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May 19, 2008

Via email (OGHA_Regulation_Comments@hhs.gov)

Michael O. Leavitt, Secretary
U.S. Department of Health and Human Services
Office of Global Health Affairs
Room 639H
200 Independence Avenue SW
Washington, DC 20201

Comments on Office of Global Health Affairs;
Regulation on the Organizational Integrity of Entities
Implementing Leadership Act Programs and Activities,
Notice of Proposed Rulemaking,
73 Fed. Reg. 20,900
April 17, 2008

Dear Secretary Leavitt:

On behalf of ten leading humanitarian, public health, and advocacy organizations, the Brennan Center for Justice at NYU School of Law submits these comments on the proposed regulation implementing the "anti-prostitution policy requirement" contained in 22 U.S.C. § 7631(f) ("the policy requirement").

Commenters

These comments are submitted on behalf of Alliance for Open Society International, Inc. ("AOSI"), Pathfinder International ("Pathfinder"), and the Open Society Institute, plaintiffs in the ongoing litigation challenging the policy requirement and its implementation.[1]

[1] *Alliance for Open Society International, Inc. v. USAID*, 430 F. Supp. 2d 222 (S.D.N.Y. 2006), *remanded mem.*, 254 Fed. Appx. 843 (2d Cir. 2007) ("*AOSI v. USAID*").

These comments are also submitted on behalf of InterAction, the largest alliance of U.S.-based international development and humanitarian non-governmental organizations ("NGOs"), and on behalf of Global Health Council ("GHC"), the nonprofit membership alliance of organizations dedicated to international public health, including many U.S.-based recipients of funding from the Department of Health and Human Services ("HHS").[2]

In addition, these comments are submitted on behalf of CARE, EngenderHealth, the International Planned Parenthood Federation/Western Hemisphere Region, and PSI. CARE is a leading humanitarian organization committed to dignity, social justice and the eradication of extreme poverty. CARE carries out a number of programs funded by HHS, as well as the United States Agency for International Development ("USAID"), that are encumbered by the policy requirement. EngenderHealth is a leading international reproductive health organization working to improve the quality of health care in the world's poorest communities. EngenderHealth currently receives U.S. government HIV and AIDS assistance from HHS, Office of the Global AIDS Coordinator ("OGAC"), and USAID. The International Planned Parenthood Federation/Western Hemisphere Region supports its 41 Member Associations throughout Latin America and the Caribbean in advancing sexual and reproductive health and rights. PSI is a non-profit social marketing firm that gets funding from USAID, HHS, OGAC and a number of non-U.S. government donors.

Finally, these comments are submitted on behalf of the Brennan Center itself. The Brennan Center represents the plaintiffs, as well as InterAction and GHC, in the *AOSI v. USAID* lawsuit and is a national expert on the free speech rights of non-profit organizations that partner with government.

Introduction

The commenters welcome the advent of a regulatory process that could limit the policy requirement's unconstitutional speech restrictions and lessen its harmful impact on privately funded public health interventions. However, the proposed regulation, which was developed without any input from the broader NGO community, fails to do either and, in some respects, worsens the most harmful elements of the policy requirement. More specifically, the proposed regulation:

I. does not even attempt to address the policy requirement's impermissible mandate that independent NGOs espouse the government's viewpoint;
II. fails to define the most basic terms such as "activities inconsistent with a policy opposing prostitution";
III. does not afford recipients a means to speak freely through privately funded affiliates;
IV. imposes separation requirements so burdensome that recipients will not be able to set up affiliates;
V. violates Congressional intent to promote efficiency in foreign aid;

[2] InterAction and GHC have sought to join the *AOSI v. USAID* lawsuit in order to obtain injunctive relief on behalf of their members. That request is pending in federal district court.

VI. undermines Congress's desire to promote public-private partnerships in the delivery of HIV/AIDS services; and
VII. contradicts HHS's own acknowledgment in the context of the faith-based initiative that separation requirements of the sort it imposes here are excessive.

Our detailed comments appear below.

I. The Proposed Regulation Does Not Even Attempt to Cure the Unconstitutional Requirement That Independent Organizations Espouse the Government's Viewpoint.

