Docket No. FDA-2017-D-2497 for "Draft Revisions to FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioids; Request for Comments."

American Society of Acupuncturists
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July 7, 2017

Dear Sir or Madam:

The American Society of Acupuncturists is a 501©6, national professional association representing approximately 4000 acupuncture professionals in the United States. We appreciate the opportunity to offer input on the *FDA Blueprint for Prescriber Education for ER and LA Opioids*. **Most specifically, we wish to advocate for clear direction to prescribers for consideration of acupuncture as a first-line, nonpharmacologic treatment method in all patients presenting with pain syndromes.** We recognize that other nonpharmacologic pain strategies also have tremendous value, but wish to focus directly on acupuncture. The recently published Acupuncture Evidence Project[1] provides a high quality, comparative literature review on the evidence base for acupuncture for numerous conditions. Meta-analyses of the data were performed, and quality of studies was carefully considered by highly qualified researchers. This group found strong evidence of a positive effect for acupuncture for 8 conditions, and moderate evidence of acupuncture's effect for another 38 conditions. (Table 1).

Furthermore, the group found acupuncture to be cost effective in a number of conditions (Table 2), and also safe (Table 3). Given the relative paucity of investment into studies on acupuncture, these results are all the more compelling. They demonstrate that even with, in some cases, a limited volume of studies, the studies that are available are supportive. **Overwhelmingly, acupuncture is showing itself to be an evidence based, cost-effective, and safe treatment option for numerous pain conditions and other conditions.**

[1]http://www.acupuncture.org.au/Portals/0/Evidence%20study/Acupuncture%20Evidence_plain%20English%20Web%20version_17_Feb.pdf?ver=2017-02-22-171448-550

Additionally, as the Joint Commission just updated its recommendations to include that hospitals provide options for nonpharmacologic options for the management of pain, so it becomes more imperative that the FDA's recommendations keep pace with that change.

Joint Commission Enhances Pain Assessment and Management Requirements for Accredited Hospitals

Effective January 1, 2018
 	
• Leadership (LD) Standard LD.04.03.13
  ○ Pain assessment and pain management, including safe opioid prescribing, is identified as an organizational priority for the hospital.
  ▪ Elements of Performance for LD.04.03.13 1. (See also PI.02.01.01, EP 19)
  • **2. The hospital provides nonpharmacologic pain treatment modalities.**

Official Publication of Joint Commission Requirements New and Revised Standards Related to Pain Assessment and Management, Volume 37, Number 7, July 2017. https://www.jointcommission.org/assets/1/18/Joint_Commission_Enhances_Pain_Assessment_and_Management_Requirements_for_Accredited_Hospitals1.PDF

Similarly, in its April 4, 2017 Clinical Guidelines for the "Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain", the American College of Physicians (ACP) notes that, "g*iven that most patients with acute or subacute low back pain improve over time regardless of treatment, clinicians and patients should select nonpharmacologic treatment with superficial heat (moderate-quality evidence), massage, acupuncture, or spinal manipulation (low-quality evidence).*"[2]

Given the available evidence, the American Society of Acupuncturists encourages the following as part of the core messages for the Blueprint for Prescriber Education:

- Inclusion of the clear and specific recommendation for acupuncture by physicians considering the treatment of pain syndromes with opioids
- Inclusion of the specific recommendation to seek out a qualified practitioner of acupuncture for treatment of said patients
- Inclusion of education on known mechanisms of acupuncture to further aid prescribers in understanding the known physiology of acupuncture mechanisms, thereby better to identify patients likely to respond to acupuncture therapy

[2] http://annals.org/aim/article/2603228/noninvasive-treatments-acute-subacute-chronic-low-back-pain-clinical-practice Accessed on-line July 8, 2017.

Table 1

The Acupuncture Evidence Project
(Mar 2013 - Sept 2016)

Evidence of positive effect

- Allergic rhinitis (perennial & seasonal)
- Chemotherapy-induced nausea and vomiting (CINV) (with anti-emetics)
- Chronic low back pain
- Headache (tension-type and chronic)
- Knee osteoarthritis
- Migraine prophylaxis
- Postoperative nausea & vomiting
- Postoperative pain

Evidence of potential positive effect

- Acute low back pain
- Acute stroke
- Ambulatory anaesthesia
- Anxiety
- Aromatase-inhibitor-induced arthralgia
- Asthma in adults
- Back or pelvic pain during pregnancy
- Cancer pain
- Cancer-related fatigue
- Constipation
- Craniotomy anaesthesia
- Depression (with antidepressants)
- Dry eye
- Hypertension (with medication)
- Insomnia
- Irritable bowel syndrome
- Labour pain
- Lateral elbow pain
- Menopausal hot flushes
- Modulating sensory perception thresholds
- Neck pain (NAD, not WAD)
- Obesity
- Perimenopausal & postmenopausal insomnia
- Plantar heel pain
- Post-stroke insomnia
- Post-stroke shoulder pain
- Post-stroke spasticity
- Post-traumatic stress disorder
- Prostatitis pain/chronic pelvic pain syndrome
- Recovery after colorectal cancer resection
- Restless leg syndrome
- Schizophrenia (with antipsychotics)
- Sciatica
- Shoulder impingement syndrome (early stage) (with exercise)
- Shoulder pain
- Smoking cessation (up to 3 months)
- Stroke rehabilitation
- Temporomandibular pain

