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Constitutional Issues Raised by States' Exclusion of Fertility Drugs from Medicaid Coverage in Light of Mandated Coverage of Viagra

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NOTES

Constitutional Issues Raised by States' Exclusion of Fertility Drugs from Medicaid Coverage in Light of Mandated Coverage of Viagra

I. INTRODUCTION

On July 2, 1998, officials at the Health Care Financing Administration ("HCFA"), the federal agency responsible for administering the Medicaid program,[1] mandated that state Medicaid programs provide coverage for the impotency drug Viagra.[2] The HCFA's announcement has proven very controversial, encountering resistance from many states who view the mandate as financially impairing their ability to provide other Medicaid services.[3] Man-

1. Medicaid, a program created by the federal government in Title XIX of the Social Security Act, authorizes the expenditure of federal funds to aid states in providing medical services to needy people. Linda M. Vanzi, *Freedom at Home: State Constitutions and Medicaid Funding for Abortions*, 26 N.M. L. REV. 433, 434 (1996).

2. *Drug Policy: Medicaid Coverage of Viagra at* http://www.hcfa.gov/medicaid/drugs/drpolicy.htm (last visited Nov. 27, 2000) ("[T]he law requires that a State's Medicaid program cover Viagra . . . .") [hereinafter *Drug Policy*]; *see also* Carole L. Stewart, *Mandated Medicaid Coverage of Viagra: Raising the Issues of Questionable Priorities, the Need for a Definition of Medical Necessity, and the Politics of Poverty*, 44 LOY. L. REV. 611, 612 (1998).

3. Stewart, *supra* note 2, at 612-13. For example, a spokeswoman for the Michigan Department of Community Health expressed concern that complying with the federal mandate would "cost [Michigan] $14 million a year—$14 million [they] could spend on maternal and infant services or people with HIV." Robert Pear, *New York and Wisconsin Will Defy Federal Directive to Provide Viagra Through Medicaid*, N.Y. TIMES, July 3, 1998, at A12. Likewise, an attor-

dated Medicaid coverage of Viagra is also curious, considering that the Medicaid statute specifically permits states to exclude fertility drugs, a category of drugs into which Viagra falls, from coverage under state Medicaid programs.[4] Moreover, most states do in fact decline to cover these drugs.[5]

Although Viagra primarily treats erectile dysfunction, it also treats male infertility in distinct cases.[6] Thus, the HCFA mandate essentially results in states providing Medicaid coverage of a male fertility drug while excluding female fertility drugs from coverage.[7]

With its mandate,[8] the HCFA has given female Medicaid recipients a constitutional aid with which to challenge the states' exclusion of female fertility drugs from Medicaid coverage. This Note identifies the potential constitutional causes of action women have against the discrepancy in Medicaid coverage, and assesses the likelihood that their arguments will succeed.

Part II of this Note explores the history of the Medicaid program as well as its current statutory construct. It discusses the general purpose of the program and its attempt to provide medical assistance to "categorically" as well as to "medically" needy individuals. The interaction between the federal and state governments in implementing and administering Medicaid programs is also explored in this part of the Note, with an emphasis on the federal government's ability to dictate the terms of state Medicaid programs. Finally, Part II discusses the federal Medicaid guidelines with respect to states' prescription drug coverage under their individualized Medicaid programs.

Part III addresses the problem of infertility in the United States. It focuses on the prevalence of infertility in distinct socioeconomic groups and explores the various types of fertility drugs used to aid women suffering from certain reproductive abnormali-

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ney with the New Haven Legal Assistance Association found it "very disturbing that the White House would allow states . . . to ration care for quadriplegics and people with cerebral palsy or Lou Gehrig's disease who need special medical equipment to keep them alive" while mandating coverage for Viagra. *Id.*

4. Social Security Act, 42 U.S.C. § 1396r-8(d)(2)(B)(ii)(1994) ("The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted . . . [a]gents when used to promote fertility.").

5. *See* Andy Miller, *Viagra to be Covered by Georgia Medicaid*, ATLANTA J. & CONST., July 29, 1998, at 03D; NAT'L CTR. FOR POLICY ANALYSIS, Feds to States: Pay for Viagra, *at* http://www.ncpa.org/health/pdh/july98a.html (last visited Jan. 15, 2001).

6. *See infra* Part IV (discussing Viagra in detail).

7. For examples of female fertility drugs excluded from Medicaid coverage, see Part III.C.

8. *See Drug Policy*, *supra* note 2 and accompanying text.

ties. Part III concludes with a discussion of both federal and state policies regarding Medicaid coverage of fertility drugs.

Part IV begins with an overview of the drug Viagra and its treatment of erectile dysfunction in men. The Note also discusses the HCFA's reasons for determining that state Medicaid programs should be required to cover Viagra, and it explores the states' reactions to the HCFA's mandate. Part IV ends with a discussion of the classification of Viagra as a male fertility drug.

Part V discusses the possibility of female Medicaid recipients bringing constitutional challenges to a state's exclusion of fertility drugs from Medicaid coverage in light of the HCFA's mandated coverage of Viagra. Part V.A first addresses a possible claim that the discrepancy in coverage violates female Medicaid recipients' substantive due process rights; however, the Note quickly dismisses this argument because of its probable failure. Next, the Note examines the more plausible claim of an equal protection violation. Part V.B describes the traditional equal protection construct used by the Court, including the standards of scrutiny applicable to various equal protection challenges. The Note proceeds to apply the traditional equal protection construct to a possible challenge of state Medicaid programs' refusal to cover fertility drugs in light of the federally mandated coverage of Viagra. As such, the Note argues that the inequality created by this situation deserves a higher standard of scrutiny than the traditional intermediate level of scrutiny used for gender classifications. It then proceeds to apply this higher level of scrutiny to the current situation to determine the likelihood that the Court would rule in the plaintiff's favor.

Part VI of the Note determines that a state's refusal to cover female fertility drugs under its Medicaid program—while at the same time covering Viagra—violates the Equal Protection Clause. The Note then concludes with a discussion of a state's options as it attempts to comply with constitutional equal protection guarantees.

II. AN OVERVIEW OF THE MEDICAID PROGRAM

A. The Purpose of the Medicaid Program

In 1965, Congress created Medicaid under Title XIX of the Social Security Act.[9] The Medicaid program seeks "to enable each

9. Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286, 343-53 (codified as amended at 42 U.S.C. § 1396 (1994)).

State, as far as practicable, to furnish medical assistance to individuals whose income and resources are insufficient to meet the costs of necessary medical services."[10]

Title XIX provides medical assistance to two classes of people: the "categorically needy" and the "medically needy."[11] The statute requires that states electing to participate in the Medicaid program provide assistance to the "categorically needy," and it permits participating states to elect whether to provide benefits to the "medically needy."[12] The "categorically needy" include families with dependent children eligible for public assistance under the Aid to Families with Dependent Children Program,[13] and the aged, blind, and disabled who are eligible for benefits under the Supplemental Security Income program.[14] Typically, to be categorically needy for Medicaid purposes, most recipients must fall below the federal poverty level.[15] Meanwhile, the "medically needy" include those patients who are above the poverty level but who are either blind, disabled or members of families with dependent children, and also those whose income after deducting medical expenses falls below the poverty level.[16]

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10. Beal v. Doe, 432 U.S. 438, 444 (1977); *see also* 42 U.S.C. § 1396 (stating that Medicaid is designed to permit states "to furnish (1) medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services, and (2) rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care . . . .").

11. *See* 42 U.S.C. § 1396(a)(10)(A).

12. *See id.*; *see also* Correll v. Div. of Soc. Servs., 418 S.E.2d 232, 234 (N.C. 1992) (noting that a state electing to participate in the Medicaid program must provide medical assistance to the "categorically needy" and has the option of providing benefits to the "medically needy").

13. *See Aid to Families With Dependent Children (5180), at* http://www.lao.ca.gov/chc-5180.html (last visited Nov. 27, 2000). The Aid to Families with Dependent Children Program "provides cash grants to families and children whose incomes are not adequate to meet their basic needs." *Id.* Families can qualify for the Program if they 1) "have a child who is financially needy due to the death, incapacity, or continued absence of one or both parents . . ." or 2) "have a child who is financially needy due to the unemployment of one or both parents." *Id.*

14. 42 U.S.C. § 1396(a)(10)(A)(i).

15. *See* Julie F. Kay, Note, *If Men Could Get Pregnant: An Equal Protection Model for Federal Funding of Abortion Under a National Health Care Plan*, 60 BROOK. L. REV. 349, 353 (1994).

16. George F. Indest III, *Legal Aspects of HCFA's Decision to Allow Recovery From Children for Medicaid Benefits Delivered to their Parents through State Financial Responsibility Statutes: A Case of Bad Rule Making through Failure to Comply with the Administrative Procedure Act*, 15 S.U. L. REV. 225, 229 (1988); *see also* 42 U.S.C. § 1396(a)(10)(A)(ii).

