Testimony for Submission by

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For the oversight hearing "Addressing Disparities in Federal HIV/AIDS CARE Programs"

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The California Office of AIDS respectfully submits testimony for the record regarding the importance of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act in helping California provide comprehensive care and treatment services to persons living with HIV/AIDS. I am the Chair of the National Alliance of State and Territorial AIDS Directors (NASTAD) and a founding member of NASTAD's ADAP Crisis Task Force, which negotiates drug prices and supplemental rebates and discounts with the pharmaceutical industry on behalf of all the ADAPs in the country. I am submitting this testimony on behalf of NASTAD as well. State AIDS directors appreciate the longstanding support of the United States Senate for the Ryan White CARE Act programs that are of the utmost importance to Americans living with HIV/AIDS.

As the Chair of NASTAD, I would like to share with you some of the views of my fellow state AIDS directors, in addition to the state of California. I have limited my comments to those that address disparities in the CARE Act or are issues covered in the ongoing GAO investigation.

California's Office of AIDS administers California's HIV/AIDS prevention and care programs, which are funded by federal and state funds, including CARE Act Title II funds. California was and remains an epicenter of the AIDS epidemic. HIV infections have penetrated nearly every metropolitan and rural community in our state. California ranks second in the nation in the number of cumulative AIDS cases as well as those living with AIDS with 137,213 cumulative cases and 57,308 individuals living with AIDS by May 31, 2005. We have had approximately 80,000 Californians die as a result of having AIDS. Of those living with AIDS, half are members of minority groups; 29% Hispanic, 19% Black, 3% Asian American, Pacific Islander or Native American. Women make up 11% compared to 89% for men. In terms of persons with HIV, California has 37,531 reported cases.

In federal fiscal year 2005, California received $221 million in Ryan White funding for Titles I and II – including $31 million for the Title II base, $90 million for ADAP, and $169,000 for our one emerging community – Bakersfield. California has nine Title I Eligible Metropolitan Areas that are funded at $99 million. Governor Schwarzenegger and the California legislature have demonstrated their commitment to HIV/AIDS care and treatment by providing $111 million in state General Fund in spite of California's budget deficit.

Importance of the Ryan White CARE Act

The CARE Act is a federal-state partnership to provide comprehensive care and treatment to low income, uninsured and underinsured people living with HIV/AIDS. Title II is designed to assure that people living with HIV have access to quality HIV care, regardless of whether they live in rural, suburban or urban areas. $1.1 billion in federal funds were appropriated to Title II in FY2005, including $797 million in dedicated funds for ADAP. In 2004, over 136,000 individuals received ADAP services.

The Ryan White CARE Act has made an enormous difference in the lives of California's men, women and children who are infected with HIV/AIDS. The CARE Act has enabled us to make a broad range of health care and supportive services available through community systems of care provided to increasing numbers of people with HIV/AIDS. For many living with HIV/AIDS, these systems are their only source of care and treatment.

California has worked hard to provide a continuum of care for all residents infected with HIV and to provide equal access to the standard of HIV care. We have taken a leadership role in promoting the coordination amongst all the CARE Act funded entities within the state. The state is committed to coordinating and planning programs that ensure that all persons living with HIV disease in California have access to basic care and support needs. We are also committed to avoiding duplication or overlap of services and obtaining services and products of the highest quality at the lowest possible cost. Through the coordination of CARE Act grantees, state and local partnerships have been established at every level.

Understanding that there are disparities between states in what they are able to offer in terms of level of services, state AIDS directors recommend keeping the Title II base formula as is. Equity among states cannot be achieved simply by rearranging the $334 million in the Title II base. The entire CARE Act has the responsibility to achieve equity for persons living with HIV/AIDS. When looking at per AIDS case funding disparities from state to state one needs to take into consideration Title III, IV and Part F in addition to Titles I and II. In 2000, the CARE Act required that new Title III awards be prioritized to states without EMAs. State AIDS directors recognize the importance of getting additional resources to states that are traditionally under resourced and are proposing to alter the Emerging Communities provision to do so.

