Lambda Legal
making the case for equality

August 17, 2009

By electronic mail

Division of Global Migration and Quarantine
Centers for Disease Control and Prevention
United States Department of Health and Human Services
Attn: Part 34 NPRM Comments
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Atlanta, Georgia 30333

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Docket No: Docket No. CDC-2008-0001
Docket Title: Medical Examination of Aliens – Removal of Human Immunodeficiency Virus (HIV) Infection from Definition of Communicable Diseases of Public Health Significance

Dear Director Frieden and Centers for Disease Control and Prevention Staff:

Lambda Legal submits these comments in support of the proposed regulations to amend 34 C.F.R § 34.2 to remove the human immunodeficiency virus ("HIV") from the list of "communicable diseases of public health significance" and to amend 34 C.F.R § 34.3 to eliminate mandatory HIV testing in the routine medical examination of foreign nationals.[1]

For over two decades, the United States ("U.S.") policy of barring people with HIV from entering this country for purposes of travel or immigration (the "HIV travel and immigration ban") has violated the fundamental rights of foreign nationals living with HIV; impeded HIV prevention, care and treatment; and fostered stigma and discrimination against people living with HIV, both in the U.S. and abroad. If this policy ever truly served any legitimate governmental goal or interest – and Lambda Legal submits that it did not – that time has long since passed. Lambda Legal strongly urges the Department of Health and Human Services, through the Centers for Disease Control and Prevention ("HHS/CDC" or "the agency") to move swiftly to finalize and implement the proposed regulations, thereby ending the discriminatory and disgraceful HIV travel and immigration ban and allowing the United States to more fully assume its role as a leader in the global fight against HIV/AIDS.

Lambda Legal Defense and Education Fund, Inc. ("Lambda Legal") is a national nonprofit organization committed to achieving the full recognition of the civil rights of lesbians, gay men, bisexuals, transgender people and those living with HIV through impact litigation, education and

[1] Medical Examination of Aliens – Removal of Human Immunodeficiency Virus (HIV) Infection From Definition of Communicable Disease of Public Health Significance, 74 Fed. Reg. 31797 (proposed Jul. 2, 2009) (to be codified at 34 C.F.R. §§ 34.2, 34.3) ("NPRM").

public policy work. Lambda Legal has represented the interests of people living with HIV since the beginning of the epidemic, and our work has ensured access to treatment, promoted effective prevention policies, and helped combat discrimination, bias and stigma.

Lambda Legal supports adoption of the Proposed Rule for the reasons set forth below.

The HIV Travel and Immigration Ban Violates Fundamental Human Rights

This country was founded on principles of freedom, equality and respect for the human rights of the individual. For the United States to live up to these principles on the world stage, we must stop barring individuals living with HIV from visiting or immigrating to this country. The current policy restricting the ability of people living with HIV to enter, remain and reside in the United States runs afoul of international human rights provisions prohibiting state-sponsored discrimination and mandating equal treatment under the law for all individuals. For instance, the International Covenant on Civil and Political Rights ("ICCPR") – to which the U.S. is a party – guarantees all persons the right to equal protection of the law without discrimination based on race, color, sex, language, religion, political or other opinion, national or social origin, property, birth, or other status.[2] "Other status" under the ICCPR has been interpreted to include actual or perceived HIV/AIDS status.[3] As a signatory to this treaty and a world leader with respect to human rights, the United States has an obligation not only to respect this right for all individuals within its territory and subject to its jurisdiction, regardless of citizenship, but also to avoid discriminating against those who seek entry or residence.[4]

Restrictions against entry, stay, and residence based on HIV status interfere with governmental obligations to protect the integrity of families, as well as the best interests of the child, and run contrary to numerous related human rights principles, including freedom of movement, freedom of association, the *non-refoulment* (unlawful return) of refugees, and the right to privacy.[5] Such

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[2] International Covenant on Civil and Political Rights, art. 26, Dec. 16, 1966, A-14668 U.N.T.S. 999.

[3] United Nations High Commissioner for Human Rights ("UNHCHR"), *The Protection of Human Rights in the Context of Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS)*, Resolution 1995/44 (March 3, 1995), *available at* http://www.unhchr.ch/Huridocda/Huridoca.nsf/0/47a2677e0c36688c8025676300599ece?Opendocument (last visited Aug. 17, 2009).

[4] *See*, *e.g.*, UNHCHR, U.N. Human Rights Committee, General Comment 18, Non-discrimination (1989), *available at* http://www.unhchr.ch/tbs/doc.nsf/0/3888b0541f8501c9c12563ed004b8d0e?Opendocument (last visited Aug. 17, 2009); UNHCHR, U.N. Human Rights Committee, General Comment 15, The Position of Aliens Under the Covenant (1986), *available at* http://www.unhchr.ch/tbs/doc.nsf/(Symbol)/bc561aa81bc5d86ec12563ed004aaa1b?Opendocument (last visited Aug. 17, 2009).

[5] *See*, *e.g.*, Office of UNHCH ("OHCHR") & Joint United Nations Programme on HIV/AIDS ("UNAIDS"), *International Guidelines on HIV/AIDS and Human Rights* (2006), *available at* http://data.unaids.org/Publications/IRC-pub07/jc1252-internguidelines_en.pdf (last visited August 17,

restrictions interfere with the individual's ability to pursue educational opportunities, to become maximally employed, to attain the highest standard of health, to seek asylum, and to live with the full dignity and respect that we, as a country, believe should be accorded every human being.

Only a dozen countries – countries such as Libya, Qatar, the Russian Federation, Saudi Arabia, South Korea and Sudan – impose immigration restrictions similar to those imposed under current U.S. policy.[6] Being counted among these countries has been denounced as shameful for our country.[7] Because the HIV travel and immigration ban cannot be justified based on public health concerns or economic considerations (both of which are discussed below), it would be unconscionable for the United States to continue this discriminatory policy, to perpetuate the violation of human rights it entails or to stand in the way of the individual's ability to reach full potential – based solely upon the fact that individual is living with HIV. Removing this discriminatory ban from U.S. immigration policy is a crucial step toward strengthening our nation's leadership in the global fight against HIV/AIDS.[8]

The HIV Ban Cannot Be Justified on Public Health Grounds

As HHS/CDC has recognized in its proposed regulations, the HIV travel and immigration ban cannot be justified on the grounds that it protects the public health.[9] For decades now, public health officials and medical professionals have known that HIV is not transmitted through casual contact and does not present the type of threat posed by diseases that are communicable through aerosol or

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2009); UNAIDS & International Organization for Migration ("IOM"), *UNAIDS/IOM Statement on HIV/AIDS-Related Travel restrictions* (2004), *available at* http://www.iom.int/jahia/webdav/site/myjahiasite/shared/shared/mainsite/activities/health/UNAIDS_IOM_statement_travel_restrictions.pdf (last visited August 17, 2009).

