



November 18, 2021

U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Submitted electronically via www.regulations.gov

RE: Docket No. FDA-2021 – N- 0951 “Reconsidering Mandatory Opioid Prescriber Education through a Risk Evaluation and Mitigation Strategy in an Evolving Opioid Crisis; Public Workshop; Request for Comments”

To Whom to May Concern:

The American Massage Therapy Association (AMTA) is pleased to submit the following comments in response to the FDA public workshop: “Reconsidering Mandatory Opioid Prescriber Education through a Risk Evaluation and Mitigation Strategy in an Evolving Opioid Crisis; Public Workshop; Request for Comments.”

AMTA is the oldest and largest national association representing massage therapists and the massage industry profession, representing over 95,000 members across the country. AMTA has worked for over 75 years to advance the massage therapy profession, advocating for responsible state licensure and ethical standards for the industry, clinical research on the efficacy and value of massage therapy for both acute and chronic pain, and greater public and provider awareness of the numerous benefits of massage therapy as a non-opioid alternative for pain management.

We were appreciative to have the opportunity in 2018 to discuss the FDA draft Opioid Analgesic REMS Education Blueprint with agency staff and to submit comments on the draft. While we appreciated FDA’s support for providers to be aware of the breadth of non-pharmacologic therapies, including massage therapy, that exist to address acute and chronic pain conditions, we were concerned that many health providers remained ignorant of the range of treatments that constitute ‘complementary’ therapies.

We requested the FDA to include a comprehensive descriptive list of these non-pharmacologic therapies that have been supported by the National Center for Complementary and Integrative Health (NCCIH) within the National Institutes of Health (NIH) for various pain conditions. In the alternative, if a complete descriptive list of recommended integrative therapies provided by state

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licensed or certified health providers was not possible, we urged the FDA to ensure that providers were at least able to easily access such information from NIH.

We were pleased to see that the final document included a link to NCCIH in the FDA September 2018 ‘Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain’.

There are a number of nonpharmacologic and self-management treatment options that have been found to be effective alone or as part of a comprehensive pain management plan, particularly for musculoskeletal pain and chronic pain. Examples include, but are not limited to, psychological, physical rehabilitative, and surgical approaches, complementary therapies, and use of approved/cleared medical devices for pain management. HCPs should be knowledgeable about the range of treatment options available, the types of pain that may be responsive to those options, and when they should be used as part of a multidisciplinary approach to pain management. HCPs should also be aware that not all nonpharmacologic options have the same strength of evidence to support their utility in the management of pain, and some may be more applicable for some conditions than others. Example, see <https://nccih.nih.gov>

Since publication of the 2018 REMS blueprint, the U.S. opioid overdose crisis has unfortunately increased. A growing body of evidence suggests that the COVID-19 pandemic, with increased social isolation and inability to access needed health care, has likely contributed to the problem. We recognize that addressing substance abuse disorders is a multi-faceted challenge and we are not proposing massage therapy – or any other integrative or complementary therapy – as a panacea for substance abuse disorders.

However, there remains a compelling need for health care providers to have better training and education in treating patients with chronic pain that includes utilization of non-opioid treatments such as massage therapy when appropriate. These goals may be achieved through mandatory provider education, which could be delivered in a variety of technology platforms. A key component of such education should include increased awareness of the role of massage therapy and other integrative therapies in treating pain, the efficacy of massage to treat many types of both acute and chronic pain, and the ability of massage therapy to reduce or eliminate opioid use. The May 2019 final report of the HHS Pain Management Task Force on Best Practices (“Task Force”) emphasizes the importance of individualized patient-centered care in the diagnosis and treatment of acute and chronic pain as well as a multidisciplinary approach that includes massage therapy among other complementary and integrative health approaches when clinically indicated. For these recommendations to be translated into effective national policies, however, we need additional efforts by the FDA and other agencies to raise public and provider awareness about the types of pain therapies that should be available to patients. As noted in the FDA public workshop, prescribers of opioid analgesics vary by specialty and type of provider. The majority of prescribers, however, are primary care physicians, followed by nurse practitioners, dentists, physician assistants and surgeons.

Massage therapy is a well-recognized and widely supported treatment for many types of pain which can mitigate over-reliance and abuse of opioids. While federal policymakers have taken additional steps in recent years to increase the availability of massage, such as including massage as a supplemental benefit in Medicare Part C plans as a non-pharmacologic treatment for pain, as well as through the Department of Veterans Affairs, we recognize that more needs to be done. AMTA encourages the FDA to consider strengthening provider education for opioids to ensure more patients are afforded access to the full range of treatment options – including non-pharmacologic therapies that exist to address pain related issues. Opioid misuse and abuse remain a serious public health crisis and we are pleased to have the opportunity to comment on this important issue.

In closing, AMTA appreciate FDA's interest in addressing this issue and we look forward to working together on ways to mitigate opioid reliance. Please feel free to reach out to me with any questions.

Sincerely,

A handwritten signature in black ink that reads "James E. Specker". The signature is written in a cursive style with a large, looped initial "J".

James Specker
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American Massage Therapy Association
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