As the payer of last resort, the CARE Act is the safety net under other public programs such as Medicaid and Medicare. As Medicaid programs are altered from state to state, the Ryan White programs must adapt to fill the gaps. State ADAPs in particular will be filling in gaps for those enrolled in the new Medicare prescription drug plans with incomes of over 150% of the federal poverty level (FPL). As the payer mixes and cost of delivery of care vary across the country, it

makes the exercise of comparing CARE Act programs from one state to another exceedingly challenging.

The state AIDS Drug Assistance Program is the largest component of the CARE Act. AIDS Drug Assistance Programs (ADAPs) provide HIV/AIDS-related prescription drugs to uninsured and underinsured individuals living with HIV/AIDS in the 50 states, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, the North Marianas and the Marshall Islands. ADAPs began serving clients in 1987, when Congress first appropriated funds to help states purchase AZT—the only approved antiretroviral at the time. In 1990, ADAPs were incorporated under Title II of the newly enacted CARE Act. Federal funding for ADAPs is allocated by formula to states and territories.

Since the advent of highly active antiretroviral therapy (HAART) in 1996, AIDS deaths have declined and the number of people living with HIV/AIDS has increased markedly. ADAPs have played a crucial role in making HAART more widely available. In a given year, ADAPs reach approximately 136,000 clients, or about 30% of people with HIV/AIDS estimated to be receiving care nationally.

The services provided by ADAPs differ from state to state. Eligibility criteria and other services provided such as resistance testing and HCV treatments all differ between states. For example, in FY2004 formularies ranged from 25 FDA approved antiretrovirals (ARVs) to all FDA-approved HIV-related drugs. There is also a tremendous range in eligibility criteria. Eligibility criteria range from 125% of the federal poverty level (FPL) in one state to 500% FPL in several states. The variation between states in the coverage gaps to be filled by ADAPs is further exacerbated by the variation in benefits and eligibility criteria of state Medicaid programs.

Congress and the President have shown strong support for ADAP. On June 23, 2004, President Bush announced immediate availability of $20 million in one-time funding outside of ADAP to provide medications to individuals on ADAP waiting lists in 10 states (registered as of June 21, 2004). Currently 1,438 individuals are enrolled in the program (as of May 12, 2005), which is administered separate from ADAPs in eligible states by BioScrip, Inc.

ADAPs are not entitlement programs; annual federal, and in most cases state, appropriations determine how many clients ADAPs can serve and the level of services they can provide. In fiscal year 2004, overall ADAP budget increases were driven by increased state contribution and increases in pharmaceutical discounts and rebates; not the federal budget. As of May 12, 2005, a total of 1,891 individuals were on ADAP waiting lists in 10 states. As mentioned above, 1,438 of these individuals are currently receiving medications through the President's Initiative, which is set to expire in September 2005. Another 453 individuals on waiting lists in eight states are not covered by the President's Initiative. Eleven ADAPs have instituted capped enrollment and/or other cost-containment measures since April 1, 2004. Eleven ADAPs anticipate the need to implement new or additional cost-containment measures during the current ADAP fiscal year ending March 31, 2006.

California has the largest ADAP in the country serving 28,095 clients in calendar year 2004. Our drug expenditures exceeded $239 million in 2004 with nearly 900,000 prescriptions filled. California is fortunate to have a robust ADAP with a financial eligibility of 400 % of FPL and

152 drugs on our formulary. This is in large part due to the generous contribution from the state of $66 million.

ADAPs receive the lowest prices in the country for antiretroviral therapies. In conjunction with my colleagues from New York, I helped establish NASTAD's ADAP Crisis Task Force to negotiate with the pharmaceutical industry on behalf of all ADAPs. Although the large states had the bargaining power, we felt it was critical that all ADAPs, large and small, had access to the same prices and discounts. The Task Force began negotiations in March 2003 with the eight manufacturers of ARVs (Abbott, Boehringer-Ingelheim, BMS, GSK, Gilead, Merck, Pfizer, and Roche). As a result of this highly successful public-private partnership, we achieved supplemental discounts/rebates and price freezes that achieved an estimated $90 million in savings during fiscal year 2004. California's ADAP would not be as robust as it is without the additional rebate money being pumped into the program. The Task Force has expanded negotiations to makers of therapies to treat opportunistic infections (OIs) and other high cost, highly utilized drugs. A recent study by the University of California, Los Angeles, verified that, as a result of these negotiations, ADAPs were achieving the lowest prices available without a federal mandate.

