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Acupuncture is "Reasonable and Necessary" for Chronic Low Back Pain

Acupuncture Now Foundation's submission to the Centers for Medicare & Medicaid Services' National Coverage Analysis of Acupuncture for Chronic Low Back Pain (CAG-00452N) February 14, 2019

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Better Health Through Better Information

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Cover Letter:

Acupuncture Now Foundation: Acupuncture is "Reasonable and Necessary" for Chronic Low Back Pain

The "Acupuncture Now Foundation" (ANF) is a U.S. based, international non-profit dedicated to educating the public, healthcare providers, and health policymakers about the practice of acupuncture. We appreciate the opportunity to offer information for your consideration to this National Coverage Analyses (NCA) regarding acupuncture for chronic low back pain.

The ANF believes the evidence supports that acupuncture is "reasonable and necessary" in the treatment of chronic low back pain (cLBP) and coverage for the treatment of cLBP should be instituted or expanded by third-party payor systems including Medicare and Medicaid as soon as possible.

Over the last few years, the ANF has submitted information regarding acupuncture research and workforce considerations to several agencies that were reviewing acupuncture research both inside and outside the U.S. including the CDC, FDA, AHRQ and the U.K.s' NICE. Those submissions can be found on our website at acunow.org under our "Research" tab. In each instance, we tried to address the specific questions or considerations those agencies were focused on, and we will do our best to do that again for the CMS's NCA review of acupuncture for cLBP. However, our experience with both the practice of acupuncture and the realm of acupuncture research has made clear to us that there is a need for reviewers of acupuncture research to try to place the body of available research into perspective.

There are two categories of research quality that will impact the reliability of any given RCT on acupuncture; the quality of the trail design methodology and the clinical quality of the acupuncture within in the trial. While there are well developed protocols for gauging the former, there are no available protocols for gauging the latter. There are no publically available clinical practice guidelines (CPGs) to guide acupuncture researchers so that they can apply acupuncture in such a way as to give it a chance to be as clinically effective as it could be. To put it bluntly: clinical quality is a crapshoot in acupuncture trials conducted in the West.

There are also no reporting guidelines to encourage researchers to state clearly if their study was intended to allow acupuncture to reach its maximum therapeutic benefit (MTB) or if the study was intended to address a limited application of acupuncture. Because of the lack of CPGs and MTB reporting guidelines many acupuncture RCTs done in the West have poor clinical quality and underestimate acupuncture's true clinical potential. For example, some RCT's have used only one acupuncture treatment, and such clearly suboptimal trials can nonetheless end up meeting the inclusion criteria of even respected reviewers (see our critique of the 2016 NICE review on low back pain).

The problem of suboptimal clinical quality in acupuncture RCTs has been greatly compounded by attempts to design placebo controls (sham acupuncture) that have largely failed to provide a truly inactive control. Put these two together and it adds-up to thousands of "sham controlled" RCTs where the sham acupuncture is not really a sham and the true/verum acupuncture is not really true. These dynamics present challenges to reviewers of acupuncture research attempting to undertake an unbiased evaluation of acupuncture's clinical effectiveness. We attempt to help the CMS reviewers gain perspective on these challenges by offering an "Expert Opinion on the Challenges Faced by CMS Reviewers and Policymakers Involved with Acupuncture Research" where we compare how three different reviewers took three different approaches to the question of how to weigh the findings of sham controlled trials.

And lastly, we offer perspective on the problem of acupuncture "dosage" and how acupuncture is "dose dependent". We describe how three different acupuncture trials each found that real and sham acupuncture had equal effectiveness at 8 weeks when 16 treatments were applied, but then the real acupuncture clearly surpassed the sham at 12 weeks and beyond. This helps to underscore that many sham-controlled trials are prone to "false negatives" and should also help CMS reviewers get an idea of how many treatments may be needed to get the greatest benefit for Medicare patients suffering cLBP.