[6] NPRM, 74 Fed. Reg. at 31800.

[7] International AIDS Society ("IAS"), *IAS Policy Paper: Banning Entry of People Living with HIV/AIDS* (2007), *available at* http://www.iasociety.org/Web/WebContent/File/ias_policy%20paper_07%2012%2007.pdf (last visited Aug. 17, 2009).

[8] For example, since 1993, the IAS has refused to hold its biannual International AIDS Conference, which brings together the leading medical experts in the field and generally draws 25,000 participants, in the United States because of the U.S. HIV travel and immigration ban. The IAS is considering holding this conference in Washington, D.C. in 2012, but only if the U.S. first changes its discriminatory policy. IAS, *supra* note 7.

[9] As stated in the discussion of "Current Scientific Knowledge for HIV Transmission" in the Notice of Proposed Rulemaking, "[w]hile HIV infection is a serious health condition, it does not represent a communicable disease that is a significant threat for introduction, transmission, and spread to the United States population through casual contact, as is the case with other serious conditions such as tuberculosis. An arriving alien with HIV infection does not pose a public health risk to the general population through casual contact." NPRM, 74 Fed. Reg. at 31800.

respiratory droplets.[10] It is well understood that, as the agency notes, HIV is transmitted "almost exclusively" by unprotected sexual activity, the sharing of contaminated needles and syringes, and mother-to-child transmission.[11] In light of the modes of transmission of HIV, public health officials and medical professionals have asserted for years that allowing foreign nationals living with HIV to enter the United States to visit or immigrate does not pose a discernible risk of exacerbating the HIV endemic that already exists in this country.[12]

In fact, many public health officials believe that ending the HIV travel and immigration ban will have a net positive overall effect on public health across the world. For far too long, the United States has been sending contradictory messages with respect to HIV care, treatment and prevention. Through our public health initiatives at home and foreign aid programs abroad, we encourage people to get tested and learn their HIV status, asserting that effective treatments are available for those who are already infected and that public health officials know how to prevent transmission to those who are not currently infected. Yet at the same time our own immigration policy is premised upon entirely outdated and thoroughly discredited misconceptions about the transmission of HIV and, in fact, provides incentives for foreign nationals to remain unaware of their HIV status, to engage in deceitful behavior when interacting with immigration officials, and even to forego treatment while visiting or residing in the United States.[13] Lifting the HIV travel and immigration ban will end the schizophrenic messages being sent across the world via our contradictory immigration, public health and foreign aid policies and will allow the United States to speak with one, clear voice in its efforts to prevent the further spread of HIV.

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[10] *See*, *e.g.*, NPRM, 74 Fed. Reg. at 31800-01; CDC, *HIV and Its Transmission* (last revised Mar. 8, 2007), *available at* http://www.cdc.gov/hiv/resources/factsheets/transmission.htm (last visited Aug. 17, 2009).

[11] NPRM, 74 Fed. Reg. at 31800-01; *see also* CDC, *supra* note 10.

[12] *See*, *e.g.*, NPRM, 74 Fed. Reg. at 31800; OHCHR & UNAIDS, *supra* note 5; World Health Organization ("WHO"), *Report: Consultation on International Travel and HIV Infection*, WHO/SPA/GLO/787.1 (1987), *available at* http://unesdoc.unesco.org/Ulis/cgi-bin/ulis,pl?catno=76034&gp=o&lin=1 (last visited Aug. 17, 2009); CDC, *Technical Questions and Answers Proposed Removal of HIV Entry Ban* (2009), *available at* http://www.cdc.gov/ncidod/dq/laws_regs/fed_reg/remove-hiv/hiv-faq-technical.pdf (last visited Aug. 17, 2009).

[13] Because individuals who seek to visit or temporarily reside in the United States are required to disclose that they have HIV, foreign nationals living with HIV have an incentive not to get tested for HIV. Moreover, foreign nationals who learn they do have HIV have an incentive, under current policy, to conceal their status – in order to travel to or remain here and avoid the cumbersome waiver process and intrusive questions into their personal and private health information required by that process – which may cause them to forego necessary treatment while visiting or residing in the United States. Lifting the HIV travel and immigration ban will eliminate this Hobson's choice between optimal health, integrity and personal privacy for foreign nationals living with HIV who intend to travel to the United States or are currently residing here under a lawful visa.

Lifting the HIV Ban Will Help Reduce the Stigma, Bias and Discrimination Faced by People Living With HIV

In addition to improving public health abroad, the proposed change will improve public health in the United States by helping to reduce the stigma, bias and discrimination associated with having HIV. Much of the stigmatization of and discrimination against people living with HIV stems from a lack of understanding about HIV and the limited ways in which it can be transmitted. The HIV travel and immigration ban sends a clear – and incorrect – message to the general public that admission of people living with HIV to the U.S. poses a threat to public health. Eliminating that false and harmful message should help decrease stigma and discrimination.[14] In turn, decreased stigma and discrimination should lead to public health benefits, such as a greater willingness to be tested for HIV (which may result in earlier detection of the virus if the person has HIV); a greater willingness to initiate and remain in care; reduced infectiousness for those receiving treatment; a reduced rate of transmission, and better overall health outcomes for people living with HIV.[15] Recognizing the benefits with respect to public health, the United States has for years – through various laws and policies – attempted to reduce the stigma, bias and discrimination faced by people living with HIV. One glaring omission in those efforts, however, has been U.S. immigration policy. As the agency notes, ending the HIV travel and immigration ban and associated HIV testing "will remove stigmatization of and discrimination against HIV-infected people who have long been denied entry into the U.S. based only on a treatable and preventable medical condition."[16] Maintaining the current policies hurts this country's efforts to reduce stigma and discrimination for people living with HIV; by ending those policies, the U.S. government will be furthering its important obligation to help end stigma, bias and discrimination against people living with HIV.[17]

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[14] *See e.g.*, IAS, *supra* note 7.

[15] *See*, *e.g.*, UNAIDS & IOM, *supra* note 5.

[16] NPRM, 74 Fed. Reg. at 31804. The stigmatizing and discriminatory impact of the current policy is not limited to those denied entry, but extends to U.S. citizens living with HIV. These individuals not only suffer the stigmatizing consequences of the misleading message the policy sends about HIV, but also suffer in the awareness that their own government engages – without any valid justification – in discrimination against people living with HIV.

