April 09, 2009

Office of Public Health and Science
Department of Health and Human Services
Attention: Rescission Proposal Comments
Hubert H. Humphrey Building
200 Independence Avenue SW
Room 716G
Washington, DC 20201

Re: Rescission Proposal (RIN 0991-AB49)

Comments of the National Latina Institute for Reproductive Health, the National Asian Pacific American Women's Forum, the Center for Reproductive Rights, and Other Organizations, In Support of the Department of Health and Human Services' Proposal to Rescind the Regulation Entitled "Ensuring that Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law."

Introduction

We, the undersigned organizations write to express our grave concerns about the current regulation entitled "Ensuring that Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law" ("Regulation") and to express our support for the proposal to rescind the Regulation.[1] Each of our organizations is committed to ensuring that every woman has access to reproductive health care, placing special emphasis on the needs of low-income women and women of color. Although the Regulation has only been in effect for a few months, it is clear that it detrimentally impacts low-income women seeking reproductive health care, and other vulnerable groups, including those seeking end-of-life care, persons affected by HIV/AIDS, and lesbian, gay, bisexual and trans-sexual individuals. In support of the Rescission Proposal, we highlight below

[1] 45 C.F.R. §§ 88.1-.6 (2009)

some of the serious flaws in the Regulation, focusing primarily on its impact on low-income and minority women.

The Regulation undermines access to health care in this country. It dramatically expands the reach of federal laws protecting health care workers, rather than simply clarifying and enforcing them. It creates uncertainty in a number of areas, including whether provisions that protect those opposed to abortion services can be relied on to deny certain forms of contraception. The Regulation also creates potential conflicts with other federal laws, including Title VII, which strikes a careful balance between the employees' right to religious freedom, the rights of employers, and the needs of patients. The Regulation allows a broad range of health care workers, including those only tangentially related to the provision of services, to deny information and access to care.

The Regulation's most glaring defect is its failure to address, much less mention, the rights and needs of patients. Instead, the Regulation limits a patient's access to health care, and creates confusion and uncertainty – the problems it will cause for individual patients is nowhere taken into account. Moreover, the cost-benefit analysis included in the Regulation is based on unfounded assumptions and does not even attempt to measure the cost of the Regulation from the "patient" side of the equation.

The Regulation is hopelessly flawed and unnecessary and must be rescinded. Health care providers in this country who entertain religious or moral objections to the provision of certain health care services are already adequately protected by federal law, and are not in need of further protections. On the other hand, low-income women and women of color struggle every day to obtain the health care they need and the Regulation only makes this struggle more difficult. Too much is at stake for the women who will be denied access to critical reproductive health care to continue on this dangerous course set by the Regulation.

The Regulation Should Be Rescinded Because It Undermines Access to Health Care

The Regulation changes three federal laws governing health care refusals in several ways that will negatively impact patients seeking medical treatment and information. The three laws affected by the Regulation are the Church Amendment,[2] the Weldon Amendment,[3] and Section 245 of the Public Health Service Act,[4] all of which already provide comprehensive protection for health care workers who do not want to provide certain services based on their religious beliefs or moral convictions.

A. The Regulation Could Lead to the Denial of Critical Contraception Options

The Regulation creates dangerous uncertainty as to whether health care providers could now rely on federal law permitting conscientious refusals to provide abortion services to deny common forms of birth control, such as the Pill and IUDs. The Department of Health and

[2] 42 U.S.C. §300a-7 (2008).
[3] Consolidated Appropriations Act, 2008, Pub. L. No. 110-161, Div. G, §508(d), 121 Stat. 1844, 2209 (Dec. 26, 2007)
[4] 42 U.S.C. §238(n) (2008).

Human Services ("the Department") created this ambiguity and the Regulation should be rescinded because it fails to clearly address this issue.

A preliminary draft of the Regulation included a definition of "abortion" that encompassed methods of contraception which can in some instances prevent implantation of a fertilized egg, such as the birth control pill and IUDs. [5] As a result, under the preliminary draft, health care providers were given explicit permission to refuse to provide these forms of contraception on the grounds that they were equivalent to providing abortion services. In the final Regulation, the definition of "abortion" was removed altogether, creating uncertainty as to the extent to which the Regulation expands current federal refusal laws. The suggestion from the preliminary draft that abortion could include some forms of contraception has opened the door for health care entities and individuals to define abortion expansively as a justification for denying care.

The negative impact of the ambiguity over whether federally funded health care providers can refuse to provide contraceptives falls directly on patients, and specifically on low-income women whose only access to prescription birth control is through federal programs such as Medicaid and Title X. While there are legal and administrative procedures in place that will ultimately determine if a health care provider was within its rights to equate contraception with abortion, those processes will not ameliorate the harm done to individual women who have been denied timely access to the birth control option that best meets their needs.

B. The Regulation Extends the Ability to Deny Services to Those with Minimal Connection to Patient Care

The Regulation extends the right to refuse health services to a broader range of workers than previously permitted, including those who are only tangentially related to the provision of health care. The Regulation defines the term "assist in the performance"[6] for the first time, and also defines some of the terms included in this definition and used elsewhere in the statutes, including, "individual,"[7] "workforce,"[8] and "health service/health service program."[9] In the

[5] The definition proposed in the preliminary draft was contrary to definitions accepted by both the American Medical Association and the American College of Obstetricians and Gynecologists. *See*, Department of Health and Human Services Proposed Rule at 30; Rachel Benson Gold, Guttmacher Inst., *The Implications of Defining When a Women Is Pregnant*, 8 Guttmacher Rep. on Pub. Pol'y 7-10, 7-8 (May 2005), *available at* http://www.guttmacher.org/pubs/tgr/08/2/gr080207.pdf (*citing* American College of Obstetricians and Gynecologists).

[6] "Assist in the Performance" is defined as "to participate in any activity with a reasonable connection to a procedure, health service or health service program, or research activity, so long as the individual involved is a part of the workforce of a Department-funded entity. This includes counseling, referral, training, and other arrangements for the procedure, health service, or research activity." Ensuring that Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices In Violation of Federal Law, 45 C.F.R. § 88.2 (2009).

[7] "Individual" is defined as "a member of the workforce of an entity / health care entity." Id.

[8] "Workforce," "includes employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a Department-funded entity, is under the control or authority of such entity, whether or not they are paid by the Department-funded entity." Id.

[9] "Health Service / Health Service Program," "includes any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded, in whole or in part, by the Department. It may also include components of State or local governments." Id.

description of the definition for "assist in the performance," the Department has previously stated that it "seeks to provide broad protection for individuals' consciences," and that it "seeks to avoid judging whether a particular activity is genuinely offensive to an individual."[10] In defining "health service program," the Department has stated that it should be understood to "include an activity related in any way to providing medicine, health care, or any other service related to health or wellness..."[11]

By defining all of these terms broadly, the Regulation expands the protection of the Church Amendment to individuals far outside the scope of those who would have reasonably been considered to provide health services under previous law, such as physicians, physician's assistants, and nurses. These new definitions allow almost any worker in a health care setting to refuse to provide services to a patient based on his or her religious or moral beliefs. Indeed, one of the two examples in the description for the definition of "assist in the performance," is of an employee whose task it is to clean instruments following a particular procedure.[12] The Regulation thus expands the right to refuse to a range of workers performing a variety of services, such as receptionists who make appointments, claim adjustors at health insurance companies, and custodians who work in clinics and hospitals. Under the Regulation, health care institutions could struggle to effectively provide care, and women could be delayed or even prevented from receiving reproductive health care.

