

[EN BANC ORAL ARGUMENT SCHEDULED FOR DECEMBER 17, 2014]

No. 14-5018

**UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

JACQUELINE HALBIG, *et al.*,

Appellants,

v.

SYLVIA M. BURWELL, SECRETARY OF HEALTH & HUMAN SERVICES, *et al.*,

Appellees.

On Appeal from the United States District Court for the District of Columbia
No. 1:13-cv-00623-PLF

**BRIEF FOR *AMICI CURIAE* HARVARD LAW SCHOOL
CENTER FOR HEALTH AND POLICY INNOVATION, AIDS ALABAMA,
THE AIDS INSTITUTE, ASSOCIATION FOR COMMUNITY AFFILIATED
PLANS, COMMUNITY CATALYST, DUKE AIDS LEGAL PROJECT, HIV
MEDICINE ASSOCIATION, NATIONAL ALLIANCE OF STATE AND
TERRITORIAL AIDS DIRECTORS, NATIONAL MINORITY AIDS
COUNCIL, NORTH CAROLINA AIDS ACTION NETWORK, THE
SOUTHERN HIV/AIDS STRATEGY INITIATIVE, AND TEXAS ONE
VOICE: A COLLABORATIVE FOR HEALTH AND HUMAN SERVICES IN
SUPPORT OF APPELLEES URGING AFFIRMANCE**

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), the Harvard Law School Center for Health Law and Policy Innovation, AIDS Alabama, the AIDS Institute, Association for Community Affiliated Plans, Community Catalyst, the Duke AIDS Legal Project, HIV Medicine Association, National Alliance of State and Territorial AIDS Directors, National Minority AIDS Council, North Carolina AIDS Action Network, Southern HIV/AIDS Strategy Initiative, and Texas One Voice: A Collaborative for Health and Human Services submit the following Certificate of Parties, Rulings, and Related Cases.

A. Parties and *Amici*. All parties and *amici* appearing before the district court and those that filed an appearance or notice of appearance in this Court at the panel stage are listed in the Appellants' Brief. As of this filing, the following *amici* have filed an appearance or notice of appearance in this Court at the *en banc* stage: Senator John Cornyn; Senator Ted Cruz; Senator Orrin Hatch; Senator Mike Lee; Senator Marco Rubio; Representative Dave Camp; Representative Darrell Issa; State of Kansas; State of Nebraska; Judicial Watch, Inc.; Pacific Research Institute; Cato Institute; Jonathan H. Adler; Michael F. Cannon; Galen Institute; AARP; American Cancer Society; American Cancer Society Cancer Action Network; American Diabetes Association; American Heart Association; Commonwealth of Virginia and the States of Arkansas, California, Delaware,

Hawaii, Illinois, Iowa, Maine, Maryland, Mississippi, New Hampshire, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Vermont and Washington; Economic Scholars; National Health Law Program; Southern Poverty Law Center; Individuals With Preexisting Conditions; Jared Blitz; Jennifer Causor; Steve Orofino; Aidan Robinson; Martha Robinson; David Tedrow; Mary Tedrow; Group of Public Health Deans, Chairs, and Faculty; Craig H. Blakely, PhD, MPH; Paul Brandt-Rauf, DrPH, MD, ScD; Paul D. Cleary, Ph.D.; Jos F. Cordero, MD, MPH; Gregory Evans, Ph.D., M.P.H.; John R. Finnegan, Jr., Ph.D.; Lynn R. Goldman, M.D., M.S., M.P.H.; Richard S. Kurz, PhD; Robert F. Meenan, MD, MPH, MBA; Philip C. Nasca, MS, Ph.D., FACE; Michael G. Perri, PhD, ABPP; Martin A. Philbert, PhD; George G. Rhoads, MD, MPH; Edwin Trevathan, M.D., M.P.H.; Robert W. Blum, MD; Kyle L. Grazier, Dr.P.H., M.P.H.; Paula Lantz, Ph.D.; Laura Rudkin, Ph.D.; Oladele A. Ogunseitan, PhD, MPH; José Szapocznik, Ph.D.; Taylor L. Burke, J.D., L.L.M.; John A. Graves, Ph.D.; Peter Jacobson, JD, MPH; Leighton Ku, Ph.D., M.P.H; Jeffrey Levi, Ph.D.; Jay Maddock, Ph.D.; Wendy K. Mariner; Michelle M. Mello, J.D., Ph.D.; Sara Rosenbaum, J.D.; Benjamin Sommers, M.D., Ph.D.; Katherine Swartz, Ph.D.; Joel Teitelbaum, J.D., LL.M.; Jane Hyatt Thorpe, J.D.; Susan F. Wood, Ph.D.; the Harvard Law School Center for Health Law and Policy Innovation; AIDS Alabama; the AIDS Institute; Association for Community Affiliated Plans; Community Catalyst; the Duke AIDS

Legal Project; HIV Medicine Association; National Alliance of State and Territorial AIDS Directors; National Minority AIDS Council; North Carolina AIDS Action Network; the Southern HIV/AIDS Strategy Initiative; and Texas One Voice: A Collaborative for Health and Human Services.

B. Rulings Under Review. References to the ruling at issue appear in the Appellants' Brief.

C. Related Cases. References to related cases appear in the Appellants' Brief.

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**CERTIFICATE REGARDING NEED FOR SEPARATE BRIEF AND
CONSENT TO FILE**

All parties have consented to the filing of this brief. *Amicus* Harvard Law School Center for Health Law and Policy Innovation filed an original notice of intent to participate as *amicus curiae* on October 24, 2014, and *amici* filed an amended notice of intent to participate as *amici curiae* on November 1, 2014.¹

Pursuant to this Court's Rule 29(d), *amici curiae* certify that a separate brief is necessary because no other *amicus* brief of which we are aware will address the issues discussed in this brief, namely the importance of the availability of tax subsidies to all low- and middle-income individuals and families nationwide and, more specifically, the importance of the subsidies to *amici*'s constituents, discussed more fully herein. *Amici* are particularly capable of presenting evidence showing the importance of those subsidies in improving access to health care and overall health care outcomes for the nation's most vulnerable members, including people living with HIV and AIDS.

¹ Pursuant to Fed. R. App. P. 29(c)(5), *amici* state that no party counsel authored this brief in whole or in part; no party or party counsel made a monetary contribution intended to fund the preparation or submission of this brief; and no person other than *amici*, its members, or its counsel made a monetary contribution intended to fund its preparation or submission.

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Circuit Rule 26.1, the Harvard Law School Center for Health Law and Policy Innovation (“CHLPI”) states that it is an unincorporated organization and its parent corporation is the President and Fellows of Harvard College, which is a 501(c)(3) corporation. CHLPI does not issue stock or debt, and no publicly held company has a 10% or greater ownership interest in it. CHLPI is a public interest center devoted to improving the health of the most vulnerable populations through advocacy and education.