[17] The current system of a blanket ban against people living with HIV and individual waivers imposes yet another particularized harm against individuals in same-sex relationships. Individual waivers, though obtained through a cumbersome and intrusive process, allow foreign nationals with specific types of familial ties to a U.S. citizen or Legal Permanent Resident to immigrate despite the HIV travel and immigration ban. Because, however, the U.S. government does not recognize the validity of marriages of same-sex couples, the waiver process is not available to foreign nationals living with HIV who are married to members of the same sex. Therefore, even in situations in which a foreign national could obtain lawful immigration status through some means that does not rely on a familial relationship (*e.g.,* an Employment-Based visa), that individual is currently not able to obtain the necessary HIV waiver to immigrate to the U.S. based on his or her marriage to someone of the same sex.

Mandatory Testing for HIV Must Also Be Discontinued

Lambda Legal strongly agrees with HHS/CDC that eliminating HIV testing as part of the immigration medical examination is the best approach. The medical examination should be limited to screening and testing for those diseases that are on the list of "communicable diseases of public health significance."[18] At the same time that HHS/CDC implements the proposed rule change to remove infection with HIV from that list, it should remove HIV testing from the routine medical exam for foreign nationals. To continue to require HIV testing as part of the medical examination for immigration purposes would be unnecessary and harmful.

As the agency notes, testing is not generally required for medical conditions, but only for those conditions on the list of "communicable diseases of public health significance." Although a person may gain some advantages from finding out that they have a particular medical condition, mandatory testing should not be imposed on any individuals, as a general principle. In the immigration context, with the removal of HIV as an issue in the admission process, there is no justification for requiring HIV testing; rather, HIV should be treated the same as other health conditions – including other serious and infectious diseases – which are not inadmissible health conditions.[19] That is, HIV testing should not be required as part of the medical examination, nor should it be suggested as part of that examination process.

To require HIV testing or even to suggest HIV testing (on either an "opt in" or "opt out" basis) would actually contribute to the HIV-related stigma and discrimination that the proposed rule seeks to end. As noted, tests for other health conditions not on the list of "communicable diseases of public health significance" are not required or suggested as part of the medical examination. Requiring or suggesting testing for HIV after it is removed from that list would continue different treatment of HIV, thus perpetuating the mistaken – and harmful – idea that the public health is put at risk if people living with HIV immigrate to the U.S.

Additional harms would be likely to flow from including a requirement related to HIV testing. Unfortunately, HIV testing raises serious concerns not present with testing for some other health conditions, due to the continuing stigma associated with an HIV diagnosis in this country and others and the discrimination that people living with HIV face here and in other countries. With respect to other countries, as the agency notes,[20] HIV test results might not be kept confidential, thus putting individuals found to have HIV at great risk of experiencing discrimination and/or stigmatization.

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[18] *See* NPRM, 74 Fed. Reg. at 31801, 31809.

[19] As the agency notes, testing is not mandated, as part of the immigration process, for infectious diseases such as hepatitis, malaria, and West Nile virus and chronic conditions such as diabetes and heart conditions. NPRM, 74 Fed. Reg. at 31801. We question whether HHS/CDC even has the legal authority to mandate HIV testing (or even mandate an offer of HIV testing) once HIV is removed from the list of "communicable diseases of public health significance."

[20] NPRM, 74 Fed. Reg. at 31802.

Moreover, the persons who conduct the required medical examination might not be qualified or trained to provide necessary information to ensure that informed consent for an HIV test is obtained or to provide the necessary counseling and linkage to care if the individual tests positive for HIV.

In our own country, people living with HIV still face significant stigma and discrimination.[21] The agency notes the risk that information that a foreign national has HIV might be used by the Department of Homeland Security in evaluating whether the foreign national would become a public charge,[22] reflecting the agency's recognition that misunderstanding of the significance for a particular individual of having HIV is widespread and that people with HIV in this country have to counter stigmatizing assumptions made about them based solely on their HIV test results. That reality underscores the importance of HIV testing being performed on a voluntary, informed basis. The coercive atmosphere of a required medical examination is not conducive to obtaining informed consent and ensuring voluntariness.

Lambda Legal opposes incorporating an offer of HIV testing into the medical examination process.[23] If HIV testing is offered in that process, meaningful safeguards must be imposed, requiring that the testing is conducted in a manner which ensures it is confidential, voluntary, and informed and that appropriate steps are taken (including post-test counseling and linkage to care) if the individual tests positive for HIV.[24]

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[21] *See*, *e.g.*, Katherine R. Waite et al., *Literacy, Social Stigma, and HIV Medication Adherence,* 23 J. Gen. Internal Medicine 1367, 1367 (2008); Kaiser Public Opinion Spotlight, *Attitudes About Stigma and Discrimination Related to HIV/AIDS* (Aug. 2006), at pp. 7-8, *available at* http://www.kff.org/spotlight/hivstigma/upload/Spotlight_Aug06_Stigma.pdf (last visited Aug. 17, 2009); Lambda Legal, *The State of HIV Stigma and Discrimination in 2007: An Evidence Based Report* (Feb. 2007), *available at* http://www.lambdalegal.org/our-work/publications/general/2007-hiv-stigma-discrimination.html (last visited Aug. 17, 2009)

[22] NPRM, 74 Fed. Reg. at 31802.

[23] The agency's reference to "all immigrants, refugees, and status adjusters [having] the opportunity . . . to be tested in the United States as recommended by the [2006 CDC recommendations for HIV testing]," 74 Fed. Reg. at 31802, is a bit puzzling. The referenced recommendations relate to HIV testing in health-care settings. To the extent that immigrants, refugees, and status adjusters seek medical care in health-care settings, they should be treated the same as other individuals with respect to HIV testing.

[24] *See* Lambda Legal, et al., *Expanding the Availability and Acceptance of Voluntary HIV Testing: Fundamental Principles to Guide Implementation* (Oct. 2007), *available at* http://www.lambdalegal.org/our-work/publications/general/voluntary-hiv-testing.html (last visited Aug. 17, 2009); *see also* Lambda Legal & American Civil Liberties Union, *Increasing Access to Voluntary HIV Testing: The Importance of Informed Consent and Counseling in HIV Testing* (Mar. 2007), *available at* http://data.lambdalegal.org/pdf/publications/hiv/informed-consent-counseling.pdf (last visited Aug. 17, 2009).