However, despite all these problems, both the methodologic and clinical quality of acupuncture trials has been gradually improving. The more recent trials and reviews of trials have found acupuncture to be clinically effective for cLBP and to surpass sham acupuncture. This can especially be seen in the AHRQ's Comparative Effectiveness Review #169 and the American College of Physicians (ACP) recent guideline on low back pain.

Thank you. We hope you find the following information of value to you and we look forward to working with all parties interested in better understanding acupuncture's strengths and weaknesses as a drug-free healthcare resource. mbauer@acunow.org
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Acupuncture in the Management of Chronic Low Back Pain: An Overview of the Most Relevant Evidence and Expert Opinion on the Challenges Faced by CMS Reviewers and Policymakers Involved with Acupuncture Research

Authored by Matthew Bauer, L.Ac and John McDonald, PhD

Executive Summary

Evidence of the unfavorable benefit-to-harm ratio of opioids as well as other pain management drugs is leading policymakers to advise Health Care Providers (HCPs) to rely more on non-pharmacologic pain management approaches including acupuncture. Due to limited third-party payment for acupuncture, HCPs find following this advice difficult. This has led to a call for both private and government health third-party payors to expand coverage for evidence-based non-pharmacologic pain management approaches including acupuncture.

This paper, complied for the Centers for Medicare and Medicaid Services' (CMS) National Coverage Analysis (NCA) by the Acupuncture Now Foundation (ANF), summarizes the most pertinent information regarding the potential of acupuncture in treating Chronic Low Back Pain (cLBP). We review the current body of research on cLBP and related considerations as well as provide an Expert Opinion on the challenges faced by reviewers of the evidence relating to acupuncture. We also provide an overview of the potential benefits and limitations of expanding acupuncture's role in pain management.

Findings

Recent quality research indicates that in the treatment of cLBP acupuncture:

1. Is up to twice as effective as conventional pain management therapies.

2. Exhibits very low rates of adverse side effects.

3. Is or could be cost effective.

4. Scores higher than U.S. national benchmark averages in patient experience/satisfaction surveys.

However, limitations include:

1. Limited or inaccurate information regarding acupuncture held by the public, HCPs, health policymakers and health insurers is restricting demand for and access to acupuncture.

2. Low overall numbers and an uneven distribution of acupuncture service providers could make access to those services difficult in the event the demand rose significantly in a short period of time.

3. Cost concerns include limited insurance coverage as well as the greatly varying rates of provider fees for acupuncture services. These factors complicate calculating acupuncture's cost effectiveness.

Conclusion

The evidence supports the conclusion that acupuncture has a favorable benefit-to-harm ratio in the treatment of cLBP and should be considered "reasonable and necessary" by the CMS as its expanded use could reduce dependency on opioids and other harmful medications. The greatest impediments to expanding acupuncture's use include a lack of accurate information about acupuncture services, cost factors, and the potential of limited access to qualified providers if demand were to rise significantly in a short period of time.

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Introduction: New Clinical Guidelines Recommending Acupuncture for Managing Pain Sparks the Need for Expanding Third-Party Payment

In March 2016, The Centers for Disease Control and Prevention (CDC) issued guidelines for prescribing opioids for chronic pain that included 12 recommendations. The first recommendation was that "Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain." Language advising the first-line use of non-drug therapies and non-opioid drugs for managing pain is now found in several guidelines being written or re-written in response to the North American opioid crisis. In February 2017, The American College of Physicians (ACP) issued guidelines for managing low back pain that took this trend further when it recommended that for cLBP "clinicians and patients should initially select non-pharmacologic treatment" and they gave acupuncture for cLBP a "strong recommendation".

The ACP's recommendation of acupuncture and a few other non-drug therapies as a first-line treatment for managing cLBP in preference to non-opioid drugs reflects the more recent evidence finding some non-drug therapies to have superior benefit-to-harm ratios. Relying more heavily on non-opioid drugs alone, in other words, is not a viable solution to the opioid crisis.

