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November 29, 2019

BY ELECTRONIC DELIVERY

Honorable Richard E. Neal
Chairman
Committee on Ways and Means
1102 Longworth House Office Building
Washington, D.C. 20515

Honorable Kevin Brady
Ranking Member
Committee on Ways and Means
1139 Longworth House Office Building
Washington, D.C. 20515

Re: Request for Information, Rural and Underserved Communities Health Task Force

Dear Chairman Neal and Ranking Member Brady:

We appreciate that the Committee is addressing the challenges associated with the delivery and financing of health care services to rural and underserved urban communities. The challenges and needs of these communities are significant and clearly warrant special attention from the Committee. We believe that there are significant opportunities to improve healthcare for individuals living in rural and underserved urban communities through expansion of evidence-based medicines and support services.

Alkermes is a fully integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to research, develop and commercialize, both with third parties and on our own, pharmaceutical products that are designed to address unmet medical needs of patients in major therapeutic areas. We have a diversified portfolio of marketed drug products and a clinical pipeline of product candidates in central nervous system (CNS) disorders such as addiction, schizophrenia, and multiple sclerosis. Our marketed drug products include

VIVITROL® (naltrexone for extended-release injectable suspension; XR-NTX)[1,2] indicated for the prevention of relapse to opioid dependence following opioid detoxification, and for the treatment of alcohol dependence; and ARISTADA® (aripiprazole lauroxil)[3], indicated for the treatment of schizophrenia, and ARISTADA INITIO® (aripiprazole lauroxil),[4] which in combination with oral aripiprazole is indicated for the initiation of ARISTADA. These medicines are long-acting injectable medications (LAIs).

Our comments are informed by our work with healthcare professionals, caretakers and people who are living with serious mental illnesses (SMIs), such as schizophrenia; and substance use disorders (SUDs), specifically alcohol dependence and opioid dependence.

A focus on improving access to treatments of SMIs and SUDs is warranted because of the significant impact these illnesses have on public health. We have focused our comments below on opportunities to improve access to medications approved by the U.S. Food and Drug Administration (FDA) for the treatment of SUDs and SMIs.

1. What are the main health care-related factors that influence patient outcomes in rural and/or urban underserved areas? Are there additional, systems or factors outside of the health care industry that influence health outcomes within these communities?

A factor impacting access to healthcare in rural and underserved urban areas is the ***behavioral health workforce shortage***.[5] Low wages for behavioral health professionals has been cited as a major factor compromising access. SUD professionals are paid less than other comparably credentialed healthcare professionals and "… low wage rates for SUD treatment professionals are associated with high turnover and difficulty in hiring qualified staff."[6] Similarly, "individuals trained to provide SUD treatment quickly move on to other professions that offer better working conditions, wages, and benefits."[7] Another study found that access to addiction medicine specialists was worse than the other medical specialties studied, with only 8% of counties having a single addiction medicine physician.[8] Again, low wages were cited as the primary cause. Another report, focusing on mental health professionals describes a similar

[1] Please see the Prescribing Information and Medication Guide for important product safety information. Alkermes, Inc. (July 2019). *VIVITROL® Medication Guide*. Revised: July 2019. Accessible at: https://www.vivitrol.com/content/pdfs/medication-guide.pdf

[2] Alkermes, Inc. (September. 2019 revision). *VIVITROL® Prescribing Information*. Revised: September 2019. Accessible at: https://www.vivitrol.com/content/pdfs/prescribing-information.pdf

[3] Alkermes, Inc. (Nov. 2018). *Aristada® Prescribing Information.* Revised: August 2019. Accessible at: https://www.aristada.com/downloadables/ARISTADA-PI.pdf

[4] Alkermes, Inc. (Nov. 2018). *Aristada Initio® Prescribing Information. Aristada Initio® Prescribing Information.* Revised: August 2019. Available at: https://www.aristadahcp.com/downloadables/ARISTADA-INITIO-PI.pdf

[5] Office of the Assistant Secretary for Planning and Evaluation, DHHS. *Substance Abuse Disorder Workforce* (2018). https://aspe.hhs.gov/system/files/pdf/259346/ExamSUDib.pdf

[6] Office of the Assistant Secretary for Planning and Evaluation, DHHS. *Examining Substance Use Disorder Treatment Demand and Provider Capacity In A Changing Health Care System: Final Report*. (Dec. 2017). Page xiii. https://aspe.hhs.gov/system/files/pdf/259356/ExamSUDfr.pdf

[7] Ibid. Page 34.