The Regulation's extension to the actions of such a broad range of non-medical personnel who "assist in the performance of" objectionable procedures clearly illustrates its lack of consideration for the needs of patients. In no other area of medicine are tangentially related individuals allowed to interfere with the provision of services in a way that may delay or deny health care. The Regulation goes too far in extending the right to deny services to individuals who are marginally related to the medical care being provided. This broad expansion could lead to serious disruptions in care and hamper the ability of health care institutions to meet the needs of patients. Once again, the Regulation tips the balance perilously away from what is best for patients, and for this reason it should be rescinded.

C. Inclusion of Counseling and Referrals in Federal Refusal Laws Could Deny Patients Timely Access to Care and Information Necessary to Make Informed Health Care Decisions

An additional problem, which justifies rescission of the Regulation is its expansive definition of what conduct amounts to "assisting in the performance" of health care services. This definition is critical because federal law allows health care providers to not only refuse to perform objectionable services, but also to refuse to "assist in the performance" of those services. The definition provided in the Regulation states that "assist in the performance" includes "counseling, referral, training, and other arrangements for the procedure, health service or

[10] Ensuring that Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices In Violation of Federal Law, 73 Fed. Reg. 50274, 50277 (August 26, 2008).
[11] Id. at 50278.
[12] Id. at 50277.

research activity."[13] While referrals are already included in the Weldon Amendment and Section 245 of the Public Health Service Act, the Church Amendment does not currently include referrals in its language. The preliminary draft of the Regulation did not include counseling within the definition.

Allowing federally-funded individuals to deny women information and referrals for reproductive health services and other health care options has the potential to eliminate some women's ability to make informed health care decisions and to provide informed consent. For instance, if health care providers refused to provide information and counseling on the full range of options to pregnant women, including those with fetal anomalies and victims of rape and incest, those women would not be able to provide informed consent for related health procedures. Women might also be denied information about the possibility of using some forms of contraception to control their reproduction, or prevent other health problems, and may not be informed of the possibility of using emergency contraception to prevent unwanted pregnancies.

Additionally, certain types of services, such as end-of-life care, may now be included based on the new definition of "health service program." The inclusion of counseling and referrals in the definition of "assist in performance" would allow health care providers to deny dying patients the full range of information about their options.

A particularly troubling aspect of the Regulation is its silence regarding Title VII, the federal law that provides protection to employees' religious beliefs, while at the same time establishing that employers need only make "reasonable accommodations" in respecting those beliefs. [14] The concerns raised by the expansion of the range of health care workers who may exercise conscientious objection and the expansive definition of "assisting in the performance," are heightened by the fact that the interaction of the Regulation with Title VII is not explicitly addressed. The Regulation should therefore be rescinded.

The Regulation's Impact on Low-Income Women and Women of Color

A. A Disproportionate Number of Low-Income Women and Women of Color Use Public Health Care and Will Be Adversely Affected By the Regulation.

A disproportionate number of low-income women and women of color rely on public health care programs. In the U.S., where access to health care depends on insurance coverage, lack of health insurance is the primary barrier to receiving reproductive health care. Overall, the number of people enrolled in public health insurance programs is decreasing and private insurance coverage continues to shrink.[15] Hence, a greater number of low-income people lack insurance of any kind because they do not have employer-based coverage and do not qualify for

[13] Ensuring that Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices In Violation of Federal Law, 45 C.F.R. § 88.2 (2009).

[14] 42 U.S.C § 2000e-1(a) (2008).

[15] U.S. Census Bureau, *Income, Poverty, and Health Insurance Coverage in the United States: 2006* 18-19 (Aug. 2007), *available at* http://www.census.gov/prod/2007pubs/p60-233.pdf, (showing a decrease from 27.3 million people covered in 2005 to 27.0 covered in 2006).

public insurance. Women of color, who disproportionately work in low-wage jobs that do not offer benefits,[16] have lower rates of insurance coverage: 39% of Latinas, 19% of API women, and 18% of African-American women are without affordable health care compared to only 10% of white women.[17]

Without affordable health care, these women turn to public programs such as Medicaid and Title X of the Public Health Service Act (Title X). Medicaid covers all prenatal and pregnancy-related care for eligible women. As of 2005, 11.5% of US women of reproductive age (15-44) were covered by Medicaid,[18] many of whom are women of color. In 2006, women of color made up 51% of non-elderly Medicaid beneficiaries, but less than 20% of the general population.[19] In addition, Title X, a program that funds reproductive health clinics that provide contraceptive services and supplies, STI testing and treatment, and preventative screenings, benefits 6.6 million low-income women, 40% of whom are women of color.[20]

B. Impact of the Regulation on Low-Income Women and Women of Color

Women of color are disproportionately affected by the Regulation because many of them rely heavily on federally-funded health care programs. As noted, the Regulation creates three significant problems: that "abortion" may be broadly defined to include contraception; that a broad range of individuals can refuse to "assist in the performance" of a health service; and that clinics can withhold information and deny informed consent. All these problems directly affect low-income women and women of color.

The Regulation allows a clinic worker to refuse to assist in the performance of a health service if it is "contrary to his religious beliefs or moral convictions." Some individuals conflate contraceptive use with abortion and therefore deem it morally wrong. However, in 2004, women attending publicly funded clinics avoided an estimated 1.4 million unintended pregnancies and the decline in unintended pregnancies over the years is largely attributed to the availability of contraceptives.[21] If the Regulation is not rescinded, clinics may refuse to distribute some

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[16] Kaiser Family Found., *Racial and Ethnic Disparities in Women's Health Coverage and Access to Care: Findings from the 2001 Kaiser Women's Health Survey* 2 (Mar. 2004), *available at* http://www.kff.org/womenshealth/upload/Racial-and-Ethnic-Disparities-in-Women-s-Health-Coverage-and-Access-to-Care.pdf. White women (70%) are more likely to have employer provided health coverage than African American women (59%) or Latinas (39%). Nat'l Inst. of Health, *Women of Color Health Data Book: Adolescents to Seniors* 107 (2006), *available at* http://orwh.od.nih.gov/pubs/WomenofColor2006.pdf [hereinafter NIH Women of Color Health Data Book].

[17] NIH Women of Color Health Data Book, *supra* note 36, at 107; Kaiser Family Found., *Women's Health Policy Fact Sheet: Women's Health Insurance Coverage* 2 (Dec. 2007), *available at* http://www.kff.org/womenshealth/upload/6000_06.pdf.

[18] Kaiser Family Found., and Guttmacher Instit., *Issue Brief: A Critical Source of Support for Family Planning in the United States* 1 (April 2005), *available at* http://www.kff.org/womenshealth/upload/Medicaid-A-Critical-Source-of-Support-for-Family-Planning-in-the-United-States-Issue-Brief-UPDATE.pdf..

[19] Kaiser Family Found., *Issue Brief: Medicaid's Role for Women* 1 (May 2006) *available at* http://www.kff.org/womenshealth/upload/Medicaid-s-Role-for-Women-May-2006.pdf.

[20] Guttmacher Inst., *Title X and the U.S. Family Planning Effort* 3 (1997), *available at* http://www.guttmacher.org/pubs/ib16.html.