The Economic Impact of the Rule Change Is Likely Not as Significant as the NPRM Suggests

The economic impact of the proposed rule change, which happens to be the most quantifiable aspect of the agency's cost-benefit analysis, must be placed in context relative to the almost entirely unquantifiable – and tremendously important – benefits of ending this stigmatizing and discriminatory policy. While Lambda Legal recognizes that the agency has an obligation pursuant to Executive Order 12866 to assess the proposed rule change to determine if it is "economically significant," we must point out that the original decision to place HIV on the list of "dangerous contagious diseases" was, at least purportedly, driven by concerns regarding the public health and not by economic considerations.[25] For over two decades now, individuals living with HIV have endured this discriminatory policy – one that is not applied to persons with almost any other medical condition which, like HIV, does not pose a public health risk to the general public through casual contact.[26] Lambda Legal notes the paradox of the economic scrutiny that is now required by the rulemaking process in order to lift a policy that should not have been imposed in the first place. This rulemaking process forces the agency to engage in one final act of discriminatory treatment, seeming to require economic justification for foreign nationals living with HIV merely to obtain the same treatment under our immigration laws accorded to individuals suffering from other chronic illnesses. The fact that the proposed rule change seeks to end an admittedly stigmatizing and discriminatory policy should significantly reduce the weight given to possible economic aspects when evaluating the "costs and benefits" of the proposed rule change.[27]

To assist it in evaluating the reasonableness of the model used to assess the economic impact of lifting the HIV travel and immigration ban, Lambda Legal (along with the Whitman-Walker Clinic ("WWC") in Washington, DC) retained the services of economic consultants at Deloitte Financial Advisory Services LLP ("Deloitte FAS"). As a *pro bono* service, Deloitte FAS provided to Lambda Legal and WWC a report regarding HHS/CDC's economic model and analysis of the economic impact of the proposed rule change (the "Deloitte FAS Expert Report"), and that report is attached to these comments as Exhibit A. The following comments are, however, solely Lambda Legal's comments and are not intended to reflect the views of Deloitte FAS regarding the proposed policy

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[25] Of course, individuals with HIV have been and will remain subject to the immigration restrictions that seek to bar the entry of *any* foreign national who may become a "public charge" and, thereby, drain resources from the U.S. economy. *See* 8 U.S.C. § 1182(a)(4).

[26] Lambda Legal notes that the list of "communicable diseases of public health significance" continues, even with the changes proposed in the NPRM, to include a few other diseases – notably gonorrhea and syphilis – that are not transmissible through casual contact. *See* 34 C.F.R. § 34.2. Continued inclusion of those diseases on the list lacks public health justification and should be ended by regulatory change.

[27] HHS/CDC appears to acknowledge this point. *See* NPRM, 74 Fed. Reg. at 31801 ("This proposed rule is not intended to correct any market failure, but to remove a government-imposed barrier that does not appear to provide a significant public health benefit and it at odds with human rights considerations.").

change. Rather, Lambda Legal's comments in this section are based on its understanding and interpretation of the analysis contained in the "Deloitte FAS Expert Report."

Lambda Legal notes that the Notice of Proposed Rulemaking ("NPRM") could provide greater clarity as to what the economic impact analysis in the proposed rule is in fact assessing.[28] In particular, it is worth noting that the estimate of the "cost" to the economy described in the NPRM is *not* the costs HHS/CDC believes will be borne by the federal government after the rule is implemented. Rather, the portion of the healthcare costs in the "economic impact" analysis for which the federal government might be directly responsible is subsumed within the figure representing the overall "costs" to the economy, because such "costs" are calculated regardless of payer. It would be helpful if the agency explicitly states that the costs to be borne by the federal government are but a fraction of the figure described as "costs" in the NPRM.

Furthermore, the comments to the proposed rule change should acknowledge that, before passing the legislation that returned to HHS/CDC the authority to determine whether HIV should be on the list of "communicable diseases of public health significance"[29] Congress assessed, through the Congressional Budget Office ("CBO"), the potential costs *to the federal government* of removing HIV from the list.[30] Subsequently, Congress amended the legislation to offset those potential costs to the federal government by increasing the visa application fees to be paid by foreign nationals seeking to visit or immigrate to the United States.[31] While HHS/CDC may not be allowed to include those offsetting monetary benefits in its analysis of the "economic impact" of the rule change,[32] the agency should at least have noted in the NPRM that Congress has already identified and evaluated the

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[28] For instance, Lambda Legal questions whether all expenditures on HIV-related healthcare for immigrants living with HIV, regardless of payer, may accurately be characterized as a "cost" *to the economy*. As noted in the Deloitte FAS Expert Report, the concept of healthcare expenditures as solely a drain on or cost to the economy may not be accurate. *See* Deloitte FAS Expert Report at 8.

[29] *See* Tom Lantos and Henry Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, Pub. Law 110-293, 122 Stat. 2963 ("PEPFAR II").

[30] While the NPRM does describe the differences between the models used by the CBO and HHS/CDC in their respective analyses, the NPRM does not make adequately clear the completely different purposes each of the analyses serves. *See* NPRM, 74 Fed. Reg. at 31804-05.

[31] CBO, Cost Estimate for H.R. 5501 (Oct. 2008), *available at* http://www.cbo.gov/ftpdocs/98xx/doc9866/hr5501.pdf (last visited Aug. 17, 2009).

[32] HHS/CDC could also clarify why it cannot include the increased revenue from visa application fees as part of the economic benefits resulting from this process of lifting the HIV travel and immigration ban. Lambda Legal believes that the reason may be that the statutory increase in visa application fees will go into effect regardless of whether HIV is now removed from the list, as Congress contemplated and HHS/CDC is now proposing, but HHS/CDC should explicitly explain in the NPRM the reasons behind its decision not to discuss the visa application fee offset placed in the legislation by Congress.

potential costs to the federal government and has implemented a mechanism for recovering those costs (as calculated by the CBO), which will therefore not be borne by the U.S. taxpayer.[33]

Lambda Legal also wishes to acknowledge the difficult task the agency faced in attempting to assess the economic impact of lifting the HIV travel and immigration ban. Because the policy created a disincentive for foreign nationals living with HIV to even consider immigrating to the United States, HHS/CDC lacks data regarding the population of individuals who might attempt to immigrate to the U.S. once the ban is lifted. Other factors – including but not limited to shifts in the demographics of the global epidemic, medical advances in the treatment of HIV, the availability of care and treatment abroad (in many countries, often at a lower cost than in the United States), changes in the standard of care within the United States itself, and improvement in public education regarding modes of transmission – continue to complicate any analysis that may be conducted. With each passing year that the HIV travel and immigration ban has been in place, it has become more difficult to develop an accurate analysis of what the economic impact would be of ending that discriminatory policy.