[8] Goodson, J.D., Shahbazi, S. and Song, Z., 2019. Physician Payment Disparities and Access to Services—a Look Across Specialties. *Journal of general internal medicine*, pp.1-3.

shortage, and again, attributes the lack of access to low wages and poor reimbursement for the delivery of healthcare.[9]

2. What successful models show a demonstrable, positive impact on health outcomes within rural or underserved communities, for example initiatives that address: a) social determinants of health (particularly transportation, housing instability, food insecurity); b) multiple chronic conditions; c) broadband access; or d) the use of telehealth/telemedicine/telemonitoring?

Access to healthcare services for individuals with SUDs and SMIs is a serious challenge for individuals in rural and underserved communities due to long-distances and limited public transportation. However, there are ***mobile vans*** staffed with healthcare professionals who provide medical, SUD and SMI treatment services that travel to the underserved communities bringing professional services.[10,11,12,13] These van-based behavioral healthcare teams maintain regular schedules at diverse community locations; delivering medical care and medication management; and providing other related support services, such as homeless outreach.

3. What should the Committee consider with respect to patient volume adequacy in rural areas?

SMIs and SUDs are highly prevalent conditions, with nearly one in five U.S. adults living with one of these conditions.[14] These conditions can emerge suddenly and can become life-threatening if they are not treated in a timely manner.[15] Unfortunately, in some communities, long wait lists due to a scarcity of service providers delays access to treatment for people with co-occurring SUDs and SMIs.[16]

4. What lessons can we glean from service line reduction or elimination in hospitals that serve underserved communities where (c.) the cause is related to a lack of flexibility in health care delivery or payment?

Access to certain treatments, such as long-acting injectable medications (LAIs) approved for the treatment of SUDs is undermined when payers require healthcare providers to request

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[9] Behavioral Health and Economics Network. Addressing the Behavioral Health Workforce Shortage Accessed at: https://www.bhecon.org/wp-content/uploads/2016/09/BHECON-Behavioral-Health-Workforce-Fact-Sheet-2018.pdf

[10] See:https://publichealthinsider.com/2015/03/19/from-mobile-medicine-to-mental-health-helping-the-homeless-take-the-next-step/

[11] CNN. Mobile addiction clinic brings help to those at heart of opioid epidemic. March 8, 2019. Accessed at: https://www.cnn.com/2019/03/08/health/mobile-addiction-treatment-clinic/index.html

[12] PEW. Federal Ban on Methadone Vans Seen as Barrier to Treatment. March 23, 2018. Accessed at: https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2018/03/23/federal-ban-on-methadone-vans-seen-as-barrier-to-treatment

[13] https://www.phila.gov/media/20190110101212/The-Opioid-Epidemic-in-Philadelphia-.pdf

[14] See https://www.nimh.nih.gov/health/statistics/mental-illness.shtml

[15] Hayes, Joseph F., et al. "Mortality gap for people with bipolar disorder and schizophrenia: UK-based cohort study 2000–2014." The British Journal of Psychiatry 211.3 (2017): 175-181.

[16] Priester, Mary Ann, et al. "Treatment access barriers and disparities among individuals with co-occurring mental health and substance use disorders: an integrative literature review." Journal of substance abuse treatment 61 (2016): 47-59.

reimbursement under a "buy-and-bill" model.[17] While some treatment providers have the infrastructure to bill for reimbursement through a buy-and-bill process, research has documented that buy-and-bill can be a major barrier for SUD treatment providers.[18] Without the ability to access LAI medications when they are clinically indicated, effective and efficient patient care in underserved areas can be undermined. Greater flexibility in reimbursement policies for SUD or SMI providers in underserved communities could be made possible by allowing providers to bill Medicaid beneficiaries under ***either*** the pharmacy benefit or the medical benefit, depending upon their administrative capabilities and preferences.