AIDS Alabama states that it is a 501(c)(3) nonprofit corporation. AIDS Alabama has no parent corporation, does not issue stock or debt, and no publicly held company has a 10% or greater ownership interest in it.

The AIDS Institute states that it is a 501(c)(3) nonprofit corporation. The AIDS Institute has no parent corporation, does not issue stock or debt, and no publicly held company has a 10% or greater ownership interest in it.

Association for Community Affiliated Plans (“ACAP”) states that it is a 501(c)(6) nonprofit organization. ACAP has no parent corporation, does not issue stock or debt, and no publicly held company has a 10% or greater ownership interest in it.

Community Catalyst states that it is a 501(c)(3) nonprofit corporation.

Community Catalyst has no parent corporation, does not issue stock or debt, and no publicly held company has a 10% or greater ownership interest in it.

Duke AIDS Legal Project states that it is an unincorporated organization and its parent corporation is Duke University, which is a 501(c)(3) corporation. Duke AIDS Legal Project does not issue stock or debt, and no publicly held company has a 10% or greater ownership interest in it.

HIV Medicine Association (“HIVMA”) states that it is an unincorporated organization and its parent corporation is the Infectious Disease Society of America, which is a 501(c)(6) corporation. HIVMA does not issue stock or debt, and no publicly held company has a 10% or greater ownership interest in it.

National Alliance of State and Territorial AIDS Directors (“NASTAD”) states that it is a 501(c)(3) nonprofit corporation. NASTAD has no parent corporation, does not issue stock or debt, and no publicly held company has a 10% or greater ownership interest in it.

National Minority AIDS Council (“NMAC”) states that it is a 501(c)(3) nonprofit corporation. NMAC has no parent corporation, does not issue stock or debt, and no publicly held company has a 10% or greater ownership interest in it.

North Carolina AIDS Action Network states that it is a 501(c)(3) nonprofit corporation. North Carolina AIDS Action Network has no parent corporation,

does not issue stock or debt, and no publicly held company has a 10% or greater ownership interest in it.

Southern HIV/AIDS Strategy Initiative (“SASI”) states that it is an unincorporated organization and its parent corporation is Duke University, which is a 501(c)(3) corporation. SASI does not issue stock or debt, and no publicly held company has a 10% or greater ownership interest in it.

Texas One Voice: A Collaborative for Health and Human Services (“One Voice Texas”)² states that it is a 501(c)(3) nonprofit corporation, has no parent corporation, does not issue stock or debt, and no publicly held company has a 10% or greater ownership interest in it.

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² Texas One Voice: A Collaborative for Health and Human Services operates under the registered trademark One Voice Texas, and filed an amended notice of intent to participate as *amicus curiae* on November 1, 2014 as One Voice Texas.

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INTEREST OF *AMICI CURIAE*

The Harvard Law School Center for Health Law and Policy Innovation (“CHLPI”) is a public interest center devoted to improving the health of the most vulnerable populations through advocacy and education. CHLPI coordinates with grassroots advocates and organizations that directly serve individuals and families who have the greatest health needs, including low-income people living with serious and chronic health conditions. CHLPI has experience building and supporting coalition infrastructure and advocacy capacity among low-income people living with chronic and serious health conditions and their health and social service providers. CHLPI has modeled the impact of the Patient Protection and Affordable Care Act (“ACA”) on access to treatment and services for human immunodeficiency virus (“HIV”) consumers, advocates, service providers and legislators; developed a toolkit for mental health consumers and advocates to use and evaluate state Medicaid managed care programs’ mental health services; and provided technical assistance in evaluating the health plans offered on ACA-created health insurance exchanges to a broad range of chronic illness-related advocates and organizations.

AIDS Alabama devotes its energy and resources statewide to helping people with HIV/AIDS live healthy, independent lives, and works to prevent the spread of HIV.

The AIDS Institute began as a grassroots community mobilization effort in the mid-1980s. With offices in Florida and Washington D.C., the AIDS Institute promotes action for social change through public policy research, advocacy, and education.

Association for Community Affiliated Plans (“ACAP”) represents fifty-eight nonprofit and community-based Safety Net Health Plans located in twenty-four states. ACAP’s mission is to support these Safety Net Health Plans in their work to improve the health of low-income and vulnerable populations.

Community Catalyst’s mission is to organize and sustain a powerful consumer voice to ensure that all individuals and communities can influence the local, state, and national decisions that affect their health.

Duke AIDS Legal Project provides free legal representation to low-income HIV positive clients in North Carolina in cases involving benefits, estate, guardianship, and discrimination.

HIV Medicine Association (“HIVMA”) represents nearly 5000 HIV clinicians and researchers that work on the frontlines of the HIV epidemic across the United States, promotes quality in HIV care, and advocates policies that ensure a comprehensive and humane response to the AIDS pandemic informed by science and social justice.

National Alliance of State and Territorial AIDS Directors (“NASTAD”) represents the nation’s chief state health agency staff members who administer HIV/AIDS and viral hepatitis health care, prevention, education, and supportive service programs that are funded by state and federal governments.

National Minority AIDS Council’s mission is to develop leadership within communities of color to end the HIV/AIDS epidemic in the United States.

The North Carolina AIDS Action Network improves the lives of people living with HIV and affected communities through outreach and public education, policy advocacy, and community-building to increase visibility and mutual support of people living with HIV throughout North Carolina.

Southern HIV/AIDS Strategy Initiative (“SASI”) is a broad-based coalition of HIV/AIDS advocates and their supporters led by the Duke AIDS Legal Project at Duke University School of Law. SASI engages in research-based advocacy to increase federal resources for the HIV epidemic in the Southern region of the United States.

Texas One Voice: A Collaborative for Health and Human Services (“One Voice Texas”) is a network of public, private, and nonprofit organizations in the greater Houston area working together to ensure that the health and human services needs of all Texans are addressed through education and awareness, program development, advocacy, regulation, and funding.

Because of their focus on the most vulnerable, *amici* serve populations that are deeply affected by the availability of subsidies under the ACA. The subsidies expand access to high-quality, affordable health care for these individuals and promote a more equitable public health environment. *Amici* offer the Court a unique insight into the devastating effect that Appellants' position would have on the nation's most vulnerable members, including low- and middle-income people living with HIV and AIDS.

SUMMARY OF ARGUMENT

The ACA, enacted by Congress in 2010, is a comprehensive health care reform act intended to make health insurance and health care coverage more affordable and accessible for millions of Americans. One of the key components of the reform involves federal tax subsidies, which are available to low- and middle-income individuals to help pay their premiums for health insurance purchased on health insurance exchanges established by the ACA.