Accountability

In a June 2004 speech, President Bush discussed for the first time the Administration's priorities for the reauthorization of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act expiring in September 2005. Bush stated, "[w]e must hold accountable organizations that receive federal help to fight AIDS by keeping track of their progress." State AIDS directors support accountability of all CARE Act programs and grantees. Provisions in the CARE Act require a variety of data to be supplied by grantees to the Health Resources and Services Administration (HRSA), the agency that oversees the CARE Act. This data provides HRSA with a detailed account of how grantees are utilizing federal resources. States and territories are monitored in a rigorous manner by HRSA. States and territories are required to provide program budget and fiscal reports and detailed contractor/provider budget packages each year. Grantees must also provide to HRSA a budget package for each Title II subgrantee with whom they contract.

States are mandated to monitor the organizations with which they subcontract to provide services to individuals living with HIV/AIDS. The majority of states have in place systems of accountability that include both fiscal monitoring and program monitoring. States must also ensure that subgrantees have quality management (QM) programs in place, which help the subgrantee and the state identify problems that may impact health status outcomes.

Additionally, since the enactment of CARE Act in 1990, the Office of the Inspector General (OIG) within the Department of Health and Human Services (HHS) has audited HRSA's HIV/AIDS Bureau (HAB) and CARE Act grantees a minimum of 25 times to ensure accountability in the usage of CARE Act resources. The OIG routinely audits states and their subgrantees for compliance with operating procedures, as well as conducting inspections and evaluations of the programs.

In 2004, the OIG performed an audit of California's Title II funds to determine whether the health department met key service-delivery performance goals and complied with program requirements; followed applicable cost requirements in the expenditure of Title II funds; and purchased prescription drugs at the lowest prices available for ADAP. The OIG found that California met its key service-delivery performance goals and complied with program requirements; complied with cost requirements in the expenditure of CARE Act Title II funds; and purchased prescription drugs at discounted prices below those mandated. The sole finding concerned the interval between the collection and expenditure of manufacturer rebates. Corrective action has been taken and rebates have for two years in a row allowed for the expansion of California's ADAP to meet caseload growth.

Recommendations for Reauthorization

The CARE Act has had a tremendous impact on the lives of people with HIV/AIDS throughout the nation, improving the availability and quality of health care services for these individuals and their families. As the largest federal program for people living with HIV/AIDS, the CARE Act is an essential source of support for HIV/AIDS care and treatment services. The number of people living with HIV/AIDS is growing, therefore, increasing the number of individuals expected to be served by CARE Act programs. The epidemic continues to grow disproportionately among people of color, women and young people. Assuring that all persons with HIV/AIDS, regardless of geographic location, have equal access to appropriate and high-quality HIV/AIDS services is our highest priority.

Disparities in the availability of resources affect the accessibility and quality of HIV services, both within and between states. State AIDS directors recognize that the structure of the Ryan White CARE Act contributes to the challenges faced by some states in effectively addressing the needs of persons living with HIV/AIDS. In many states, the current structure is a contributing factor to funding disparities that affects availability, accessibility and quality of services, both within and between states, as well as the coordination of HIV care and the efficient delivery of essential services. While the Ryan White CARE Act cannot be viewed as the sole mechanism for equalizing these inherent differences, the current structure of the CARE Act leaves many states struggling with the delivery and coordination of HIV services, while trying to meet legislative mandates to provide for the public health of citizens within their respective jurisdictions.

We recognize that alternative proposals for serving persons living with HIV/AIDS have been developed, including the Institute of Medicine's report *Securing the Legacy of Ryan White.* This report attempts to respond to these challenges. These proposals are worthy of and warrant further study, consideration and discussion.

State AIDS directors recommend retaining the current structure of the CARE Act. We do so while establishing the following two goals which are reflective of our vision for improved HIV care services in the nation: (1) to enhance the availability of ADAP resources and services for persons living with HIV/AIDS in need in all areas of the nation, and (2) to provide additional resources to states chronically insufficient Title II base funds through the Emerging Communities mechanism.