B. Federal/State Cooperation and the Medicaid Program

The Medicaid program receives joint funding from the federal and state governments.[17] The federal government reimburses states for a portion of their Medicaid expenditures at a rate established by the Department of Health and Human Services ("HHS"),[18] and states typically receive reimbursement for fifty to eighty-three percent of Medicaid expenditures.[19]

Although states may elect not to participate in the Medicaid program, if a state does decide to participate, it must comply with all federal statutory and administrative rules.[20] More specifically, these federal regulations mandate that states choosing to participate in the Medicaid program furnish five general types of services to qualified individuals: (1) various inpatient services; (2) "outpatient hospital services;" (3) "other laboratory and X-ray services;" (4) nursing and clinic services, including "family planning services;" and (5) various "physicians' services."[21] Furthermore, state Medicaid agencies may not "arbitrarily deny or reduce the amount, duration, or scope of a required service . . . to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition."[22] States may, however, place "appropriate limits on a [required] service based on such criteria as medical necessity or on utilization control procedures."[23]

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17. 42 U.S.C. § 1396a(a)(2) (stating that states must provide funding for at least 40% of their own Medicaid program expenditures).

18. *See* Rachel B. Gold & Daniel Daley, *Public Funding of Contraceptive, Sterilization and Abortion Services, Fiscal Year 1990*, 23 FAM. PLAN. PERSP. 204, 204-05 (1991).

19. *See id.*

20. Alexander v. Choate, 469 U.S. 287, 289 n.1 (1985) ("Once a State voluntarily chooses to participate in Medicaid, the State must comply with the requirements of Title XIX and applicable regulations."); Harris v. McRae, 448 U.S. 297, 301 (1980) ("Although participation in the Medicaid program is entirely optional, once a State elects to participate, it must comply with the requirements of Title XIX."); Stewart, *supra* note 2, at 614.

21. 42 U.S.C. §1396d(a)(1-25).

> Basic or mandatory Medicaid services generally include inpatient hospital services; outpatient hospital services; prenatal care; vaccines for children; physician services; nursing facility services for persons aged 21 or older, family planning services, rural health clinic services, home health care for person eligible for skilled nursing services; laboratory and x-ray services; pediatric and family nurse practitioner services; nurse midwife services; Federally-qualified health center services and early and periodic screening, diagnosis and treatment (EPSDT) services for children under age 21.

Claudia Schlosberg & Sareena Jerath, National Health Law Program (NHELP), *Fact Sheet: Prescription Drug Coverage under Medicaid*, at n.2 (July 1999), *at* http://nhelp.org/pubs/1999080 8MedicaidDrugs.html.

22. 42 C.F.R. § 440.230(c) (1999).

23. *Id.*

C. Prescription Drug Coverage Under State Medicaid Programs

Medicaid classifies prescription drugs as "optional services";[24] yet, if a state decides to cover prescription drug services in its program, the state must comply with federal guidelines in doing so.[25] These federal guidelines provide that most prescription drugs should be covered under Medicaid statutes if they have been approved by the Food and Drug Administration ("FDA").[26] The guidelines, however, permit states to exempt FDA-approved drugs from their Medicaid programs in a variety of instances.[27] First, states need not provide payment for prescription drugs if "the prescribed use is not for a medically accepted indication."[28] Second, states are not required to cover prescription drugs that are "subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary [of Health and Human Services]."[29] Third, states are not required to cover prescription drugs that have been specifically excluded by the federal Medicaid statute.[30]

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24. 42 U.S.C. § 1396d(a); *see also* Schlosberg & Jerath, *supra* note 21 (noting that prescription drugs are optional services along with home health services, dental services, diagnostic services, clinic services, intermediate care facilities for the mentally retarded, prosthetic devices, rehabilitation and physical therapy services, hospice care, case management services, respiratory care services, and alcohol and drug treatment). A state that decides to provide certain optional services is eligible to receive matching federal funds. *Id.*

25. 42 U.S.C. § 1396a(a)(54) ("[I]n the case of a State plan that provides medical assistance for covered outpatient drugs . . . , [the State must] comply with the applicable requirements of section 1396r-8 of [Title XIX].").

26. 42 U.S.C. § 1396r-8(k)(2)(A)(I) (stating that a covered outpatient drug is one "which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act").

27. *See* 42 U.S.C. § 1396r-8(d) (listing limitations on drug coverage).

28. *Id.* § 1396r-8(d)(1)(B)(i). The statute defines a medically accepted indication as "any use for outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et. seq.] or the use of which is supported by one or more citations included or approved for inclusion in [the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, or the American Medical Association Drug Evaluations]." *Id.* § 1396r-8(k)(6).

29. *Id.* § 1396r-8(d)(1)(B)(iii). In order for payment to be available from the federal Medicaid program to the states for covered outpatient drugs, the manufacturer of the drug must have entered into a rebate agreement, as provided for in 42 U.S.C. § 1396r-8(b), with the Secretary of Health and Human Services, on behalf of states. *Id.* § 1396r-8(a)(1). The rebate agreement requires the manufacturer to provide a specified rebate for covered outpatient drugs dispensed by the manufacturer during a given period of time that were paid for under the State Medicaid plan. *Id.* § 1396r-8(b)(1)(A). The agreement also requires the state to report to the "manufacturer not later than 60 days after the end of each rebate period . . . information on the total number of units of each dosage form and strength and package size of each covered outpatient drug . . . for which payment was made under the plan during the period . . . ." *Id.* § 1396r-8(b)(2)(A).

30. *Id.* § 1396r-8(d)(1)(B)(ii). Pursuant to the statute,

The federal guidelines also allow states some flexibility in limiting the amount, duration, and scope of those prescription drugs whose coverage is required under the federal Medicaid program.[31] States typically use this flexibility to limit access to prescription drugs in four ways: (1) by limiting the number of prescriptions that a beneficiary can have filled in a given time period;[32] (2) by imposing co-payments for prescription drugs;[33] (3) by restricting access to specified drugs;[34] and (4) by requiring prior approval of a prescription drug before it is dispensed for any medically accepted indication.[35]

D. Review of State Medicaid Programs by the Federal Government

Title XIX requires that states submit medical assistance plans[36] for approval by the Secretary of Health and Human Services.[37] In 1984, however, the Secretary of the HHS delegated his authority to carry out federal Medicaid duties under Title XIX to the Administrator of the HCFA, an agency within the HHS.[38]

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[t]he following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted: (A) Agents when used for anorexia, weight loss, or weight gain. (B) Agents when used to promote fertility. (C) Agents when used for cosmetic purposes or hair growth. (D) Agents when used for the symptomatic relief of cough and colds. (E) Agents when used to promote smoking cessation. (F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations. (G) Nonprescription drugs. (H) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee. (I) Barbiturates. (J) Benzodiazepines.

Id. § 1396r-8(d)(2).

31. *See* Schlosberg & Jerath, *supra* note 21.

32. Federal law allows a state to "impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or abuse by individuals . . . ." 42 U.S.C. § 1396r-8(d)(6).

33. States are prohibited from charging certain recipients, such as minors and pregnant women, co-payments; states also cannot charge co-payments for specified categories of services, such as family planning services. Schlosberg & Jerath, *supra* note 21.

34. *See* discussion *supra* notes 27-30.

35. Federal law only permits a state to require prior approval "if the system for providing such approval (a) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization, and (b) . . . provides for the dispensing of at least a 72-hour supply of a covered outpatient drug in an emergency situation." 42 U.S.C. § 1396r-8(d)(5).

36. A medical assistance plan provides information such as which individuals will be eligible for state Medicaid benefits, what services will be provided under the state's Medicaid program, and the rates to be charged for various services. *Id.* § 1396a(a).

37. *Id.* § 1396a (setting forth the standards for states' medical assistance plans); *see also* Fargo Women's Health Org., Inc. v. Wessman, No. A3-94-36, 1995 WL 465830, at *1 (D.N.D. Mar. 15, 1995).

38. *See* 42 U.S.C. § 1302.

Hence, the HCFA Administrator both interprets the Medicaid statute and also determines whether a state's Medicaid plan meets the federal requirements.[39] If he or she determines that the plan meets the federal requirements, the state will receive federal funding as long as it administers the Medicaid program within federal parameters.[40] Conversely, if the HCFA Administrator determines that the federal requirements are not met, he or she may issue an official disapproval of the plan.[41] A state whose Medicaid program has been disapproved may seek both administrative and judicial review of the disapproval.[42]

E. Challenges to Federal Medicaid Requirements Under the Administrative Procedures Act

In 1946, Congress passed the Administrative Procedures Act ("APA") to provide for judicial review of federal agency decisions.[43] According to the APA, a person[44] who has suffered a legal wrong or who has been adversely affected or aggrieved by some federal agency action is entitled to judicial review of the agency action or decision.[45] Two United States Supreme Court cases set forth the scope of judicial review of federal agency decisions as well as detail the appropriate deference to be accorded such decisions: *Citizens to Preserve Overton Park, Inc. v. Volpe*[46] and *Chevron U.S.A., Inc., v. Natural Resources Defense Council, Inc.*[47] In *Overton Park*, the Court held that courts reviewing agency decisions should refrain from "de novo" review and instead review the case on the basis of the administrative record—unless the reviewing court is evaluating an "adjudicatory" agency decision and the agency's fact-finding pro-

39. 42 C.F.R. § 430.10 (1999).

