U. S. Department of Justice
Drug Enforcement Administration
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Springfield, Virginia 22152

www.dea.gov

NOV 0 4 2019

Kevin N. Nicholson, R.Ph., J.D.
Vice President, Public Policy and Regulatory Affairs
National Association of Chain Drug Stores
1776 Wilson Boulevard
Suite 200
Arlington, Virginia 22209

Dear Mr. Nicholson:

This is in response to your letter dated July 12, 2019, to the Drug Enforcement Administration (DEA), where you asked the DEA to clarify its position on whether the Department of Justice and/or the DEA has a medical position on the medical basis of specific prescription drug therapies. The DEA appreciates the opportunity to address your letter. Identical responses have been sent to Mr. Menighan and Ms. Hauser, co-signers of your original inquiry to the DEA.

The DEA may only address its position based on the authority granted by the Controlled Substances Act (CSA) and its implementing regulations. As a general matter, it has been the DEA's longstanding policy not to provide legal advice to private parties. In that vein, we can provide the following general information. Please be advised that this is not meant to be an exhaustive list of every statutory provision or regulation that might apply to your inquiry.

The CSA established a closed system of distribution with built-in checks and balances to ensure appropriate medical care and to maintain the integrity of the system through an accountability process. One of the most important principles underlying the CSA and its implementing regulations is that to be valid every prescription for a controlled substance must be based on a determination by an individual practitioner that the dispensing of controlled substances is for a legitimate medical purpose in the usual course of professional practice. *United States v. Moore, 423 U.S. 122 (1975)* and Title 21, Code of Federal Regulations, Section 1306.04(a) (21 C.F.R. § 1306.04(a)). Federal regulations do not define the term legitimate medical purpose nor do they set forth the standards of medical practice. It is up to each DEA-registered practitioner to treat a patient according to his or her professional medical judgement, as long as it is generally recognized and accepted in the United States. Although the DEA is the agency responsible for administering the CSA, the DEA does not act as the federal equivalent of a state medical board overseeing the general practice of medicine. The DEA lacks the authority to issue guidelines that constitute advice relating to the general practice of medicine.

The DEA has not promulgated new regulations regarding the treatment of pain. Federal law and DEA regulations do not impose a specific quantitative minimum or maximum limit on the amount of medication that may be prescribed on a single prescription, or the duration of treatment intended

with the prescribed controlled substance. The DEA has consistently emphasized and supported the prescriptive authority of an individual practitioner under the CSA to administer, dispense, and prescribe controlled substances for the legitimate treatment of pain within acceptable medical standards. This is outlined in the DEA's policy statement published in the Federal Register (FR) on September 6, 2006, titled, Dispensing Controlled Substances for the Treatment of Pain, 71 FR 52716. A copy is enclosed for your convenience.

I trust this letter adequately addresses your inquiry. For information regarding the Diversion Control Division, please visit www.DEAdiversion.usdoj.gov. If you have any additional questions on this issue, or any other, please contact the Diversion Control Division Policy Section at (571) 362-3260.

Sincerely,

Thomas W. Prevoznik
Deputy Assistant Administrator
Diversion Control Division

Enclosure