The regulation does not even purport to remedy one of the central constitutional problems with the policy requirement: its mandate that independent, non-profit organizations adopt the government's viewpoint on prostitution in order to be eligible to provide HIV/AIDS programming. *See AOSI v. USAID*, 430 F. Supp. 2d at 274 (requirement that recipients adopt a policy "espousing the government's preferred message" violates First Amendment).

An opportunity to set up an affiliate to engage in restricted speech – even a real opportunity, which the regulation does not provide – could not cure the harms that flow from a law that compels recipients to speak the government's message. In order to cure the ongoing constitutional violation, HHS should refrain again from enforcing the policy requirement against U.S.-based non-governmental organizations.[3]

II. The Proposed Regulation Fails to Define the Most Basic Terms and Therefore Exacerbates the Unconstitutional Vagueness of the Policy Requirement.

The "Definitions section" of the proposed regulation, Section 88.1, fails to define the most critical terms and therefore fails to "give the person of ordinary intelligence a reasonable opportunity to know what is prohibited" and "provide explicit standards for those who apply them," as the Constitution requires. *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972); *see also Forsyth County, Ga. v. Nationalist Movement*, 505 U.S. 123, 130 (1992) (striking down a permit requirement that delegated "overly broad licensing discretion to a government official"). In addition, the failure to define basic terms places recipients in the untenable position of not knowing whether privately funded interventions with sex workers violate the policy requirement and consequently must be performed through an affiliate.

a. The proposed regulation is impermissibly vague because it fails to define "activities inconsistent with a policy opposing prostitution."

The proposed regulation requires recipients to maintain "objective integrity and independence from any affiliated organization that engages in activities inconsistent with a policy opposing prostitution and sex trafficking," 45 C.F.R. § 88.2(a), but never says

[3] HHS previously refrained from enforcing the policy requirement against U.S. groups from its enactment in May 2003 through May 2005.

what those forbidden activities are. This vagueness places recipients in an untenable position. Commenter Pathfinder, for example, does not know if the government views its privately funded HIV prevention program in India, which organizes prostitutes and does outreach to brothel owners to foster safer sex, as "restricted" such that it would have to be run out of a separate affiliate. Recipients also do not know if silence on the issue of prostitution is "inconsistent with a policy opposing prostitution."

This failure stands in marked contrast to the Legal Services Corporation ("LSC") program integrity regulation on which this regulation purportedly is based, which spells out in great detail the activities that grantees are prohibited from engaging in, and which was promulgated under a statute that likewise spelled out in great detail the prohibited activities. *See* 45 C.F.R. § 1610.2(b) (incorporating by reference statutory and regulatory definitions of prohibited activities).[4]

b. The failure to define "affiliate" renders the proposed regulation impermissibly vague and subjects recipients to risk of sanction for routine relationships with third parties.

There do not appear to be any limits on the organizations that can be considered "affiliates" or "affiliated organizations" of recipients. "Affiliate" is defined elsewhere by HHS and other federal agencies quite broadly. In the food and drug regulations, for example, HHS defines "[n]onprofit affiliate" as "any not-for-profit organization that is either associated with or a subsidiary of a charitable organization as defined in section 501(c)(3) of the Internal Revenue Code of 1954." 21 C.F.R. § 203.3(t). This failure has the following consequences:

1. **Recipients will have to scrutinize the activities and speech of all the NGOs with which they work in order to ensure that none may cause the recipient to violate the regulation.** For example, grantees risk running afoul of the regulation if they locate their offices in the same building with, share employees or equipment with, or are associated in the public mind with an NGO that engages in research or advocacy regarding the legal approach to prostitution best calculated to help the fight against HIV/AIDS.

2. **The regulation, which HHS claims will provide recipients a means of speaking freely with private funds, restricts even more speech than does 22 U.S.C. § 7631(f), by subjecting recipients to risk of sanction for casual or routine relationships with third parties.** The regulation endows the government with extraordinarily broad and illegitimate authority to penalize recipients for their casual or routine relationships with other organizations. Every relationship with another organization is subject to scrutiny by the government, and may result in sanction. This is an unprecedented expansion into the First Amendment-protected

[4] Similarly, the failure to define restricted activities is out of step with HHS's program integrity regulation at issue in *Rust v. Sullivan*, which listed the forbidden activities that would be deemed to "encourage, promote or advocate abortion as a method of family planning." 500 U.S. 173, 180 (1991).

freedoms of expression and association of recipients and of other, non-recipient, organizations that have no business with the government. The regulation may even prevent grantees from engaging in some of the affiliations in which they were expressly permitted and even encouraged to engage before the regulation. For example, previously, U.S.-based grantees could work with indigenous organizations, and, so long as those organizations were legally separate, grantees did not have to worry that the organizations' activities would be imputed to them in any way.