40. *Id.*

41. *Id.* § 430.15(c). Official disapproval of a state's Medicaid program may result in the state being denied federal reimbursement for expenditures under its Medicaid program. Louisiana v. United States Dep't of Health & Human Servs., 905 F.2d 877, 878 (5th Cir. 1990).

42. *Dep't of Health & Human Servs.*, 905 F.2d at 878 (5th Cir. 1990) (affirming Louisiana's authority to seek administrative and judicial review of the HCFA Administrator's disapproval of Louisiana's Medicaid program).

43. *See* 5 U.S.C. §§ 551-59, 701-06 (1994 & Supp. II. 1996).

44. "Person" is defined as "an individual, partnership, corporation, or public or private organization other than an agency." *Id.* § 551 (1994).

45. *See id.* § 702 (1994).

46. Citizens to Pres. Overton Park, Inc. v. Volpe, 401 U.S. 402 (1971) (involving judicial review of a decision by the United States Secretary of Transportation).

47. Chevron U.S.A., Inc., v. Nat'l Res. Def. Council, Inc., 467 U.S. 837 (1984) (involving judicial review of an Environmental Protection Agency action).

cedures are inadequate.[48] Meanwhile, in *Chevron*, the Court held that a reviewing court must defer to any reasonable agency interpretation of a statute and may only invalidate a federal agency's interpretation that is "arbitrary, capricious, or manifestly contrary to the statute."[49]

Moreover, in *Sullivan v. Everhart*, the Court held that the *Chevron* doctrine applies to judicial review of decisions made by the Secretary of HHS.[50] Furthermore, the standard of review for the Secretary of HHS and the Administrator of the HCFA's decisions regarding the Medicaid program has generally been that of only overturning actions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law."[51]

III. MEDICAID COVERAGE OF FEMALE FERTILITY DRUGS

The medical community defines infertility as being unable to conceive an intrauterine pregnancy after attempting to do so for twelve months.[52] Infertility results from medical conditions in either the male or female partner, or both; however, fifty to seventy

48. *Overton Park*, 401 U.S. at 415 ("[D]e novo review is [only] authorized when the action is adjudicatory in nature and the agency fact-finding procedures are inadequate.").

49. *Chevron*, 467 U.S. at 844 (1984).

50. Sullivan v. Everhart, 494 U.S. 83, 89 (1990) (stating that the *Chevron* "principles apply fully to the Secretary's administration of the Act"); *see generally* Schweiker v. Gray Panthers, 453 U.S. 34 (1981) (deferring to the Secretary of the HHS' decision in promulgating regulations under his authority as delegated by Congress); Batterton v. Francis, 432 U.S. 416, 424-26 (1977) (stating that a court is not entitled to "set aside . . . regulations simply because it would have interpreted the statute in a different manner").

51. 5 U.S.C. § 706(2)(A) (1994) (providing the standard of review used for governmental agency decisions). *See generally* New Mexico Dep't of Human Servs. v. Dep't of Health & Human Servs., 4 F.3d 882 (10th Cir. 1993) (challenging the disapproval by the Secretary of HHS of a Medicaid plan amendment for calculating financial eligibility of married Medicaid applicants using property law); Utah Dep't of Health v. Health Care Fin. Admin., No. 899531, 1991 WL 80901 (10th Cir. Jan. 8, 1991) (challenging disapproval of a proposed amendment to the Utah Medicaid plan); Louisiana v. Dep't of Health & Human Servs., 905 F.2d 877 (5th Cir. 1990) (challenging the HCFA's disapproval of a proposed amendment to its Medicaid plan to estimate pharmacist's acquisition costs for certain drugs); Stewart, *supra* note 2, 621-22 (discussing the Court's ruling in *Sullivan*).

52. Lisa M. Kerr, *Can Money Buy Happiness? An Examination of the Coverage of Infertility Services Under HMO Contracts*, 49 CASE W. RES. L. REV. 599, 601 (1999) (defining infertility as the "inability to conceive an intrauterine pregnancy after a year of sexual intercourse without contraceptives"); ADVANCED REPRODUCTIVE CARE (ARC), What is Infertility and Who Can Help You?, *at* http://www.fertilityusa.com/what_is_infertility.html (last visited Jan. 16, 2001). One must note an important distinction between infertility and sterility; infertility simply means that becoming pregnant is a challenge, whereas sterility means that an individual cannot "conceive a child under any circumstance." MAYO CLINIC, Fertility Challenges and Therapies: Fertility Drugs—Make an Educated Choice, *at* http://www.mayohealth.org/-home?id=HQ00680 (last visited Jan. 16, 2001).

percent of the time the woman is the infertile partner.[53] Currently, ten to fifteen percent of American couples suffer from infertililty,[54] and this figure continues to increase in the United States.[55]

A. Socioeconomic Status and Infertility

Not only does infertility affect more women than men,[56] but researchers have found that it also affects a disproportionate number of women of lower socioeconomic status.[57] Indeed, research illustrates that "women with less than a high school education (a standard measure of lower socioeconomic status) are more likely to be part of an infertile couple than are their more educated counterparts."[58] Furthermore, "[m]any lower income people also suffer from poor nutrition and health care, making them more likely to suffer infertility."[59] Thus, it logically follows that many impoverished women—who are the most likely to qualify for Medicaid benefits[60]—will encounter the problem of infertility; thus they are more likely to require medical treatment in order to conceive a child.

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53. MAYO CLINIC, *supra* note 52. According to the Mayo Clinic, ovulation disorders, such as irregular or absent menstrual periods due to hormonal imbalances, frequently cause female infertility. *Id.*; *see also* AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE, Patient's Fact Sheet: Infertility, *at* http://www.asrm.org/Patients/FactSheets/Infertility-Fact.pdf (last visited Jan. 16, 2001) ("[I]rregular or abnormal ovulation accounts for approximately 25% of all female infertility cases.").

54. MAYO CLINIC, *supra* note 52. Infertility is estimated to affect 6.1 million American women and their partners. AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE, *supra* note 53.

55. Kerr, *supra* note 52, at 601 ("Estimates of the number of infertile couples in the United States range from 2.4 million to 5 million and these numbers are increasing each year."); *see also* John A. Robertson, *Embryos, Families, and Procreative Liberty: The Legal Structure of the New Reproduction*, 59 S. CAL. L. REV. 939, 945 (1986) (stating that "changes in sexual behavior, work roles, and postponement of marriage and childrearing" explain the rising rate of infertility). Infertility is particularly on the rise for women in certain age groups: "the percentage of infertile women between ages 35 to 39 rose from 18.4% to 24.6% [from 1966 to 1982], and the rate among women ages 20 to 24 more than doubled, from 3.6% in 1965 to 10.6% in 1982." Elizabeth Heitman, *Infertility as a Public Health Problem: Why Assisted Reproductive Technologies Are Not the Answer*, 6 STAN. L. & POL'Y REV. 89, 93 (1995).

56. *See* discussion *supra* note 53 and accompanying text.

57. *See* Segvei O. Aral & Willard Cates, Jr., *The Increasing Concern with Infertility: Why Now?*, 250 JAMA 2327, 2327 (1983); *see also* Heitman, *supra* note 55, at 93.

58. Heitman, *supra* note 55, at 93.

59. Kerr, *supra* note 52, at 605. Some causes of infertility include strenuous exercise and "eating disorders . . . , poor nutrition, stress, smoking, and alcohol and drug use." *Id.* at 602.

60. States are required to provide Medicaid services to the "categorically needy," which includes those individuals living below the poverty level. *See* discussion *supra* notes 11-15 and accompanying text.

B. Female Fertility Drug Treatments

The medical community has developed a multitude of techniques in an attempt to diminish infertility.[61] For the purposes of this Note, however, only currently available fertility drugs will be discussed, because of their classification as prescription drugs capable of being covered by state Medicaid programs.[62]

For a woman to become pregnant, the processes of ovulation and fertilization must occur to completion.[63] Ovulation disorders in women frequently prevent the completion of these processes, thereby resulting in infertility.[64] Fertility drugs use various mechanisms to regulate or induce ovulation; most typically, they create signals designed to replace the signals provided by natural follicle-stimulating and lutenizing hormones.[65] The most commonly used fertility drugs for treating ovulation disorders in women include:

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61. *See* Kerr, *supra* note 52, at 602 (stating that standard infertility treatments include "hormones, fertility drugs, and tubal surgery"); Robertson, *supra* note 55, at 942 ("[T]here is a vast array of infertility treatments, ranging from fertility drugs to tubal reconstruction by microsurgery and artificial insemination."); *see also* Roger J. Chin, *Assisted Reproductive Technologies Legal Issues in Procreation*, LOY. CONSUMER L. REV. 190, 192-94 (1996) (discussing various techniques of artificial insemination known as "assisted reproductive technologies"); STADLANDERS PHARMACY, TREATMENT OF INFERTILITY: CURRENTLY AVAILABLE DRUGS, *at* http://www.stadtlander.com/fertility/fertilmeds.html (last visited Jan. 21, 2000) (describing available forms of fertility drugs) [hereinafter TREATMENT OF INFERTILITY].

62. States may opt to include FDA-approved prescription drugs in their state Medicaid programs. 42 U.S.C. §1396d(a)(12) (1994).