Table 2

Conditions with evidence of cost effectiveness

- Allergic Rhinitis
- Low back pain
- Ambulatory Anaesthesia
- Migraine
- Chronic Pain - Neck Pain (plus usual medical care)
- Depression - Osteoarthritis
- Dysmenorrhoea
- Post-operative nausea and vomiting
- Headache

Table 3

Conditions with evidence of safety

- Acupuncture generally prior to this review:
  - Acupuncture can be considered inherently safe in the hands of well-trained practitioners.
- Allergic Rhinitis
  - **Safe** and cost-effective
- Ambulatory Anaesthesia
- Acupuncture **safe**, cost-effective and effective as an adjunctive therapy.
- Alzheimers disease
  - Acupuncture is **Safe.**
- Cancer-related psychological symptoms
  - Strong evidence for **safety.**
- Depression
  - Strong evidence for **safety.**
  - Effective and **safe** for major depressive disorder.
- Low back pain
  - **Safe** and well tolerated.
- Migraine
  - Moderate to high quality evidence
  - Cost effective. Promise in **safety** and effectiveness. Serious adverse events were not reported in any trial.
- Osteoarthritis of the Knee Promise in **safety** and effectiveness.
- Prostatitis pain/chronic pelvic pain syndrome Acupuncture superior to both sham and to usual care
- and **safe.**

Recommendations for acupuncture inclusion could be included in the FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioids as follows:

I. Assessing Patients for Treatment with ER/LA Opioid Analgesic Therapy

c. Prescribers should understand when to appropriately refer high risk patients to pain management specialists ***including providers of complementary modalities such as acupuncturists.***
d. Prescribers should be informed on how to identify qualified providers of nonpharmacologic pain management services, such as via national certification standards when available.
e. Prescribers should be familiar with the basic literature available on mechanisms of pain analgesia targeted by nonpharmacologic methods such as acupuncture.

II. Initiating Therapy, Modifying Dosing, and Discontinuing Use of ER/LA Opioid Analgesics

c. Prescribers should be knowledgeable about when and how to supplement pain management with immediate-release analgesics, opioids, non-opioids, ***and nonpharmacologic pain management modalities***.

h. Prescribers should understand that tapering the opioid dose is necessary to safely discontinue treatment with ER/LA opioid analgesics when therapy is no longer needed, ***and that tapering may be facilitated by complementary use of nonpharmacologic pain management strategies.***

III. Managing Therapy with ER/LA Opioid Analgesics

a. Prescribers should establish analgesic and functional goals for therapy, ***including regular and sufficient use of nonpharmacologic pain management strategies,*** and periodically evaluate pain control, functional outcomes, side-effect frequency and intensity, and health-related quality of life.

b. Prescribers should be aware of the existence of Patient Prescriber Agreements (PPAs).

i. PPAs are documents signed by both prescriber and patient at the time an opioid is prescribed.
ii. PPAs can help ensure patients and caregivers understand the goals of treatment, the risks, and how to use the medications safely.
iii. PPAs can include commitments to return for follow-up visits, to comply with appropriate monitoring (such as random drug testing), ~~and~~ to safeguard the medication***, and to comply with nonpharmacologic pain management strategies.***

c. Prescribers should monitor patient adherence to the treatment plan, especially with regard to misuse and abuse by:

i. Recognizing, documenting, and addressing aberrant drug-related behavior ***and failure to comply with nonpharmacologic pain management recommendations.***
ii. Utilizing state Prescription Drug Monitoring Programs, where practical, to identify behaviors that may represent abuse.
iii. Understanding the utility and interpretation of drug testing (e.g., screening and confirmatory tests), and using it as indicated.
iv. Screening and referring for substance abuse treatment as indicated.
v. Performing medication reconciliation as indicated.

d. …

e. Prescribers should be aware that there are no adequate and well-controlled studies of ER/LA opioid analgesics in pregnant women. ER/LA opioid analgesics should be used during pregnancy only if the potential benefit justifies the risk to the fetus. ***Prescribers should prioritize nonpharmacologic pain control strategies especially during pregnancy.***

f. …
g. …
h. …

i. Prescribers should be familiar with referral sources***, including acupuncture resources and other nonpharmacologic therapies,*** for the treatment of abuse or addiction that may arise from the use of ER/LA opioid analgesics.

IV. Counseling Patients and Caregivers about the Safe Use of ER/LA Opioid Analgesics

a. to p…

q. Prescribers should counsel patients and caregivers to inform them about side effects.

r. Prescribers should counsel patients about the importance of using nonpharmacologic pain management strategies to minimize dependence on opioid use and alleviate underlying causes of pain.

s. Prescribers should counsel patients that opioids do not cure the underlying cause of pain, but merely mask symptoms allowing higher functionality.

t. Adverse events should be reported to the FDA at 1-800-FDA-1088 or via http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919. pdf.

Thank you for your consideration, and we remain available to help further in the development of these guidelines and their resource materials. **Our best hope in battling the opioid crisis is to decrease the use of opioids in the first place, and to minimize their use wherever else possible. The unequivocal inclusion of recommendations for evidence based, non-opioid pain control options is paramount to any success for our national strategy.**

Sincerely,

David W. Miller, MD, LAc
Chair, American Society of Acupuncturists