Acupuncture researcher Steven Birch has been compiling information on clinical guidelines that recommend acupuncture. In the case of guidelines recommending acupuncture for cLBP, Dr. Birch and has found at least 4 guidelines in the U.S., and a total of at least 43 in 27 countries including three that specifically recommend acupuncture for cLBP in the elderly. Dr. Birch submitted this information to the CMS along with other research materials.

When the CDC invited feedback to its proposed recommendations to its opioid prescribing guidelines, it received critical comments from many mainstream medical organizations. Several samples of those comments are presented in Appendix A.

Groups such as the American Medical Association, the American Society of Anesthesiologists, the American Academy of Physical Medicine & Rehabilitation, and many others pointed out that, while they agreed with the recommendation on using non-pharmacologic therapies, carrying out this recommendation would be difficult for their members to follow because of a lack of insurance coverage for those services and limited knowledge about how to utilize those therapies. In 2017, 37 U.S. States Attorneys Generals signed a petition sent to America's Health Insurance Plans President and CEO urging them to expand coverage for non-drug therapies to help combat the opioid crisis.

They included acupuncture as one of those evidenced based therapies needing expanded coverage.

Section One: The Evidence

A. Overview of the Evidence

In addition to the studies on cLBP we highlight below, a section on acupuncture mechanism findings can be found in Appendix B, as such studies strongly suggest that acupuncture stimulates important intrinsic biochemical changes, including the production of endogenous opioids and anti-inflammatory compounds.

We believe no other therapy has as much science behind it, suggesting it is possible to safely invoke such a range of natural pain-reducing internal chemistry. We also reference some cost-effectiveness studies on acupuncture for cLBP, since cost is important when considering initiating or expanding third-party payment for a therapy. In addition, such studies also underscore acupuncture's effectiveness. A therapy cannot be cost effective if it is not also clinically effective.

Before getting to this data, we offer a brief commentary on the criticism that acupuncture is just a placebo and the ethics of interpreting evidence in light of the opioid crisis.

B. The Stigma that "Acupuncture is a Placebo" and the Ethics of Interpreting Evidence in the Age of the Opioid Crisis

When the claim is made that acupuncture's effects are due to placebo, the effects being referred to are the positive clinical outcomes seen in thousands of research trials on tens of thousands of people. Those positive effects themselves are not controversial, as they have been clearly and consistently demonstrated. The only controversy is over how those effects are generated and, specifically, how clearly the active therapy outperforms the controls in controlled clinical trials.

In most two-or multi-arm controlled clinical trials, the "real" acupuncture will outperform the "sham" controls, but sometimes not to the extent some would deem as a "statistically significant" degree. When the real acupuncture does not outperform the sham controls to a statistically significant degree, it is often labeled as a negative trial, no matter how clinically effective the acupuncture may have been. For example, two of the better-known trials on acupuncture for chronic low back pain found it to be nearly twice as effective as conventional care. The "conventional care" acupuncture was compared to physical

therapy and the use of commonly prescribed pain medications, including opioids. However, because the real acupuncture in these two trials did not outperform the sham acupuncture controls to a predetermined statistically significant degree, critics cited these trials as proof that acupuncture is only a placebo [1,2].

We find ourselves in the midst of an opioid epidemic that is killing thousands of Americans each month and devastating communities. The gravity of this crisis makes it imperative that we seriously consider all possible solutions where evidence finds better benefit to harm ratios.

The dictum in medicine is to "First, do no harm", not "Frist, do no placebo". When evidence shows a relatively infrequently used therapy to be nearly twice as effective as higher risk conventional care in the treatment of such a difficult-to-manage condition as cLBP, this should be seen as a positive outcome, not a negative one.

C. Research Findings for the Effectiveness cLBP

(See References starting on Page 33.)

Recent reviews have found acupuncture to be an effective intervention for cLBP.

In the "Acupuncture Evidence Project" – a review comprised of 136 systematic reviews, along with three network meta-analyses and nine reviews of reviews - acupuncture was found to show "evidence of positive effect" (the highest rating) for chronic low back pain and "evidence of potential positive effect" for acute low back pain [3].