In 2012, the Internal Revenue Service ("IRS") issued a rule providing that the ACA's tax subsidies are available to individuals who purchase insurance on either a state-run or federally-run exchange. Thirty-four states have opted out of creating their own exchanges; in these states, the federal government operates exchanges. The premium subsidies are currently available to individuals in all states with household incomes between 100% and 400% of the Federal Poverty

Level (“FPL”), which in 2014 included incomes between \$11,670 and \$46,680 for an individual or \$23,850 and \$95,400 for a family of four. In 2013, approximately 58% of the nonelderly U.S. population had incomes within that range. Kaiser Family Found., *Distribution of the Nonelderly Uninsured by Federal Poverty Level (FPL)*, available at <http://kff.org/uninsured/state-indicator/distribution-by-fpl-2/> (last visited Oct. 27, 2014). As Judge Edwards noted in dissent, the subsidies are fundamental to Congress’s goal that nearly all Americans have health insurance coverage. *Halbig v. Burwell*, 758 F.3d 390, 418-421 (D.C. Cir. 2014) (Edwards, J., dissenting). The structure of the ACA has been described as a “three legged stool,” comprised of three “legs” that work “in tandem, each one a necessary component.” *Id.* at 418-419. The three “legs” are (1) the nondiscrimination prohibitions applying to insurers, (2) the requirement that each individual obtain health insurance coverage, and (3) the subsidies described above, which defray premium costs. *See id.* at 418-420. Without any one of these three legs, the “fundamental policy structure and goals” that Congress sought to advance through the ACA will not be achievable. *Id.* at 418.

Amici believe this Court should affirm the district court’s conclusion that “Congress has directly spoken to the precise question of whether an Exchange under 26 U.S.C. § 36B includes federally-facilitated Exchanges,” because “the plain text of the statute, the statutory structure, and the statutory purpose make

clear that Congress intended to make [subsidies] available on both state-run and federally-facilitated Exchanges.” *Halbig v. Sebelius*, Civil Action No. 13-0623 (PLF), ___ F. Supp. 2d ___, 2014 WL 129023, at *18 (D.D.C. Jan. 15, 2014) (quoting *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984)) (internal quotation marks omitted). Even if this Court finds that the relevant statutory language is ambiguous—though it is not—the correct course is that charted by the Fourth Circuit and by Judge Edwards’s dissent: to uphold the IRS rule implementing the premium tax credits as a permissible construction of the ACA and entitled to deference under *Chevron*. See *Halbig*, 758 F.3d at 427 (Edwards, J., dissenting); *King v. Burwell*, 759 F.3d 358, 376 (4th Cir. 2014); see also *City of Arlington v. FCC*, 133 S. Ct. 1863, 1868 (2013) (“Statutory ambiguities will be resolved, within the bounds of reasonable interpretation, not by the courts but by the administering agency.”).

Great strides have been made in making previously unaffordable insurance accessible as Congress provided in the ACA; this progress will help reduce the number of Americans with medical bills they cannot afford to pay, reduce the costs to taxpayers and health providers of treating the underinsured and uninsured, and reduce the costs to patients and their employers of lost work time and productivity.

In particular, people living with HIV/AIDS and other chronic health conditions have benefitted tremendously from the ACA’s subsidies, which have

enabled them to access affordable and comprehensive health insurance. As described in more detail below, those living with chronic and serious health conditions who have gained so much under the ACA risk losing it all if the panel majority's decision striking down the IRS rule is reinstated. Rather than undo the progress that Congress and the Executive Branch have already made in providing low- and middle-income Americans with affordable health insurance, the Court should affirm the judgment of the district court.

ARGUMENT

I. SUBSIDIES ARE NECESSARY TO MAKE AFFORDABLE HEALTH CARE ACCESSIBLE TO LOW- AND MIDDLE-INCOME INDIVIDUALS.

A. Prior To The Affordable Care Act, The Subsidy-Eligible Population Had Great Difficulty Obtaining Affordable Health Care Coverage.

For low- and middle-income individuals and families, pre-ACA health premiums were, at best, difficult to afford. Households with incomes at or below 400% FPL—in 2014, this included incomes less than or equal to \$46,680 for an individual or \$95,400 for a family of four—were much more likely to lack health insurance than those with incomes above that threshold. Of the 47.3 million people who were uninsured in 2012, 90% had incomes below that threshold.

Kaiser Comm'n on Medicaid and the Uninsured, *The Uninsured: A Primer: Key Facts About Health Insurance on the Eve of Health Reform* 6 (Oct. 2013), available at <http://kaiserfamilyfoundation.files.wordpress.com/2013/10/7451-09->

the-uninsured-a-primer-key-facts-about-health-insurance.pdf [hereinafter *Uninsured: A Primer*].

There are several causes for the disproportionately high percentage of uninsured among low- and middle-income households. First, even if employed, many individuals in this population worked for employers who did not offer health care benefits. In 2013, only 23% of organizations with a high proportion of low-wage employees offered health insurance, whereas 60% of organizations that employed fewer low-wage employees offered health insurance. *Id.* at 2.

Second, when employers did offer health benefits, the costs were often prohibitive. Organizations with a high proportion of low-wage workers offered plans to their employees that on average required the employees to contribute 39% of the cost of their insurance premiums. *Id.* at 3. Organizations with a low proportion of low-wage workers, on the other hand, offered plans to their employees that on average required the employees to contribute only 29% of the cost of their insurance premiums. *Id.*³

Third, before the ACA, a significant portion of the relevant population was ineligible for Medicaid, in part because states had considerable flexibility in determining Medicaid eligibility requirements and covered benefits. Nat'l Conference of State Legislators, *States Implement Health Reform: Medicaid and*

³ These premiums included coverage for the employees and their families.

the Affordable Care Act 1-2 (June 2011), available at

<http://www.ncsl.org/documents/health/HRMedicaid.pdf>. Most states required that individuals meet stringent income requirements and fall into one of the state's covered "categories," such as pregnant women, children, and people with disabilities. *Id.*

Finally, those who were unable to access insurance through their employers and were ineligible for government programs such as Medicaid could only access insurance through the non-group, or individual, market. Because the non-group market was subject to far less regulation than employer-sponsored health plans in most states, insurance companies were often permitted to exclude those with chronic or serious health conditions from coverage, rescind policies, vary premiums based on health status, increase premiums without justification, and shift a larger percentage of medical costs to enrollees by providing less comprehensive benefits. Kaiser Family Found., *Survey of People Who Purchase Their Own Insurance 1-6* (June 2010), available at

<http://kaiserfamilyfoundation.files.wordpress.com/2013/01/8077-r.pdf>. Unlike those whose employers offered and often heavily subsidized premium costs, individuals without employer-sponsored health insurance often faced prohibitively high premiums as well as higher deductibles and copayments. *Id.* at 5. As a result,

low- and even middle-income households were often unable to afford insurance through the individual markets.