Given the limitations imposed by the lack of reliable data on many crucial points, Lambda Legal believes that the economic model presented in the NPRM is, in most respects, a reasonable analysis of the potential economic impact of lifting the HIV travel and immigration ban.[34] As Deloitte FAS notes, for the most part, where the agency lacked solid data and was forced to make assumptions, it made clear on what information those assumptions were based, pointed out the effects adjusting those assumptions might have, and conducted sensitivity testing to provide a range of values within which the actual figures might fall.[35] It appears that HHS/CDC has been as transparent as possible in evaluating the economic impact of the proposed rule change and has affirmatively sought comment with respect to specific choices it has made and assumptions it has been forced to draw in the face of a paucity of data on certain topics.[36]

Benefiting in large part from the analysis conducted by Deloitte FAS, Lambda Legal can identify several choices and assumptions that it believes result in some degree of overestimation of the economic costs and an underestimation of the economic benefits involved in lifting the HIV travel and immigration ban. For instance, the assumption that the prevalence of HIV among those immigrating to the U.S. will be the same as the prevalence in the general population of a particular region seems questionable. As HHS/CDC admits, "[t]here are several possible reasons as to why

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[33] *See* Deloitte FAS Expert Report at 8.

[34] *See* Deloitte FAS Expert Report at 4.

[35] *See id.*

[36] Based on the work of the economic consultants at Deloitte FAS, Lambda Legal learned that a calculation error and a transcription error were made in the NPRM, resulting in cost overstatements of approximately $3 million and $81 million, respectively. *See* Deloitte FAS Expert Report, at 5-6. Although it is important for HHS/CDC to review this data and correct any errors it confirms, it should be noted that Deloitte FAS believes that the HIVEcon model remains sound. *See id.* at 6.

the proportion of HIV-infected immigrants could be less or more than the prevalence of HIV-infected persons in the region of origin."[37] Nonetheless, given the lack of reliable data on the subject, the choice HHS/CDC made in this regard – perhaps to overestimate somewhat the number of individuals living with HIV who would seek to immigrate to the U.S. – was not outside the range of what might be considered reasonable. Furthermore, the sensitivity testing conducted in the model – and set forth in the NPRM – reveals what the resulting economic impact would be if the assumption was changed to reflect both higher and lower prevalence rates among those seeking to immigrate to the United States from a particular region.

In the HHS/CDC model and analysis, there does exist however one suspect foundational assumption for which no sensitivity testing was conducted. As noted in the Deloitte FAS Expert Report, HHS/CDC has based its analysis on the total number of immigrants to the United States for 2007 and has assumed that lifting the HIV travel and immigration ban will not by itself result in any increase in the number of immigrants to the U.S.[38] A flaw in that assumption, however, is that it ignores the fact that immediate relatives – which according to the Deloitte FAS Expert Report account for 40-47% of all immigrants to the U.S. – are not subject to numerical caps. Therefore, immediate relatives with HIV would not simply replace (or "crowd out") an immigrant who is not HIV-positive, as the HIVEcon model assumes. The model captures HIV-related healthcare expenditures for these new immigrants, but the model fails altogether to account for the economic *benefits* – such as increased productivity and additional tax revenue – of these immediate family member immigrants.[39] Lambda Legal submits that one cannot conduct an accurate cost-benefit analysis while looking only at the debit side of the ledger sheet. In order to assess the economic impact of lifting the HIV travel and immigration ban, the economic benefits of the incremental increase in the total number of immigrants must also be taken into account.[40] Lambda Legal believes that including such benefits in the analysis would have reduced the HHS/CDC's assessment of the degree of economic impact resulting from its decision to lift the HIV travel and immigration ban.[41]

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[37] NPRM, 74 Fed. Reg. at 310803.

[38] Deloitte FAS Expert Report at 7-8.

[39] *See id.*

[40] Although HHS/CDC acknowledges that immigration "produces net economic gains for the U.S.," citing a study finding that "immigrants, in general, create an annual economic impact of between $1 billion and $10 billion," NPRM 47 Fed. Reg. at 31804, the agency completely ignores these incremental benefits because of the assumptions discussed above.

[41] Even if the figure at which the HHS/CDC model arrives in terms of HIV-related healthcare costs for immigrants living with HIV is accurate, the figure must be viewed in context. When viewed in an "apples to apples" comparison with the total spent on healthcare in the U.S. (*i.e.*, all expenditures, regardless of payer), the incremental amount spent on healthcare for immigrants living with HIV is dwarfed to the point of being insignificant. *See* Deloitte FAS Expert Report at 10.

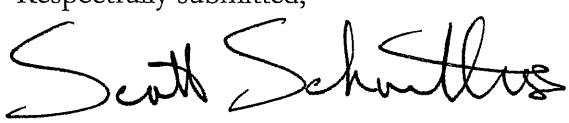
Additional Steps That Should be Taken Once the Proposed Rule is Adopted

Once, as HHS/CDC proposes and Lambda Legal urges, the HIV travel and immigration ban is lifted, the agency should work with other relevant U.S. agencies to ensure that these changes are well publicized. In order to ensure that this significant change in long-standing policy is properly administered, policy guidance and training of consular personnel and other immigration processors is crucial, and the agency should work closely with the Department of Homeland Security and Department of State to ensure that occurs promptly. Finally, the agency needs to take effective measures to ensure that persons who have been denied entry, stay, or residence because they are living with HIV do not face bias or discrimination if they reapply for admission, stay or residence.

Conclusion

Although difficult to quantify, the benefits – both at home and abroad – that will accompany the lifting of the HIV travel and immigration ban are very substantial. Lifting the ban, and the related requirement for HIV testing, will end requirements that lack medical or public health justification and are harmful to individuals, U.S. society, and the global community. Lambda Legal commends HHS/CDC for proposing these regulatory changes and urges the agency to adopt promptly the Proposed Rule and then to take the additional steps outlined above to ensure that the U.S. government's discrimination against foreign nationals living with HIV is brought to a complete halt.

Respectfully submitted,



Scott A. Schoettes
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Exhibit A

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Re: Medical Examination of Aliens--Removal of Human Immunodeficiency Virus (HIV) Infection From Definition of Communicable Disease of Public Health Significance.

Dear Gentlemen:

Pursuant to an engagement letter dated July 21, 2009, Deloitte Financial Advisory Services LLP ("Deloitte FAS") was asked to evaluate a model included in the Notice of Proposed Rulemaking ("Notice") issued by the Centers for Disease Control and Prevention ("CDC") within the U.S. Department of Health and Human Services ("HHS") entitled "Medical Examination of Aliens--Removal of Human Immunodeficiency Virus (HIV) Infection From Definition of Communicable Disease of Public Health Significance."[1] That model estimates the potential healthcare costs and benefits to the American economy associated with eliminating the ban on immigration of persons with HIV/AIDS.

Our evaluation was performed by Thomas Dunn, a Ph. D. economist and Senior Manager in the Economic and Statistical Consulting group in collaboration with his colleagues.

[1] See *Federal Register*, Volume 74, Number 126 (July 2, 2009), pp. 31797-31809.