In the "Agency for Healthcare Research and Quality Comparative Effectiveness Review #169" titled "Non-Invasive treatment for Low Back Pain" they compared twenty-five nonpharmacological interventions [4]. Acupuncture vs no acupuncture was one of only three therapies that scored as high as "moderate" in both magnitude of effect for pain reduction and functional improvement. Out of these three, only the acupuncture "strength of evidence" was rated as moderate for both pain reduction and functional improvement. This means that only "acupuncture vs. no acupuncture" had the highest rating across the board of "moderate" in all four possible categories. Acupuncture was also found to have a moderate effect in reducing pain as compared to sham acupuncture and no effect for improving function.

This review also compared different pharmacological treatments for chronic low back pain and only NSAIDs and Tramadol scored as high as a "moderate" for reducing pain and showed a "small" magnitude for improving function. Most drugs did not show any measurable reduction of pain or improvement of function, while opioids showed "small"

effects for both pain and function. Only acupuncture was measured against medications for cLBP and was found to have a "small" effect favoring acupuncture over medications for both pain and function.

In other words, this review found acupuncture as effective and, in most cases, more effective for reducing pain than the therapies currently rated and "reasonable and necessary" by CMS and covered under Medicare including when measured against sham.

An updated "American College of Physicians' Clinical Guideline on Low Back Pain" recommended acupuncture for both chronic low back pain (moderate quality evidence; strong recommendation) and for acute and sub-acute low back pain (low quality evidence; strong recommendation) [5].

The "Scottish Intercollegiate Guidelines Network's" guideline titled the "Management of Chronic Pain" also recommended acupuncture (Grade A recommendation) for chronic low back pain [6].

In the "Comparative clinical effectiveness of management strategies for sciatica: systematic review and network meta-analyses" acupuncture was found to be more effective than opioids for sciatica [7]. Acupuncture ranked as the second most effective intervention in both global effect and reduction of pain intensity, while opioids were ranked 16th out of 20 interventions for global effect and 14th out of 18 interventions for reduction in pain intensity. The reviewers concluded that the "findings of this review do not support the effectiveness of opioid medication, either for pain intensity or global effect".

Two studies found that acupuncture is likely to be cost-effective for low back pain or chronic non-specific low back pain, respectively [8-9].

Adjunctive acupuncture can reduce required dosages of opioid-like medication (OLM)

Some studies have reported reduced consumption of opioid-like medication (OLM) by more than 60% following surgery when acupuncture is used [10-11]. A pilot RCT also showed a reduction of 39% in OLM use in non-malignant pain after acupuncture, an effect that lasted less than 8 weeks after acupuncture treatment ceased [12].

Given that acupuncture analgesia activates the production and release of endogenous opioids and activates μ, δ, and κ opioid receptors, it is feasible that acupuncture, used in

conjunction with OLM, might alleviate pain with a lower OLM dose for patients already taking OLM [13]. For patients not yet prescribed OLM, acupuncture should be recommended prior to OLM prescription commencing. This would be in line with existing guidelines that recommend non-opiate alternatives that are safe and effective should first be exhausted before resorting to OLM.

Results of a Large Acupuncture Patient Experience/Satisfaction Survey

As the CMS considers approving acupuncture for Medicare patients suffering cLBP, having objective data on how other patients rate their experience and satisfaction with obtaining acupuncture services would be helpful. Until recently, very little data was available about the use of acupuncture under real world conditions in the U.S. In 2016, a two-year retrospective study was published by American Specialty Health, Inc. (ASH), a company that specializes in the development and management of managed care plans for non-pharmacological physical medicine services. The study reflected the experience of 89,000 acupuncture patients treated in 2014 and 2015 through a network of 6,000 U.S. acupuncturists. The patients experiences reflected in this survey include both patients who were "self-referred" and a subset who were referred by their physician.