Increase ADAP Stability

We recommend the establishment of a guaranteed minimum level of new funding to ADAP for use in providing access to HIV/AIDS drugs and care, and to direct a portion of this new funding to states with waiting lists, inadequate formularies and restrictive income eligibility criteria. State AIDS directors recommend that a minimum increase of $60 million be provided annually to support ADAPs. While $60 million does not represent the entire need (ADAPs traditionally require a minimum of $100 million in growth each year in order to meet demands), this guaranteed funding would enable states to provide treatments to low-income individuals, consistent with U.S. Public Health Service guidelines, while enabling them the flexibility to make formulary decisions based on the financial status of their ADAPs.

If the annual appropriation increase for the ADAP earmark is less than $60 million, we recommend that an amount necessary to ensure a minimum increase of $60 million be provided through the following mechanisms:

1. Redirect to the ADAP earmark any unexpended funds from all titles of the CARE Act from all years with the exception of the previous two grant periods (e.g., in year 16, utilize all unexpended funds from year 13 and earlier).
2. Redirect to the ADAP earmark any unexpended funds that exceed HRSA's approved percentage of any CARE Act grantee's award amount (using the FSR submitted 90 days following the conclusion of each grant award) from all titles of the CARE Act. Grantees would be able to spend up to the approved amount of their previous year's award for use during the next grant cycle – the remaining amount of unexpended funds for each grantee for that year would be reserved for this provision during the next award cycle for Title II/ADAP grants.
3. Institute an equal percentage tap on all CARE Act titles, excluding ADAP.

Additional resources to states without EMAs

Authorized in 2000, the Title II Emerging Communities (ECs) Supplemental grants sought to address the challenges faced by areas with a significant burden of AIDS cases but that lacked the density of cases to be a Title I Eligible Metropolitan Area (EMA). The goal of the grants was to provide resources to smaller communities to enhance local health care infrastructure to provide HIV care services. The EC provision, as currently written, places traditionally underserved rural areas at a disadvantage. A significant number of largely rural states are ineligible to receive any of these supplemental funds because they do not have urban areas that meet the EC eligibility criteria.

Since its creation, ECs have been subject to significant funding fluctuations, due in large part to ECs not permanently being eligible once they begin receiving funds. The number of areas eligible for these supplemental grants has continued to diminish over the five-year authorization period because of reductions in the number of AIDS cases. In the past four years, 14 ECs have been eliminated altogether.

State AIDS directors believe the current EC provision should be modified to address the needs of states with a severe lack of Title II base resources that fund critical primary care and support services. States with chronically insufficient Title II base funds have long wait times for primary

care and struggle to meet the needs of persons in rural areas that lack the density to secure Ryan White resources. We are seeking to redistribute EC dollars to provide resources to states with significantly fewer dollars per AIDS case[1] than the national average. States without Title I EMAs comprise the vast majority of states with a per AIDS case funding rate below the national average.

Specifically, we are recommending redefining the current provision to target additional funding to states that have a CARE Act per capita funding level below the national average. Funds should be redirected to states without Title I EMAs that do not receive minimum award funding and to those states with Title I EMAs in which 50% or greater of their state's cases reside outside of their Title I EMA(s). States would use the additional monies for activities allowed under the Title II base authorization and HRSA guidance and direct resources to the communities where cases within their states reside. This proposal maintains the original intent of the EC provision by directing resources to states with epidemics that are not highly concentrated enough to be eligible for Title I funding. NASTAD recommends an authorizing level and funding of $35 million to address disparities through a revised EC provision.

In addition, state AIDS directors recommend reducing Title I eligibility to 1,500 estimated living AIDS cases during the previous five years. There is one EC, Memphis, Tennessee, that is an outlier among ECs having 360 more cases on average over the past five years than the next lowest EC. In FY2005, Memphis has 1,666 cases with the next lowest EC having 1,193. Therefore, NASTAD recommends that Memphis and communities in the future with 1,500 cases or more be deemed a Title I EMA.

Incorporation of HIV into Formula

The CARE Act currently calls for the use of HIV data in distribution formulas in fiscal year 2007. We strongly support this transition which will promote more effective targeting and distribution of CARE Act resources. We believe the use of HIV cases in addition to AIDS cases in CARE Act allocation formulas is preferable and more closely reflects the epidemic than living AIDS cases.

