Together making meaningful advances in the prevention, screening, and treatment of viral hepatitis
Dear Partners,

Since 2010, the Viral Hepatitis Action Coalition (Coalition) has provided the Centers for Disease Control and Prevention’s (CDC) Division of Viral Hepatitis (DVH) with invaluable support in its effort to bring together science and public health practices to eliminate viral hepatitis. Since its inception, the Coalition has promoted solidarity around viral hepatitis issues and fostered collaborative relationships essential to achieving CDC’s mission and goals.

Protecting the health and lives of people against the threat of viral hepatitis has its ongoing challenges. However, the engagement of Coalition members and implementing partners has increased the capacity of CDC to study the burden of viral hepatitis and prevention strategies, and then translate this knowledge into a diverse set of interventions needed to implement CDC recommendations for prevention of viral hepatitis transmission and disease. As the work of the Viral Hepatitis Action Coalition concludes, the prevention experiences made possible by the Coalition help lay the foundation for the next phase of the CDC’s prevention work—eliminating viral hepatitis as a public health threat in the United States and together with partners, globally.

You, our partners in viral hepatitis prevention, should be proud. Over the past few years, great progress has been made in the global fight against viral hepatitis in large part because of the momentum made possible by collaboration. The CDC Foundation is grateful for all the Coalition has achieved and looks forward to future opportunities to work with partners to overcome challenges and seize opportunities to eliminate viral hepatitis.

Thanks to your partnership, suffering is being diminished and lives are being saved on a population-wide basis. I am pleased to share this report in commemoration and celebration of the Coalition’s achievements.

Judy Monroe, MD, FAAFP
President and CEO
CDC Foundation

Introduction
Viral Hepatitis Action Coalition

Since 2013, viral hepatitis has become a leading cause of death worldwide, causing more deaths than a combination of other commonly reported diseases, i.e., HIV, malaria, and tuberculosis. Despite great efforts to decrease the burden caused by viral hepatitis, hepatitis B virus (HBV) infection still disproportionally affects developing countries in Asia and Africa, while hepatitis C virus (HCV) infection has eclipsed other infectious diseases as a leading cause of death in the United States. Challenges to viral hepatitis prevention have included limited public health funding, gaps in program capacity, and lack of cohesion among stakeholders.

Progress has been made in viral hepatitis prevention during recent years, including availability of highly effective treatments, updated public health recommendations, and national viral hepatitis prevention plans in the United States and other countries. The Viral Hepatitis Action Coalition (Coalition) was created in 2010 to help increase public awareness of viral hepatitis B and hepatitis C and help CDC expand the reach of its public health prevention efforts. Since its inception, the Coalition has provided a framework to support the initiation of research and program evaluation through partnerships that promote information sharing, stakeholder collaboration, and shared commitment to public health initiatives.

The Coalition’s efforts have been particularly invaluable during important viral hepatitis-related milestones, such as the 25th anniversary since the discovery of hepatitis C; the development of direct-acting antivirals for the treatment of hepatitis C virus infection; and publication of the U.S. Preventive Services Task Force testing recommendations to screen persons at high risk for HBV and HCV infection.

The Coalition also has helped create many firsts for viral hepatitis prevention. For instance, the Coalition’s support and donations from Coalition members have allowed CDC to access previously untapped data sources and provided new channels for communicating important viral hepatitis prevention messages. This report highlights the activities, accomplishments, and efforts supported through donations to the CDC Foundation by Coalition members during its lifespan.
Support received by Coalition members served as the cornerstone for raising public awareness of viral hepatitis, as donations from Coalition members helped implement large-scale awareness efforts. The Coalition has also successfully used meetings, summits, and forums as platforms to publically discuss topics that no single organization could address individually.

**Know More Hepatitis Campaign**

*Merck & Company, Inc. and Vertex Pharmaceuticals*

Most persons with hepatitis C virus (HCV) have no symptoms until decades after they are infected and often after the virus has caused liver disease. Thus, it is important to identify infected persons early in the course of their disease so they can be treated and cured. To facilitate early identification among persons unknowingly living with HCV infection, in 2012 CDC expanded its previous HCV testing guidelines to recommend testing of all persons born during 1945-1965, a birth-cohort at high risk for HCV-related morbidity and mortality. Prior to this time, routine HCV testing was recommended based on a known association between a certain risk factor and acquiring hepatitis C infection.

