrics and Gynecology at Yale Medical School and Ms. Griswold was the executive director of Connecticut Planned Parenthood).


See Eisenstadt v. Baird, 405 U.S. 438 (1972) (deciding, on Equal Protection grounds, that a Massachusetts law banning the distribution of contraceptives was invalid).


See William A. Kaplin, American Constitutional Law: An Overview, Analysis, and Integration, 264 (Carolina Academic Press, 2004) (acknowledging that when an equal protection claim arises under the Federal Government, the 5th Amendment’s Due Process Clause is triggered because the Supreme Court has determined that it applies in the same manner as the equality concept of the 14th Amendment applies to the states).

See Timothy Stoltzfus Jost, The Tenuous Nature of Medicaid Entitlement, Health Affairs (2003), http://content.healthaffairs.org/cgi/content/full/22/1/145. (noting that unlike Medicare which has express entitlement language, Medicaid’s entitlement was recognized through a series of Supreme Court cases between 1968–1975).


Id. at 234.

See 118 U.S. at 373-374. ([T]he cases present the ordinances in actual operation, and the facts shown establish an administration directed so exclusively against a particular class of persons as to warrant and require the conclusion that, whatever may have been the intent of the ordinances as adopted, they are applied by the public authorities charged with their administration, and thus representing the State itself, with a mind so unequal and oppressive as to amount to a practical denial by the State of that equal protection of the laws which is secured to the petitioners, as to all other persons, by the broad and benign provisions of the . . . Constitution of the United States).


Id. at 280.


Id.

Id.

Letter from the United States Senate to the Secretary of the Department of Health and Human Services, (July 15, 2008).

Letter from Senators, supra note 84.

Crego v. Coleman, 615 N.W.2d 218, 228 (2000).


518 U.S. at 545-546.


518 U.S. at 531.

Crego v. Coleman, 615 N.W.2d 218, 228 (2000).

Id.


Petermann v. Int’l Brotherhood of Teamsters, 344 P.2d 25 (1959). See also Pub. L. 85-554 § 2, 72 Stat. 415 (1958) (amending 28 U.S.C. § 1332(c), provided that a corporation is to be deemed a citizen of any State in which it has been incorporated and of the State in which it has its principal place of business. 78 Stat. 445 (1964), amending 28 U.S.C. § 1332(c), was enacted to correct the problem revealed by Lumbermen’s Mutual Casualty Co. v. Elbert, 348 U.S. 48 (1954)).

See Nicole Coffin, MA, Yvonne Green, RN, MSN, CNM, Prevention Works for Women: Women’s Health at the CDC, available at http://www.amwa-doc.org (emphasizing the critical role the Center for Disease Control and Prevention (CDC) plays in promoting health and safety of women “across the lifespan, through the programs on human immunodeficiency virus infection, injury, contraceptive safety and efficacy, adolescent health, smoking breast and cervical cancer, cardiovascular disease and reproductive health.”).

Maine v. Thiboutet, 448 U.S. 1, 4-8 (1980) (addressing that § 1983 is available to enforce a particular statute depending on two factors: (1) Congress must not have foreclosed private enforcement of the statute and (2) the statute must create enforceable rights); see also, On First Impression, Tenth Circuit Holds That An Unincorporated Business Is Not A “Person” Within the Meaning of 42 U.S.C. § 1983 (Nov. 16, 2006), available at http://lawprofessors.typepad.com/unincorporated_business/2006/11/on_first_impres.html (noting that, “under common law, unincorporated associations, unlike corporations, did not have the capacity to sue or be sued.”).


Id.

Children’s Hosp. of Philadelphia v. Horizon NJ Health, No. 07-5061 (E.D. Pa. Sept. 22, 2008) (according to the court, “a private party may be deemed a state actor if it: (1) is acting under government compulsion (see Bentwood acad. V. Tenn. Secondary School Athletic Ass’n., 531 U.S. 288, 296 (2001)); (2) performs a function that has traditionally been the exclusive domain of the government (see Rendell-Baker v. Kohn, 457 U.S. 830, 842 (1982)); or (3) has a symbiotic relationship with the government.”).

Id. (“taking the allegations of the first amended complaint as true, Children’s Hospital of Pennsylvania (CHOP) has alleged a significant, albeit covert, encouragement by government officials to steer Horizon members away from CHOP.”).


Id.

See Crego v. Coleman, 615 N.W.2d 218, 229 (2000) (citing Blum v. Yartsey, 457 U.S. 991, 1004 (1982)) for the proposition that other cases make clear that “state action would also be found if the state has coerced or compelled the challenged action.”

Spring 2009