Forty-three jurisdictions have name-based HIV reporting. The remaining 13 jurisdictions utilize a code or name-to-code system for reporting HIV cases. Several jurisdictions have only recently implemented HIV reporting and therefore their HIV data is not yet considered "mature" enough to be reliable. CDC has not accepted HIV case report data from the 13 jurisdictions that collect and report HIV case data using codes or name-to-code systems, determining that these systems do not meet national performance and evaluative standards.

California is the only state among the five largest that uses an HIV reporting system different than its AIDS reporting system. The Schwarzenegger administration is concerned that by not converting to a name-based HIV reporting system, California risks losing its fair share of CARE Act funds when the funding formula changes. While legislative attempts were unsuccessful this year to change from code to name-based reporting, a spirited dialogue in California continues. Having said that, state AIDS directors unanimously agree that our Title II funds should not be

[1] The state per AIDS case rate was determined by totaling a states Title I, II, III IV, and Part F (excluding Emerging Communities and SPNS) and dividing by a state's estimated living AIDS cases.

withheld in order to force states to switch reporting systems. We believe surveillance is within the domain of the states; states should determine what methodology best serves the needs of their citizens.

Regardless of which reporting system is utilized, there are still states with data derived from systems which remain immature. To incorporate HIV data in fiscal year 2007, CDC will need to develop a methodology to estimate HIV cases for these states. State AIDS directors urge that CDC be required work with the states when developing this methodology.

Redirection of Unexpended CARE Act Funds

While administering CARE Act funds, states and Eligible Metropolitan Areas (EMAs) periodically finish fiscal years with small amounts of unspent funds. These amounts, typically ranging from five or ten percent of overall awards, may be requested in the subsequent fiscal year to provide services during that fiscal year. The unspent funds typically result from delays in notice of grant awards from the federal government, timing issues related to subcontracting of services, payroll savings due to state hiring delays or freezes, expenditure of other grant funds for similar services, or other unanticipated fluctuations in spending at the state level. Occasionally, the amount of unexpended funds reaches beyond ten percent of a grantee's overall award for reasons specific to the individual jurisdiction. California currently has $5,319 in carryover, which is significantly less than the $1.7 million figure recently released by HRSA. Some states have reported that the figures do not exclude funds that have been approved for expenditure by states. The accounting of carryover needs to be improved so that it's an accurate reflection of unobligated funds.

State AIDS director unanimously agree that expiring unexpended funds must be put back into the CARE Act rather than being returned to the Treasury as is currently the case. States with excessive and chronic amounts of unobligated funds need immediate technical assistance from HRSA to address issues that are hindering a state from spending their award.

Our ADAP proposal would redistribute unobligated funds from all Titles back into the ADAP program. Although this would be considered one-time-only funding, it would allow states to provide life saving therapy to individuals in need for a year, as well as assist states with transitioning clients currently participating in the President's $20 million waiting list initiative, scheduled to expire September 30, 2005.

Hold Harmless

State AIDS directors support the continuation of a hold harmless provision for Title II at a reduced rate of loss. Experience shows that after the last reauthorization, due to the unintended consequences of changes in the law, 30 states were held harmless from significant funding losses Hold harmless provisions limit shifts in Title II base and ADAP earmark funding that otherwise could help address funding disparities that exist from state to state. However, with limited funding, as well as two consecutive years of cuts to the Title II base, these disparities cannot be corrected via major shifts in Title II resources without impacting critical existing services in jurisdictions that would lose funding.

We do support the removal of one of the two hold harmless provisions under Title II. The first of the two provisions ensures that the amount of a grant awarded to a state or territory for a fiscal year under either the Title II base or the ADAP earmark is not less than a defined percentage of the amount the jurisdiction received in fiscal year 2000. We are requesting a change to this provision to reflect a 1.5% loss each year (based on FY2005 funding levels) with a maximum possible loss of 7.5% over a five-year period, or 92.5%.

We are requesting removal of the second hold harmless to the overall Title II award that includes the Title base, ADAP earmark, ADAP Supplemental Grants, Emerging Communities, and Minority AIDS Initiative funding. The second hold harmless has resulted in the unintended affect of reducing the amount of money available for the ADAP Supplemental due to significant fluctuation in the Emerging Communities funding. The ADAP Supplemental is a 3% set-aside of the ADAP earmark designed to increase access to care in states with ADAP restrictions.