Increasing the public’s awareness of hepatitis C can be challenging because of the low level of knowledge throughout communities experiencing a high burden of hepatitis C infection and a lack of awareness of CDC’s testing recommendations by providers caring for people vulnerable to infection. In response to these challenges, Coalition members provided donations to help launch CDC’s national efforts to improve public awareness of hepatitis C, namely the Know More Hepatitis education initiative. Developed by CDC and U.S. Department of Health and Human Services and launched in 2012, Know More Hepatitis aimed to publicize CDC’s new birth-cohort HCV testing recommendations with a particular focus on populations experiencing HCV-related health disparities. Specific examples of Coalition contributions included funding to help organize independent focus groups for the Know More Hepatitis education awareness initiative and a modest digital advertisement purchase.

**Faces of Hepatitis**

*The Coalition*

Given the important role that screening and awareness have in preventing hepatitis B and C in the United States, CDC recognized the need to create novel approaches for connecting with the American public to close gaps in awareness and reduce the stigma associated with HBV and HCV infection. Storytelling can be a powerful, multi-dimensional tool to enhance community-based public health programs, strategic communication, and advocacy, particularly first-hand accounts from persons personally impacted by these viruses. In 2011, the Coalition produced a series of video stories called the Faces of Hepatitis to support CDC’s efforts toward raising awareness about HBV and HCV infection. The Faces of Hepatitis stories provided a unique approach to increasing conversations about viral hepatitis B and C by featuring practitioners who treat hepatitis, patients with a hepatitis diagnosis or their family members, community advocates, Coalition partners (industry and community), and hepatitis experts from several major U.S. cities (e.g., Atlanta, Chicago, Detroit, and New York City). Using cinematic imagery, the mini-videos connected with viewers by following the daily lives and experiences of current and former chronic viral hepatitis patients from many walks of life. Through personal interviews and cinema style filming, the mini- documentaries helped to dispel the myths, stereotypes, and fears associated with living with chronic hepatitis B and C. The Faces of Hepatitis initiative successfully conveyed the critical message that anyone can be infected with hepatitis B and hepatitis C.

**Hepatitis C Testing Stakeholder Panels**

*Abbvie*

During 2015, the Coalition co-hosted and/or sponsored stakeholder meetings for healthcare providers, healthcare payers, and state health organizations to inform these groups about CDC’s HCV birth-cohort recommendations and to foster discussions on ways to meet the challenges to their implementation. The meetings were seen as a timely approach to communicating across public and private sectors about the recommendations. For example, a national level meeting of large health plans and payers, opened by the Assistant Secretary of Health, helped public health officials have frank discussions regarding the financing of HCV testing in routine clinical practice. At a state and local meeting, barriers to advancing adoption and improving access to therapies in Pennsylvania (e.g., restrictive Medicaid regulations) were discussed; as a benefit of the panel discussion, key stakeholders from this state endorsed implementation of the guidelines. Donated funding from a Coalition member provided essential logistical support and an unprecedented opportunity for hepatitis stakeholders to participate in the meeting.
Testing, care, and treatment greatly reduces mortality risks while improving quality of life for persons living with HBV and HCV infection. This viral hepatitis “care cascade” can be monitored to determine existing gaps and identify areas that can be strengthened to improve health outcomes for persons infected with viral hepatitis by reducing associated morbidity and mortality. Enhanced surveillance data and data from other sources (e.g., commercial laboratory data) facilitate this effort. Evaluation data from existing strategies to improve the care cascade are also important in efforts to identify best practices and guide future prevention efforts.

Leveraging Data for Hepatitis C Surveillance

AbbVie and Quest Diagnostics

Strengthening surveillance of viral hepatitis in the United States is a public health priority. Fragile surveillance systems can influence public health’s capability to detect viral hepatitis disease, recognize and describe transmission patterns, and monitor health disparities. CDC prioritizes providing surveillance support to states and jurisdictions throughout the United States. Due to budgetary constraints, however, only a few states have received funding from CDC to perform viral hepatitis surveillance activities. The relationships gained through the Coalition have made it possible for CDC to use supplemental data sources that enhance surveillance and monitoring activities.