3. **By discouraging cooperation among NGOs, the regulation violates Congressional intent.** Congress specifically contemplated that funds allocated under the U.S. Leadership Against HIV/AIDS, Tuberculosis & Malaria Act of 2003 ("Leadership Act") would be spent not only to help its grantees fight HIV/AIDS, but also to "assist[ ] indigenous organizations in severely affected countries" in doing so, 22 U.S.C. § 7601(18); *see also* 22 U.S.C. § 7601(22)(F); and to improve coordination among NGOs and other entities working on the problem. 22 U.S.C. §§ 2151b-2(c)(3), (d)(7)(C); 22 U.S.C. § 7603(1).

c. The regulation is impermissibly vague because it fails to provide recipients with clear notice of what type of organizational policy is required.

The regulation does not state what type of organizational policy opposing prostitution and sex trafficking HHS will consider sufficient to meet the requirement in 22 U.S.C. § 7631(f). As a result, the regulation fails to provide recipients with clear notice as to their obligations under the policy requirement.

d. The regulation does not contain clear standards for the amount of separation required between a recipient and affiliate.

The proposed regulation requires recipients to maintain "objective integrity and independence from any affiliated organization" but does not set forth clear standards for determining whether two organizations are sufficiently physically and financially separate. *See infra*, Section IV.b.1. The vagueness of this determination is exacerbated by the vagueness of several of the individual factors many of which use inherently vague terms such as "the extent to which" and "the degree of." *See* 45 C.F.R. §§ 88.3(iii), (iv), and (v). Recipients have no way of knowing how much of any of these factors is too much. As a result, they must comply with the broadest interpretation of each to avoid potential penalties. *See Gentile v. State Bar of Nevada*, 501 U.S. 1030, 1048-49 (1991) (statute allowing attorney to describe at press conference the "general nature of the defense without elaboration" was problematic because "general" and "elaboration" "are both classic terms of degree" that do not provide sufficient guidance for determining whether conduct is unlawful).

III. The Inclusion of a Separate Governance Factor Prevents Recipients From Being Able to Speak Through Affiliates.

In a departure from the Legal Services Corporation ("LSC") regulation on which this regulation is purportedly modeled, Section 88.2(3)(i) calls for separation of management and governance between the recipient and affiliate. This requirement penalizes the grantee for controlling its privately funded affiliate through overlapping boards of directors and speaking through that affiliate. In recognition of its obligations under the First Amendment, LSC declined to use this factor, saying that its intention was to "allow control at the Board level, [so] recipients will have an avenue through which to engage in restricted activities." 62 Fed. Reg. 27,695, 27,697 (May 21, 1997) (LSC statement explaining its change of proposed program integrity regulation to ensure that grantees' boards could control affiliates). HHS should do the same.

It is not sufficient to note that the separate governance factor is one of multiple factors and therefore may not be applied as an absolute requirement in every case. Its inclusion in a vague, multi-factor test will force recipients to have separate governance to some degree in order to ensure compliance with the requirement.

IV. The Legal, Physical and Financial Separation Requirements Impose Unconstitutional Burdens on Recipients.

The separation requirements in the proposed regulation are so harsh that recipients will not be able to surmount them to set up affiliates. The proposed rule does not take into account at all the international context in which the Leadership Act programs take place. The multi-factor test for adequate separation is so vague and indeterminate that recipients must sacrifice their First Amendment rights by maintaining the maximum level of separation between themselves and any other organizations engaged in work that poses a risk of sanction. We describe these concerns in detail below.

a. The requirement that recipients set up a legally separate entity, Section 88.2(a)(1), is prohibitively burdensome in the international context and will harm the ability of recipients to raise funds.