B. The Subsidies Available Through The Post-ACA Exchanges Make Insurance Affordable For Low- And Middle-Income Individuals.

The ACA addressed the deficiencies in the non-group market by establishing the exchanges and subjecting the insurance market to various reforms, such as prohibiting exclusion from coverage on the basis of preexisting conditions. By passing the ACA, Congress intended to expand coverage to those who were unable to purchase insurance because of cost or practices that restricted access, and to those whose insurance provided inadequate benefits. *See* David Blumenthal & Sarah R. Collins, *Health Care Coverage Under the Affordable Care Act – A Progress Report*, 37 *New Eng. J. Med.* 275, 275-276 (2014).

Beginning in 2014, under the ACA, households with incomes between 100% and 400% FPL—between \$11,670 and \$46,680 for an individual, and between \$23,850 and \$95,400 for a family of four in 2014—qualify for premium subsidies that can be used to purchase a health insurance plan on an exchange. These individuals and families are also eligible for cost-sharing subsidies to reduce out-of-pocket expenses for covered health benefits. Subsidy amounts are calculated on a sliding scale, based on household income. For example, households with incomes between 100% and 133% FPL (between \$11,670 and \$15,521 for an individual, and between \$23,850 and \$31,721 for a family of four in 2014) pay

only 2% of household income for a particular level of coverage. Households with incomes between 300% and 400% FPL (between \$35,010 and \$46,680 for an individual, and between \$71,550 and \$95,400 for a family of four in 2014) pay up to 9.5% of household income for a particular level of coverage. Additionally, the subsidies vary by state in order to account for local differences in premium costs.

For example, Phil Sherburne and his wife own a small business in Utah. Because of a pre-existing shoulder injury, Mr. Sherburne had been unable to access affordable insurance through the non-group market for himself, his family, or for the employees of his small business. Many insurers denied him family and small group coverage altogether; others only offered plans with prohibitively high premiums. In October 2014, after implementation of the ACA, Mr. Sherburne enrolled himself, his wife, and his three children in a family insurance plan through the federally-operated exchange in Utah. Mr. Sherburne and his family make less than 400% FPL, and are thus eligible for subsidies. Without the subsidies, Mr. Sherburne's monthly premium would be \$850; with the subsidies, his premium is just \$123 per month.

Similarly, Jennifer Busco, a small business owner from North Carolina, could not afford health insurance on the non-group market until the subsidies made it possible. Prior to the ACA, her premiums on the non-group market would have been approximately \$400-500 per month. Her infant son needed eye surgery while

they were uninsured; this surgery cost between \$5000 and \$6000, and she is still working to pay it off. After signing up for a plan through a federally-run exchange in North Carolina, Ms. Busco now pays just \$26 per month in premiums for herself and her son. Ms. Busco's coverage ensures that she will not incur additional medical debt for herself or her son.

II. EXPANDED HEALTH CARE COVERAGE FOR THE LOW- AND MIDDLE-INCOME POPULATION IMPROVES HEALTH OUTCOMES AND REDUCES A SIGNIFICANT BURDEN ON THE UNINSURED AND SOCIETY AS A WHOLE

The lack of coverage for the low- and middle-income American population was a pressing issue that drew national attention because of its high social and economic costs. Uninsured individuals have limited access to preventive and timely health care, leading ultimately to high medical bills and increased rates of disability. Poorer health outcomes due to lack of insurance not only increase health care costs for individuals, federal and state governments, and health care providers, but also reduce workforce productivity to the detriment of employers.

A. Expanded Health Insurance Coverage Reduces The Societal Burden Of Insufficient Insurance.

The burden of insufficient insurance falls on uninsured individuals themselves and on society as a whole. Uninsured individuals must pay out of pocket for any services received, often at higher rates than would be paid by health insurers and public programs. The uninsured also typically seek care in the most costly settings, such as emergency rooms. In California in 2007, it cost \$321 to

treat a patient with strep throat in the emergency room but only \$91 to treat the same patient in a doctor's office. Blue Shield of Cal. Press Release, *Have Insurance? Covering the Uninsured Will Help You Too* (Mar. 27, 2007), available at <https://www.blueshieldca.com/bsca/about-blue-shield/newsroom/covering-uninsured.sp>. In 2008, the uninsured paid \$30 billion out of pocket for their health care. Jack Hadley et al., Kaiser Comm'n on Medicaid and the Uninsured, *Covering the Uninsured in 2008: A Detailed Examination of Current Costs and Sources of Payment, and Incremental Costs of Expanding Coverage* 13 (2008), available at <http://kaiserfamilyfoundation.files.wordpress.com/2013/01/7809.pdf>. Federal, state, and local funds paid another \$42.9 billion to cover care for the uninsured. *Id.* at 47. The remaining \$14.5 billion was largely absorbed by hospitals and other health care providers. *Id.* at 50. These costs can pose an enormous burden on providers, especially "safety net hospitals"—hospitals that provide a disproportionate amount of care to low-income, uninsured, and vulnerable populations. See Nancy M. Kane, *Strained Local and State Government Finances Among Current Realities that Threaten Public Hospitals' Profitability*, 31 Health Affairs 1680 (Nov. 2012).

The uninsured crisis also adversely affects employers. Due to the higher prevalence of serious health problems among the uninsured, these individuals are more likely to have reduced workforce participation and productivity. Employers

suffer when their employees miss work, leave their jobs, or retire early for health reasons. Karen Davis, *The Costs and Consequences of Being Uninsured*, 60 *Med. Care Res. & Rev.* 89S-99S (June 2003). One study estimated that the economic cost to the U.S. economy resulting from the reduced workforce participation of the uninsured due to poorer health and shorter lifespan was between \$102 and \$204 billion in 2006. Sarah Axeen & Elizabeth Carpenter, New America Foundation, *Cost of Failure: The Economic Losses of the Uninsured* (Mar. 2008), available at http://www.newamerica.net/files/Cost_Of_Failure.pdf.

