National Indian Health Board

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December 21, 2017

The Honorable Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
U.S. Department of Health and Human Services Attention:
10903 New Hampshire Ave
Silver Spring, MD 20993–002

RE: U.S. Food and Drug Administration: Opioid Policy Steering Committee; Establishment of a Public Docket; Request for Comments, Docket No. FDA-2017-N-5608

Dear Commissioner Gottlieb:

On behalf of the National Indian Health Board, I write to submit comments on the request for comments entitled: Opioid Policy Steering Committee; Establishment of a Public Docket.

Established in 1972, the NIHB is an inter-Tribal organization that advocates on behalf of Tribal governments for the provision of quality health care and public health to all American Indians and Alaska Natives (AI/ANs). The NIHB is governed by a Board of Directors consisting of a representative from each of the twelve Indian Health Service (IHS) Areas. Each Area Health Board elects a representative to sit on the NIHB Board of Directors. In areas where there is no Area Health Board, Tribal governments choose a representative who communicates policy information and concerns of the Tribes in that area with the NIHB. Whether Tribes operate their entire health care program through contracts or compacts with IHS under Public Law 93-638, the Indian Self-Determination and Education Assistance Act (ISDEAA), or continue to also rely on IHS for delivery of some, or even most, of their health care, the NIHB is their advocate.

We appreciate the opportunity to provide comments and commend the U.S. Food and Drug Administration (FDA) for taking steps to further address the scourge of opioid related overdoses and dependence. Without a doubt, the opioid epidemic is one of the most pressing public health emergencies facing the United States today, and this is especially true for Tribal Nations across the United States. As one of the primary agencies tasked with developing a coordinated response to the epidemic, we hope that the FDA will take the appropriate measures to address the significant disparities facing Tribal communities in their efforts to reduce opioid related mortality and dependence.

Background

The United States has a unique legal and political relationship with AI/AN Tribal governments established through and confirmed by the United States Constitution, treaties, federal statutes, executive orders, and judicial decisions. Central to this relationship is the Federal Government's trust responsibility to protect the interests of Indian Tribes and communities, including the provision of healthcare and public health services to AI/ANs. Nevertheless, Tribes remain behind many other communities in their public health infrastructure, capacity, and workforce capabilities as a result of

being largely left behind when the nation was developing its own public health infrastructure. These obstacles have made it particularly difficult for Tribal communities to assemble a coordinated and comprehensive response to major health emergencies, including the opioid epidemic.

According to national data statistics available from the Centers for Disease Control and Prevention (CDC), in 2014 the opioid-related death rate for AI/ANs was 8.4 per 100,000 – the highest rate by race in the country. Nonmedical use of opioids in AI/AN youth over the age of 12 were reported to be twice the rate of Whites and three times the rate of African Americans, according to a 2012 CDC report. In Washington State from 2006-2016, AI/ANs died of drug overdoses at a rate of 29 per 100,000, compared to a rate of 12 per 100,000 for Whites, 11 per 100,000 for Blacks, 3 per 100,000 for Hispanics, and 2 per 100,000 for Asians, according to the Washington State Department of Health.

The Northwest Portland Area Indian Health Board, which represents Tribes in the states of Washington, Oregon and Idaho reported that from 2006 to 2012, drug overdoses accounted for 4.3% of all deaths among Northwest AI /ANs in their three state region, as compared to 1.7% of all deaths among Non- Hispanic Whites in the same three states. Of those drug overdose deaths, 65.3% of AI/AN deaths were from prescription drugs. A 2011 Great Lakes Inter-Tribal Council community assessment reflecting aggregated data from 10 Tribal nations across Minnesota, Wisconsin and Michigan found that 30.9% of youth, 27.7% of minor adults, and 24.9% of adults intentionally misused prescription medication.

These statistics only begin to scratch the surface of the needs, barriers and challenges Tribal communities face in their efforts to curb opioid related mortality and dependence. This is partially because data collection measures for AI/AN specific data are often insufficient, leading to AI/AN data often being intermixed with other races as an "other" category; racial misreporting and misclassification of AI/AN on national and statewide demographic surveys; and lack of access to Tribally specific data for Tribal health departments and Tribal epidemiology centers. Consequently, it is highly likely that the aforementioned rates are below the actual rates.

As one of many federal agencies charged with fulfilling the federal trust responsibility to all Tribal Nations, the FDA must play a larger role in ensuring that Tribes have the resources they need to combat the epidemic in their communities. We commend the FDA's decision to establish a steering committee and hope that the comments and recommendations included below will lead to a coordinated effort that will improve health outcomes for all 567 federally recognized Tribal Nations. To that end, NIHB has organized its recommendations based on the priorities outlined in the FDA's request for comments.