5. If states or health systems have formed regional networks of care, leveraging for example systems of transport or the use of telehealth/telemedicine, what states or entities are these, what approaches did they use to form these networks, what challenges did they overcome, and what challenges persist?

Project ECHO has created numerous telehealth networks throughout the United States, enabling healthcare professionals to greatly expand professional training and service delivery.[19] Based at the University of New Mexico School of Medicine, Project ECHO has developed telehealth networks of care for a broad range of health conditions, including SUD and SMI. Extensive information about Project ECHO, including challenges which they've overcome, are described in detail in various publications listed in their online bibliography.[20]

6. What successful models show a demonstrable, positive impact on addressing workforce shortages in rural and underserved areas? What makes these models successful?

To increase the number of physicians and other prescribers who were trained and willing to provide treatment to patients with opioid dependence and alcohol dependence, the State of Florida, in conjunction with their SUD treatment provider association, implemented a program which achieved an 900% increase in the number of prescribers over a five-year period.[21] To accomplish this, the State established bundled payments for the work performed; and offered a prescriber mentorship program which enabled new prescribers to received training and mentorship by experienced colleagues. This statewide program for uninsured, indigent individuals, serves rural and urban communities.

[17] Our review of FFS Medicaid coverage for XR-NTX as of October 2019 found that six (6) states maintained a buy-and-bill policy that presented significant barriers for providers to prescribe specialty medications, such as XR-NTX. In these six states that employ the buy-and-bill reimbursement requirement, utilization of XR-NTX is significantly lower than states that allow this medication to be billed under the pharmacy benefit.

[18] Alanis-Hirsch, Kelly, et al. "Extended-release naltrexone: A qualitative analysis of barriers to routine use." Journal of substance abuse treatment. 62 (2016): 68-73. See page 8 for discussion of buy-and-bill.

[19] See https://echo.unm.edu/locations/us

[20] See https://echo.unm.edu/doc/Project-ECHO-Bibliography.pdf

[21] See Florida Alcohol and Drug Abuse Association (FADAA). (2018). *Vivitrol Program History* (website). Accessible at: https://www.fadaa.org/page/VIV_history . For additional information about the Florida Alcohol and Drug Abuse Association (FADAA) XR-NTX model, contact FADAA at (978) 537-6324 .

7. Access to providers that address oral, behavioral, and substance use needs in rural and underserved communities can be particularly limited. What approaches have communities or states taken to address such gaps in care delivery?

Individuals with SMIs and SUDs are at risk for relapse when there is a disruption in treatment of their SUD or SMI after they have been released from a correctional facility.[22] Often, their health insurance is terminated during incarceration, and significant gaps in continuity of care occur. However, a recent publication by the Substance Abuse and Mental Health Services Administration (SAMHSA) highlighted several jail reentry approaches that have been helpful in urban communities such as Middlesex County (Boston), Massachusetts.[23] A similar community-based program for justice-involved individuals with SMIs has been implemented in Miami-Dade, Florida.[24] Additionally, reimbursement and provider educational approaches, like the one implemented in Florida (see #6, above) have been successful in increasing the number of prescribers who provide medications to individuals in underserved communities.

8. The availability of post-acute care and long-term services and supports is limited across the nation but can be particularly challenging in rural and underserved areas facing disproportionately large burdens of chronic and disabling conditions. What approaches have communities taken to address these gaps in care delivery and the associated challenges of social isolation?

The State of Kentucky has successfully established a network of recovery housing programs for justice-involved individuals with SUDs, such as Recovery Kentucky[25] and the Healing Place.[26] Although these centers are housing programs, they have managed to also develop and deliver a wide range of recovery support services including detoxification, medication-assisted treatments, counseling and other related services. Participants in these programs may receive these clinical services and housing for a year or more. Regarding their impact on social isolation, these programs work to integrate their participants into peer support groups such as the 12 Step Fellowship. When participants complete the program, they can remain connected through alumni programs and their 12 Step Fellowships, which have meetings throughout the community and at the facilities. Programs such as Recovery Kentucky and The Healing Place, rely on corporate sponsorship, donations and contracts with state agencies, such as the Department of Corrections. As the Committee considers solutions to the many challenges in rural and underserved communities, it may wish to consider blended solutions which meld innovative approaches to public housing that also integrate and deliver a broad range of health services, including SUD treatment.