63. During ovulation, a "follicle-stimulating hormone (FSH) is secreted by a woman's pituitary gland, signaling the ovaries to mature an egg follicle . . . ." MAYO CLINIC, *supra* note 52. When at least one of the follicles has reached maturity, the pituitary gland releases a substance called lutenizing hormone ("LH"). *Id.* The LH then carries the message to the largest matured follicle to release its egg, and the egg is picked up by the fallopian tube. *Id.* Fertilization occurs when sperm unites with the egg in the fallopian tube. *Id.*

64. *Id.*

65. *Id. See generally* discussion *supra* note 63.

clomiphene citrate,[66] gonadotropins with GnRH agonsists,[67] progesterone,[68] bromocriptine,[69] and corticosteroids.[70]

C. Federal Requirements for State Medicaid Coverage of Fertility Drugs

State coverage of prescription drugs, including fertility drugs, is an optional service that any state can elect to provide through its Medicaid program.[71] Although the federal Medicaid program provides that a state should cover all FDA-approved prescription drugs if it elects to cover prescription drugs in its Medicaid program,[72] federal law allows states to refuse coverage of fertility drugs.[73]

Currently, all state Medicaid programs, as well as the District of Columbia's Medicaid program, offer prescription drug coverage.[74] Yet, very few state Medicaid programs include fertility drugs

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66. The trade names for clomiphene citrate are clomid and serophene. ADVANCED REPRODUCTIVE CARE (ARC), HORMONAL THERAPY, *at* http://www.fertilityusa.com/hormonetherapy.html (last visited Jan. 16, 2001) [hereinafter HORMONAL THERAPY]. The drug

> blocks estrogen receptors in a part of the brain called the hypothamalus, which causes the hypothalamus to signal the pituitary gland to release more FSH (follicle stimulating hormone) and LH (luteinizing hormone) into the bloodstream. The increased levels of FSH lead to the development of the follicle and egg which secretes more estrogen into the bloodstream.

Id. The elevated levels of estrogen in the blood trigger an LH surge, and the LH surge then triggers ovulation. *Id.*

67. Brand names for gonadotropins with GnRH agonists include Pergonal, Humegon, Repronex, Gonal F, and Follistim. *Id.* These drugs act directly on the ovaries, stimulating follicle growth and maturation by imitating the body's natural FSH. *Id.*

68. The trade names for progesterone include Crinone, Suppositories, Prometrium, and Troches. *See* TREATMENT OF INFERTILITY, *supra* note 61. Progesterone is prescribed when the body's natural supply of progesterone is insufficient. *Id.* The drug "prepares the uterus to receive a fertilized egg for implantation and then acts to maintain the corpus luteum during pregnancy." *Id.*

69. The brand names for bromocriptine include parlodel and pergolide. Bromocriptine lowers the levels of prolactin—a hormone produced by the pituitary gland that promotes lactation—in a woman's body, thereby preventing irregular menstrual cycles. HORMONAL THERAPY, *supra* note 66.

70. Corticosteroids lower the levels of androgens—male type hormones—in a woman's body, promoting normal follicular development and ovulation. *Id.*

71. *See* discussion *supra* note 24 and accompanying text.

72. 42 U.S.C. § 1396r-8(k)(2)(A) (1994).

73. *Id.* § 1396r-8(d)(1)(B)(2)(B) (allowing a state to exclude drugs that promote fertility from coverage in state Medicaid programs).

74. *See* Schlosberg & Jerath, *supra* note 21; *see also* NAT'L CTR. FOR POLICY ANALYSIS, *supra* note 5 ("While states may decide whether or not to pay for prescription drugs, every state has chosen to do so."); Robert Pear, *White House Plans Medicaid Coverage of Viagra by States*, N.Y. TIMES, May 28, 1998, at A1 ("States do not have to cover prescription drugs under Medicaid, the health program for low-income people, but all states do so, in part because drugs reduce the use of hospitals and other costly services.").

in their prescription drug coverage.[75] As a result, infertile women who are denied coverage for fertility drugs under their state Medicaid programs must forego treatment altogether,[76] frequently leaving them unable to conceive a child.

IV. MEDICAID COVERAGE OF VIAGRA

Viagra[77] is an oral medication commonly used to treat erectile dysfunction.[78] The drug works by blocking phosphodiesterase 5, the enzyme that breaks down the chemical mediators of erection.[79] By allowing the chemical mediators of erection to last longer, Viagra helps improve the blood flow into the penis, thereby creating erections in men who would otherwise be impotent.[80]

A. Federal Requirements for State Medicaid Coverage of Viagra

On July 2, 1998, the United States Department of Health and Human Services sent a letter to the nation's governors ordering them to pay for the costs of Viagra under their state Medicaid programs.[81] Prior to the Department of Health and Human Services mandate, at least a dozen states had decided not to reimburse for the cost of Viagra under their Medicaid programs.[82]

The head of the HCFA[83] told the nation's governors that the provisions of Title XIX mandated coverage of Viagra.[84] She rea-

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75. *See* NATIONAL CENTER FOR POLICY ANALYSIS, *supra* note 5 (stating that virtually none of the states cover fertility treatments for women); Miller, *supra* note 5 (asserting that states objecting to mandatory Medicaid coverage of Viagra have pointed out that few Medicaid programs cover infertility treatments for women).

76. These women must forego treatment because they cannot afford to pay the costs out of their own pockets.

77. Viagra, whose generic is Sildenafil, has been approved by the FDA. CENTER FOR MALE REPRODUCTIVE MEDICINE (CMRM), WHAT'S NEW, *at* http:// www.malereproduction.com/whatsnew.htm (last visited Jan. 16, 2001) [hereinafter *What's New*].

78. *Id.* Erectile dysfunction, also referred to as impotence, is the "inability of a man to achieve or maintain an erection." CENTER FOR MALE REPRODUCTIVE MEDICINE (CMRM), FREQUENTLY ASKED QUESTIONS, *at* http://www.malereproduction.com /faq.htm (last visited Jan. 16, 2001).

79. WHAT'S NEW, *supra* note 77.

80. *Id.* "Viagra can work in up to 70% of men with impotence." *Id.*

81. "Any state Medicaid program that pays for prescription medicines must also pay for the expensive male impotence drug." NAT'L CTR. FOR POLICY ANALYSIS, *supra* note 5.

82. *See id.*; *see also* Amy Goldstein, *U.S. Tells States to Cover Viagra Prescriptions Under Medicaid*, WASH. POST, July 3, 1998, at A21.

83. Nancy-Ann Minn DeParle was the acting head of the HCFA at the time the letter was distributed.

84. Goldstein, *supra* note 82, at A21.

soned that Viagra had been approved by the FDA for the treatment of impotence and that impotence drugs were not allowed to be excluded from coverage pursuant to the statute because they were "medically necessary."[85] Furthermore, she informed the states that they would be free to set limits on how many pills patients could get in each prescription and on how many refills patients could receive.[86]

State governors responded extremely negatively to the HCFA's mandate.[87] Estimates concluded that the directive will add $100 to $200 million dollars nationwide to states' Medicaid expenses.[88] Many view the added expense as diverting funds "from other important health programs such as maternal and child welfare, H.I.V., and programs for the disabled so that roughly 10% of Medicaid recipients[89] can have adequate sex lives."[90] Furthermore, the states asserted that the mandate placed them in the "untenable position of covering Viagra for men while virtually none of them cover birth control or infertility treatments for women."[91] Finally, the states argued that the exception in Title XIX that permits states to exclude coverage of drugs used to promote fertility[92] applies to Viagra, and, thus, the HCFA's mandated coverage of Viagra violates the express provisions of Title XIX.[93]

B. Viagra as a Fertility Drug

The states' contention that Viagra should be considered a fertility drug has merit. Dissenters argue that Viagra primarily treats erectile dysfunction[94] and that it does not have any known

85. *Id.* For a listing of drugs specifically excluded from mandatory coverage by the statute, see the discussion *supra* note 30.

86. *Id.*

87. Stewart, *supra* note 2, at 612-13.

88. NAT'L CTR. FOR POLICY ANALYSIS, *supra* note 5 (citing estimates provided by the American Public Welfare Association).

89. "[Ninety percent] of Medicaid beneficiaries are women and children." Stewart, *supra* note 2, at 626.

90. *Id.*

91. Goldstein, *supra* note 82 at A21.

92. *See* 42 U.S.C. § 1396r-8(d)(2)(B) (1994) ("The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted: . . . [a]gents when used to promote fertility.").

93. Goldstein, *supra* note 82 ("[S]tates argue that the exception for fertility drugs should pertain to Viagra.").

94. *See* discussion *supra* note 78 and accompanying text.

effect on sperm production, shape, movement, or count.[95] However, a man can be infertile simply because he cannot achieve an erection, regardless of whether he has a deficiency in sperm production, shape, movement, or count. Indeed, a man unable to maintain or achieve an erection is also unable to release the sperm necessary for the fertilization process.[96] By restoring potency to men suffering from erectile dysfunction, Viagra can increase the probability that conception will be achieved.[97] Because of its ability to assist an otherwise impotent man in impregnating a woman, Viagra necessarily constitutes a fertility drug.