The requirement that recipients set up legally separate entities in order to speak freely with private funds imposes an insuperable barrier for recipients seeking to use their private funds to engage in unrestricted speech. NGOs that operate in the developing world must navigate cumbersome and often hostile regulatory regimes in multiple countries in order to be able to establish affiliates. The legal separation requirement has the following effects:

1. **The legal separation requirement forces recipients to register new legal entities with multiple host countries in order to operate. As the State Department has documented, registration requests are often denied and the process can be prohibitively long, expensive and**

cumbersome.[5] In most developing countries where Leadership Act recipients operate, all NGOs must register with and obtain the approval of the host country prior to operating. In order to establish a new, legally separate NGO, recipients will be required to secure a new registration for the new entity in multiple countries and explain to foreign government authorities – often multiple authorities at different levels – why such a structure is necessary. Commenter Pathfinder International, for example, operates in 27 countries; Leadership Act grantee CARE operates in over 35 countries. The registration process is burdensome and can result in outright denial of the request to operate a new entity. For example, in India and Bangladesh, where recipients Pathfinder and CARE run privately funded HIV prevention programs targeting sex workers, the process for registering and establishing a new entity typically takes months or years and requires clearances from multiple government agencies, including intelligence authorities. Past practice indicates that there is no guarantee that a new, separate entity will even be allowed to operate in either country.[6]

2. **The challenge of registering new entities is compounded by myriad host country rules regarding tax-exempt status**, **which the new entity will have to navigate.** In certain cases, a request to register a new, related entity may prompt a national government to become suspicious of, and even question or revoke the hard-won, tax-exempt status of, an existing grantee organization.

3. **The legal separation requirement will harm recipients' ability to raise funds.** If the newly formed affiliate organization is to be privately funded, it will encounter problems attracting funding from the private sector due to the absence of a proven record of past performance and experience. Because of the extensive amount of separation required, the newly formed affiliate, operating with different personnel, cannot rely on the track record of the original entity. On the other hand, if the newly formed entity is to receive Leadership Act funds, it will be at a disadvantage because it will not be able to point to its past performance,

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[5] *See*, *e.g.*, Bureau of Democracy, Human Rights, & Labor, U.S. Dep't of State, *Country Report on Human Rights Practices in Tajikistan – 2006*, § 2(b) (2007), available at http://www.state.gov/g/drl/rls/hrrpt/2006/78843.htm. ("All NGOs must register with the [Ministry of Justice]. International NGOs, particularly ones supported by Western donors and involved in democracy-building activities, face[ ] registration problems from the government . . . ."). *See also* David Moore, Safeguarding Civil Society in Politically Complex Environments, 9:3 *International Journal of Not-for-Profit Law (July 2007), available at* www.ijnl.org; *International Federation of Red Cross and Red Crescent Societies (IFRC),* Law and Legal Issues in International Disaster Response: A Desk Study (2007), at 13, available at http://www.reliefweb.int/rw/lib.nsf/db900sid/EVOD-78PH4N/$file/ifrc-06nov.pdf?openelement (describing inability of many humanitarian organizations to obtain registration in Thailand in wake of 2004 tsunami).

[6] *See*, *e.g.*, Leon Irish, Karla Simon, and Fawzia Karim Feroze, Legal and Regulatory Environment for NGOs in Bangladesh 10 (April 17 2005), *available at* http://www.iccsl.org/pubs/bangladeshfinalreportmay15.pdf.

which HHS and other agencies consider when evaluating grant applications.[7]

b. The physical and financial separation requirements, Section 88.2(3), unconstitutionally burden the use of recipients' private funds.

The physical and financial separation requirements, Section 88.2(3), unconstitutionally burden the use of recipients' private funds for the following reasons:

1. **The multi-factor test fails to inform recipients how much separation will be deemed sufficient to comply with the regulation.** Rather than listing clear standards for determining physical and financial separation, the regulation lists five non-exclusive factors, none of which is given any particular weight. The agency reserves the right to determine, on a case-by-case basis and based on the totality of the facts, whether sufficient physical and financial separation exists and reserves the right to take other, as yet undisclosed, factors into account. Given the enormous financial and even criminal penalties that may flow from a violation of the policy requirement and regulation, recipients will be forced to comply with each factor, and thus maintain the maximum level of separation between themselves and any affiliates.