The societal costs of insufficient insurance go beyond the pecuniary costs borne by health care providers and the public, however. Evidence shows that insufficient insurance has an adverse spillover effect on community health that reaches even the insured population. Inst. of Med., *America's Uninsured Crisis: Consequences for Health and Health Care* 91-95 (2009), available at <http://www.iom.edu/Reports/2009/Americas-Uninsured-Crisis-Consequences-for-Health-and-Health-Care.aspx> [hereinafter *America's Uninsured Crisis*]. Communities with high rates of uninsured individuals tend to have insufficient health care delivery capacity, reduced access to emergency medical services, and a lessened availability of clinical specialists. *Id.*

Insufficient insurance also poses a threat to population health. The Institute of Medicine found that state and local public health programs that devote resources

to uninsured residents are adversely affected because resources are reallocated from population-based health programs that support disease surveillance and community-wide health interventions. Inst. of Med., *A Shared Destiny: Community Effects of Uninsurance* 144 (2003), available at <http://www.iom.edu/Reports/2003/A-Shared-Destiny-Community-Effects-of-Uninsurance.aspx>. This diversion of resources weakens the ability of health departments to respond effectively to outbreaks of contagious or communicable diseases that threaten community health and to emerging threats such as the Ebola virus or infectious diseases linked to bioterrorism. *Id.* at 13.

B. Access To Affordable Premiums Improves Health Outcomes For Individuals And Fosters Better Utilization Of The Health System.

Unsurprisingly, uninsured people have greater difficulty than those with insurance in accessing the care they need. In 2013, 25% of adults without coverage reported that they went without care in the previous year, largely due to cost, compared to only 4% of adults with coverage. *See Uninsured: A Primer, supra*, at 12. Correspondingly, adequately insured adults benefit substantially from health insurance because they are more likely to receive regular preventive care, reducing the number of undiagnosed and untreated conditions, and increasing the likelihood of experiencing better health outcomes due to timely diagnosis. Stacey McMorro et al., *Determinants of Receipt of Recommended Preventive Services: Implications for the Affordable Care Act*, *Am. J. Pub. Health* e1-e6 (published

online ahead of print Jan. 16, 2014), *available at* <http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2013.301569>. Adequately insured adults are also more likely to comply with prescribed treatment regimens and follow-up care, which contribute to better health outcomes.

Regular preventive care and interventions tend to be low-cost and help reduce total health care spending. However, adults without health insurance utilize significantly less preventive care than adults with health insurance. *America's Uninsured Crisis, supra* at 68. Lack of adequate insurance causes delayed or forgone treatment, later-stage cancer diagnoses, acute conditions such as heart attacks or strokes, and premature death. *Id.* at 69-73. The ACA addresses two barriers to preventive care by increasing access to insurance through subsidies and eliminating cost-sharing obligations for recommended preventive services. Recent studies suggest that improved access to care resulting from coverage gains by the subsidy-eligible population is already evident. *See* Benjamin D. Sommers et al., *Health Reform and Changes in Health Insurance Coverage in 2014*, 371 *New Eng. J. Med.* 867, 870-873 (2014); Benjamin D. Sommers et al., *The Affordable Care Act Has Led to Significant Gains in Health Insurance and Access to Care for Young Adults*, 32 *Health Affairs* 165, 168-172 (Jan. 2013).

Kimberly Tonyan of North Carolina has personally experienced tremendous gains through access to preventive care screening. For years as a working single

mother, she was unable to afford health insurance for herself and her two daughters. Although Ms. Tonyan took her daughters to their check-ups, she had not gone in for her own annual exams or screenings, such as physicals or pap smears, for years, because she could not afford them. Although North Carolina has not established its own exchange (*see* Kaiser Family Found., *State Decisions for Creating Health Insurance Marketplaces*, available at <http://kff.org/health-reform/state-indicator/state-decisions-for-creating-health-insurance-marketplaces/> (last visited Nov. 1, 2014) [hereinafter *State Decisions*]), she was able to sign up for health insurance through a federally-run exchange in North Carolina in March 2014. Due to her income of approximately \$20,000, she was eligible for subsidies that brought the cost of her premiums down from \$279 to \$27.91 per month. A few months later, she began experiencing pain in her abdomen. Because she was now insured, she visited a doctor, who diagnosed her with uterine fibroid tumors and an ovarian cyst. After she had a hysterectomy, her doctors discovered that she had endometrial cancer. Luckily, the cancer was caught and removed early, which meant there was no need for further, more extensive and expensive treatment, such as chemotherapy or radiation. Moreover, because endometrial cancer is rare in women in their 40s, Ms. Tonyan's doctor recommended genetic testing. This testing revealed that Ms. Tonyan has Cowden syndrome, a genetic condition associated with a greatly increased risk of breast, thyroid, uterine, and kidney

cancer. Because she now knows that she has an 85% risk of developing breast cancer, Ms. Tonyan chose to have a preventive mastectomy. Ms. Tonyan credits the ACA with saving her life. Without the subsidies that made it possible for her to purchase insurance on a federally-facilitated exchange, Ms. Tonyan would not have gone to the doctor when she began experiencing pain in her abdomen, and by the time she eventually did see a doctor, it is possible the cancer would have already spread much further. It is also unlikely that she would have sought testing for Cowden syndrome if she lacked comprehensive health insurance, which would have left Ms. Tonyan unaware of her increased risk for breast cancer and unable to pursue the preventive measures she has taken to preserve her health.

Beyond preventive care, uninsured and underinsured individuals without coverage are also more likely to forgo prescribed medications and less likely to obtain all recommended health care services than insured individuals due to cost. Robin A. Cohen et al., Nat'l Ctr. for Health Statistics, *Strategies Used by Adults to Reduce their Prescription Drug Costs* 1-6 (2013), available at <http://www.cdc.gov/nchs/data/databriefs/db119.pdf>. These cost barriers to effective treatment can seriously undermine attempts to control conditions that require complex medical management, such as HIV or diabetes. One study found that 40% of uninsured adults and 25% of underinsured adults with at least one chronic condition reported skipping doses or not filling a prescription because of

cost. *Uninsured: A Primer, supra*, at 12. Uninsured individuals thus tend to have higher mortality rates and are more likely to be hospitalized for avoidable health problems. *See id.* Congress sought to reduce the negative health outcomes that result from individuals forgoing necessary care due to costs by increasing access to affordable insurance. *See* Lance Gable, *The Patient Protection and Affordable Care Act, Public Health, and the Elusive Target of Human Rights*, 39 J. L. Med. & Ethics 340, 340-341, 346-350 (2011). Foreclosing the ACA's subsidies to the populations of the thirty-four states using federally-facilitated exchanges would undermine Congress's public health goals and obstruct access to care for low- and middle-income households.

III. WITHOUT SUBSIDIES, MILLIONS OF LOW- AND MIDDLE-INCOME AMERICANS IN THIRTY-FOUR STATES WILL LOSE ACCESS TO AFFORDABLE HEALTH INSURANCE.