V. CONSTITUTIONAL CHALLENGES TO THE EXCLUSION OF FERTILITY DRUGS FROM MEDICAID COVERAGE IN LIGHT OF THE MANDATED MEDICAID COVERAGE OF VIAGRA

The classification of Viagra as a fertility drug raises severe constitutional implications for states that must now cover Viagra, yet continue to refuse coverage of female fertility drugs under their Medicaid programs. In attempting to force state Medicaid programs to cover fertility drugs, female Medicaid recipients can attack the constitutionality of the programs' current distribution of benefits. Because all state action must satisfy the constitutional requirements of both substantive due process and equal protection,[98] these recipients can certainly allege that the state Medicaid programs violate both of these constitutional requirements.

A. Substantive Due Process Claims

The first attack on a state's failure to provide coverage for prescription fertility drugs is to maintain that such failure constitutes a violation of substantive due process.[99] Female Medicaid re-

95. Mark Perloe, *Viagra & Fertility*, *at* http://www.allhealth.com/content/0,1625,69-70,00.html (last visited Jan. 16, 2001).

96. *See supra* Part III.A.2 (discussing the fertilization process).

97. Perloe, *supra* note 95 ("Viagra may improve the chances for achieving conception."). However, simply by increasing potency, Viagra does not necessarily induce the ejaculation necessary for fertilization; the drug may simply increase rigidity. *Id.* Still, Viagra may restore a man's ability to ejaculate in some cases. *Id.*

98. Thomas R. McCoy, *Recent Equal Protection Decisions—Fundamental Right to Travel or "Newcomers" as a Suspect Class?*, 28 VAND. L. Rev. 987, 988 (1975).

99. The right to general substantive due process was first recognized in the case of *Lochner v. New York*, 198 U.S. 45 (1905). The guarantee of substantive due process applies directly to the federal government through the Fifth Amendment and, as a result of the incorporation doctrine, applies to the states through the Fourteenth Amendment. *See id.* at 53-54. The constitutional

cipients seeking fertility drugs would argue that a state's refusal to cover these drugs in its Medicaid program interferes with a woman's fundamental right to procreate. In establishing a constitutionally recognized right to procreation for substantive due process purposes, these women must argue that the right to privacy[100] found in the Constitution encompasses procreation.[101]

Even if women succeed in persuading the Court that the right to privacy includes a right to procreate, however, any substantive due process claim would fail. While the Due Process Clause forbids the State from depriving an individual of "life, liberty, or property, without due process of law,"[102] the Clause "generally confer[s] no affirmative right to governmental aid, even where such aid may be necessary to secure life, liberty, or property interests of which the government itself may not deprive the individual."[103] Thus, a state actor does not have any constitutional obligation to

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right to substantive due process ensures that laws cannot "impinge upon a fundamental right explicitly or implicitly secured by the Constitution." Harris v. McRae, 448 U.S. 297, 312 (1980).

100. The seminal case recognizing a right to privacy is *Griswold v. Connecticut*, 381 U.S. 479 (1965). In *Griswold*, the Court held that a law prohibiting the distribution of contraceptives to married couples violated the couples' constitutional right to privacy. *Id.* at 485-86. Justice Douglas, who delivered the opinion of the Court, found that the right to privacy existed in the "penumbras" of the First, Third, Fourth, Fifth, and Ninth Amendments. *Id.* at 484.

101. For a general discussion of the constitutionally recognized right to procreation, see Chin, *supra* note 61, at 198-215. A number of cases support the argument that the right to privacy encompasses the right to procreation. First, in *Eisenstadt v. Baird*, the Court stated that "if the right to privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child." Einstadt v. Baird, 405 U.S. 438, 453 (1972). Second, in *Carey v. Population Services International*, the Court stated that "the teaching of *Griswold* is that the Constitution protects individual decisions in matters of childbearing from unjustified intrusion by the State . . . [and] it [is] clear that among the decisions that an individual may make without unjustified government interference are personal decisions 'relating to marriage; procreation; contraception; family relationships; and child rearing and education.' " Carey v. Population Servs. Int'l, 431 U.S. 678, 684-87 (1977). Third, in *Skinner v. Oklahoma*, the Court stated that "[m]arriage and procreation are fundamental to the very existence and survival of the race." Skinner v. Oklahoma, 316 U.S. 535, 541 (1942).

102. U.S. CONST. amend. V.

103. Chin, *supra* note 61, at 215 (referring to the Court's decision in *DeShaney v. Winnebago County Dep't of Soc. Servs.*, 489 U.S. 189, 196 (1989)). Several cases have recognized the lack of affirmative obligation by the government with respect to reproductive services. In *Maher v. Roe*, the Court noted that "[t]he Constitution imposes no obligation on the States to pay the pregnancy-related medical expenses of indigent women, or indeed to pay any of the medical expenses of the indigents." Maher v. Roe, 432 U.S. 464, 469 (1977). Furthermore, in *Harris v. McRae*, the Court stated that "[a]lthough the liberty protected by the Due Process Clause affords protection against unwarranted government interference with freedom of choice in the context of certain personal decisions, it does not confer an entitlement to such funds as may be necessary to realize all the advantages of that freedom." Harris v. McRae, 448 U.S. 297, 317-18 (1980).

either provide fertility drugs or to fund them,[104] and the substantive due process claim is largely without merit.

B. Equal Protection Claims

With the failure of their substantive due process argument, the female Medicaid recipients should instead focus on an equal protection claim. The Fourteenth Amendment provides that "[n]o State shall . . . deny to any person within its jurisdiction the equal protection of the laws."[105] In essence, any time a state actor makes a law resulting in a favored and a disfavored class, a potential equal protection problem arises.[106] The recipients could argue that the provisions regarding Medicaid coverage of Viagra and fertility drugs clearly favor men over women, and, accordingly, the regulation must either be altered so that it mandates coverage of fertility drugs for women, or that the government must retract the requirement that states provide Medicaid coverage of Viagra.

1. The Traditional Equal Protection Construct

Judicial precedent has established a traditional equal protection construct identifying the factors that the Court takes into account when deciding whether a regulation violates the constitutional guarantee to equal protection. Namely, the Court examines three factors in making its decision: whether an inequality of treatment exists; the nature of the right affected by the inequality; and whether the inequality is based on a suspect classification.[107]

a. Determining Whether an Inequality of Treatment Exists

The first step in any equal protection case involves the determination of whether a given law treats two classes of people dif-

104. *See* Chin, *supra* note 61, at 215 (recognizing that a state neither has to fund nor provide reproductive services).

105. U.S. CONST. amend. XIV, § 1.

106. Candace Saari Kovacic-Fleischer, *United States v. Virginia's New Gender Equal Protection Analysis with Ramifications for Pregnancy, Parenting, and Title VII*, 50 VAND. L. REV. 845, 858 (1997).

107. *See generally* McCoy, *supra* note 98 (analyzing recent equal protection decisions involving "newcomers" and the fundamental right to travel).

ferently.[108] The Court typically does not find that an inequality exists when a regulation disadvantages an "opt-in/opt-out" class;[109] however, if the Court detects that the class affected by the regulation cannot readily change the characteristic that initially subjected them to the regulation, the Court will likely find that the class is not "opt-in/opt-out" and that an inequality of treatment exists.[110] Furthermore, if the Court can detect a discriminatory purpose for the regulation, it will likely find that an inequality of treatment exists.[111] In the majority of equal protection cases, the Court finds an inequality of treatment; however, the possibility always remains that they will decline to do so.[112]

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108. *See, e.g.*, Ry. Express Agency, Inc. v. New York, 336 U.S. 106 (1949) (discussing a regulation which distinguishes between "advertisements of products sold by the owner of [a] truck" as opposed to "general advertisements").

109. An opt-in/opt-out class is one in which the members may freely choose to be affected by the regulation. *See id.* at 109 (The regulation prohibited truck owners from advertising anything other than their own products.).

110. For example, in *Railway Express Agency, Inc. v. New York*, a city ordinance banning rented vehicular advertising, yet continuing to allow truck owners to advertise their own businesses on their trucks, was challenged on equal protection grounds. *Id.* at 106. Although the argument could be made that this regulation only affected an opt-in/opt-out class because any individual was free to buy his own truck and engage in vehicular advertising, the Court still found that an inequality of treatment existed as a result of the regulation. *Id.* at 109. In doing so, the Court implied that it was willing to overlook the fact that a class could technically be described as opt-in/opt-out when an individual had already opted-in to a particular class before the state enacted the regulation and, therefore, there was a smell of permanence about the class because its membership was defined independently of the regulation. *See id.* at 110-11; *see generally* Skinner v. Oklahoma, 316 U.S. 535 (1942) (finding that a state statute providing for mandatory sterilization of three-time felons convicted of felonies involving moral turpitude resulted in an inequality of treatment because, although felons could technically choose to commit felonies involving moral turpitude and thereby place themselves in the affected class, felons who had entered the class prior to enactment of the law could not choose to opt-in or opt-out).