   Moreover, the proposed regulation contains no process by which recipients may seek approval for affiliation proposals. Even if there were such a process, without clear standards in the multi-factor test, recipients will either have to submit proposals containing maximum separation in order to ensure HHS approval, or submit many different proposals with many different levels of separation in order to figure out the least burdensome configuration that would meet with HHS' approval. Either way, recipients will be forced to sacrifice First Amendment rights.

2. **The separate personnel and management factors in Section 88.2(3)(i) will impose considerable costs and logistical barriers in the international context.** The separate personnel and management factors are particularly onerous because recipients operate in developing countries. Recipients try to hire as country representative and senior management the people with the best experience both working in that particular country or region, and carrying out the particular types of programs that field office runs. In awarding grants, funders place great weight on the qualifications of the country representative and other key people running a program. For example, in evaluating Pathfinder's application for a grant to do home-based care in Tanzania, the Centers for Disease Control and Prevention ("CDC") found it to be a strength

[7] *See* ExpectMore.gov, "Detailed Information on the President's Emergency Plan for AIDS Relief: Focus Countries Assessment," available at http://www.whitehouse.gov/omb/expectmore/detail/10004619.2005.html (last visited May 1, 2008).

that staff members were "local with a wide range of skills and a wealth of experience working with other United States Government partners and NGOs" and had "5-18 plus years of experience in the HIV/AIDS universe of OI/HIV/STD."[8] In many countries, the pool of people with such experience is extremely limited. That means that hiring duplicate sets of country representatives and senior management for each country will be extremely difficult, and may force recipients to hire people with fewer qualifications than they need to run their programs.

While recipients attempt to employ local residents, in many of the countries where they operate there is no professional level workforce from which to hire senior managers. Consequently, many country representatives are either United States expatriates or nationals of another country. If recipients had to maintain two field offices in each country instead of one, they would have to seek visas and work permits for that additional set. Many developing countries may refuse to issue visas or work permits for additional American and other foreign personnel. Substantial waiting times and approval procedures are routine and, typically, entities to which such foreign individuals will be assigned must be fully registered and approved before visas can be issued.

To give just two examples, Pathfinder was unable to obtain an Indian work permit for a Bangladeshi employee with needed HIV expertise last year, and has been trying for five months without success to obtain a Tanzanian visa for another employee.

3. **The Regulation's Separate Accounts Factor, Section 88.3(ii), will cause enormous obstacles in the international aid context.** In many countries, an entity must be registered with the government before it can open a bank account. Some governments limit the number of bank accounts or even prohibit multiple accounts per organization, per donor, or per project. India, for example, exercises close control over NGO bank accounts through its Foreign Contribution (Regulation) Act, which limits foreign NGOs to receiving foreign funds into only one bank account. *See* Foreign Contribution (Regulation) Act, § 6 (India). Even when opening a second bank account is technically allowed, many governments exercise such a tight level of control that opening such an account is either impossible or entails long delays. For example, it recently took nearly a year for Pathfinder to obtain permission to have a local Indian employee added as a signatory to an existing account.

[8] Summary Statement, Program Announcement # 04208, Scale-Up of Home Based Care Activities for People Living With HIV/AIDS in the United Republic of Tanzania, attached as Exhibit F to Declaration of Daniel E. Pellegrom dated Feb. 7, 2008, *AOSI v. USAID*, 05-CV-8209 (S.D.N.Y.), available at http://brennan.3cdn.net/70b8710cc064927756_zvgm6u55l.pdf.

The establishment of new and separate affiliates would also almost certainly cause havoc and long delays in the receipt of funds from abroad. For example, India's Foreign Contribution (Regulation) Act strictly regulates which Indian nonprofits and charitable affiliates can receive and use foreign charitable donations. The U.S. State Department has noted thousands of instances in which Indian authorities have used this act to prohibit organizations from seeking and receiving charitable funds.[9]

4. **The Regulation's Separate Facilities, Equipment, and Supplies Factor, Section 88.3(iii), is also extremely onerous.** U.S. NGOs often must engage in the highly cumbersome and time-consuming process of importing necessary vehicles and office equipment into the countries in which they operate. In India, for example, it can be very difficult to obtain government authorization for duty-free import of vehicles and office equipment, and may be particularly difficult to obtain those permissions for two affiliates of the same foreign organization. Securing appropriate office space, telephone and Internet access and other necessary services for an additional office location is likely to take months or longer.