1. Assessing Benefit and Risk in the Opioids Setting

Specific to assessments on benefits and risk, NIHB continues to hold regular Tribal listening sessions to gain a more complete understanding of prevention and treatment gaps, technical assistance needs, and regulatory and legislative barriers to effective response. These sessions have included Tribal leaders, behavioral health program managers, epidemiologists, and other public health program leadership and staff. The overwhelming response has been that Tribal providers, and by extension their clients, do not have the necessary education to understand the long-term health consequences of chronic non-medical opioid use. Representatives shared anecdotal accounts of how clients are sharing medication with family members and friends, and are easily obtaining new prescriptions without inquiry. Although this points to a prescription drug monitoring issue, it also points to a lack of education about proper dosing, prescribing and usage.

NIHB requests that the FDA work in unison with the Indian Health Service (IHS) and other agencies

to develop targeted culturally competent educational campaigns for providers and patients on the risks of opioid misuse and dependence, and establish a workgroup of Tribal providers to ensure that they remain apprised of new studies, programs and policies and can then take the information back to their communities and colleagues to ensure up-to-date information is accessible for all patients and providers.

2. Steps to Promote Proper Prescribing and Dispensing

As previously stated, many Tribal providers and patients have not had education on the risks of long-term opioid misuse and also lack the necessary knowledge of treatment based measures such as medication-assisted treatment and naloxone. For many providers, there is still an overarching stigma associated with drug misuse and dependence, further exacerbating access to treatment for many chronic users. Some states have taken measures to impose legal limits on opioid prescriptions, and some Tribes have adopted similar measures. Nevertheless, providers are the most in need of training as to the benefits of these restrictions. Moreover, although proper labeling of recommended duration of treatment can be a good plan of action to take, it does not include the necessary follow-ups with patients and providers to discuss why those recommended treatment durations are important. Furthermore, NIHB recommends that FDA also include informational pamphlets for providers and patients to educate them on why these restrictions are important, while also encouraging providers to have open dialogue with their patients on proper dosing and usage.

3. Requirements for Prescriber Education

In 2000, the Drug Addiction Treatment Act (DATA) significantly expanded the clinical applications of medication assisted treatments for opioid dependence such as buprenorphine. However, the statute does not require the Drug Enforcement Agency to require that all prescribers undergo a continuing medical education program on proper opioid prescribing prior to renewing their license. Although addressing this issue will take a legislative fix, states have taken matters into their own hands with requiring trainings for healthcare professionals. We request that the FDA play a more significant role in support of such measures. Overprescribing and lack of opioid education are rampant across many Tribal providers, and it is imperative that efforts to address this issue occur immediately to stop the flow of excessive opioid analgesics into communities. The IHS has taken several steps to educate their providers on proper prescribing, but the education has not reached Tribal providers. In addition, data sharing mechanisms are lacking, making it increasingly difficult for providers to have knowledge on when and how their patients may have received prescriptions from other providers.

Instituting mandatory trainings can help ensure that every provider has the necessary knowledge to make informed decisions about how, when and what quantity to prescribe opioids. The NIHB recommends that the FDA hold formal Tribal consultations with representatives from each IHS Area to discuss how such a training can be operationalized. Having representation from each area will ensure that the unique concerns and needs of each area are honored. Given the significant transportation issues many Tribal communities face, NIHB recommends that any training or curriculum be made virtually available as well. The NIHB also recommends that the FDA coordinate efforts with the IHS and regional Area Indian Health Boards already engaged in such efforts to minimize duplication and ensure a comprehensive response, while also ensuring the development of culturally appropriate materials. The NIHB stands ready to facilitate such partnerships should the FDA request it.

Request for Further Tribal Consultation

Executive Order 13175 requires all federal agencies to engage in meaningful, robust consultation with Tribes and Tribal organizations prior to enacting policies that may have implications for Indian

Country.[1] Although we applaud the FDA's request for comments on this issue, we believe that the most important and needed recommendations will come from open dialogue with Tribes. Therefore, we encourage FDA to engage with Tribal Nations directly and gain their input on how best to meet the needs American Indians and Alaska Natives.

Conclusion

NIHB and Tribes stand ready to work with the FDA to develop new innovations around addressing the opioid epidemic. We thank you for this opportunity to provide our comments and recommendations for the FDA Opioid Steering Committee and look forward to further engagement with the FDA on curbing the opioid epidemic within Tribal communities. Please contact NIHB's Director of Federal Relations, Devin Delrow, at ddelrow@nihb.org if there are any additional questions or comments raised in this letter.

Sincerely,

Vinton Hawley,
Chairman, National Indian Health Board

[1] *See, e.g.*, 25 U.S.C. § 1601 ("Federal health services to maintain and improve the health of the Indians are consonant with and required by the Federal Government's historical and unique legal relationship with, and resulting responsibility to, the American Indian people."); The White House, *Memorandum for Heads of Executive Departments and Agencies re: Tribal Consultation* (Nov. 5, 2009), https://www.whitehouse.gov/the-press-office/memorandum-Tribal-consultation-signed-president.