111. *See* Harper v. Va. Bd. of Elections, 383 U.S. 663, 668-70 (1966). In *Harper v. Virginia State Board of Elections*, an equal protection challenge was brought against Virginia's imposition of $1.50 poll tax. *Id.* at 664 & n.1. Although the classes affected by the poll tax could be described as opt-in/opt-out, because anybody could choose to pay the $1.50 and vote, the Court found that an inequality of treatment did exist in the regulation. *See id.* at 668-70. In doing so, the Court seemed to focus on the exclusionary purpose of the regulation. *See id.* Clearly, the regulation sought to keep the poor away from the polls, and, since the poor were comprised largely of racial minorities, courts could infer an intent to discourage racial minorities from voting. *See id.*

112. *See, e.g.*, James v. Valtierra, 402 U.S. 137 (1971) (holding that requiring advocates of low-income housing to get approval from both the legislature and local municipalities to effect change did not violate equal protection). In *James v. Valtierra*, the plaintiffs challenged a state constitutional requirement that advocates of low-income housing had to get approval from both the legislature and the local municipality, while advocates of other subsidized housing only had to get approval from the legislature. *Id.* at 139. The Court rejected the equal protection claim. *Id.* at 142-43. It is possible that the Court applied the rational basis test and the requirement failed it. However, the fact that the Court never referenced the appropriate standard of scrutiny creates a strong possibility that the Court actually determined that there was no inequality in making groups who have been the "losers" in the majoritarian process go through extra electoral hurdles.

b. Classification of the Interest Affected by the Unequal Treatment

Assuming the Court finds an inequality of treatment, it next evaluates the type of interest affected by the inequality. The Courts recognize two types of interest for equal protection purposes: fundamental interests and non-fundamental interests. Fundamental interests for equal protection purposes necessarily encompass all rights deemed fundamental for substantive due process purposes,[113] but, for the most part, the Court uses its subjective judgment to decide whether a right should be classified as fundamental for equal protection purposes.[114] Furthermore, the Court has held that a state benefit scheme cannot be considered a fundamental right for equal protection purposes.[115] Economic interests also tend to be classified as non-fundamental rights for equal protection purposes.[116]

Once the Court classifies the interest affected by the unequal treatment, it applies a standard of scrutiny to the challenged regulation based on that classification. A regulation that creates unequal treatment affecting a non-fundamental interest receives the rational basis test: The Court determines whether the regulation serves a legitimate government interest and whether the means used are rationally related to the achievement of that interest.[117] The rational basis test affords a high level of judicial deference to

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113. While the Founding Fathers created the legislature to interfere with individual rights, they did not intend for the legislature to interfere with individual rights unequally. Thomas R. McCoy, Address to the Vanderbilt Law School Constitutional Law II Class (Oct. 21, 1999). Thus, there should necessarily be a longer list of fundamental rights in equal protection cases than in substantive due process cases because the legislature should be subjected to strict scrutiny when it attempts to interfere with individual rights unequally. *Id.*

114. *See* Kay, *supra* note 15, at 370 n.83 (noting that "[r]ights are identified as 'fundamental' based on a substantive decision by the Court") (citation omitted).

115. *See, e.g.*, San Antonio Indep. Sch. Dist. v. Rodriguez, 411 U.S. 1, 38-39 (1973). In *Rodriguez*, a state scheme of funding public education based on district property taxes and distributing more money to districts that paid more in property taxes faced a challenge on equal protection grounds. *Id.* at 5-6. In addressing the issue of whether public education was a fundamental right, the Court stated that the key to deciding whether a right is fundamental lies in determining whether that right is "explicitly or implicitly guaranteed by the Constitution." *Id.* at 33. The Court next reasoned that public education was a state benefit and, therefore, was neither explicitly or implicitly guaranteed by the Constitution. *Id.* at 35-36. Accordingly, the Court refused to recognize the right to public education as a fundamental right. *Id.* at 33-36.

116. *See generally* Ry. Express Agency, Inc. v. New York, 336 U.S. 106 (1949) (refusing to afford the heightened scrutiny of the compelling interest test to a regulation that prohibited rented vehicular advertising, thereby implying that the individual interest in rental income at stake was not fundamental for equal protection purposes).

117. *Rodriguez*, 411 U.S. at 55 (stating that the rational basis test to be applied when dealing with a non-fundamental right is "whether the challenged state action rationally furthers a legitimate state interest or purpose").

the legislature, and very rarely does a state regulation *not* pass the rational basis test. Alternatively, a regulation that creates unequal treatment affecting a fundamental interest receives the compelling governmental interest test: The Court decides whether the regulation serves a compelling government interest and whether the means are narrowly tailored to achieve that interest.[118]

c. Unequal Treatment Based on a Suspect Classification

When considering whether a regulation's inequality of treatment violates the Equal Protection Clause, the Court also looks to see if the regulation creates a suspect classification. Although the government "may classify individuals or 'draw lines' when creating and implementing certain laws," any groupings that are arbitrary or based on impermissible criteria are deemed suspect classifications.[119]

In determining whether a regulation creates a suspect classification, the Court first inquires whether the classification affects a "suspect class." Traditional equal protection doctrine finds a suspect class exists if the class meets three criteria:[120] (1) the class has an immutable characteristic;[121] (2) the class is a political minority;[122] and (3) the class has been traditionally disadvantaged.[123]

If the Court finds that the inequality created by the regulation does not affect a suspect class, it applies the rational basis test to the regulation.[124] Conversely, if the classification does affect a

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118. *Id.* at 31 (stating that when a regulation penalizes the exercise of a constitutional right, the regulation must be necessary to promote a compelling governmental interest).

119. Kay, *supra* note 15, at 369.

120. Lyng v. Castillo, 477 U.S. 635, 638 (1986) (stating that suspect classes are comprised of members who have been subjected to discrimination, who exhibit obvious, immutable, or distinguishing characteristics that define them as a discrete group, and who are a minority or politically powerless).

121. An immutable characteristic is one "not susceptible to change; unchanging or unchangeable." AM. HERITAGE DICTIONARY 346 (2d ed. 1983). In *Frontiero v. Richardson*, when determining whether women constituted a suspect class, the Court stated that immutable characteristics are "determined solely by the accident of birth." Frontiero v. Richardson, 411 U.S. 677, 686 (1973).

122. The Court deems a class a political minority if the group is "incapable of protecting its interests through the usual political process." McCoy, *supra* note 98, at 1017. The "traditional indicia of suspectness" are that the class be "saddled with such disabilities, or subjected to such a history of purposeful unequal treatment, or relegated to such a position of political powerlessness as to command extraordinary protection from the majoritarian political process." *Rodriguez*, 411 U.S. at 28.

123. A class is traditionally disadvantaged if it suffers from a "long history of irrational or unnecessary legal discrimination." McCoy, *supra* note 98, at 1020.

124. *See id.* at 993 ("Any inequality in the treatment accorded two separate classes of persons by the state must be rationally related to the effectuation of a legitimate state interest.").

suspect class, the Court affords the regulation a higher standard of scrutiny.[125] The level of heightened scrutiny applied by the Court when it finds that a suspect classification exists may be either intermediate scrutiny or strict scrutiny, depending on whether the Court classifes the underlying suspect class as clearly suspect[126] or quasi-suspect.[127] If the Court finds the underlying suspect class to be clearly suspect, it affords the regulation the strict scrutiny of the compelling government interest test, looking to see whether the regulation serves a compelling government interest and whether the means used to achieve this legislative goal are narrowly tailored to achieve that interest.[128] On the other hand, if the Court discovers that the underlying suspect class is merely quasi-suspect, the regulation only receives intermediate scrutiny, and the government must show "that the classification serves 'important governmental objectives and that the discriminatory means employed' are 'substantially related to the achievement of those objectives.' "[129]

2. The Equal Protection Problem Created by State Medicaid Programs Covering Viagra While Excluding Other Fertility Drugs

In challenging mandated Medicaid coverage of Viagra, female Medicaid recipients would need to convince the Court that a state refusing to provide Medicaid coverage for female fertility drugs while providing Medicaid coverage for Viagra denies the recipients' their constitutional right to equal protection of the laws. The recipients would first argue that an inequality of treatment does in fact exist as a result of the coverage discrepancies. If the Court accepts the contention that an inequality of treatment exists, the recipients can next argue that the Court should afford the coverage plans a heightened level of judicial scrutiny, as opposed to the

125. *See id.* at 992-94.

126. The Court defines a class as clearly suspect when it meets all three suspect class criteria. Currently, courts clearly treat race, alienage, and lineage as characteristics for valid suspect classes. *Id.* at 991 ("[O]nly race, alienage, and lineage have been clearly established as 'suspect' classifications for equal protection purposes.").

127. A class is likely to be deemed quasi-suspect when it meets some, but not all, of the suspect class criteria. *See* Thomas R. McCoy, Address to the Vanderbilt Law School Constitutional Law II Class (Nov. 11, 1999).

128. *See* San Antonio Indep. Sch. Dist. v. Rodriguez, 411 U.S. 1, 56 (1973).