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[22] Substance Abuse and Mental Health Services Administration. Guidelines for Successful Transition of People with Mental or Substance Use Disorders from Jail and Prison: Implementation Guide. (SMA)-16-4998. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2017. Page 14.
[23] Ibid. Page 45.
[24] Iglehart, J.K., 2016. Decriminalizing mental illness—the Miami model. *New England Journal of Medicine*, *374*(18), pp.1701-1703.
[25] https://www.kentucky.com/opinion/op-ed/article200721094.html
[26] https://www.thehealingplace.org/

9. There are known, longstanding issues with the availability and integrity of data related to rural and urban community health. What data definitions or data elements are needed to help researchers better identify the causes of health disparities in rural and underserved areas, but are unavailable or lack uniformity?

The challenge of establishing common data definitions which can help policy makers and researcher better understand the causes of health disparities in rural and underserved areas has been addressed, to a large degree, by the Commonwealth of Massachusetts.[27,28,29] In response to a state law, Massachusetts Department of Public Health developed a collaborative data sharing methodology which enables them to look at the interrelationships between multiple, diverse datasets including: a) all medical claims; b) corrections; c) courts; d) education and e) child welfare. By establishing a multi-stakeholder database, Massachusetts enables policy makers and public health officials to see the full impact of policy decisions, and efforts at correction.

10. Are there two or three institutional, policy, or programmatic efforts needed to further strengthen patient safety and care quality in health systems that provide care to rural and underserved populations?

The undertreatment of SUDs and SMIs is a well-recognized and extraordinarily costly problem.[30, 31] According to the White House Council of Economic Advisors, the opioid crisis cost America an estimated $2.5 trillion over four years, due to the impact on health, safety and productivity. Over the past several years, Congress has appropriated funds specifically designed to address the opioid crisis, by expanding access to treatment through grant programs.[32] However, our nation's capacity to successfully treat SUDs and SMIs is inadequate in large part due to underfunding, and lack of adequate funding for care.[33] Increased investment in the expansion of our nation's ability to identify and treatment SUDs and SMIs needs to be continued and expanded, not just through grants but also consistent funding. In particular, Certified Community Behavioral Health Clinics (CCBHCs) are an important innovation which should be supported through further expansion.[34,35]

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[27] Rose, Adam J., et al. "Potentially inappropriate opioid prescribing, overdose, and mortality in Massachusetts, 2011–2015." *Journal of general internal medicine* 33.9 (2018): 1512-1519.

[28] Schiff, Davida M., et al. "Fatal and nonfatal overdose among pregnant and postpartum women in Massachusetts." *Obstetrics & Gynecology* 132.2 (2018): 466-474.

[29]Department of Public Health. Commonwealth of Massachusetts. An Assessment of Fatal and Nonfatal Opioid Overdoses in Massachusetts (2011 – 2015) August 2017. https://www.mass.gov/doc/legislative-report-chapter-55-opioid-overdose-study-august-2017/download

[30] See: https://store.samhsa.gov/system/files/pep17-ismicc-rtc.pdf

[31] U.S. Department of Health and Human Services (HHS), Office of the Surgeon General, *Facing Addiction in America: The Surgeon General's Spotlight on Opioids.* Washington, DC: HHS, September 2018.

[32] See https://www.samhsa.gov/newsroom/press-announcements/201909041245

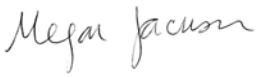
[33]See: https://www.bhecon.org/wp-content/uploads/2016/09/BHECON-Behavioral-Health-Workforce-Fact-Sheet-2018.pdf

[34] https://www.thenationalcouncil.org/wp-content/uploads/2017/11/What-is-a-CCBHC-11.7.17.pdf

[35] https://www.samhsa.gov/sites/default/files/ccbh_clinicdemonstrationprogram_071118.pdf

We thank you for your attention to these important matters and for your consideration of our comments. Please do not hesitate to contact Megan Jackson, Senior Director, Government Affairs and Policy, at (202) 304-1760 or megan.jackson@alkermes.com if you have any questions regarding our comments.

Sincerely,



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