



Kathleen Davies
Office of Medical Products and Tobacco
US Food and Drug Administration
10903 New Hampshire Avenue Bldg 1, Rm 2310
Silver Spring, MD 20993

Submitted Electronically

Re: Docket No. FDA-2017-N-5608; Opioid Policy Steering Committee; Establishment of a Public Docket; Request for Comments

December 28, 2017

Dear Ms. Davies:

The Acupuncture Now Foundation is a U.S. based international non-profit organization dedicated to educating the public, healthcare providers and health policymakers about the practice of acupuncture. We appreciate the opportunity comment on the Food and Drug Administration's (FDA) Establishment of a Public Docket; Request for Comment for the FDA's newly established Opioid Policy Steering Committee.

In response to the opioid crisis and the evidence that non-opioid pain management drugs also carry substantial potential harms, there has been a greatly increased interest in non-pharmacologic (non-drug) therapies over the last two years. A flurry of research reviews on non-drug therapies has been taking place. These reviews consistently find evidence that several non-drug therapies are clinically effective and cost effective. Based on these research findings, several public and private healthcare agencies have published guidelines encouraging the use of non-drug therapies for pain management.

While the recent interest in non-drug pain management is a step forward, there are some problems with how well this desire to move toward an expanded role for non-drug therapies is taking place. The FDA, with its influence within the medical community, could help address these problems while also

achieving the goals of the FDA's Opioid Policy Steering Committee (OPSC). After identifying and commenting on these problems, we will offer input on how these relate to the OPSC's call for input.

Problem #1. Lack of or limited insurance coverage for many non-drug therapies.

When the CDC was drafting its most recent opioid prescribing guideline, it asked for public comments. Their draft guideline included 12 recommendations. The number one recommendation was that health care professionals (HCPs) should first look to prescribe non-drug therapies or non-opioid drugs to address patients' pain. The CDC received nearly 2 dozen comments from mainstream medical groups pointing out that the lack of insurance coverage would make following this recommendation difficult for their members to follow. Many stated in the starkest terms that an expansion of coverage for these therapies was badly needed. We include some of those comments in our resource list below.

Problem #2. Lack of guidelines to advise HCPs when to recommend non-drug therapies.

Most mainstream HCPs are not very familiar with the strengths and weaknesses of various non-drug therapies and so feel uncomfortable advising their patients about their use. Few, if any, guidelines have been developed to help these HCPs make informed recommendations to their patients about these therapies. Some of the same mainstream organizations that responded to the CDC about the lack of insurance coverage also mentioned the lack of non-drug therapy guidelines.

Problem #3. Lack of outreach to experts in non-drug therapies to aid in the development of policies to reduce dependence on drug therapies.

When governmental and non-governmental agencies form advisory committees/panels to produce advice on how to reduce the use of opioids, they seldom reach out to experts in non-drug therapies to get their input in the early stages. Several organizations have been formed over the last few decades that dedicate themselves to providing expert information on non-drug therapies and the professions that provide those therapies. Mainstream medical experts need to reach out to these largely non-mainstream authorities to best learn how to appropriately integrate those services into mainstream medicine. Simply rewriting guidelines on when to prescribe what quantity of opioids or when to use other drugs instead of opioids is not enough to address this crisis. We absolutely need the involvement of experts in non-drug therapies. And, while we are at it, we should not limit this to pain management. Our ongoing overdependence on drug-based therapies is causing harms in other areas of healthcare where non-drug therapies could also be playing a larger role. We should not wait for the next benefit to harm crisis to unfold before we look for how we can employ safer alternatives in all areas of healthcare.

Recommendation: Form a task force.

A task force should be formed to address the three problems of expanding insurance coverage for non-drug therapies, developing evidence-based guidelines for their use, and how to ensure the involvement of experts in these fields. Of course, experts in these non-drug therapies should be sought out in the early stages of developing this task force. The Acupuncture Now Foundation would look forward to participating in such a task force and working with experts in other non-drug therapies, mainstream

medicine/public health, and third party payment systems. Perhaps this task force could be part of the FDA's OPSC. If financing such a task force is an issue, there should be ways to incentivize the pharmaceutical industry to pay for it.

Our Comments to the FDA's "Key Areas":

In the "request for comments", the FDA asked for comments especially on three key areas and we would offer the following on two of those key areas:

What more can or should the FDA do to ensure that the full range of available information, including about possible public health effects, is considered when making opioid-related regulatory decisions?

Should the FDA require some form of mandatory education for health care professionals who prescribe opioid drug products, and if so, how should such a system be implemented?

We have already advised that the FDA could play a role in supporting the development of guidelines to help HCPs make informed decisions regarding non-drug therapies. Such guidelines would play an important role in any sort of effort to educate HCPs about opioid prescribing.