129. Miss. Univ. for Women v. Hogan, 458 U.S. 718, 724 (1982) (citation omitted).

rational basis test, so that they increase their chances of a successful outcome.[130]

a. The Existence of an Inequality

A state Medicaid program's refusal to cover fertility drugs while providing coverage for Viagra results in an inequality of treatment. By providing coverage for Viagra, a state gives men who receive Medicaid benefits and who suffer from infertility a means of overcoming their problem through the use of a male fertility drug.[131] Meanwhile, women who receive Medicaid benefits and suffer from infertility cannot undergo treatment with female fertility drugs unless they pay for the treatment themselves.[132] Moreover, women cannot freely change their sex; therefore, they are not part of an opt-in/opt-out class and cannot freely choose to be affected by the regulatory scheme. Indeed, this bolsters the case for finding an inequality of treatment.[133]

b. The Inequality as Affecting a Fundamental Right

Due to the fact that fundamental interests for equal protection purposes encompass all rights deemed fundamental for substantive due process purposes,[134] a petitioner may argue that a state's refusal to cover female fertility drugs under Medicaid denies women the fundamental right to procreate. In arguing the existence of a fundamental right to procreate for equal protection purposes, a petitioner would reiterate and parallel the argument made in proclaiming the existence of a fundamental right to procreation for substantive due process purposes, citing to cases such as *Eisenstadt*, *Carey*, and *Skinner*.[135]

However, just as in substantive due process, any argument made that the state Medicaid program's denial to women of the fundamental right to procreate will fail. Through its Medicaid pro-

130. For an explanation of why the rational basis test decreases the chances of a successful outcome for the recipients, see discussion *supra* Part V.B.1.b.

131. For a discussion of Viagra as a male fertility drug, see discussion *supra* Part IV.B.

132. As discussed earlier in this Note, the fertility drugs currently available are designed to correct reproductive abnormalities in women. *See supra* notes 66-70 and accompanying text. Before Viagra, men who suffered from infertility had to resort to either surgical procedures or to artificial reproductive technologies to try and correct their problem.

133. *See* discussion *supra* Part V.B.1.a.

134. *See supra* note 114 and accompanying text.

135. For a discussion of these cases and their use as support for the notion that a fundamental right to procreate exists, see *supra* note 101.

gram, the state distributes a benefit to individuals, and the Court has explicitly held that state benefit schemes cannot be considered fundamental rights for equal protection purposes.[136]

Hence, the Court would classify the interest affected by the inequality as non-fundamental and would apply the rational basis test,[137] and the recipients would most likely lose under this highly deferential standard.[138]

c. The Inequality as Based on a Suspect Classification

A state Medicaid program that covers Viagra and does not cover fertility drugs distributes benefits unequally among men and women.[139] The Court has held that inequalities defined by gender distinctions must be considered inequalities based on a suspect classification.[140]

1. The Need for a Heightened Standard of Scrutiny

The Court typically affords gender classifications the intermediate level of scrutiny[141] and requires that the "classification serve[ ] 'important governmental objectives and that the discriminatory means employed' are 'substantially related to the achievement of those objectives.' "[142] Nevertheless, in *United States v. Virginia* (*VMI*),[143] the Court indicated its willingness to deviate from the traditional intermediate level of scrutiny when dealing with

136. San Antonio Indep. Sch. Dist. v. Rodriguez, 411 U.S. 1, 55 (1973) (holding that the state benefit of public education could not be deemed a fundamental right).

137. *Id.* at 55 (holding that the rational basis test should be applied to an inequality affecting a non-fundamental right).

138. Due to a high level of judicial deference to the legislature, the state passes the rational basis test a majority of the time. *See* McCoy, *supra* note 98, at 989 (describing the rational basis test as a "tolerant standard").

139. Men necessarily have no use for the kind of fertility drugs excluded from coverage, considering that drugs essentially treat ovulation disorders and men do not ovulate. Likewise, because Viagra treats infertility by restoring the ability to sustain an erection, women cannot use Viagra for fertility purposes.

140. *E.g.*, Craig v. Boren, 429 U.S. 190, 197-99 (1976).

141. *Id.* at 199-200. Gender classifications are afforded an intermediate level of scrutiny rather than the strict scrutiny of the compelling governmental interest test because women have been identified as a "quasi-suspect" class. *See* Frontiero v. Richardson, 411 U.S. 677, 686 (1973) (recognizing that women meet the criteria of having an immutable characteristic and being traditionally disadvantaged, but stating that women do not constitute a small and powerless minority).

142. Miss. Univ. for Women v. Hogan, 458 U.S. 718, 724 (1982) (citation omitted).

143. United States v. Virginia, 518 U.S. 515 (1996) [hereinafter *VMI*] (challenging the Virginia Military Institute's male-only admissions policy).

gender classifications. Instead of applying the intermediate level of scrutiny, the *VMI* Court elevated the applicable level of scrutiny, stating that the government must show an "exceedingly persuasive" justification for the inequality of treatment.[144]

The *VMI* Court implicitly justified its heightened scrutiny of the regulation by focusing on the history of discrimination against women in the area of public education.[145] The Court stressed that women had been deliberately excluded from educational opportunities for hundreds of years, and that even after some opportunities were opened to women, the resources made available to women were "far from equal" to those made available to men.[146] Thus, one can conclude that, by raising the requisite government interest from important to "exceedingly persuasive,"[147] the *VMI* Court recognized the need to protect women from regulations that perpetuated a tradition of historical gender discrimination.

Just as they have faced repeated discrimination in education, women have encountered recurrent discrimination in the area of health care.[148] The United States health care industry and medical profession have their basis in "patriarchy and a demeaning view of women."[149] Women's health interests have been consistently overlooked by the legislature, and the minimal amount of women's health care legislation passed addresses women solely in the role of childbearer and childraiser.[150] Repeated attempts by the government to limit impoverished women's reproductive rights serve as even greater proof of discrimination against women in the realm of health care.[151]

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144. *Id.* at 533; *cf. Craig*, 429 U.S. at 197 (stating that the government must show that the inequality serves "important government objectives and must be substantially related" to that objective).

145. *VMI*, 518 U.S. at 531-32

146. *Id.* at 538. The Court held that: "[T]he historical record indicates action more deliberate than anomalous: First, protection of women against higher education; next, schools for women far from equal in resources and stature to schools for men . . . ." *Id.* at 538.

147. *See id.*

148. Susan L. Waysdorf, *Fighting for their Lives: Women, Poverty, and the Historical Role of United States Law in Shaping Access to Women's Health Care*, 84 KY. L.J. 745, 746 (1995-96) ("With regard to health care, a key sphere of life, women continue to constitute an oppressed group, disempowered legally, politically, and as consumers in the health care system.").

149. *Id.* at 756.

150. *Id.* at 767-68. Furthermore, the government has used women's role as childbearers to prevent women access to improved health care. *See id.* at 768 n.70 ("[F]ederal rules and regulations have traditionally excluded women from participating in potentially beneficial clinical research and drug trials precisely because of women's reproductive role.").

151. Beginning in 1990, multiple bills were introduced in state legislatures that attempted to force women receiving public assistance to use Norplant, a hormonal contraceptive implant that has a duration of five years. Sarah Gill, *Discrimination, Historical Abuse, and the New*

Accordingly, in order to maintain consistency with the *VMI* Court's reasoning that an invidious history of gender discrimination warrants scrutiny greater than intermediate scrutiny, any inequality of treatment favoring men over women in the area of health care must be afforded a heightened level of scrutiny because of the long history of discrimination against women in health care policies. Indeed, the appropriate level of heightened scrutiny is precisely the one articulated in *VMI*:[152] whether the government can show an "exceedingly persuasive" interest in the inequality of treatment and whether the discriminatory means employed are substantially related to the achievement of the government's interest.[153]

2. Applying the Standard of Scrutiny

Under the *VMI* standard of heightened scrutiny, the burden falls on the state to demonstrate an exceedingly persuasive justification for the inequality of treatment resulting from covering Viagra while excluding coverage of female fertility drugs under Medicaid. The state would likely advance two arguments that such a justification exists. First, the state would assert that the substantial difference in cost between Viagra and female fertility drugs justifies the coverage discrepancy. Second, the state would argue that Viagra is medically necessary and must be covered under Medicaid, whereas female fertility drugs, while perhaps beneficial, are not medically necessary.

Norplant Problem, 16 WOMEN'S RTS. L. REP. 43, 45 (1994). One such bill conditioned receipt of public assistance benefits on Norplant insertion, and another bill provided financial incentives for low-income women who agreed to use Norplant. *See id.* Likewise, several bills offered recipients of Aid to Families with Dependent Children benefits similar incentives to either obtain depo provera injections or become sterilized. *See id.*

152. The argument has been made that gender classifications should receive the same level of scrutiny as racial classifications: the strict scrutiny of the compelling governmental interest test. *E.g.*, Kay, *supra* note 15, at 372-80 (advocating applying strict scrutiny to gender classifications). This has not been a winning argument, however, and it appears that the greatest chance for obtaining anything greater than intermediate scrutiny from the Court involves waging a *VMI* argument.

153. This level of scrutiny is actually a hybrid of intermediate scrutiny and "exceedingly persuasive scrutiny." The "exceedingly persuasive" interest replaces the intermediate level of scrutiny's "important governmental objective," but the remainder of the intermediate level of scrutiny, which addresses whether the discriminatory means employed are substantially related to the achievement of that interest, remains the same. The *VMI* Court only heightened the government interest requirement; they did not mention any changes as to the relation the means must have to achieving the interest and, thus, it is assumed that the means requirement remained the same.