In 2013, the CDC Foundation hosted partners to discuss important issues related to viral hepatitis, including gaps in surveillance. As a result of the discussion, Quest Diagnostics offered to share their commercial lab data with CDC. These data have significantly enhanced the standard surveillance data that states voluntarily share with CDC. The benefits of commercial data are numerous. Compared with public health surveillance data, they allow for more timely access, enable analysis of both positive and negative test results, provide more detailed information about providers, and contain additional information about serologic markers.

2014, Coalition member organization AbbVie provided funding to support statistical analyses of commercial lab data. The analyses helped provide invaluable information on the number of persons born within the birth-cohort (1945-1965) who had HCV antibody testing before and after the introduction of the CDC screening guidelines and the type of providers ordering HCV tests for this population. Moreover, the commercial lab data revealed for the first time the severity of liver disease among HCV-infected persons in the birth-cohort. Reports generated through this activity and subsequent CDC-funded contracts have been shared with state health departments to improve estimates of the number of persons infected with HCV.

Both of these examples illustrate the Coalition as being a valuable mechanism for information-sharing for stakeholders. In fact, other CDC programs are now recognizing the value of developing public-private relationships to gain access to the data. The information provided by Quest Diagnostics and AbbVie has improved CDC’s capacity to monitor the care cascade and the implementation of CDC and U.S. Preventive Services Task Force testing recommendations.

Development of Clinical Decision Support Tools and Performance Measures

EPIC Corporation

In 2014, Coalition members AbbVie, Bristol-Myers Squibb, and Janssen donated funding to co-sponsor the National Summit on HCV Prevention and Cure. The purpose of this summit was to gather a diverse group of stakeholders for discussion around public health issues on viral hepatitis prevention, testing, linkage to care, and treatment. The Summit also afforded CDC an opportunity to share its testing recommendation strategy to a broad audience of public health payers, state health departments, private health organizations, and policymakers.

A representative from software-development corporation EPIC was among those who presented work on novel approaches to screening. At that time, EPIC Corporation maintained millions of electronic health records used in a variety of settings, including hospitals and multi-specialty groups. The ensuing discussion among Summit participants prompted EPIC to redesign its clinical decision making system to improve delivery of preventive services. CDC guidance was incorporated into the EPIC software for infection-specific treatments (e.g., HCV, HIV, and STDs), and the software was made available for users to download on EPIC’s updated version of the system. This effort underscores the importance of Coalition partnerships in improving the impact of surveillance and prevention initiatives through collaboration, an effort that will ultimately help providers implement testing as a part of routine care.
Demonstration Projects for HBV and HCV Early Identification and Linkage to Care

Bristol-Myers Squibb, Genentech, and Gilead Sciences

As demonstrated by its epidemiology, HCV infection disproportionately affects many persons who rely on non-traditional health settings for primary-care health services. To improve access and linkage to care for this population, CDC needed to better understand the barriers to HCV treatment at the patient, provider, and health-system levels.

During 2013-2016, Coalition support helped CDC improve the viral hepatitis care cascade by evaluating practices for incorporating HCV diagnosis and linkage to care into routine clinical services at two locations. The HBV and HCV Early Identification and Linkage to Care project was a viral hepatitis testing initiative implemented by two organizations, John Hopkins University through the Baltimore City Health Department and the University of Alabama Birmingham Emergency Department. Data obtained from each site helped researchers and clinicians explore different options for and uncover challenges to implementing CDC’s birth-cohort testing recommendations.

John Hopkins University & Baltimore City Health Department

The CDC Foundation received Coalition member donations to evaluate the impact of rapid testing and patient navigation services on rates of HCV testing and care among a large population of medically underserved patients seeking healthcare at a public STD clinic in Baltimore, Maryland. Populations living in large, urban cities like Baltimore typically have a high burden of HCV infection, and those most vulnerable tend to rely upon non-traditional healthcare settings to receive primary health services. To improve early identification of HCV infection and promote linkage to care and treatment in this often difficult-to-reach population, researchers at John Hopkins University partnered with clinicians at the Baltimore City Health Department to evaluate the feasibility of leveraging the health department’s STD clinic as a setting for HCV testing and linkage to care. The study, which was conducted over a 12-month period during 2013, identified a high prevalence of HCV infection among clinic patients; of those identified as being infected with HCV, 82% were linked to care, treatment, and prevention services. The study illuminated the factors contributing to improved rates of patient follow-up and timeliness of linkage to care.