As to the question of if this education should be mandatory, we feel that question is best left to the experts in the professions that prescribe those medications.

In closing, we would like to also stress that as much as we believe every effort should be made to expand the role non-drug therapies play in pain management, we also believe drug therapies, including opioids, play a vital role. Pain management is a serious issue and all resources should be made available to maximize patients' choices. It is not a matter of if we use opioids or non-opioid drugs or use non-drug approaches. It is a matter of finally seriously investigating the benefit to harm ratio of different approaches, including combined approaches, and offering the right approaches for the right patients.

Thank you for the opportunity to provide this feedback. Please make note of the resources we provide below. To discuss our task force recommendation or any issues relating to the FDA's interest in curbing opioid abuse, please feel free to contact me directly at matthewb@acupuncturenowfoundation.org.

Sincerely,



Matthew Bauer, L.Ac.
President, The Acupuncture Now Foundation

Resources:

Please visit our website at www.AcupunctureNowFoundation.org for information regarding acupuncture as a health care resource, White Papers we have produced, submissions we have made to governmental agencies, and a range of issues regarding acupuncture research.

The following organizations have experts in the fields of acupuncture and traditional Chinese medicine:

The Acupuncture Now Foundation (ANF)

The American Society of Acupuncturists (ASA)

The American TCM Association (ATCMA)

National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM)

The **Integrative Health Policy Consortium (IHPC)** has representatives from several non-drug professions within its leadership

Excerpts from mainstream medical organizations commenting to the CDC regarding their Opioid Prescribing Guidelines with links to their full comments.

American Medical Association:

“Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Providers should only consider using opioid therapy if expected benefits for pain and/or function are anticipated to outweigh risks. In order to achieve this goal, public and private payer policies must be fundamentally altered and aligned to support payment for non-pharmacologic treatments and multimodal care.” <https://www.regulations.gov/document?D=CDC-2015-0112-3132>

Medical Board of California:

“While it is true that many non-pharmacologic modalities are effective for the treatment/control of chronic pain, the [draft] Guidelines fail to address the fact that many patients do not have access to these modalities, due to lack of insurance coverage or low availability.”
<https://www.regulations.gov/document?D=CDC-2015-0112-3934>

American Society of Anesthesiologist:

“Insurance coverage: A major challenge in incorporating the Guideline in daily practice is that some of these recommendations may not be covered by the patient’s insurance, which inhibits physicians’ ability to treat patients using non-opioid approaches. We recommend that the Guideline clearly state that the federal government should encourage insurance coverage for therapies that would prevent opioid dose escalation or decrease. In addition, insurance coverage should include non-pharmacological therapies (all modalities available), and payers should reduce patient co-insurance and co-pays to encourage the

use of non-pharmacological therapies.” <https://www.regulations.gov/document?D=CDC-2015-0112-3059>

American Academy of Pain Management:

“At a bare minimum, recommendations that payers provide universal coverage for the five types of nonpharmacologic care mentioned in the [Department of Defense/Veteran’s Administration] pain guideline (physical manipulation, massage, acupuncture, biofeedback, and yoga) should be issued.” <https://www.regulations.gov/document?D=CDC-2015-0112-3162>

Association of State and Territorial Health:

“Address reimbursement barriers for alternative treatments. The draft guideline states that “non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain.” Lack of reimbursement is a major barrier to including nonpharmacological approaches as a realistic treatment option for people with pain. Alternative treatments for pain management, including some physical modalities, relaxation and mind/body therapies, etc., are often not covered by health insurance plans, forcing an over-reliance in some cases on opioid medications. In order for this recommendation to be put into practice, ASTHO encourages CDC and other state and federal entities to develop a business model for reimbursement of nonpharmacologic therapies.” <https://www.regulations.gov/document?D=CDC-2015-0112-4081>

American Academy of Addiction Psychiatry and American Osteopathic Academy of Addiction Medicine

“The guidelines emphasize using alternatives to the use of opioids, including non-opioid pharmacological approaches and behavioral health interventions. The "elephant in the room" is that such alternatives are time consuming, may not be adequately reimbursed, and that primary care clinicians often are not trained in the use of such approaches. While this is discussed, the guidelines may not be realistically implemented should the recommended changes in reimbursement and training fail to occur. Then what is the PCP to do?” <https://www.regulations.gov/document?D=CDC-2015-0112-4067>

An informative article about the call for insurance coverage for non-drug therapies.

Influential U.S. Medical Organizations Call for Insurance Coverage of Non-Pharmacologic Approaches to Pain. The Journal of Alternative and Complementary Medicine Volume 22, Number 12, 2016, pp. 947–949. Mary Ann Liebert, Inc. DOI: 10.1089/acm.2016.29016.jjw <http://online.liebertpub.com/doi/abs/10.1089/acm.2016.29016.jjw>

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