The survey utilized the "Clinician & Group Consumer Assessment of Healthcare Providers and Systems" (CG-CAHPS®) survey. All surveys officially designated as CAHPS surveys have been approved by the CAHPS Consortium, which is overseen by the AHRQ. CAHPS surveys are designed to provide a standardized tool to measure patients' experiences with healthcare providers, health plans, and health systems. Independent, accredited contractors administer surveys, and the results are compiled into a database establishing national benchmarks. CAHPS is being widely adopted as *the* standard for measuring patient perceptions of the quality of care they receive from their HCPs.

The ASH study is titled "Does Acupuncture Provided Within a Managed Care Setting Meet Patient Expectations and Quality Outcomes?" [14] The majority of patients in this survey suffered musculoskeletal pain syndromes, with lower back followed by neck pain as the two most prevalent conditions. The average age of the ASH network acupuncture patient respondents for 2014 was 59 – 60.9 years and for 2015 was 60.2 – 60.4 years.

The survey found that acupuncture providers and their practices scored above national benchmark averages in an array of standardized questions regarding patient experiences with provider communication, office conditions, and staff helpfulness. Of particular interest to the issue of acupuncture for cLBP management was the inclusion of an additional proprietary question built into the survey. This question asked patients if their

acupuncturist was successful in addressing their primary complaint. Of the patients in the national survey, 93% responded that they agreed or strongly agreed with that statement.

A subsection of this study looked at the responses of a number of patients that were referred to acupuncture providers by several pain management clinics in California. In order to be considered for a referral for acupuncture services, these patients must first be seen by their primary care provider and then, if deemed necessary, referred to pain management physicians. Many of these intractable pain patients had already been treated with multiple "conventional" therapies, including opioids, before receiving treatment with acupuncture. In this subset of difficult-to-manage patients, 85% indicated their acupuncturist was successful in addressing their primary complaint.

While understanding that patient responses to surveys, even to a "gold standard" survey such as CG-CAHPS®, are not the same as findings from controlled clinical trials, the results of this survey show that even patients responding poorly to conventional pain management approaches report high levels of success when treated by acupuncturists who met credentialing standards.

These high success rates may be due in part to the fact that these patients received a full range of therapies—such as heat therapy, massage therapy and so forth—that many licensed acupuncturists typically provide, while acupuncture alone is studied in most clinical trials. In addition, these patients all had insurance coverage for acupuncture, which may have resulted in them receiving a higher number or greater frequency of treatments than might be the case for patients without insurance coverage or that patients may receive in controlled clinical trials.

Other highlights of this study include:

- 95%-99% of the patients rated their overall quality of care as good to excellent.
- 80%-87% patients rated their acupuncturists at a 9 or a 10 on a 1- to10-point scale.
- 0.014% (13 out of 89,769) patients reported a minor adverse event and no serious adverse events were reported.

Section Two: *Safety, Cost Effectiveness and Their Interrelationship*

The most common adverse events found with acupuncture are bruising and bleeding, followed by transient pain and then dizziness or state of deep relaxation bordering on syncope. Virtually all of these "side-effects" are self-limiting and do not require any further treatment so it is questionable if they should even be labeled as a side-effect/adverse reaction. Serious complications such as punctured organs, infections, or nerve injury do happen and are found in the literature, albeit at a very low rate. But most of those were the result of improper protocol (malpractice) from those ether poorly trained or not following professionally recognized standards of care. As malpractice insurance rates for licensed/certified acupuncturists cost approximately, $1,000 per year, it seems likely that those U.S.-trained practitioners are rarely practicing in an unsafe manner. A German study of 73,406 patients with chronic low back and chronic neck pain found only 0.6% had adverse reactions requiring medication and/or follow-up by a physician and 0.03% required treatment in a hospital [15].

Because adverse events associated with acupuncture that require any medical follow up are so rare, this adds to acupuncture's cost effectiveness as compared to other therapies especially drugs used to manage pain. When comparing cost effectiveness of more labor intensive hands-on therapies like acupuncture against conventional care such as pain management medications, calculating the cost of managing adverse events should also be considered, not just the upfront cost of delivering that care.