Executive Summary

Our observations are as follows:

- Overall, the model appears to be a reasonable attempt to estimate future healthcare expenditures attributable to the elimination of the ban on immigration for HIV-positive persons. The model appears to be thoughtfully constructed; it is well-documented and easy to use; it incorporates "real world" data from reputable sources; it appears to perform the required mathematical operations reliably; it clearly states assumptions; and it can accommodate alternative values for key parameters.
- Without challenging the choice of parameter values in the model, there are reasons to believe that the estimates presented in the Notice overstate the potential net costs to the U.S. economy.
    - An apparent transcription error overstates the total annual HIV-related healthcare expenditures by $81 million or 22%.
    - Benefits (labor productivity, tax payments) associated with incremental immigrants are not counted against the incremental healthcare costs.
    - Healthcare expenditures, like other expenditures, can be expected to generate additional economic activity through a multiplier effect on the order of 2.3 to 2.7 that would act to offset the incremental costs.
- As calculated by the model, the total annual healthcare expenditures attributable to the removal of the ban on immigration of HIV-positive would amount to 0.16% of U.S. healthcare expenditures in calendar year 2007.

Subsequent sections of this report describe Deloitte FAS' assessment approach and conclusions in more detail.

Assessment of the Healthcare Cost-Benefit Model

Our assessment of the CDC's HIVEcon healthcare expenditure model has five main parts: a description of the purpose of the model; an evaluation of the model's structure, assumptions, and calculations; discussion of two potential errors in calculations; a comparisons of the draft and final versions of the Notice; and an overall assessment of the model and comments on the cost and benefit concepts used in the model.

Purpose of the HHS model

The HIVEcon model is designed to estimate the potential expenditures to the U.S. economy, pursuant to Executive Order 12866, from changing the Part 34 regulation that would effectively allow the immigration of HIV-infected persons. The model focuses on healthcare expenditures and compares the expenditures to a baseline case, under which HIV-infected persons are not admitted or not allowed to adjust their status to permanent resident. The benefits of allowing the immigration of HIV-positive persons are characterized as either non-pecuniary or difficult to quantify: family reunification, acquisition of highly-demanded skilled labor, increased life expectancy, reduction of

stigma and discrimination, and reputational effects to the U.S.[2] As described below, the pecuniary benefits (such as labor productivity or taxes paid) generated by admitting HIV-positive immigrants are assumed to be identical to those that would be generated by HIV-negative immigrants if the HIV immigration ban were to remain in place.

We obtained the HHS' Notice published in the *Federal Register* on July 2, 2009 and the draft version dated June 16, 2009. We also obtained from the CDC's webpage, its Excel-based model that calculates potential healthcare costs ("HIVEcon") and its accompanying technical appendix.[3]

Model Structure and Assumptions

The HIVEcon model has five key components:

1. *Estimates for the number of potential HIV-infected immigrants that may arrive in the U.S. or be adjusted to permanent resident status within the U.S. under the new proposed rule*. This calculation relies on data from the Department of Homeland Security, Office of Immigration Statistics on the number and region-of-origin mix of legal permanent residents to the U.S. in 2007; data on HIV prevalence rates in regions of the world drawn from various United Nations reports; and assumptions about the number and regional mix of immigrants to the U.S. and HIV-prevalence rates among immigrants, and assumptions about changes in these values over time. The discussion in the Notice provides Primary, High and Low Estimates corresponding to various values of HIV prevalence among immigrants. The HIVEcon model allows the user to change the regional mix, the HIV-prevalence rates, and the growth in immigration over time.
2. *Life expectancy tables of HIV-infected persons*. These tables are based on research using national HIV surveillance data and assumptions about the average age at immigration. The HIVEcon model allows the user to change the average age at immigration.
3. *Onward transmission rate of HIV infections*. Most of the Notice assumes an average onward transmission rate of 1.51 per 100 among HIV-infected immigrants based on scholarly research and an assumption about the social behavior of immigrants.[4] Estimates assuming a low value of 0% and a high value of 4.53% are also provided. The HIVEcon model allows the user change the onward transmission rate..
4. *Annual cost of treatment*. Most of the discussion in the Notice assumes an annual cost of treatment of $25,200 per year based on research published in a medical journal.[5] The model allows the user to change the annual cost of treatment.

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[2] See Notice, pages 31803 and 31804.

[3] See www.cdc.gov/ncidod/dq/laws_regs/part34/hivecon.html.

[4] The average rate onward transmission rate due to sexual activity in the U.S. is 3.02 per 100 HIV-infected persons Pinkerton, S.D. "How many sexually-acquired HIV infections in the USA are due to acute-phase HIV transmission?" *AIDS*. 21(12, July 31, 2007) : 1625–1629.

[5] Schakman et al., "The Lifetime Cost of Current Human Immunodeficiency Virus Care in the United States," *Medical Care* 44, 11 (November 2006): 990- 997.

5. *Discount rate for converting dollar values in the future to their present value*. Most of the discussion in the Notice assumes a discount rate of 3%. The HIVEcon model allows the user to input a value for this parameter.

The model relies on a number of parameters that reflect national immigration policy, the prevalence of HIV around the world, HIV transmission patterns, and the annual costs and lifetime benefits of HIV treatments and how these things change over time. The model appears to have relied on reputable data sources for baseline parameter estimates. The assumptions are clearly stated, the sources are cited, and the choice of a particular value is justified. The future time paths for the number and mix of immigrants, the HIV-prevalence rates and onward transmission rates, and annual HIV-related healthcare costs are assumed to be flat at the most recent value to avoid having to make additional assumptions about the evolution of the parameters over time.

The HIVEcon model allows flexibility in specifying parameter values. In the discussion of results in the Notice, lower and upper bounds for some of the key parameters are provided, which allow for reader to determine which parameters have the largest influence on the results. Finally, in the Notice the CDC explicitly requests guidance from subject matter experts on the reasonableness of its assumptions and more realistic parameter values.

The HIVEcon model compares favorably to forecasting models that are commonly used in litigation and business consulting engagements. The HIVEcon model is thoughtfully crafted and contains all of the relevant components necessary to produce a reasonable range of estimates of HIV-related healthcare expenditures induced by the proposed rule change. The HIVEcon model is well-documented with citations of data sources and clear user instructions. The model is transparent in that assumptions are clearly explained and the sensitivity of the results to assumptions on key parameter values can be tested quite easily from the input "dashboard." The model calculates expenditures in the first, fifth, tenth, twenty fifth and fiftieth year after promulgation of the rule.. Additionally, the model is constructed in a way that would allow for easy alteration to accommodate alternative specifications of the model components.

