Institute *for the* Study *of* Regulation

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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 16, 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 FR 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

[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)).

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 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.