V. The Separation Requirements Undermine Congressional Intent to Promote Efficiency in Foreign Assistance.

As is described above, the creation of an affiliated organization with duplicate boards, management, personnel, accounts, facilities and equipment is certain to result in significant expense to recipients. The resultant waste undercuts Congress's intent that Leadership Act funds and foreign assistance more generally be spent in the most efficient manner possible. *See* 22 U.S.C. § 2151b-2(d)(7)(B). *See also* 22 U.S.C. § 2151(a) (declaring that "development resources [should] be effectively and efficiently utilized" to meet federal development policy goals); S. Rep. No. 110-128, at 33 (2007) (Senate Appropriations Committee urging that separation guidelines implementing Policy Requirement be based on faith-based model "so as to avoid requirements that waste resources that could otherwise be used to save lives.").

VI. The Separation Requirements Undermine Congressional Intent to Promote Public-Private Partnerships.

Throughout the Leadership Act, Congress made clear its desire to conduct its fight against HIV/AIDS through independent non-profits. 22 U.S.C. § 2151-1(b)(8) ("United States cooperation in development should be carried out to the maximum extent possible through the private sector, including those institutions which already have ties in the developing areas, such as . . . private and voluntary agencies."); *see also* Section II.b.3, *supra*.

[9] U.S. Department of State, Country Reports on Human Rights Practices 2006, India Section (March 2007), *available at* www.state.gov/g/drl/rls/hrrpt/2006/78871.htm.

In the face of this Congressional desire, the proposed regulation makes it dangerous at best, and potentially illegal, for recipients to affiliate with, or even work in coordination with, other U.S. and indigenous NGOs. For example, recipients risk running afoul of the regulation if they locate their offices in the same building with, share employees or equipment with, or are associated in the public mind with an NGO that engages in research or advocacy regarding the legal approach to prostitution best calculated to help the fight against HIV/AIDS. They even risk running afoul of the regulation if they work in coalition with an organization that engages in the restricted activities to whatever degree the government determines to be too much. *See* 45 C.F.R. § 88.3(3)(iv) (stating that "[f]actors relevant to the determination" of whether recipient is sufficiently separate from an affiliated organization include "the extent of … restricted activities by the affiliate").

Moreover, by forcing recipients to increase their administrative costs, the proposed regulation undercuts their ability to raise funds from government and the private sector. NGOs are increasingly judged, ranked and rated by independent judging and certification organizations, in response to concerns about effectiveness and efficiency in the American charitable sector. Dividing the work that these organizations do in their U.S. headquarters, and in dozens of countries abroad, into new and separate affiliates, each with significantly increased administrative costs, would likely result in a downgrading of rankings and ratings because of the higher ratio of administrative to program costs resulting from the regulation.[10] In turn, less favorable rankings or ratings can hurt the ability of organizations to raise funds from the private sector and the government.

VII. The Proposed Regulation's Harsh Burdens Contradict HHS's Previous Conclusion That Separation Requirements of the Sort Imposed Here Are Excessive.

In issuing its regulation implementing President Bush's faith-based initiative, HHS provided that NGOs may receive federal funds as long as they ensure that no federal funds are spent on inherently religious activities and that federally funded activities are conducted either at a different time or in a different place than any privately funded, religious activities such as worship and proselytization.[11] HHS has recognized that this level of separation is sufficient to ensure that the government neither funds nor endorses a grantee's message. Therefore, such separation would be sufficient to ensure that HHS does not endorse any privately funded speech related to prostitution by recipients.

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[10] *See, e.g.*, Charity Navigator, "How Do We Rate Charities?" at www.charitynavigator.org (describing how administrative and program expenses factor into efficiency ratings).

[11] *See* 69 Fed. Reg. 42,586(July 16, 2004) . *See also* Executive Order No. 13279; White House Office of Faith-Based & Community Initiatives, *Guidance to Faith-Based and Community Organizations on Partnering With the Federal Government* (2002), available at http://www.whitehouse.gov/government/fbci/guidance_document_01-06.pdf.

The commenters take no position here on the Faith-Based Initiative or whether it enables the government to fulfill its constitutional obligations.