[21] Heather D. Boonstra, Guttmacher Inst., *The Impact of Government Programs on Reproductive Health Disparities: Three Case Studies*, 11 Guttmacher Pol'y Rev. 3 at 8, (Summer 2008).

contraceptives to patients, a large proportion of whom are low-income women and minority women.

The Regulation also allows a broad range of individuals to refuse to "assist in the performance" of a health service if they find it contrary to their religious beliefs or moral convictions. As stated above, this suggests many scenarios that could affect a woman's reproductive health. For instance, a receptionist may refuse to make an appointment for an individual seeking contraceptives or a nurse may refuse to sterilize equipment used in the performance of abortion. Hence, there is not only a danger that many low-income women and women of color who go to public health clinics to seek contraceptives or reproductive health options may be turned away, but also the creation of potential health hazards to the patients.

In addition, the Regulation allows clinics to withhold information and deny informed consent, which directly contradicts the requirement to provide information and counseling on prenatal care and pregnancy termination set forth in Title X.[22] Under the Regulation, health care centers and institutions could not only refuse to give information about abortion or contraceptives, but also refuse to refer their patients to someone who will answer those questions.

The impact of the Regulation falls most heavily on low-income women seeking reproductive health care services in federally-funded health care settings. When low-income women, non-English speakers, rural women, and women who depend upon public transportation seek reproductive health services such as abortion care, they often face significant obstacles associated with missed work, child care, and other logistics, such as transportation. If these women are then turned away from health care providers, they may not have the resources to locate another provider and make their arrangements a second time. For example, if a woman visits a clinic to obtain contraceptives, and is denied, she may not have the means or opportunity to go to another clinic.

The Regulation also affects low-income women's ability to access health care services outside of reproductive health. Many low-income women already experience discrimination in the health care system based on their inclusion in a specific class of persons, such as those with HIV/AIDS, those of a certain race or ethnicity, or based on immigration status. Because the regulation expands the types of workers covered and types of services that can be denied under federal refusal laws, discrimination against persons in those vulnerable groups could increase.

Moreover, because it does not provide a definition of "moral convictions," the Regulation could create avenues for providers and entities to refuse services or information because of discrimination, self-interest, or distaste for certain procedures. This creates a unique problem for low-income women and women of color. They may be easily discriminated against due to their socioeconomic status, gender, sexual orientation, or race under the guise that the action to be

[22] 42 C.F.R. § 59.5 (2008).

taken is contrary to the providers' "moral convictions." For example, a same-sex couple could be denied infertility services.[23]

Thus, the Regulation creates a myriad of ways for health care institutions and individuals to refuse to provide health services and/or information or referrals. It is clear that these issues will directly affect low-income women and women of color because many of them rely on public health programs for these services.

The Regulation Does Not Meaningfully Address Important Issues of Diversity in the Workplace

The text of the Regulation discusses "an environment in the health care field that is intolerant of individual conscience" as a factor that may discourage diversity in the health care workforce, claiming that people of various religious, ethnic and cultural groups might be excluded without this regulation in place. This claim is misguided in several ways.

First, the implication that religious, ethnic and cultural minorities feel a specific way regarding reproductive health services is a simplistic and inaccurate generalization. Communities of color have been and continue to be instrumental in the fight for access to reproductive health care, and to imply that these communities are opposed to basic reproductive health procedures on a larger scale than other communities is an unfounded assumption.

Second, the notion that making it easier to refuse to provide services will diversify the health care workforce is questionable at best. While diversifying the health care workforce is a commendable objective, and one that is sorely needed ─13% of the United States population identifies as Latino/a and 12% identify as Black,[24] but only 6.4% and 6.5% of medical school graduates in 2004 were Latino/a or Black, respectively,[25] and only 2.8% and 3.3% of physicians practicing in 2004 were Latino/a or Black, respectively[26]─ the Regulation does not accomplish this objective. Diversifying the health care workforce would mean establishing a pipeline for minority physicians, researchers, and other health care professionals through the elimination of obstacles that communities of color face in educational attainment. Some ways these obstacles can be addressed include the creation of federal and state funded scholarships, loan forgiveness, mentoring programs for young people of color, tuition assistance, increased financial aid and affirmative action; it is steps like these that truly begin to eliminate the barriers to a diverse health care workforce.

Another area of concern is that the Regulation takes no account of diversity among patients. The Regulation is written broadly enough so that health care workers may not only refuse to participate in particular procedures, but also refuse to treat particular groups of people.

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[23] American College of Obstetricians and Gynecologists, *The Limits of Conscientious Refusal in Reproductive Medicine*, Committee Opinion Number 385, at 4 (Nov. 2007).
[24] U.S. Department of Commerce, Economics and Statistics Administration, U.S. Census Bureau, *Census 2000 Brief, Overview of Race and Hispanic Origin* 3 (March 2001) *available at* http://www.census.gov/prod/2001pubs/c2kbr01-1.pdf
[25] Association of American Medical Colleges, *Minorities in Medical Education: Facts and Figures 2005* at 27 (Spring 2005).
[26] Association of American Medical Colleges, *Diversity in the Physician Workforce: Facts and Figures 2006*, at 15 (Summer 2006).

This kind of 'moral' refusal is not unheard of. Lupita Benitez was refused artificial insemination by two physicians in her provider network because she is a lesbian, Not only did she have to incur the monetary costs of an out-of-network provider to receive the insemination during the critically short fertility time window, she also had to endure the emotional burden incurred due to this kind of discrimination.[27] The Regulation seems to condone and encourage this kind of discrimination, the brunt of which will be felt by visible minorities and marginalized populations, such as LGBT people, undocumented people, immigrants, and people living with HIV/AIDS. Whether these actions are actually within the realm of the law will be of little relevance to the countless patients whose health will suffer due to the refusal of treatment that this Regulation will foster.

The Regulation Creates a Culture of Refusal

In addition to the specific concerns detailed above, the Regulation also further exacerbates the imbalance between the rights of conscience and women's rights to reproductive health care. The Regulation is intended to expand a network of federal and state conscientious refusal laws that have created a "culture of refusal," in which women's reproductive health care needs and rights are accepted as being secondary to the conscience of providers. These laws often ignore health care providers' responsibilities and ethical duties to provide care to patients in a way that is respectful of patient autonomy, timely, effective, evidence-based and non-discriminatory.[28] Instead, together with numerous other federal and state laws, they are politically motivated attempts to prevent women from accessing abortion and family planning services that use conscience as a smokescreen for their goals.

Refusal laws exist in significant numbers at the federal and state levels. As noted, the Church Amendment,[29] the Weldon Amendment, [30] and the Public Health Service Act Sec. 245[31] already provide strong protection for individual health care providers and institutions to exercise their religious or moral beliefs regarding reproductive rights. These laws, along with Title VII,[32] already allow individuals, health care entities, and research programs that receive federal funding to refuse to participate in or provide training for abortions, sterilizations, and in some cases any activity that is contrary to their moral convictions or religions beliefs.