University of Alabama at Birmingham Emergency Department

Through the CDC Foundation, the University of Alabama at Birmingham’s Emergency Department received funding to implement the first ever HCV screening program in a U.S. emergency-department setting. The project screened over 5,000 unique patients for HCV infection during the testing period. The research team implemented routine opt-out HCV testing of baby boomers in the emergency department and found that of the 1,529 individuals tested for anti-HCV, 11% were infected with hepatitis C, revealing a high prevalence within this academic emergency department setting. The surveillance and demographic information collected through the project helped to increase understanding of the HCV epidemic and provided insight into models for HCV testing and linkage to care that expand access to testing, patients’ knowledge of HCV status, and linkage to care services. The project has since been replicated in many emergency departments across the country.

“The implementation and cost-effectiveness evaluation of a [birth-cohort-based] hepatitis C screening has important implications about the possibility to provide strong evidence about the most accurate and cost-efficient screening to recommend for screening guidelines. BEST-C has demonstrated the usefulness of collecting large datasets obtained in the clinical domain and informs future research about how this can be used to advance practice.”

– David Rein, PhD, NORC at the University of Chicago

The Birth-Cohort Evaluation to Advance Screening and Testing for Hepatitis C (BEST-C) Study

AbbVie, Genentech, Janssen, Merck & Company, Inc., and Vertex Pharmaceuticals

The Birth-Cohort Evaluation to Advance Screening and Testing for Hepatitis C (BEST-C) study compared the effectiveness of a birth-cohort approach to HCV screening with previously used (i.e., risk-based) HCV screening strategies in detecting unidentified persons living with HCV infection receiving health care in primary care systems (Icahn School of Medicine at Mount Sinai medical center, Henry Ford Health Systems, and the University of Alabama Department of Medicine). BEST-C evaluated the feasibility and effectiveness of distinct interventions designed to increase HCV testing and linkage to care: a birth-cohort based approach for routine one-time screening of all persons born from 1945 through 1965 versus a risk-based HCV screening strategy in detecting previously unidentified persons living with HCV infection who receive health care in primary care systems. Results from BEST-C demonstrate that birth-cohort testing was five times as effective in identifying HCV positive patients compared with existing risk-based testing strategies. The project also found that after adjusting for sex, ethnicity, race, socioeconomic status, and birth-cohort, HCV testing was significantly more common in the intervention than the control group in each of the sites. At each of the sites, the project examined costs of HCV testing per patient tested and per positive HCV patient in the intervention vs. risk-based groups. NS recommends deleting because it does not explain the difference between the interventions/approaches.
The Chronic Hepatitis Cohort Study (CHeCS)

*Abbott/AbbVie, Bristol-Myers Squibb, Genentech, Gilead Sciences, Janssen, and Vertex Pharmaceuticals*

The Chronic Hepatitis Cohort Study (CHeCS) represents a major research effort by CDC and multiple implementing partners to investigate when persons in care for hepatitis across the United States received HBV and HCV screening, their stage of disease when tested, receipt of recommended interventions, and impact of those interventions. These data are critical for evaluating the impact of CDC’s screening recommendations and informing efforts to prevent viral hepatitis-related morbidity and mortality, particularly in the era of more effective therapies.

Before implementation of CHeCS, very little was known about the spectrum of chronic hepatitis disease, access to and delivery of care, and population effectiveness of current drug therapies. The CHeCS study, which included HBV- and HCV-infected patients receiving care at four comprehensive health organizations in the United States, resulted in collection of all electronic records and interview information for 17,000 chronic HCV and over 6,000 chronic HBV patients. A total of 30 analyses using CHeCS study data have been published to date, greatly informing public health and decision making, as well as many medical and clinical epidemiologic activities in the United States. Based on information obtained through CHeCS, investigators have estimated the rate at which U.S. patients have been tested for HCV, referred for specialist care, treated, and cured.

“VHAC members’ financial support has been vital to the establishment and maintenance of the CHeCS cohort, which continues to provide the benchmark for understanding HCV and HBV health care access and quality in the United States.”