Model Calculations

As part of our assessment, we "looked under the hood" to test the soundness of the construction of the model. While we did not fully deconstruct the model and verify the accuracy of every data element, formula and calculation, we conducted the following validation tests:

- Check that key data from external sources was accurately entered (the number of legal permanent residents in 2007 by region of origin, number of HIV cases by region, annual cost of HIV-related treatment)
- Check that formulas were accurately coded (for example, formulas for calculating weighted averages, discounting future values, and converting number of cases to dollars of treatment costs)

- Check that references to values from one part of the model to another part of the model were coded correctly and were operational.

Our inspection detected no errors in transcription from data sources, no mistakes in formulas, and no faulty cell references.

We also ran the HIVEcon model under several dozen scenarios using various combinations of values for key parameters, such as HIV prevalence rates, onward transmission rates, annual HIV-related healthcare costs, discount rate, immigration growth rate, and age at immigration. In this testing, the model output changed in expected directions and with expected magnitudes. We were also able to reproduce key results presented in the Notice and in the model's technical appendix, with the two exceptions that are described below.

Reconciliation of Expenditure Estimates Presented in the Notice

In the reconciliation of the healthcare expenditure estimates reported in the Notice to the calculations in the HIVEcon model, we identified two potential calculation errors. The first one only affects the expository flow of the discussion of the sensitivity of the estimates to a specific parameter assumption. The second instance, on the other hand, results in a significant overstatement of the potential healthcare expenditures presented in the Notice.

First, the discussion on page 31806 of the Notice of the sensitivity of the model to the choice of onward transmission rates appears to contain a calculation error. The "upper bound" scenario is described as an onward transmission rate of 4.53 per 100 HIV-infected persons. The number of onward transmitted cases is presented as 261 with an associated expenditure of $8.1 million. We believe the correct calculation for an onward transmission rate of 4.53% applied to the 4,275 annual new HIV-positive immigrants is 194 new cases (4,275*.0453) with an associated expenditure of $4.9 million (194*$25,200).[6]

The second potential calculation error is in the lower panel of Table 2, the Annualized Monetized Healthcare Expenditures for cases of onward transmission. It appears that the expenditure estimate was incorrectly transcribed from the HIVEcon model. Table 2 shows the Primary Estimate of 676 HIV-positive cases due to 1.51% onward transmission. This number of cases can be confirmed using the HIVEcon model with the "Primary Estimate" set of assumptions. At an annual treatment cost of $25,200 per case, the discounted annual expenditures in the fifth year after the rule promulgation should be $15 million, not $96 million as displayed in Table 2.

[6] The 261 figure is consistent with a rate of 6.09%, a value that is mentioned elsewhere in the Notice as the upper bound for HIV-prevalence rate among immigrants, rather than the upper bound on the onward transmission rate.

This calculation is confirmed by the HIVEcon model's estimate of total expenditures under the Primary Estimate set of assumptions. That total is $357 million for the combined 16,431 HIV-positive immigrants and onward transmission cases, not $438 million as stated on page 31806 in the Notice. This difference of $81 million represents a 22% overstatement of the actual total expenditures in the fifth year after the rule promulgation.[7] This potential error in the Notice does not undermine our opinion of the robustness of the HIVEcon model, rather it appears to be simply a mistake in transcribing output from the model to the Notice.

Draft versus Final Version of Notice

Another element of our assessment is a comparison of the calculations and the description of methods and results in the draft version of the Notice to the final version of the Notice. Both versions are based on calculations from the HIVEcon model and employ the same set of assumptions about parameter values and their evolution over time. Where the two versions differ is in the choice of the time horizon at which expenditures are measured.[8] Specifically, the draft version of the Notice highlights expenditures in year 20 after the rule is promulgated, while the final version focuses on the expenditures in the fifth year after the rule is promulgated. The final version of the Notice argues that the shorter time horizon is more appropriate to mitigate the uncertainty about the future time paths of the key inputs to the model citing the "rapid pace of change in HIV treatment, HIV prevalence in other countries, as well as potential changes in overall immigration policy." (p. 31806) [9]

Given that the model results are highly sensitive to these and other parameters and assumptions— as demonstrated by the range of estimates presented in the Notice— and given the uncertainty about the future values of these parameters and given that Executive Order 12866 provides no specific guidance on the time horizon to be used in a cost-benefit analysis and given that estimates for other time horizons are available in supporting documents, the selection of the five-year time horizon in the final version of the Notice is a reasonable choice.

Overall Assessment

Notwithstanding the apparent errors in exposition or transcription of results in the Notice, the HIVEcon model can be viewed as a reasonable attempt to estimate the healthcare expenditures associated with eliminating the ban on immigration for HIV-infected persons for the reasons given above. The estimates depend critically on the parameter and baseline assumptions on immigration patterns, HIV prevalence, HIV transmission, and HIV-related healthcare costs and treatment options.

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[7] Similarly, the Low Estimate in Table 2 should be $4 million, not $24 million and the High Estimate should be $22 million, not $145 million.

[8] The draft version also presents more sensitivity analyses, most of which now appear in the Technical Appendix to the HIVEcon model.

[9] The CBO cost estimate uses a ten-year horizon.

The model is flexible enough to accommodate changes to these parameters and baseline assumptions and it is to be expected that different assumptions will have significant impacts on the number of cases of HIV infection and the total expenditures resulting from elimination of the ban on immigration of HIV-positive persons.

For example, the model assumes all HIV-infected immigrants and persons who acquired HIV through onward transmission receive the "optimal" standard of care for all the remaining years of their lives, which comes at a cost of $25,200 per year for every remaining year of life, at every age, and in all years in the future.[10] In the model, this cost per year enters the expenditure calculation as a simple scalar to the number of HIV-infected immigrants; this means that a 10% decrease (or increase) in the treatment cost per year will reduce (increase) the total (undiscounted) expenditures in any year by exactly 10%. If not all persons seek or receive this level of care or if the average cost of care is lower than the "optimal" treatment costs, then the total healthcare expenditures estimated in the model would fall.

Comments on Cost and Benefit Concepts

Our assessment of the model also includes a consideration of the concepts of costs and benefits in the model.

Fixed Number of Immigrants and Omitted Benefits

The model assumes that the number of immigrants is held fixed at the 2007 level for each year in the future and that that each HIV-positive immigrant replaces an HIV-negative immigrant. Furthermore, the HIV-positive immigrants incur HIV-related healthcare expenditures that are estimated in the model, but on all other aspects of productivity, other healthcare expenditures, and costs to the government, the HIV-positive immigrants are identical to the HIV-negative immigrants they replace.