Additionally, nearly every state has a policy explicitly allowing some health care professionals or certain institutions to refuse to provide or participate in abortion, contraceptive services or sterilization services. Forty-six states allow some individual health care providers to refuse to provide abortion services, and forty-three of those states allow health care institutions to refuse to provide abortion services.[33] Thirteen states allow some individual health care

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[27] Lambda Legal, *Benitez v. North Coast Women's Care Medical Group Questions and Answers (*June 22, 2005), *available at* http://www.lambdalegal.org/our-work/publications/facts-backgrounds/page.jsp?itemID=31987395.
[28] Id. at 3.
[29] 42 U.S.C.A. §300a-7 (2008).
[30] Consolidated Appropriations Act, 2008, Pub. L. No. 110-161, Div. G, §508(d), 121 Stat. 1844, 2209 (Dec 26, 2007).
[31] 42 U.S.C.A. §238(n) (2008).
[32] 42 U.S.C § 2000e-1(a) (2008).
[33] Guttmacher Inst., *State Policies in Brief, Refusing to Provide Health Services Factsheet* (Sept. 1, 2008), *available at* http://www.guttmacher.org/statecenter/spibs/spib_RPHS.pdf.

providers to refuse to provide services related to contraception and nine of those states allow health care institutions to refuse to provide services related to contraception.[34] Seventeen states allow some health care providers to refuse to provide sterilization services and fifteen of those states allow health care institutions to refuse to provide sterilization services.[35] Even in states without explicit refusal statutes, an individual health care professional's actions may be legally protected by statutes prohibiting discrimination against employees, based on their religious objections.[36]

Expanding the culture of refusal, as the Regulation does, has a particularly severe impact on women of limited means, who are disproportionately women of color in this country. These women already face significant barriers in accessing health care overall, even without the added difficulties created when providers in under-resourced communities refuse care to women. The United States Office of Women's Health found "[s]everal…factors limit the access of minority women to the U.S. health care system. They include social disadvantages, cultural values, discrimination, lack of culturally appropriate services, inadequate childcare, and transportation…"[37] Additionally, a study by the Kaiser Family Foundation found that low-income women faced twice as much difficulty as other women in obtaining the flexible work schedules, transportation, and child care necessary to access health care services for themselves.[38]

The existing barriers that women face in accessing health care become especially burdensome when coupled with refusal clauses as sweeping as those in the Regulation. As the American College of Obstetricians and Gynecologists recently recognized, when low-income women and minority women are refused services, turned away, or given incomplete information about their reproductive health care options, they often do not have the opportunity to access other health care providers. "For instance, a refusal to dispense contraception may place a disproportionate burden on disenfranchised women in resource-poor areas. Whereas a single, affluent professional might experience such a refusal as inconvenient and seek out another physician, a young mother of three depending on public transportation might find such a refusal to be an insurmountable barrier to medication because other options are not realistically available to her."[39]

The Regulation also puts the United States increasingly out of step with international human rights standards and norms. International standards require a balance between health and conscience and require a recognition that health is of primary importance.[40] So, while

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[34] Id.
[35] Id.
[36] Id.
[37] U.S. Dept. of Health & Human Services, Office on Women's Health, *The Health of Minority Women* 4 (July 2003), *available at* http://www.4woman.gov/owh/pub/minority/minority.pdf.
[38] Kaiser Family Found., *Women and Health Care: A National Profile* 24 (July 2005), *available at* http://www.kff.org/womenshealth/upload/Women-and-Health-Care-A-National-Profile-Key-Findings-from-the-Kaiser-Women-s-Health-Survey.pdf.
[39] American College of Obstetricians and Gynecologists, *The Limits of Conscientious Refusal in Reproductive Medicine*, Committee Opinion Number 385, at 4 (Nov. 2007).
[40] International Covenant on Civil and Political Rights, Art. 18, *opened for signature* December 19, 1966, 999 U.N.T.S. 85 (entered into force March 23, 1976).

practitioners have a right to respect for their conscientious convictions and should not suffer from discrimination on the basis of their convictions, refusal clauses must reflect prevailing standards of medical ethics that make patient's health care of primary consideration. Refusal clauses cannot be overbroad: only those providers participating in the procedure may object, not those providing care before or after, or those performing administrative services.[41] Providers must promptly tell patients that they refuse to provide certain health services and patients are entitled to be referred immediately, in good faith, for procedures that providers object to undertaking.[42] Despite growing international consensus on these standards, none of these protections for patient care are included in the Regulation.

The Cost-Benefit Analysis Purporting to Support the Regulation is Inadequate.

The cost-benefit analysis conducted by the Department was poorly performed and therefore provides no reliable information on the Regulation's actual impact. As described in greater detail in the attached analysis prepared by the Institute for Policy Integrity at the New York University School of Law (formerly the Institute for the Study of Regulation) ("IPI Analysis"):

> The Department has engaged in an incomplete, cursory, and inadequate cost-benefit analysis in support of the proposed rule. First, the rule fails to prove the existence of the problem it is designed to solve. Second, the analysis fails to quantify benefits of the regulation. Finally, the analysis fails to identify and account for serious costs arising from, *inter alia*, potential failures to inform women of their health choices and a decreased availability of medical procedures and/or contraception. The analysis performed by the Department falls below a reasonable standard of an appropriate cost-benefit analysis as required by EO 12,866. Accordingly, this flawed cost-benefit analysis cannot be used to justify the promulgation of the proposed rule. Under EO 12,866, the Department is obligated to undertake a more formal accounting of the impacts of the proposed regulation in economic terms.

Of particular concern is the Department's failure to adequately address the costs associated with the Regulation, and in particular its impact on subgroups including low-income women and women of color. As the IPI Analysis points out, the Department is required "to assess how the costs and benefits are distributed among subpopulations." In spite of this mandate, the Department's cost-benefit analysis makes no attempt to assess the impact on these vulnerable groups.

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[41] *See, e.g., Janaway v. Salford Health Authority*, 2 All E.R. 1079 (H.L. 1988) (conscience objection clause in UK abortion law only applies to participation in treatment); Regulations for the Implementation of the Act dated June 13 1995 no. 50 concerning Termination of Pregnancy, with Amendments in the Act dated 16 June 1978 no. 66 cf. § 12 of the Act, laid down by Royal Decree, 1 December 1978, § 20 (Nor.) (Regulations implementing Norway's abortion law expressly provide that the right to refuse to assist in an abortion belongs only to the personnel who perform or assist the actual procedure).

[42] *See, e.g.*, Code de la Santé Publique, arts. L22212-8 and R4127-18 (Fr.) (2001) (France's Public Health code places a legal obligation on providers to immediately communicate their refusal to perform an abortion).

Given the gravity of the interests at stake – access to health care by low-income women and women of color who already disproportionately experience poorer reproductive health – the failure of the Department to meet its obligation to undertake a well-conducted and balanced cost-benefit analysis is reason enough to rescind the Regulation.

Conclusion

Women seeking reproductive health care services already face tremendous obstacles. If left in place, the Regulation will exacerbate those problems. For all of the foregoing reasons, we urge you to rescind this dangerous, unnecessary and misguided regulation.