Indeed, when finalizing the separation requirements applicable to faith-based grantees, HHS rejected as too burdensome suggestions that federally funded social services and privately funded religious activities be performed by legally separate organizations and that more stringent physical separation be imposed between federally funded and religious activities. *See* 69 Fed. Reg. 42,586, 42,587-88, 42,591-92 (July 16, 2004). HHS warned of the burdens of requiring organizations to operate federally funded programs in separate facilities, stating:

> [A] prohibition on the use of religious icons would make it more difficult for many faith-based organizations to participate in Department programs than for other organizations by forcing them to procure additional space. It would thus be *an inappropriate and excessive restriction* ….

69 Fed. Reg. at 42,588 (emphasis added).

VIII. Other Comments

a. The Regulatory Flexibility Act analysis contradicts HHS's previous findings about the burden of separation.

HHS's certification, under 5 U.S.C. § 605(b), that this rule will not result in a significant impact on a substantial number of small entities is erroneous in light of HHS's own statements regarding the impact that similar separation requirements would have on faith-based entities. *See* Section VII, *supra.* This conclusion also ignores the substantial evidence already in HHS's possession regarding the burdensome nature of the separation requirement.[12] And, it is contradicted by Section V of this submission. Moreover, the notice of proposed rulemaking fails to provide any factual basis for this conclusion, as required by 5 U.S.C. § 605(b). Accordingly, HHS should instead conduct the appropriate regulatory flexibility analysis required by 5 U.S.C. §§ 603, 604.

b. The findings under Executive Order 12866—Regulatory Planning and Review contradict HHS's previous findings about the burden of separation.

HHS's conclusion that "[t]he cost of this rule is unlikely to be significant" is contradicted outright by HHS's conclusions regarding the impact that a separation requirement in the faith-based context would have on recipients. *See* Section VII, *supra*. It also ignores the substantial evidence already in HHS's possession regarding the burdensome nature of the separation requirement.[13] And, it is contradicted by Section IV of this submission.

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[12] *See* Memorandum in Support of Motion of Plaintiffs for Leave to File a Second Amended Complaint and Motion by Global Health Council and InterAction for a Preliminary Injunction dated Feb. 8, 2008 and Reply Memorandum in Support of Plaintiffs' Motion for Leave to File a Second Amended Complaint and Motion by Global Health Council and InterAction for a Preliminary Injunction dated April 7, 2008, *AOSI v. USAID*, 05 Civ. 8209 (S.D.N.Y.).

[13] *See id.*

In addition, HHS claims that it has "provided means for the public to comment on th[e] Guidance, including whether the document is economically significant under definitions provided by the Office of Management and Budget," but "no one has submitted comments." On the contrary, this is the first time that HHS has formally solicited comments. In addition, it has received letters from concerned members of Congress and the public about the formation of and content of the guidance that preceded this proposed regulation[14] and has been served with lengthy submissions regarding the impact of those guidelines in the *AOSI* litigation.

c. The proposed certification in Section 88.3(d)(1) is missing words and therefore fails to provide recipients and the rest of the public with notice as to how the regulation will be enforced.

The description of the certification that recipients must complete appears to be missing words. It is therefore unclear what recipients must certify to on their funding applications.

Thank you for consideration of our comments.

Sincerely,

Rebekah Diller
Deputy Director, Justice Program

[14] *See id.*; S. Rep. No. 110-128, at 33 (2007) (Senate Appropriations Committee "will view unfavorably any requirements that impose more costly and burdensome restrictions than those that apply to faith-based grantees."); Ltr. from Rep. Henry A. Waxman, Chairman, House Committee on Oversight and Government Reform, to Hon. Alberto Gonzales, Attorney General (June 29, 2007), *available at* http://oversight.house.gov/documents/20070629123546.pdf; Ltr. from Reps. Henry A. Waxman and Tom Lantos to Hon. Michael O. Leavitt, Secretary, HHS (July 20, 2007), *available at* http://oversight.house.gov/documents/20070720162655.pdf; Ltr. from Reps. Henry A. Waxman and Tom Lantos to Hon. Henrietta H. Fore, Acting Administrator, USAID (July 20, 2007), *available at* http://oversight.house.gov/documents/20070720162731.pdf; Ltr. from Samuel Worthington, President and CEO, InterAction to Hon. Henrietta H. Fore, Acting Administrator, USAID and Hon. Michael O. Leavitt, Secretary, HHS (Aug. 30 2007).