With regard to its first argument, the state would emphasize the fact that Viagra costs ten dollars a pill,[154] while female fertility drug treatments can cost up to three thousand dollars before conception is achieved.[155] The state would then argue that Medicaid coverage of female fertility drugs would divert a tremendous amount of funds from other important aspects of the program, such as child welfare and programs for the disabled. While this argument sounds credible on its face, a close examination of the actual circumstances surrounding the use of the various drugs by Medicaid recipients illustrates its downfalls.

Although Viagra costs only ten dollars a pill, men may use Viagra multiple times a month.[156] States can limit the amount of Viagra a recipient receives each month,[157] but, even then, the recipient still will likely receive at least four pills per month.[158] Furthermore, men can use Viagra throughout their life spans.[159] Thus, the actual cost of providing Viagra could potentially reach at least four hundred and eighty dollars a year over several years.[160]

Meanwhile, fertility drugs may be used only during the years that a woman menstruates and will only be taken if a woman attempts to conceive a child. Very few female Medicaid recipients will make use of the coverage of fertility drugs in comparison to the number of male Medicaid recipients who will seek coverage for Viagra.[161] Low-income women, who are the most likely to face infertility problems,[162] are the least likely to seek infertility services.[163] Although some of the reluctance to seek infertility treatments results from the unavailability of coverage for such treatments, low-income women, in general, are less likely to see infertility as a medical problem and, therefore, are less likely to view it as a correctable condition.[164] Hence, even if Medicaid coverage is made

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154. *See Viagra May be Linked to Six Heart Deaths*, 14 No. 1 ANDREWS PHARM. LITIG. REP. 3 (June 1998), *at* http://www.westlaw.com.

155. *See* Kerr, *supra* note 52, at 605.

156. Because Viagra enables men to achieve and maintain an erection, it becomes necessary for impotent men to use it whenever they desire to have sex.

157. *See Viagra May be Linked to Six Heart Deaths*, *supra* note 154.

158. *See* Miller, *supra* note 5 (stating that some insurers limit use to four pills per month).

159. This is in contrast to a woman's limited use for fertility drugs.

160. This number was derived by multiplying the ten dollars a pill by an estimated four allowed pills a month for twelve months.

161. *See infra* note 163.

162. *See* Heitman, *supra* note 55, at 93; *see also* discussion *supra* Part III.A.1.

163. *See* Heitman, *supra* note 55, at 93 (noting that only 8% of poor women sought specialized fertility services, compared with 32% of affluent women).

164. *Id.*

available for female fertility drugs, it remains unlikely that a large number of female Medicaid recipients will make use of those services and, accordingly, the cost of supplying fertility drugs under Medicaid will not be consuming.

The states' contention that providing Viagra coverage under Medicaid costs less than providing fertility drugs is true only if one does not actually consider all of the circumstances surrounding the use of the various drugs. Once all of the information is examined, however, it becomes clear that paying for Viagra could actually cost the state more over time than paying for female fertility drug treatments. Considering this fact, the Court should not find that a state's claim that the cost difference among the drug treatments constitutes an exceedingly persuasive justification for the inequality created by the contrasting coverage schemes.

The state would next attempt to persuade the Court that fertility drugs for women should not be covered because they are not medically necessary, whereas Viagra is necessary to treat a medical condition. The state's argument would likely focus on the claim that Viagra is used to treat erectile dysfunction, a disease that makes a man unable to achieve and sustain an erection. The state would contend that any effect that Viagra has in treating infertility is secondary to its intended use for impotence and that Viagra cannot accurately be classified as a fertility drug. Meanwhile, the state would also attempt to convince the Court that infertility is not a disease, and, thus, the use of fertility drugs is not medically necessary.

These arguments can be defeated rather easily. Several courts have officially defined "disease", and the definitions advanced have included "[a] deviation from the healthy or normal condition of any of the functions . . . of the body," and "[a] disturbance in function or structure of any . . . part of the body."[165] Thus, because any person suffering from infertility obviously has an abnormal reproductive system, there is accordingly no doubt that infertility is, and should be treated as, a disease.

> [M]any poor and non-white women who have endured other hardships and who consequently may not focus on issues of personal control, may experience infertility more in terms of general adversity. If infertility is one in a series of negative, seemingly irreversible events in a woman's life, she may be more likely to attribute it to fate or God's will than to seek to address it through science.

Id. at 94.

165. Kerr, *supra* note 52, at 607 (quoting *Order of the United Commercial Travelers v. Nicholson*, 9 F.2d 7, 14 (2d Cir. 1925), Blalock v. City of Portland, 291 P.2d 218, 221 (Or. 1955)).

Furthermore, fertility drugs for women are a medical necessity if these women wish to ever become pregnant. Infertile women cannot remedy their condition without fertility drugs or other fertility treatments, such as in vitro fertilization. Some commentators have argued that, because fertility drugs do not cure a women's reproductive abnormalities but instead provide temporary relief from the problem, the drugs cannot be considered a medical necessity.[166] This argument is self-defeating, however, as it destroys the assertion that Viagra is medically necessary.[167] Viagra does not permanently cure erectile dysfunction; it merely provides temporary relief from the problem so that a man can have sexual intercourse. Thus, if the state does proceed with this line of reasoning, the Court should be able to clearly see the hypocrisy in the states' assertions that infertility is not a disease and that fertility drugs are not medically necessary. As a result, the Court should again refuse to acknowledge this distinction as a persuasive justification for the inequality of treatment. Accordingly, the state will have failed to meet its burden of producing any exceedingly persuasive justification for covering Viagra under Medicaid while refusing to cover other forms of fertility drugs for women.[168]

VI. CONCLUSION

Due to the state's failure to produce an exceedingly persuasive interest that is served by the inequality of treatment, courts must mandate that, in order to correct the state's violation of the Equal Protection Clause, any state covering Viagra under its Medicaid program must also cover fertility drugs for women. Of course, because all states are required to cover Viagra by HCFA mandate, this means that all states will thus be required to amend their Medicaid programs to cover fertility drugs.

Following such a ruling, the state may attempt to avoid covering fertility drugs by challenging HCFA-mandated Viagra coverage. The state will allege that the HFCA's mandate that state Medicaid programs cover should be revoked because it violates the

166. *E.g.*, Kinzie v. Physician's Liab. Ins. Co., 750 P.2d 1140, 1142 (Okla. Ct. App. 1987) (holding that in vitro fertilization procedures were not medically necessary for purposes of insurance coverage because they do not cure or preserve a woman's health and because it is not medically necessary to a woman's health to have a baby).

167. The argument that Viagra is medically necessary has been advanced by the Department of Health and Human Services. *E.g.*, Pear, *supra* note 74 at A1.

168. Because no legitimate exceedingly persuasive interest served by the inequality will be advanced by the state and accepted by the Court, there will be no need for the Court to even inquire into whether the means chosen serve the exceedingly persuasive government interest.

Equal Protection Clause by failing to also provide mandatory coverage for female fertility drugs.[169] In this sense, the state will make the same argument to the Court that the female Medicaid recipients wanting coverage for fertility drugs made: In order to be constitutional, mandated coverage of Viagra must be accompanied by mandated coverage of fertility drugs.[170]

In the face of such a challenge, it is probable that the HCFA will rethink its mandate. Requiring states to cover both Viagra and other fertility drugs would be very costly to state Medicaid programs.[171] Moreover, taxpayers have been resistant to the coverage of these types of programs,[172] and, as a government agency, the HCFA must take public response into account when making its decisions.[173]

Hence, a successful challenge to a state's refusal to cover fertility drugs for women while providing Viagra to men could result in either mandated coverage for both Viagra and fertility drugs, or may have the converse effect of eliminating coverage for both Viagra as well as fertility drugs. Either one of these outcomes, regardless of its desirability, would in fact rectify the equal protection problem inherent in the current scheme of funding.

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169. As one commentator observed, "The standard of judicial review used for both the Secretary of the Department of Health and Human Services' and the Administrator of the Health Care Financing Administration's decisions regarding the Medicaid program has generally been that of 'arbitrary, capricious, abuse of discretion, or otherwise not in accordance with the law.' " Stewart, *supra* note 2, at 621-22. For a more detailed discussion of the procedures necessary to challenge a federal Medicaid mandate, see *supra* Part II.E.

170. For a discussion of states' options in challenging the HCFA's mandated Medicaid coverage of Viagra, independent of the equal protection argument, see generally Stewart, *supra* note 2.

171. *See* discussion *supra* notes 156-160.

172. Heitman, *supra* note 55, at 91.

> The public [has] objected most strongly to coverage for the treatment of [ ] infertility: 63% of the 260 women receiving fertility drugs . . . already had one or more children, and 2 had 8 children each. Critics of the program insisted that the desire to have children was not a medical problem, and that treating infertility at state expense worked against society's interest in preventing the birth of children who would be dependent on public assistance.

Id.

173. The HCFA necessarily considers the public's response to its decisions because the agency is accountable to the President of the United States, and the President typically views the public's response as important for re-election purposes.

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