Sincerely,

National Latina Institute for Reproductive Health
National Asian Pacific American Women's Forum
Center for Reproductive Rights

American Medical Student Association
Black Women for Reproductive Justice
Cedar River Clinics - Renton, Tacoma, Yakima in Washington State
Center for American Progress Action Fund
Center for Constitutional Rights
Center for Health and Gender Equity (CHANGE)
Center for Inquiry Office of Public Policy
Center for Women Policy Studies
Colorado Organization for Latina Opportunity & Reproductive Rights (COLOR)
Civil Liberties and Public Policy Program at Hampshire College
Feminist Abortion Network
Feminist Women's Health Center, Atlanta
Florida Legal Services
Human Rights Watch
IBIS Reproductive Health
International Women's Health Coalition
IPAS
Law Students for Reproductive Justice
Boston University Law Students for Reproductive Justice
Cardozo Law Students for Reproductive Justice
Rutgers - Newark Law Students for Reproductive Justice
Seattle University Law Students for Reproductive Justice
Law Students for Reproductive Justice at University of California, Berkeley
University of Maryland Law Students for Reproductive Justice
Law Students for Reproductive Justice at Hamline University School of Law
Korean American Resource and Cultural Center (KRCC)
Korean Resource Center (KRC)
Maryland Chapter, National Organization for Women
Memphis Center for Reproductive Health

NARAL Pro Choice Maryland
National Advocates for Pregnant Women
National Asian Pacific American Families Against Substance Abuse
National Association of Nurse Practitioners in Women's Health (NPWH)
National Council of Jewish Women
National Institute for Reproductive Health
National Korean American Service & Education Consortium (NAKASEC)
National Network of Abortion Funds
OCA
Pro-Choice Public Education Project
Reproductive Health Access Project
Reproductive Health Technologies Project
SisterSong Women of Color Reproductive Health Collective
Southwest Women's Law Center
The American Humanist Association
The Women's Health and Education Fund
WV FREE (West Virginia Focus: Reproductive Education and Equality)

Institute for Policy Integrity
New York University School of Law

Memorandum

To: Janet Crepps, Deputy Director, Domestic Legal Program
Center for Reproductive Rights

From: Inimai M. Chettiar, Legal Fellow
Michael A. Livermore, Executive Director

Date: September 15, 2008

Re: Critique of Department of Health and Human Service's Cost-Benefit Analysis in Support of Proposed Rule RIN 0991-AB48

We are providing this memo to the Center for Reproductive Rights in response to your request for an evaluation of the cost-benefit analysis conducted by the Department of Health and Human Services ("the Department") in support of its proposed regulation, entitled "Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law." RIN 0991-AB48, 73 Fed. Reg. 50274 (Aug. 26, 2008) (to be codified at 45 C.F.R. pt. 88).

This proposed regulation would strengthen protections for health care professionals who refuse to participate in abortions and other medical procedures due to religious or moral objections. The Department preformed a cost-benefit analysis in support of the new rule; however, this analysis included an incomplete and cursory evaluation of the costs and benefits of this rule. While measuring and monetizing costs and benefits in this area can be difficult, given that the Department decided to complete a cost-benefit analysis and presumably relied on it, the Department should have undertaken a more formal and rigorous accounting of the impacts of the proposed regulation in economic terms.

This memo first discusses the legal framework for when and how cost benefit analyses should be conducted. This memo next describes the cost-benefit analysis conducted by the Department for this proposed regulation. This memo then provides an analysis detailing the Department's superficial valuation of the costs and benefits of the proposed rule. Finally, this memo briefly mentions other irregular deviations from the traditional rulemaking process engaged by the Department in proposing this rule.

I. Mandate to Perform Cost-Benefit Analysis

Executive Order 12,866, as amended by Executive Order 13,422, governs regulatory planning and review conducted by federal agencies. Exec. Order No. 12,866, 58 F.R. 51735 (Sept. 30, 1993) (amended by Exec. Order No. 13,422, 72 F.R. 2703 (Jan. 18, 2007)) (the "Order").

As a preliminary matter, before engaging in any rulemaking, the Order mandates that "each agency shall identify in writing the specific market failure . . . or other specific problem that it intends to address . . . that warrant new agency action, as well as the significance of that problem, to enable assessment of whether any new regulation is warranted." Order § 1(b)(1). The Office of Management and Budget ("OMB") issued a Circular that expands upon this mandate for agencies. OMB, "Regulatory Analysis," Circular A-4 (Sept. 17, 2003). If the regulation is not designed to correct a market failure, the agency "should also provide a demonstration of compelling social purpose and the likelihood of effective action. Although intangible rationales do not need to be quantified, the analysis should present and evaluate the strengths and limitations of the relevant arguments for these intangible values." *Id.* at 4.

The Order also provides that if a rulemaking is classified as a "significant regulatory action," an agency must provide "an assessment of the potential costs and benefits of the regulatory action" before issuing the rule. Order § 6(3)(B). The Order classifies a rule as a "significant regulatory action" if it is "likely to result in" any of a number of specified effects, including: "an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities." *Id.* § 3(f)(1). This language is clearly expansive and designed to subject a broad array of regulatory actions to cost-benefit analysis and review by OMB.

The Order lists specific analyses agencies must undergo when assessing the potential costs and benefits of a rule classified as a significant regulatory action under Section 3(f)(1). Agencies must provide:

- "[a]n assessment, including the underlying analysis, of the benefit anticipated from the regulatory action (such as, but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias) together with, to the extent feasible, a quantification of those benefits;"

- "[a]n assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets . . ., health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs;" and

- "[a]n assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives."

Id. § 6(3)(C).

The Order further mandates that "costs and benefits" must by understood by agencies "to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantity, but nevertheless essential to consider." *Id.* § 1. Agencies "should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity)" unless a statute requires another approach. *Id.* "[D]istributive impacts" refers to the manner in which costs and benefits are distributed among subpopulations.

Under the Administrative Procedures Act ("APA"), actions of federal agencies, including rulemakings, are generally subject to judicial review by federal courts. A court will hold an agency action unlawful if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). An agency action is considered "arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1989) (construing 5 U.S.C. § 706(2)(A)). This judicial review includes both review of the factual basis of an agency's action and review of an agency's reasoning.

II. Cost-Benefit Analysis Conducted by the Department

As the Department has classified RIN 0991-AB48 as a significant regulatory action, it is required to perform a cost-benefit analysis in accordance with the mandates of EO 12,866. As this classification is presumably under Section 3(f)(1) of the Order, the Department must also perform the detailed assessments enumerated in Section 6(3)(C). The Department has included its analysis in the proposed regulation. *See* 73 Fed. Reg. at 50279-81.

The Department describes the "problem" the proposed regulation is intended to address as the Department's "concern[] that the public and many health care providers are largely uninformed of the protections afforded to individuals and institutions under [the federal physician's conscience] provisions." *Id.* at 50276. According to the Department, "[t]here appears to be an attitude toward the health care professions that health care professionals and institutions should be required to provide or assist in the provision of medicine or procedures to which they object, or else risk being subjected to discrimination." *Id.* As evidence of this "attitude," the Department points to a Bulletin of the American Board of Obstetrics and

Gynecology ("ABOG") and an Opinion of the American College of Obstetricians and Gynecologists ("ACOG"), which require physicians and other health care professionals "to refer patients in a timely manner to other providers if they do not feel that they can in conscience provide the standard reproductive service that patients request." *Id.*

[1] The Department believes that this "attitude," as exemplified by the Bulletin and Opinion, has led, or will lead to violations of federal laws protecting a physician's right to refuse to perform morally objectionable procedures. Thus, the Department seeks through this proposed rule to increase awareness among the public and the health care industry of these laws.