A recent CDC study estimated the cost of the opioid epidemic to be $78.5 billion a year with 25% of that shouldered by public sources such as Medicare and Medicaid [16]. Other popular pain management drugs also cause adverse reactions requiring medical follow up at a rate and cost that is significantly higher than for acupuncture. And of course, this is not even considering the cost of human suffering seen as a result of these medications.

Unfortunately, there is little if any data on the costs of treating side effects of commonly used drugs such as those used in managing cLBP. We will never know the true costs of different therapies until we factor in the cost of managing adverse events in addition to the upfront costs. When both costs are factored in, the safer non-pharmacologic therapies like acupuncture start to look like a much better bargain than they may have seemed at first glance.

When it comes to cost for acupuncture, there is a wide range of charges seen for similar services. Some of those rate differences are due to the same factors seen in many

industries such as the need to cover high overheads from higher cost of living areas but other factors seem more to be related to the number of patients being seen.

As we will discuss in the following section on workforce issues, many acupuncturists are seeing a low number of patients and this may well be influencing them to charge relatively higher rates. Rates near the $80-$100 per treatment range or more are not uncommon and patients are typically treated in individual treatment rooms. At the other end of the spectrum are practices following what is called "community acupuncture" practice models that treat several patients at once in larger rooms often in recliner chairs. There are about 170 such clinics in the U.S. that are part of the "People's Organization of Community Acupuncture" (POCA) that see a relatively higher volume of patients, charge on a sliding scale of $15- $50 per treatment, and do not accept medical insurance reimbursements. POCA clinics deliver approximately one million treatments per year. We highlighted a survey of 89,000 patients managed by the insurance company ASH. They have a network of 6,000 credentialed acupuncturists and their payment for acupuncture is typically a per diem of $41 per treatment – a lower fee than many of these practitioners charge but is accepted in the expectation of referrals.

Considering the above, there is good reason to believe that if acupuncturists were to start to see a higher volume of patients because new or expanded third-party payment coverage was making it easier for HCPs to follow guidelines and refer their patients for acupuncture, the economies of scale could encourage a lower cost per treatment average than is seen today.

Section Three: *Workforce Issues*

We regret that we are unable to provide comprehensive details regarding the numbers and distribution of acupuncturists in the U.S. We do our best to provide what data we could compile but the level of information on these issues are not as well researched as would be ideal. We encourage the CMS to review workforce data submitted by the National Certification for Acupuncturists and Oriental Medicine (NCCAOM), and also seek the input of the American Society of Acupuncturists (ASA) as well as American Academy of Medical Acupuncture (AAMA).

The bottom line as we see it is that while some acupuncturists and acupuncture training programs are doing well financially, a good portion are not and are operating at well below capacity. If there were to be greater demand for acupuncture services there is a great deal of room to accommodate a higher demand, although some bottlenecks in meeting demand could occur especially in rural areas. We therefore believe workforce capacity concerns should not impede an effort provide Medicare coverage for cLBP.

There are two significant uncertainties that cloud the picture of the workforce capabilities for expanding acupuncture services. The first is that there are greatly varying differences in the training of differing "acupuncturists" and just what services they offer. The second uncertainly is that even in the case of the more regulated and thus easier to count "licensed" or "certified" acupuncturists, no one knows how many of these who maintain their licensing/certification are actively practicing.

All of the states in the U.S. have laws that require some sort of licensing or certification for a healthcare provider to legally perform acupuncture. However, these laws vary considerably from state to state including whether or not they require those authorized to provide acupuncture to be registered with the state as such. This makes it impossible to get a count of all legally authorized acupuncture providers.

Most, but not all states, allow medical doctors and osteopaths to practice acupuncture without requiring them to undergo any formal training or examination in that subject. Some states allow chiropractors or naturopaths to perform acupuncture with some training but no required examination. Still other states allow podiatrists, dentists, physician's assistants, nurses, or even drug detox specialists to perform acupuncture in some restricted manner. Some of these are authorized without any required formal education or examination. Should everyone authorized by law to stick an acupuncture needle into a patient even with no required training be considered an "acupuncturist" and part of the potential workforce for providing that service?