This assumption that the HIV-positive immigrants "crowd out" HIV-negative immigrants may make sense if there are annual numerical caps on immigration so that there is "competition" for the available slots. However, a large percentage of immigrants, some 47% in 2007 (and around 40% historically), were immediate relatives of U.S. citizens, a category of immigrants that is exempt from annual numerical limits.[11]

In the HHS model, HIV-positive immediate relatives would currently be excluded from immigration; when the ban is lifted, in the absence of annual numerical limits, they would not "crowd out" HIV-negative immigrants, rather they would be incremental to the 2007 number of immigrants. All the HIV-related healthcare expenditures for these new

[10] The $25,200 figure (in 2004 dollars) and the description of the care as "optimal" is from Schakman et al., "The Lifetime Cost of Current Human Immunodeficiency Virus Care in the United States," *Medical Care* 44, 11 (November 2006): 990- 997. The application of this cost in all future years is an assumption made in the HIVEcon model.

[11] Jeffreys, K. and R. Monger, "U.S. Legal Permanent Residents: 2007" Annual Flow Report, Office of Immigration Statistics, U.S. Department of Homeland Security, March 2008.

immigrants are already captured in the model, whether the HIV-positive immigrants replace HIV-negative immigrants or they are incremental. However, if the immediate family members are incremental to the total number of immigrants, the benefits that they generate— in the form of labor productivity or tax revenues— should be modeled and counted as an offset to their healthcare expenditures. While we have not attempted to calculate the value of these benefits, it is likely that they would offset a considerable portion of the healthcare expenditures and reduce the net cost to the U.S. economy.

Cost Concept

In the Notice healthcare expenditures are characterized as a cost to the economy. While a topic of great concern these days, healthcare expenditures should not be viewed solely as a drain on or cost to the economy. It is a tenet in economics that an expenditure has ripple effects in the economy as the new expenditure is a source of income for the recipient that then induces a further expenditure elsewhere in the economy, and so on. Models that measure the economic impact of infrastructure projects and other expenditures typically estimate the effects on economy-wide employment and output, known as "multipliers", generated by additional expenditures in specific industries in the economy.

IMPLAN, a widely used economic impact model, contains output multipliers that have been estimated for hundreds of industries.[12] The 2007 IMPLAN output multipliers for subsectors of the healthcare industry range from 2.37 to 2.71.[13] This means that each additional $1,000,000 of healthcare expenditure in these subsectors eventually generates $2.37 million to $2.71 million of output in the U.S. economy. This compares to multipliers in road construction of 2.82 and in public education of 2.24.

Not All of the Expenditures are a Cost to the Federal Government

Not all the healthcare expenditures presented in the Notice are costs to be borne by the U.S. government; rather, the figure includes expenditures paid by other sources including private health insurance, personal funds, state and local governments. The Congressional Budget Office ("CBO") calculated the cost to the federal government of eliminating the ban on immigration of HIV-positive persons, under a different set of assumptions, in October, 2008 in the cost estimate for HR 5501, "Tom Lantos and Henry J. Hyde U.S. Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008." The CBO estimated additional government expenditures over ten years of $83 million (through Medicare, Medicaid, and other programs) which were more than offset by $104 million of additional revenue generated from an increase in visa application fees.

Expenditures in Context

[12] IMPLAN is a proprietary software package produced by Minnesota IMPLAN Group, Inc. and requires a subscription to access its data and documentation. The company's website is www.implan.com.

[13] This includes these industry codes: 394 Offices of physicians, dentists, and other health practitioners; 395 Home health care services; 396 Medical and diagnostic labs and outpatient and other ambulatory care services; 397 Hospitals; 398 Nursing and residential care facilities.

The incremental healthcare expenditure estimate can be viewed in the context of recent healthcare expenditures for HIV-related treatment and care. The estimate of incremental annual healthcare expenditures in the fifth year after promulgation of the rule is $357 million (corrected from $438 million in Notice as described earlier), which includes all payer sources: private insurance, charities, and federal and state governments.

According to the Kaiser Family Foundation summary of recent U.S. federal funding of HIV/AIDS, the FY 2009 expenditures on treatment and care paid by the federal government (through the Ryan White Program, Medicare and Medicaid) was $11.4 billion.[14] Data for HIV-related healthcare paid by private insurance, charities, and state governments in FY 2009 were not readily available for this assessment, which prevents an "apples to apples" calculation, but does provide a kind of upper bound: the annual expenditures modeled in the Notice account for about 3% ($357 million/$11.4 billion) of the federal government outlays for HIV-related healthcare in FY 2009. In another comparison of healthcare expenditures by all payer sources, the annual expenditures modeled in the Notice account for 0.16% of the total ($2.2 trillion) healthcare spending in the U.S. in calendar year 2007.[15]

Summary

Our assessment of the healthcare expenditure model presented in the Notice can be characterized as follows:

- The HIVEcon model appears to be reasonable attempt to estimate future healthcare expenditures that are very sensitive to parameters that reflect national immigration policy, the prevalence of HIV around the world, HIV transmission patterns, and the annual costs and lifetime benefits of HIV treatments.
- The model relies on actual, recent values for parameters when they are available and clearly states its assumptions about the evolution of the parameters over time.
- The CDC recognizes that its choices for parameter and baseline values are "best guesses" and provides high and low values to demonstrate the sensitivity of the results and the importance of the assumptions.
- The CDC specifically solicits expert opinion on the reasonableness of the values and seeks more accurate values. Furthermore, the model appears to be able to handle changes in parameter and baseline values easily and is capable of generating new expenditure estimates with the new parameter values.
- The Notice presents what appears to be an error in the transcription of the treatment expenditures for onward transmitted HIV infections that potentially overstates the Primary Estimate of expenditures by $81 million or 22%.

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[14] "U.S. Federal Funding for HIV/AIDS: The President's FY 2010 Budget Request", *HIV/AIDS Policy Fact Sheet* (publication #7029-05), The Henry J. Kaiser Family Foundation, May 2009.

[15] Source for U.S. healthcare spending in 2007: National Health Expenditures Fact Sheet, "Historical NHE, including Sponsor Analysis, 2007", www.cms.hhs.gov/NationalHealthExpendData/25_NHE_Fact_Sheet.asp, accessed August 13, 2009.

- The total annual healthcare expenditure figure, $357 million in the fifth year after the rule promulgation, is characterized as a cost to the economy. However, the incremental healthcare expenditures, like other expenditures, can be expected to generate additional economic activity through a multiplier effect on the order of 2.3 to 2.7.
- In the context of overall health care expenditures, the total annual healthcare expenditures attributable to the removal of the ban on immigration of HIV-positive persons, $357 million in the fifth year after the rule promulgation (corrected for an apparent calculation error), amount to 0.16% of U.S. healthcare expenditures attributable to all payers in calendar year 2007.

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My Deloitte FAS colleagues and I appreciate the opportunity to work in support of Hogan & Hartson, Whitman-Walker Clinic and Lambda Legal as they prepare their responses to the Notice of Proposed Rule Making.

Yours truly,

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