The Department's impact analysis lists the following as the sole benefit of the regulation: "more diverse and inclusive [health care] workforces" created by informing health care workers of their rights and fostering an environment in which individuals and organizations from many different faiths, cultures, and philosophical backgrounds are encouraged to participate." *Id.* at 50280. The analysis states that the Department "cannot accurately account for all of the regulations' future benefits [in these areas], but the Department believes that the future benefits will exceed the costs of complying with the regulation." *Id.*

The Department mentions no public health cost associated with this regulation, and believes that "this regulation does not limit patient access to health care." *Id.* at 50277. *See also* News Release, U.S. Dept. of Health & Human Servs., Regulation Proposed to Help Protect Health Care Providers from Discrimination (Aug. 21, 2008). According to the Department, because the statutes containing the provider's conscience provisions have been in place for a number of years, the "regulatory burden associated with this rule, if finalized, is largely associated with the incremental costs of a recipient [of federal funds] certifying compliance to the federal government and the cost of collecting and maintain records of [written] certification statements . . . ." 73 Fed. Reg. at 50280.

The Department estimates that the entities required to submit written certifications under the proposed rule would number approximately 600,000 (including recipients, sub-recipients, or both). This number has been compiled from information gathered from the Department agencies, U.S. Department of Labor, General Services Administration, NAICS Code, National Center for Workforce Analysis, and a number of professional organizations including the National Community Pharmacies Association and American Dental Education Association. *Id.* at 50280-81. The analysis lists three sub-categories of potential costs for recipients and sub-recipients of the Department funds: (1) direct costs associated with review and completion of written certifications (born by recipients of federal funds); (2) direct costs associated with collecting and maintaining certifications (born by the Department staff), and (3) indirect costs associated with certifications (born by both). *Id.* at 50281. The analysis estimates the labor costs to recipients to read and fill out the certifications at $42.5 million (584,294 employees (one at each recipient) * $145.45 per hour wage * .5 hours of labor). The labor costs to the government

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[1] Citing News Release, U.S. Dept. of Health & Human Servs., HHS Secretary Calls on Certification Group to Protect Conscience Rights (Mar. 14, 2008) (citing ABOG, Bulletin for 2008 Maintenance of Certification (Nov. 2008); ACOG Ethics Comm. Op., No. 385, The Limits of Conscience Refusal in Reproductive Medicine (Nov. 7, 2007)).

to collect and maintain written certification records is estimated at $2 million (77,333 per form (one for each grant award and contractor) * $30 per hour wage * 1 hour of labor). The Department estimates as negligible the indirect costs associated with certification (such as staffing/scheduling changes and internal reviews to assess compliance), as the statues containing the conscience provisions have been in place for many years. The Department specifically requests comments on this latter assumption. *Id.*

The Department estimates the total quantifiable costs of the proposed regulation as $44.5 million per year. *Id.* Given the Department's belief that the benefits will exceed the costs, the Department apparently believes the rule will create "more diverse and inclusive workforces" in the health care industry worth more than $44.5 million.

III. Critique of Cost-Benefit Analysis Conducted by the Department

When considering any regulation, a responsible regulator must estimate all costs and benefits of that regulation. Any agency engaging in a significant regulatory action must engage in such an estimate in accordance with the mandates of EO 12,866. Even for regulation motivated by goals other than economic efficiency, such as the regulation at hand, costs and benefits are clearly a relevant consideration under the Order. While measuring and monetizing costs and benefits in this area can be difficult, other agencies, such as the Environmental Protection Agency and the Occupational Safety and Health Administration, conduct cost benefit analyses on a routine basis of regulations that involve effects on the environment or public health that are difficult to quantify and monetize. These agencies routinely value exposure to toxic chemicals in the workplace, safety features that reduce mortality or morbidity risks, pollution control in a variety of media, and reductions in mortality risks. Agencies have even developed a sophisticated methodology to estimate the monetary value that individuals place on the "existence" of certain natural resources. While developing these valuations may be difficult, it is essential to conducting meaningful cost-benefit analysis.

The Department has engaged in an incomplete, cursory, and inadequate cost-benefit analysis in support of the proposed rule. First, the rule fails to prove the existence of the problem it is designed to solve. Second, the analysis fails to quantify benefits of the regulation. Finally, the analysis fails to identify and account for serious costs arising from, *inter alia*, potential failures to inform women of their health choices and a decreased availability of medical procedures and/or contraception. The analysis performed by the Department falls below a reasonable standard of an appropriate cost-benefit analysis as required by EO 12,866. Accordingly, this flawed cost-benefit analysis cannot be used to justify the promulgation of the proposed rule. Under EO 12,866, the Department is obligated to undertake a more formal accounting of the impacts of the proposed regulation in economic terms.

A. Failure to Provide Evidence of the Existence of the Problem

At the outset, the proposed rule fails to accurately identify or quantify the harm that it is intended to relieve. The rule simply states that "[t]here appears to be an attitude" toward health care professionals that they should be forced to perform objectionable procedures and that the

Department is "concerned" that the public and many health care providers are uninformed of physician's conscience protections. 73 Fed. Reg. at 50276. The proposed rule does not state nor provide any reasonable basis or evidence for the Department's belief that this problem exists. Surely, the Department can obtain evidence of whether or not this discrimination or lack of awareness exists through a number of means – including statistical evidence, samplings of populations, or administration of self-report surveys to health care workers. What the Department offers is mere conjuncture.

The only "evidence" the rule relies on are the ABOG Bulletin and the ACOG Opinion. However, the Department has no evidence that the Bulletin or Opinion are actually creating any type of discrimination against health care workers who object to medical procedures, or that the Opinion and Bulletin were issued because those organizations were unaware of federal physician's conscience laws. Again, the Department could actually have looked into whether this was actually the case.

Clearly, this offered rationale cannot be a "compelling social purpose" if the Department is certain neither that the problem exists nor its size. Further, the Department has not evaluated the likelihood that this regulation will alleviate or eliminate that problem. The Department has utterly failed to identify the specific problem that warrants this new agency action, in violation of the mandate of EO 12,866.

B. Failure to Quantify Benefits

The Department has engaged in a completely superficial analysis of the benefits of this regulation. The proposed rule lists as the major, and only, benefit of the regulation an "assumption" that "the health care industry . . . will benefit from more diverse and inclusive workforces" by "fostering an environment in which individuals and organizations from many different faiths, cultures, and philosophical backgrounds are encouraged to participate." 73 Fed. Reg. at 50280. The analysis then states that the Department "cannot accurately account for all of the regulations' future benefits [in these areas], but the Department believes that the future benefits will exceed the costs of complying with the regulation." *Id.*

First, according to the proposed rule itself, this benefit "analysis" is based on nothing more than an assumption. The Department has failed to proffer any scientific, statistical, or empirical data in support of this claimed benefit. The Department cannot be certain that the regulation will actually result in a "more diverse and inclusive workforce," and has offered no evidence to show that this is a probable outcome of the regulation.

Second, the analysis fails to specify how many individuals will be conferred this benefit. The Department has not quantified, in exact or approximate terms, the number of individuals that will benefit from a more diverse and inclusive workforce. For example, answers to the following questions, among others, remain unknown:

- How many individuals actually find certain medical procedures morally objectionable?

- How many of these individuals actually desire to refuse to participate in such medical procedures?
- How many individuals who do not find these medical procedures objectionable will benefit from the inclusion in the workforce of those individuals who do?
- How many individuals in the health care industry as a whole will benefit from this more diverse workforce?