State Match and Maintenance of Effort

The CARE Act contains two provisions designed to assure state funding support for HIV care and treatment programs. To prevent federal funds from offsetting specific HIV-related budget reductions at the state level and to encourage increased state contributions to HIV care services, Title II contains a state funding match and maintenance of funds assurance requirement. It is critically important to continue the state commitment and keep these provisions in law with the exception of the match requirement for the ADAP Supplemental Grants. Because of a 1:4 state match requirement for ADAP Supplemental Grants, some eligible states have been unable to access the funds. This match requirement has resulted in a loss of funds to several state ADAP programs that are in dire need of additional resources. We support the removal of the match requirement for the ADAP Supplemental only, with other state match and maintenance of effort requirements continuing in a reauthorized CARE Act.

Integration of Prevention into Care Setting

Federal agencies, health departments, and communities understand the growing importance of close linkages between HIV prevention and care services to ensure that individuals learn their HIV status and receive referrals to appropriate services. HIV prevention is increasingly seen as a standard of care for persons living with HIV. Studies indicate that HIV-positive individuals take steps to protect their partners from infection, with 70% reporting reductions in risky behaviors even at one year after diagnosis.

Health departments use partner counseling and referral services (PCRS) as one tool to identify HIV-positive individuals and ensure their linkage to medical, support, and prevention services. Research has found PCRS to be a cost effective strategy for identifying HIV infected persons unaware of their serostatus. The CARE Act allows Titles I and II to conduct early intervention services (EIS). Previously, early intervention activities were only allowed among Title III and IV grantees. The 2000 CARE Act amendments also added grants to states for carrying out programs providing PCRS. While the CARE Act called for $30 million to be appropriated in FY2001 for the new PCRS grants, no money has ever been provided to states through this grant mechanism.

Currently, all states and territories conduct PCRS as a requirement of their prevention cooperative agreement through the Centers for Disease Control and Prevention (CDC). PCRS includes three basic elements: 1) Seeking the names of partners who may be at risk for infection (partner elicitation), 2) Locating partners and notifying them of their risk (partner notification), and 3) Providing HIV testing and risk reduction counseling to partners (partner counseling). PCRS is not limited to the time of initial diagnosis but is offered continuously to provide on-going support for positive persons related to serostatus disclosure and to ensure that both positive persons and their partners have access to prevention services. Partner notification, a key public health strategy to fight communicable disease, lies within the authority of health departments as part of their mission to protect public health.

State AIDS directors support the continuation of funding for PCRS through the CDC cooperative agreements with the states and six directly funded cities.

Perinatal Prevention

Perinatally acquired AIDS cases have decreased dramatically due, in large part, to HIV testing among greater numbers of pregnant women and their subsequent treatment. In 2003, the CDC reported only 152 new cases of perinatally transmitted AIDS. This represents an 84% decline from a high of 954 new AIDS cases in 1992. Only three states account for over 50% of all new perinatal cases reported to the CDC. 22 states reported no pediatric AIDS cases. Perinatal initiatives developed by state and local health departments have contributed to the significant decline in perinatally acquired AIDS cases from the peak in the early 1990s.

In 1996, Congress authorized through Section 2625 of the CARE Act $10 million for grants to support counseling, testing, and outreach to pregnant women and infants. Priority in funding was given to states with the highest prevalence of perinatal transmission cases.

California had 14 cases reported in 2003. California has an opt out/opt in process for testing previously untested pregnant women. We treat each case of perinatal transmission as a sentinel event and follow-up to determine where the woman fell through the cracks in the health care system. We still find that access to prenatal care is the largest barrier to reducing the number of perinatally-acquired infections to zero with many of the women knowing their HIV status before delivery. The lack of access to care and fear of seeking care for non-citizens and substance using women remains the primary barrier.

The prevention of mother to child transmission is one of our greatest prevention successes. One way to continue the reduction in cases is to provide hospitals serving the un- and underinsured with HIV rapid tests for use in the labor and delivery setting. This would require resources for the test kits as well as training for hospital staff on counseling and administration of the screening test.

The California Office of AIDS thanks the Chairman, Ranking Member and members of the Subcommittee for their thoughtful consideration of our recommendations to revise the CARE Act to increase equitable access to critical CARE Act funded services.