– Stuart Gordon, MD, Henry Ford Health System

Expanding Access to Hepatitis Care and Treatment

The availability of affordable, curative HCV therapies helps to ensure that those persons testing positive for this infection are promptly linked to care and treatment. With expanded CDC and USPSTF recommendations for HCV testing, more and more persons are becoming aware of their infection status, greatly increasing demand for these interventions. Traditionally, viral hepatitis testing and care has been provided by specialists (e.g., gastroenterologists and hepatologists), but growing numbers of Americans seeking testing, care, and treatment necessitate new strategies for the provision of HCV care, such as expanding capacity within primary care. Funding from Coalition members has been used to explore the utility of novel methods like telemedicine to expand access to effective care and treatment for persons living with viral hepatitis.

**Extension for Community Healthcare Outcomes (ECHO)**

*Bristol-Myers Squibb, Gilead Sciences, and Vertex Pharmaceuticals*

Coalition members provided support to provide technical assistance, guidance, consultation, and training for two rural, state-based programs in Arizona and Utah to implement a Project ECHO (Extension for Community Health Outcomes) model. Project ECHO connects urban medical center HCV experts with rural general practitioners and community health representatives over a tele-health network, enabling them to effectively treat patients on site who would otherwise have to travel to urban healthcare facilities for specialty treatment. The goal of this project was to facilitate measurement of provider performance and improvement in access to care for underserved populations facing barriers to HCV testing, care, and treatment. The platform provided health information technology to identify clinical quality measures for testing, link infected persons to care, validate the developed measures, and develop corresponding clinical decision support tools. Using telemedicine, this pilot program helped primary care physicians begin to treat HCV infection in areas with a shortage of HCV specialists by implementing clinical decision support guidelines and videoconferencing with specialists.

**Prevention, Evaluation, and Treatment of Hepatitis C among Patients on Opiate Agonist Therapy (PET-C)**

*Abbott/AbbVie, Vertex Pharmaceuticals*

Persons who inject drugs (PWID) face many obstacles when seeking treatment for hepatitis C. Some of those barriers include lack of education about the disease, lack of awareness of the status of the infection, a concern of side effects of treatment, and discomfort in conventional health care settings. To increase access to HCV treatment among PWID, Coalition members Abbott/AbbVie and Vertex Pharmaceuticals provided donations for the Preven-
tion, Evaluation and Treatment of Hepatitis C among Patients on Opiate Agonist Therapy (PET-C) project to help implement a telemedicine-based model for hepatitis C care among individuals on methadone maintenance. The project was conducted in collaboration with CDC, the State University of New York at Buffalo, and START Treatment and Recovery Centers [an opiate agonist treatment (OAT) program]. The donations were used by partners to assess patient attitudes toward participation in hepatitis C education and treatment and develop a model for delivery of hepatitis C-related education among patients receiving OAT.

The Coalition’s global contributions in the countries of Egypt, Georgia, and Vietnam have played an important role in advancing policy efforts and scaling up access to treatment in high burden countries in the developing world. Without the Coalition as a vehicle for the global work, there would have been less opportunity for cross-sector stakeholder collaboration toward helping to drive that global work forward. Although a lot of work has been done within the U.S., the Coalition has been an important vehicle for action at the global level.”

– Paul Schaper, MBA, MS, Merck & Company, Inc.

In the past, scarce funding and lack of understanding about the true burden of viral hepatitis-associated morbidity and mortality (due largely to poor data collection in the hardest-hit countries) diminished U.S. attempts to provide expert advice for the development of global viral hepatitis prevention programs. Addressing the global burden of hepatitis infection has required additional resources, and Coalition members have demonstrated their commitment to this critical endeavor.

Global Technical Assistance Project/Viral Hepatitis Fellowship Program, Viral Hepatitis in Resource Limited Countries Project

Gilead Sciences and Merck & Company, Inc.

As a result of these projects, CDC provided onsite consultation and technical assistance for approximately 14 countries with a high burden of chronic viral hepatitis. As part of the “Viral Hepatitis in Resource-Limited Countries” project, CDC had opportunities to implement different aspects of viral hepatitis planning, surveillance, and prevention interventions. For example, in collaboration with the World Health Organization and Ministry of Health agencies, CDC implemented activities in the countries of Egypt, Pakistan, Uganda and Vietnam. Funding from the fellowship has supported development and implementation of a nationwide HBV and HCV sero-prevalence survey and the ongoing monitoring and evaluation of Georgia’s hepatitis C elimination plans.