This empirical information is easily ascertainable, especially given that the Department has already identified the exact number of affected entities. The Department could collect statistics from those employers, advocacy groups, or federal agencies. The Department could also perform statistical sampling of populations, administer anonymous self-report surveys to health care workers, or hire outside consultants to undertake this endeavor, as has been done on numerous occasions by other federal agencies when conducting impact analyses.

Third, not only has the Department not quantified how many people will be conferred this benefit, it has also failed to quantify how large this benefit would be. The Department has failed to demonstrate how the new rule will affect individuals when compared to the current protections. For example, the Department has not investigated the answers to the following questions:

- How many individuals will object to performing certain procedures with the new rule in place?
- How many of these individuals would not have objected before the rule was in place?
- How individuals have currently chosen not to work at certain institutions because they believe their provider's conscience rights will not be respected?
- How many of these individuals would chose to work at such institutions specifically because of the proposed rule's stronger protections?
- Will this rule actually lead to more public awareness of physician's conscience provisions? If so, how much more?
- Will this rule increase the productivity in the health care work force? (Or might it decrease it?)
- Will this rule increase job competition in the health care work force? (Or might it decrease it?)

Finally, the Department's analysis does not even attempt to quantify this benefit in economic terms. Although non-tangibles such as these are hard to quantify, EO 12,866 requires an agency to attempt to quantify this impact, and federal agencies have repeatedly engaged in such quantifications. The only attempt by the Department to quantify the benefit is a sweeping conclusory statement that the Department "believes" that the benefits outweigh the costs. Again, this statement is based on nothing more than conjuncture. Clearly, more than a one sentence assumption of a speculative benefit is needed for the in depth benefits analysis required under EO 12,866.

C. Failure to Recognize and Value Costs.

The clearest error in the Department's impact analysis is its complete failure to accurately estimate and assess the costs of the regulation.

First, the Department has only taken into consideration the administrative costs associated with written certifications. However, there are several important facets to this regulation beyond the written certifications – the costs associated with these elements have received no attention by the Department. The other provisions in the new regulation are part of the significant action under examination and the whole must be evaluated in terms of its costs and benefits. Under EO 12,866, the Department must make a full accounting of *all* costs anticipated from a proposed regulation, including any adverse effects on the economy, public health and safety, or the environment. Order at § 6(3)(C).

Second, the Department has completely overlooked the potentially large negative effects on public health, particularly women's health. The Department has claimed, without providing any evidence, that "this regulation does not limit patient access to health care." 73 Fed. Reg. at 50277. By failing to account for any public health costs, the Department presumably believes that this regulation will have absolutely no impact on public heath. This sweeping conclusion is without a basis in fact. Under EO 12,866, the Department bears the burden of assessing whether effects will occur, and if it believes these effects will not occur, the Department must provide evidence of this conclusion. It has not done so. There are a number of ways to assess this impact, including: retrospective cohort studies (e.g. studying the conditions of women's health in the 1960's and 1970's when information on abortion was limited); cohort studies in other countries or states where abortion counseling and referral is restricted; prospective cohort studies (i.e. a pilot program testing the regulation on a subset of the population); self-report surveys administered to a sample population of women (assessing, for example, their awareness of the existence of and details of abortion procedures); estimations of the potential effects by using statistics in the current environment as indicators; or any other of a number of epidemiological and other studies that are routinely performed by public health professionals when evaluating policies that affect public health.

Secretary Leavitt himself acknowledges that a potential effect of the rule could be that "so many doctors will refuse [to perform abortions] that it will somehow make it difficult for a woman to get an abortion." Secretary Mike Leavitt's Blog, "Physician Conscience Blog II" (Aug. 11, 2008). There are a number of potential effects on pubic health and other areas that the Department has ignored in its cost analysis and must take into consideration. These include, but are not limited to, the following:

- Decreased Supply of Health Care Workers: The regulation also creates a major change in the status quo by expanding the definition of health care "workforce." The new definition applies to all employees, administrative staff (such as receptionists), volunteers, and trainees, in addition to health care professionals. Proposed Rule § 88.2, 73 Fed. Reg. at 50282. This provision would allow many more individuals to object to any procedure "with a reasonable connection to" abortion or another medical procedure.

See id. This will result in less available individuals to assist with or perform abortions or sterilizations.

- Restricted Access to Contraception: Because the regulation does not define abortion, it is unclear whether health care provides may be able to equate abortion with certain methods of contraception that work to block a fertilized egg, for example an oral contraceptive or IUD. This restricted access to contraception would impose severe costs on women seeking the most effective methods for preventing pregnancy and resulting in a potential increase in unwanted pregnancies.
- Decrease in Medical Information: This regulation creates a major change in the current law by allowing health care workers to withhold information on abortion, and possibly on contraception, as a medical option when counseling pregnant women and refuse to refer women to other providers who may be willing to perform the procedure. *Id.* This will decrease the amount of information available to pregnant women, potentially leading to less informed choices and poor decision-making. Even if a woman is aware of a federal right to an abortion, she may not fully understand that contours of that right or the medical procedure itself. For example, she may not know how far along in the pregnancy she may get an abortion, she may not understand the medical consequences, or she may think that the option is not available in her state.
- Decreased Supply of Counseling Services: If the regulation will increase the number of doctors who refrain from referring and counseling women on procedures to which they morally object (as implied by the Department's benefit analysis), then the quantity, and perhaps quality, of doctors available to women who seek counseling services will decrease, thus resulting in a calculable cost on these women.
- Costs Imposed on Other Doctors: If the regulation will increase the number of doctors who refrain from performing and counseling woman on procedures to which they morally object, other doctors will need to perform these procedures. This could lead to more overtime hours and a decrease in quality of life for those doctors.
- Decreased Availability of General Medical Services: Proposed sections 88.3(g) and 88.4(d) of the rule impose additional prohibitions on certain entities that receive federal funding through Department programs. *Id.* These entities cannot require any individual to perform or assist in the performance of "any part of a health service program" if that individual would find such service or activity morally or religiously objectionable, or discriminate against individuals who refuse to perform or assist in performing "in any lawful health service" due to moral or religious objection. It appears that these provisions allow health care workers to object on conscience grounds to any type of service not just abortion. Coupled with the broad definition of "assist in the performance" contained in proposed section 88.2, these provisions could have profound detrimental effects on public health by inviting broad and limitless refusals by health care workers to a multitude of medical services.
    - For example, health care workers could make objections and refuse to provide end-of-life services, including withdrawing feeding tubes, aggressive pain care management, or providing support to a patient choosing to voluntarily stop eating and drinking. Moreover, workers could even fail to inform patients of these services and refuse to refer patients to another provider when the patient requests those procedures. This regulation would serve to exaggerate the already