The majority of the American population consists of people living in households with annual incomes below 400% FPL, including 90% of the nearly 55 million Americans who had a gap in health insurance coverage in 2012. Sarah R. Collins et al., The Commonwealth Fund, *Insuring the Future: Current Trends in Health Coverage and the Effects of Implementing the Affordable Care Act* 15 (Apr. 2013), available at http://www.commonwealthfund.org/~media/files/publications/fund-report/2013/apr/1681_collins_insuring_future_biennial_survey_2012_final.pdf. In

many cases, this population does not have access to health insurance through their employers or through Medicaid, such that—absent the system created under the ACA—they will only be able to access health insurance through the expensive and unfavorable non-group market.

The ACA's subsidies have already played a critical role in reducing the number of uninsured and underinsured Americans. In the first enrollment year, 6.7 million individuals—or 85% of all individuals newly enrolled in health plans through the federally-run exchanges—obtained access to affordable insurance through federal subsidies. Timothy Jost, *Implementing Health Reform: A Summary Health Insurance Marketplace Enrollment Report*, Health Affairs Blog (May 1, 2014), available at <http://healthaffairs.org/blog/2014/05/01/implementing-health-reform-a-summary-health-insurance-marketplace-enrollment-report>. In the thirty-four states where federally-facilitated exchanges operate, 5.3 million individuals enrolled in new health plans (U.S. Dep't of Health & Human Servs., Office of the Assistant Sec'y for Planning and Evaluation, *ASPE Issue Brief: Health Insurance Marketplace: Summary Enrollment Report for the Initial Annual Open Enrollment Period 35* (2014), available at http://aspe.hhs.gov/health/reports/2014/marketplaceenrollment/apr2014/ib_2014apr_enrollment.pdf), and 4.6 million individuals (87% of enrollees) obtained access to affordable insurance through subsidies. Larry Levitt & Gary Claxton, *The*

Potential Side Effects of Halbig, Kaiser Family Found. (July 31, 2014), available at <http://kff.org/health-reform/perspective/the-potential-side-effects-of-halbig>. If the panel majority's decision striking down the IRS rule is reinstated, nearly 5 million Americans would face an average premium increase of 76%, causing many to lose the health care access and financial protections they gained under the ACA. Julie Rovner, *Appeals Court Strikes Down Subsidies in Federal Health Exchange*, NPR (July 22, 2014), available at <http://www.npr.org/blogs/health/2014/07/22/334048664/appeals-court-strikes-down-subsidies-in-federal-health-exchange>.

IV. CASE STUDY: THE HIV EPIDEMIC

A. Insufficient Insurance Undermines HIV Care And Treatment.

Although the need for subsidies is not unique to low- and middle-income people living with HIV, their current high rates of uninsurance, despite the importance of adequate health care to promote both individual and public health, highlight the importance of ensuring that this population with a chronic and serious health condition has comprehensive health coverage.

Although there is no cure for HIV, the goal of HIV care is to move patients along a “continuum of care” from infection to diagnosis; treatment; and finally, viral suppression. Viral suppression helps people with HIV live longer, healthier lives because suppression preserves the immune system, the virus evolves more

slowly, and there is a lower risk of drug resistance. Also, at the viral suppression stage, the individual's ability to transmit HIV to others is reduced by 96%, slowing the spread of the epidemic.⁴ Ctrs. for Disease Control & Prevention, *Prevention*

Benefits of HIV Treatment, available at

<http://www.cdc.gov/hiv/prevention/research/tap/> (last visited Oct. 22, 2014).

Achieving viral suppression requires comprehensive and coordinated care.

Unfortunately, in part as a result of high rates of uninsured—projected at 30%,

more than twice the national average of uninsured in the United States (Ctrs. for

Disease Control & Prevention, *The Affordable Care Act Helps People Living with*

HIV/AIDS, available at <http://www.cdc.gov/hiv/policies/aca.html> (last visited Oct.

28, 2014))—only 25% of Americans living with HIV are virally suppressed. See

Jeffrey S. Crowley & Jen Kates, *Updating the Ryan White HIV/AIDS Program For a New Era: Key Issues and Questions For the Future* 5-6 (Apr. 2013), available at

<http://kaiserfamilyfoundation.files.wordpress.com/2013/04/8431.pdf>; Katerina A.

Christopoulos & Diane V. Havlir, *Overcoming the Human Immunodeficiency Virus*

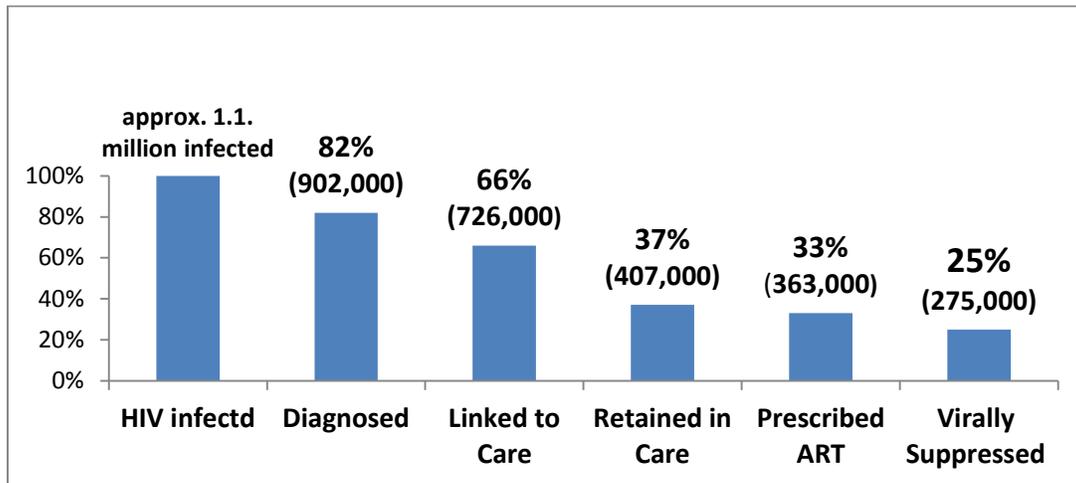
Obstacle Course, 133 JAMA Internal Med. 1344, 1344 (July 22, 2013). The

⁴ The average lifetime treatment cost of each new HIV infection is estimated to be \$379,668 in 2010 dollars. Ctrs. for Disease Control & Prevention, *HIV Cost-Effectiveness*, available at

<http://www.cdc.gov/hiv/prevention/ongoing/costeffectiveness> (last visited Oct. 24, 2014).

following chart shows the sharp drop-off in engagement in the various treatment stages for HIV in the United States:

Engagement in Selected Stages of HIV Care⁵



Although the government does offer some programs for those with HIV, they are discretionary and limited in scope. Prior to the implementation of the ACA, approximately 56,000 individuals living with HIV were uninsured but participated in the AIDS Drug Assistance Program (“ADAP”). Nat’l Alliance of State and Territorial AIDS Directors, *ADAP Supports Expanded Access to Care* (2014), available at <http://www.nastad.org/docs/Fact-Sheet-ADAP-RW-ACA-Enrollment-May-2014-FINAL.pdf>. ADAP, which is part of the Ryan White

⁵ This chart is based on data from H. Irene Hall et al, *Differences in Human Immunodeficiency Virus Care and Treatment Among Subpopulations in the United States*, 173 JAMA Internal Med. 1337, 1340 (June 17, 2013).