Relationships made possible through the Coalition facilitated a collaboration between Gilead Sciences and Ministry of Health officials in the country of Georgia, which has one of the highest burdens of HCV infection in the world. This collaboration culminated in Gilead Sciences providing free therapeutics for Georgia’s HCV elimination program, the first program of its kind. CDC used funding from the Global Technical Assistance and Viral Hepatitis in Resource Limited Countries projects to provide technical assistance for the country of Georgia’s elimination program in areas of laboratory quality and program evaluation; CDC also helped establish an agenda for prevention research.

Increasing Global Viral Hepatitis Prevention Efforts
## Project Funders & Co-Implementing Partners

### Birth-Cohort Evaluation to Advance Screening and Testing for Hepatitis C (BEST-C)
- AbbVie
- Genentech
- Henry Ford Health System
- Icahn School of Medicine at Mount Sinai
- Janssen
- Merck & Company, Inc.
- NORC at the University of Chicago
- University of Alabama
- Vertex Pharmaceuticals

### Chronic Hepatitis B and C Cohort Study (ChECS)
- Abbott
- AbbVie
- Alaska Native Tribal Health Consortium
- Bristol-Myers Squibb
- Geisinger Health System
- Genentech
- Gilead Sciences
- Henry Ford Health System
- Janssen
- Kaiser Permanente Northwest
- Kaiser Permanente Hawaii
- Vertex Pharmaceuticals

### Chronic Hepatitis B Infection is Tanzania
- Gilead Sciences
- Mnazi Mmoja Hospital
- Muhimbili National Hospital

### Electronic Health Records for Hepatitis C Testing
- Gilead Sciences
- PCPI® Foundation

### Extension for Community Healthcare Outcomes (ECHO):
- Technical Assistance Project
- Bristol-Myers Squibb
- Gilead Sciences
- Project ECHO Program
- University of New Mexico Health Sciences Center
- Vertex Pharmaceuticals

### Global Technical Assistance / Global Viral Hepatitis Fellowship
- Merck & Company, Inc.

### HBV and HCV Early Identification and Linkage to Care Project
- Baltimore City Health Department
- Bristol-Myers Squibb
- Genentech
- Gilead Sciences
- John Hopkins University
- University of Alabama-Birmingham Emergency Department

### Hepatitis C Testing Stakeholder Panels
- AbbVie
- AdCare Educational Institute
- City of Philadelphia Department of Public Health
- Florida Department of Health
- Health Federation of Philadelphia
- Massachusetts Department of Public Health
- Pennsylvania Department of Health
- The AIDS Institute

### Leveraging Data for Hepatitis C Surveillance
- AbbVie
- Quest Diagnostics

### National Viral Hepatitis Education Campaign
- Merck & Company, Inc.
- Vertex

### Prevention, Evaluation and Treatment of Hepatitis C Among Patients on Opiate Agonist Therapy (PET-C)
- Abbott
- AbbVie
- START Treatment and Recovery Centers
- State University of New York at Buffalo
- Vertex Pharmaceuticals

### Viral Hepatitis in Resource Limited Countries
- Boston University
- Gilead Sciences
- Pakistan Health Resource Council
- Ministry of Labour, Health and Social Affairs of Georgia
- Partnership for Health Advancement in Vietnam (PHealth)
- Task Force for Global Health-TEPHINET Program
- University of Bristol

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### VHAC Members Past & Present

- Abbott
- AbbVie
- Association of State and Territorial Health Officials
- Bristol-Myers Squibb
- CDC Foundation
- Gilead Sciences
- Janssen
- Merck & Company, Inc.
- National Viral Hepatitis Roundtable
- OraSure Technologies
- Quest Diagnostics
- Siemens Healthcare Diagnostics

### Former Members

- Alere
- Bayer Health Care Pharmaceuticals
- Boehringer-Ingelheim
- Genentech
- GlaxoSmithKline
- Gen-Probe
- Kadmon
- Onyx Pharmaceuticals
- Tibotec Therapeutics
- Vertex Pharmaceuticals

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### Viral Hepatitis Action Coalition

Helping CDC Shine New Light on a Silent Epidemic