significant problem with the quality of patients' end-of-life services throughout the country.
    - As another example, health care workers could also make objections to blood transfusions based on religious beliefs.
    - Because the regulation applies to counseling, individual providers will be able to withhold information on any type of health care service when counseling patients. This will decrease the amount of information available to patients, leading to uninformed choices and poor decision-making among patients at large.
- Refusals of Medical Services to Groups: Further, health care workers may interpret the vague provisions of proposed sections 88.3(g) and 88.4(d) as an invitation to pick and choose which care they will provide, when, and to whom. It is unclear whether health care workers could object to performing procedures on entire subgroups of populations because they have a moral objection to that population. For example, it is unclear whether a health care worker could refuse to provide any kind of medical service to members of an interracial or interfaith family or homosexual or transgendered individuals or families based on a moral or religious objection to those lifestyles. There would clearly be a large cost imposed by this regulation if it would allow entire populations of individuals to be refused medical treatments.
- Denial of Health Services Outside Scope of Regulation: The regulation fails to set clear guidelines as to what constitutes "discrimination." *See id.* at 50283. As a result, health care entities could be subject to a large number of discrimination claims. Further, a health care entity may be unclear as to what constitutes discrimination and would therefore be willing to accept an employee's erroneous interpretation of the regulation for fear of losing its federal funding. For example, if a health care worker refused to provide an interracial couple prenatal care and stated that he was doing so under his rights under the regulation, an employer may accept his view to avoid a potential discrimination claim. The result is a cost to patients in the form of violated rights and decreased access to health care.
    - Additionally, this regulation may create confusion with existing standards under Title VII of the Civil Rights Act of 1964. Title VII requires employers to accommodate employee's religious objections to providing health care services so long as the accommodation does not pose an undue hardship on the employer's overall ability to provide healthcare services to its patients. 42 U.S.C.§§ 2000e2(a)(1), 2000e(j). Presumably, employers have already put in place mechanisms to comply with the Title VII requirement. The interaction of the proposed regulation and Title VII – including redundant compliance burdens imposed under the two regimes – have not been adequately explained, and the costs of any potential conflict and resulting confusion have not been properly analyzed.

Third, the Department has not assessed how this regulation would affects subgroups of the population. EO 12,866 requires the Department to assess how the costs and benefits are distributed among subpopulations. Order § 1. For example, subpopulations could be affected in the following ways:

- Immigrant Women: Recent immigrants may be less well informed on the availability of reproductive health care in the U.S., and therefore in greater need of the consulting and referral services that this regulation covers. No special analysis has been done of the effect of this regulation on this group.
- Rural Women: Allowing health care providers to refuse to provide counseling or referrals may create a greater problem for women who live in rural areas than women at large. Because of their relative geographic isolation, greater travel and time costs are imposed on these women to seek out providers of health care services. No analysis has been done of the special burdens faced by rural women.
- Low Income Women: Women with lower incomes have fewer resources available to allocate to transportation and child care. If refused counseling or referral services, these women may suffer greater costs when seeking alternative health care providers. The refusal may even result in an insurmountable obstacle to obtaining the health service sought. No analysis has been conducted of the special burdens faced by low income women.
    - Additionally, women utilizing Title X clinics may be affected by this regulation. The federal government's Title X program funds low-cost, confidential family planning services that would otherwise be out of reach for more than five million individuals. Most of these women are poor and insured, and Title X clinics are their only source of family planning. Although Title X funds cannot be used to provide abortions, Title X projects must offer pregnant women neutral and factual information, non-directive counseling, and referrals upon request for all of their pregnancy options – including prenatal care, foster care or adoption, or abortion. 42 U.S.C. § 300-300a-6. Because this regulation applies to counseling services, it is unclear whether the regulation allows health care workers in Title X projects to exclude abortion in their non-directive counseling to pregnant women. If this were an effect of the regulation, many low income women would potentially have reduced access to information about abortion, resulting in uninformed decision-making.
- Women of Color: Women of color disproportionately earn lower incomes and live in underserved areas. If refused counseling or referrals, these women may experience greater burdens to seek alternative health care providers. No special analysis has been done of the effect of this regulation on this group.
- Homosexual or Transgendered Individuals: As described above, it is unclear whether this regulation would allow health care workers to refuse to provide any type of medical service to homosexual or transgendered individuals (or families) based on moral or religious objections. If so, this would drastically decrease the quantity and quality of health care available to that population.
- Individuals with HIV/AIDS: It is unclear whether the regulation would allow health care professionals to refuse to provide any type of medical service to individuals with HIV/AIDS. For example, a health care worker could contend that touching or providing any care to a person living with HIV would violate their religious or moral beliefs. If so, this could decrease the quantity and quality of health care available to that population.

- Interracial/Interfaith Families: As described above, it is unclear whether this regulation would allow workers to refuse to provide any type of medical services to interracial or interfaith families because they morally object to such relationships. Whether or not such refusal would be lawful, these patients may be denied services.

The Department must take into consideration these and other potential effects to perform an accurate cost analysis. Finally, after the Department actually identifies potential costs on public health or other costs, the Department must monetize these costs to the extent feasible. Again, as with the benefits, although this is not an easy task, there are methodologies to monetize costs that are deployed on a regular basis by other agencies. The Department must then weigh the full costs against the full benefits in a complete analysis. Accordingly, the current cost benefit analysis is completely insufficient.

IV. Procedural Irregularities

Finally, the Department has engaged in a variety of deviations from the traditional rulemaking process in proposing this rule.

First, the proposed regulation is in clear violation of a White House directive and the Administration's expressed commitment to principled regulation. On May 9, 2008, the White House directed the heads of executive departments and agencies to submit all proposed regulations they wish to finalize before the end of the Bush Administration by June 1, 2008, except in "extraordinary circumstances." Mem. from Joshua B. Bolten, White House Chief of Staff, to Heads of Executive Departments and Administrator of Office of Information and Regulatory Affairs, at 1 (May 9, 2008). This directive explicitly sought to "resist the historical tendency of administrations to increase regulatory activity in their final months." *Id.* Presumably, the purpose of the deadline was to ensure that agencies did not engage in ill-conceived rulemakings prior to a change of administration. This deadline represented sound policymaking procedure by creating a sufficient window for the vetting and review of new rules and discouraging "last-minute" policymaking. Unfortunately, in recent months, there have been a number of new rules proposed, including the rule at hand, in violation of the White House instruction. The Department must comply with that directive – either by explaining why these regulations are proposed under "extraordinary circumstances," or, if the Department cannot make this showing, by withdrawing the proposed rule.

Second, the Department has shortened the comment time on this proposed regulation to 30 days as opposed to the traditional 60 day notice-and-comment period. *See* 73 Fed. Reg. at 50274. Under EO, 12,866, an "agency should afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days." Order § 6(a)(1). The Department should increase its public comments period to at least 60 days, or perhaps longer, given the potentially large effects of this proposed rule.

V. Conclusion

The cost-benefit analysis performed by the Department is lacking in substance and is insufficient to comply with the mandates of EO 12,866. Not only has the Department failed to articulate an existent problem, the Department has also failed to provide an accurate, realistic, or scientific assessment of the potential benefits and costs. The impact analysis is cursory and pro forma, and does not enhance the rationality of regulation. Such a flawed impact analysis cannot be used to justify promulgation of this regulation. Agencies are mandated by EO 12,866 to select approaches to regulations that maximize net benefits. By failing to accurately quantify costs and failing to accurately account for and quantify benefits, the Department lacks information on whether this regulation maximizes net benefits. Further, the Department performed no assessment of any potential alternatives to the proposed regulation that may result in a greater maximization of net benefits. The Department must fulfill its obligations under EO 12,866 and perform an accurate and substantive accounting of the potential effects in terms of costs of benefits of this regulation, particularly on public health.

The Department entirely failed to accurately consider the costs and benefits of the proposed rule. By relying on a superficial analysis in promulgating this regulation, the Department is in violation of EO 12,866. Because of the inadequacy of its analysis, the Department's regulation may be "arbitrary and capricious" under Section 706(2)(A) of the Administrative Procedures Act.