Program,⁶ provides low-income individuals who have limited or no prescription drug coverage with prescription drugs for the treatment of HIV. However, coverage and income range eligibility under these programs vary widely by state, and many programs contain costs by instituting waiting lists for new patients. See Kathleen A. McManus, *Current Challenges to the United States' AIDS Drug Assistance Program and Possible Implications of the Affordable Care Act*, AIDS Res. & Treatment 3 (published online Mar. 18, 2013), available at <http://www.hindawi.com/journals/art/2013/350169/>. In general, ADAP programs do not provide comprehensive health care coverage, and some programs only cover HIV medications. *Id.* For individuals living with HIV who have health needs beyond HIV—as most do—ADAP coverage is simply not enough.

Without reliable access to affordable health care, people living with HIV are less likely to obtain effective treatment and achieve viral suppression; they accordingly remain infectious and increase the risk and costs to the national population.

⁶ The Ryan White Program, administered by the U.S. Department of Health and Human Services, serves the unmet needs of people living with HIV by providing funding to cities, states, and community-based organizations. Enacted in 1990, the Ryan White Program has provided critical assistance to low-income individuals and families affected by HIV that lack sufficient health care resources for HIV care. See U.S. Dep't of Health & Human Servs., *Health Resources and Services Administration: HIV/AIDS Programs, About the Ryan White Program*, available at <http://hab.hrsa.gov/abouthab/aboutprogram.html> (last visited Oct. 22, 2014).

B. Subsidies Have Helped Extend Coverage To A Significant Percentage Of Previously Uninsured Individuals Living With HIV.

Todd Haley of North Carolina has personally benefitted from comprehensive coverage through a subsidized insurance plan purchased on a federally-run exchange. Mr. Haley is a self-employed auditor who had been without insurance since 2007. In 2008, he was diagnosed with HIV, which ultimately reduced his ability to work and led to depression. Because North Carolina has no state-run exchange (*see State Decisions, supra*), Mr. Haley signed up for Blue Cross Blue Shield health insurance on a federally-run exchange in April 2014. He is eligible for ACA subsidies that lower his monthly premiums from approximately \$360 to \$126 per month. His copayments range between \$5 and \$10, and he pays approximately \$15 per month total for his HIV medications. Mr. Haley estimates that his monthly costs for these medications would be approximately \$3700 without his insurance coverage. The subsidies have enabled Mr. Haley to improve his mental health and advance in his career. If the IRS rule providing subsidies to those who purchase insurance on federally-run exchanges is overturned, he may lose access to his medications and would certainly be limited in his ability to seek the mental health care he needs.

Evidence shows that enrollment in health insurance plans of previously uninsured people living with HIV has had a positive impact on health outcomes

and has significantly helped control the HIV epidemic. In 2001, Massachusetts expanded Medicaid coverage to pre-disabled people living with HIV whose income was less than 200% FPL (\$23,340 for an individual in 2014). Harvard Law School Ctr. for Health Law & Policy Innovation, *Massachusetts HIV/AIDS Resource Allocation Project 3* (Dec. 13, 2011), available at http://www.law.harvard.edu/academics/clinical/lsc/documents/Data_Needs_for_MA_HIV_Resource_Allocation_Project.pdf. In 2006, Massachusetts introduced a subsidized insurance plan for those whose income was less than 300% FPL (\$35,010 for an individual in 2014). *Id.* In large part, as a result of increased coverage, both individual and public health outcomes in Massachusetts are dramatically improved compared to the national average. *See* Harvard Law School Ctr. for Health Law & Policy Innovation, *Massachusetts Case Study: Health Reforms Lead to Improved Individual and Public Health Outcomes and Cost Savings* (June 2012), available at http://www.law.harvard.edu/academics/clinical/lsc/documents/FACT_SHEET_%20MA_Case_Study_on_Health_Reforms6-27-12.pdf. One study showed that, between 2006 and 2009, new HIV diagnoses fell by 25% in Massachusetts as compared to a 2% national increase. *See id.* A more recent study (as yet unpublished, but attached hereto) shows that, from 2000 to 2011, the number of HIV-related deaths in Massachusetts declined by 41%, and the number of HIV

infection diagnoses decreased by 44%. Harvard Law School Ctr. for Health Law & Policy Innovation, *Massachusetts Case Study: Health Reforms in Conjunction with the Ryan White Program Lead to Improved Individual and Public Health Outcomes and Cost Savings* (see Addendum). In contrast, across the United States, HIV-related deaths and new HIV diagnoses remained relatively unchanged. *Id.*

Extending health insurance coverage to low-income individuals has made a measurable difference in the HIV epidemic in Massachusetts. Continued access to the subsidies will likely have a similar effect on individuals living with HIV throughout the country. Without the subsidies, however, this population in the thirty-four states using federally-run exchanges will likely lose much of the health care coverage gained through the ACA reforms, and will have to continue to rely upon discretionary programs, such as Ryan White and ADAPs, that are of limited scope and receive limited funding. Without subsidies, those with HIV are significantly less likely to receive the complex and comprehensive treatment necessary to viral suppression, resulting in a higher likelihood of the virus spreading to others.

CONCLUSION

The subsidies created by the ACA are of critical importance to ensuring that all Americans—including those living in the thirty-four states using federally-run exchanges—have affordable health care coverage. Without health insurance, many

if not most low- and middle-income Americans are unable to access timely and appropriate care, leading to poorer health outcomes and greater costs to individuals as well as to society as a whole. Congress addressed these concerns in the ACA by creating subsidies to offset taxes and enable low- and middle-income individuals to use the resulting savings to purchase health insurance. The IRS has been faithful to Congress's mandate by providing that the subsidies are available to low- and middle-income Americans who seek insurance on federally-run exchanges as well as state-run exchanges. The subsidies are achieving Congress's desired ends. *Amici* accordingly urge this Court to affirm the district court's judgment.

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ADDENDUM

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Harvard Law School Ctr. for Health Law & Policy Innovation,
*Massachusetts Case Study: Health Reforms in Conjunction with
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TAB 1

Massachusetts Case Study: Health Reforms in Conjunction With the Ryan White Program Lead to Improved Individual and Public Health Outcomes and Cost Savings

PREPARED BY THE CENTER FOR HEALTH LAW AND POLICY INNOVATION OF HARVARD LAW SCHOOL

Since 2001, Massachusetts has enacted health reforms that later became the basis for many of the reforms included in the Affordable Care Act (ACA). These reforms include an individual mandate, expansion of Medicaid, and expanded access to subsidized private insurance. Massachusetts' health reforms have translated into dramatically improved individual and public health outcomes, as well as reduced healthcare costs – successes that can be replicated in federal ACA reforms if properly implemented.

PROMOTES ACCESS TO EFFECTIVE TREATMENT

Among people living with HIV/AIDS in Massachusetts, the overwhelming majority has access to and is engaged in care and treatment (see Figure 1).ⁱ Massachusetts' reforms have translated into over 75% of those who need HIV medications actually having those medications. That is more than twice the 33% national average. Further, over 59% of Massachusetts' HIV-positive population has suppressed viral loads (compared to 25% nationally).

IMPROVES INDIVIDUAL AND PUBLIC HEALTH OUTCOMES

Massachusetts has experienced significant decreases in both HIV diagnoses and deaths among HIV-positive individuals. Over the period from 2000-2011, the number of HIV infection diagnoses decreased 44% and deaths declined 41% (see Figure 2).ⁱⁱ Of note is that new HIV diagnoses decreased equivalently across all races and ethnicities. In contrast, nationally, both new HIV diagnoses and deaths among persons with AIDS have remained relatively stable over a similar period of time.ⁱⁱⁱ

FIGURE 1: MA OUTCOMES VS NATIONAL OUTCOMES

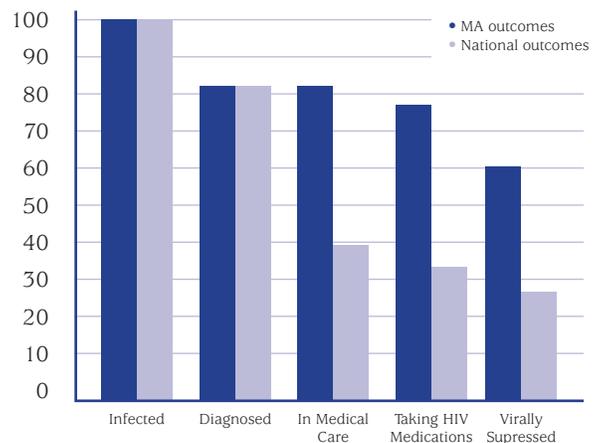
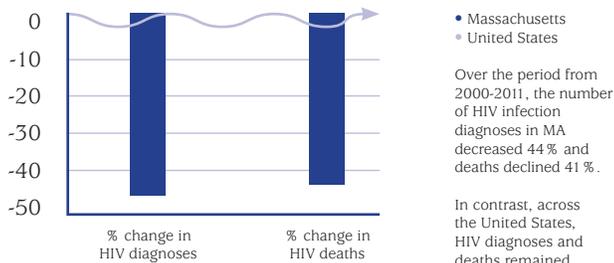


FIGURE 2: PERCENTAGE CHANGE IN HIV DIAGNOSES AND DEATHS, 2000-2011, MA AND US



Sources: US Centers for Disease Control and Prevention; Massachusetts Department of Public Health (see notes ii and iii)

Over the period from 2000-2011, the number of HIV infection diagnoses in MA decreased 44% and deaths declined 41%.

In contrast, across the United States, HIV diagnoses and deaths remained relatively stable.

REDUCES COSTS

The Massachusetts Department of Health estimates that these reforms, in part due to rapidly declining transmission rates, have saved the state approximately \$1.5 billion in HIV/AIDS healthcare expenditures over the past ten years.

MAXIMIZES EFFECTIVENESS OF RYAN WHITE PROGRAM

Health reforms that provide access to comprehensive healthcare for most people living with HIV/AIDS allow limited Ryan White Program resources to be used most effectively. In Massachusetts, the Ryan White Program has been adapted to address coverage gaps in vital health and support services and gaps in insurance affordability (premiums and copays). Massachusetts' health reforms and the Ryan White Program work together and complement each other to improve both public health and individual health status and outcomes for people living with HIV/AIDS in the Commonwealth.

ⁱ MA outcomes in Figure 1 are based on *Massachusetts and Southern New Hampshire HIV/AIDS Consumer Study Final Report*, December 2011, JSI Research and Training, Inc.; National outcomes are based on Cohen, Stacy M, et al. *Vital Signs: HIV Prevention Through Care and Treatment – United States*, CDC MMWR, 60(47); 1618-1623 (December 2, 2011); (National Outcomes HIV-infected, N=1,178,350; HIV-diagnosed, n=941,950); in Chart 1, for both MA and national outcomes, the percentages used are taken from a baseline of those infected, using the same estimated percentage diagnosed (82%) both nationally and for Massachusetts, based on the MMWR. The definitions of "In Medical Care" and "Virally Suppressed" may differ slightly between the MA data and the MMWR.

ⁱⁱ MA statistics in Figure 2 from presentation by H. Dawn Fukuda, Director, Massachusetts Department of Public Health (MDPH), Office of HIV/AIDS, *HIV/AIDS in Massachusetts: Challenges and Opportunities to Enhance the Public Health Response*, Fenway Community Health Center, May 14, 2013. See also MDPH, Office of HIV/AIDS, *Massachusetts HIV/AIDS Data Fact Sheet: The Massachusetts HIV/AIDS Epidemic at a Glance*, April 2013.

ⁱⁱⁱ See, eg, Centers for Disease Control and Prevention, *Today's HIV/AIDS Epidemic*, December 2013 ("...the number of new infections has been relatively stable since the mid-1990s"); Kaiser Family Foundation, *Fact Sheet: The HIV/AIDS Epidemic in the United States*, April 2014 ("While the number of new HIV infections...is down from its peak in the 1980s, new infections have remained at about 50,000 for more than a decade"); CDC HIV Mortality Slide Series ("...the annual rate of death due to HIV infection peaked in 1994 or 1995...decreased rapidly through 1997, and continued to decrease much more slowly thereafter:").

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), the undersigned hereby certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B)(i).

1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(a)(7)(B)(iii) and Circuit Rule 32(a)(1), the brief contains 5,808 words.
2. The brief has been prepared in proportionally spaced typeface using Microsoft Word 2010 in 14 point Times New Roman font. As permitted by Fed. R. App. P. 32(a)(7)(B), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

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CERTIFICATE OF SERVICE

I hereby certify that on this 3rd day of November, 2014, I electronically filed the foregoing Brief for *Amici Curiae* Harvard Law School Center for Health Law and Policy Innovation *et al.* in Support of Appellees with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

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