At the other end of the spectrum are approximately 38,000 specialists usually titled as a licensed or certified acupuncturist. All but three states – Alabama, Oklahoma, and South Dakota – have laws authorizing acupuncture to be performed by a licensed/certified acupuncturist. All of these licensed/certified acupuncturists are required to have completed an accredited educational program and pass a formal examination. Consumers in the four states that do not have laws regulating acupuncture specialists can usually still find those specialists in their state. Most, but not all states require these licensed/certified acupuncturists to be registered in their state so some count of their numbers can be traced, although some of these practitioners may be registered in more than one state.

The latest figures we could find based on numbers from agencies in each state that regulates licensed/certified acupuncturists was from a 2013 survey by the NCCAOM as part of their job training analysis. That survey found that 92% of licensed/certified acupuncturists worked in private practices. Again, no one knows how many of these practitioners are in active practice.

Chiropractors Practicing Acupuncture

Chiropractors are allowed to practice acupuncture in 34 states, while16 states require a separate acupuncture license. The additional training required for Chiropractors to practice acupuncture range from 100-300 hours. Some require an exam, others do not. There is no way to determine how many Chiropractors have met the requirements to

practice acupuncture in those 34 states and out of those how many actually practice acupuncture [17].

Physicians Practicing Acupuncture

The American Academy of Medical Acupuncture (AAMA) is the professional society of physicians (MDs and DOs) in North America who have incorporated acupuncture into their traditional medical practice. AAMA currently represents more than 1,300 physician acupuncturists in North America. Membership requirements for the Academy have been established in accordance with the "Limited" training guidelines established by the World Health Organization-recognized World Federation of Acupuncture and Moxibustion Societies for physicians practicing acupuncture. As most states allow MDs and DOs to practice acupuncture without additional training, certification or registration, it is impossible to estimate the number of physicians currently practicing acupuncture.

Although the lack of reliable data makes it impossible to calculate the number of those actively practicing acupuncture, between the licensed/certified acupuncture specialists, MDs and DOs, and Chiropractor fields alone, it seems reasonable to estimate there may be in excess of 50,000 professionals practicing acupuncture in the U.S. at this time in 2019. It would be very helpful if a more accurate count could be taken and especially a density map of where those practicing are located. A study looking at these issues would be helpful.

The Job Training Analysis published by the NCCAOM in 2013 also found 46% of the licensed/certified acupuncturists indicated they practiced less than 30 hours a week, and 69% less than 40 hours a week. 35% indicated these practice hours were due to a lack of patients and 38% indicated this was due to personal choice. 25% indicated they had other jobs as well as their acupuncture work. Of that 25% how many have other jobs out of financial necessity and would rather work more in their practice of acupuncture is uncertain.

With nearly 70% of licensed/certified acupuncturists practicing less than 40 hours a week and just 38% indicating this is due to personal choice, it seems clear there is room within the licensed/certified acupuncturist profession for a significant increase in patient load. This may be true for MDs, Dos, and Chiropractors as well.

There are also over 60 Acupuncture/Chinese Medicine colleges operating in the U.S. with 57 of these being members of the Council of Colleges of Acupuncture and Oriental Medicine (CCAOM). All of the CCAOM's member schools have obtained either full accreditation or accreditation candidacy status with the Accreditation Commission for Acupuncture and Oriental Medicine, a national organization recognized by the U.S. Department of Education to accredit Acupuncture and Oriental Medicine schools and programs in the U.S.

As is the case with practicing licensed/certified acupuncturists, some of these schools appear stable and to be doing well financially, while others seem to be less stable. If there

were to be a significantly increased demand for acupuncture services, these schools, like a good percentage of practicing acupuncturists, could no doubt ramp-up their capacity and start producing greater numbers of graduates. This would be especially true if salaried job positions, such as in Joint Commission certified hospitals or large integrative clinics were to materialize.

Considering the magnitude of the opioid crisis and the need to encourage evidenced base safer therapies like acupuncture by expanding third-party payment, the ANF believes CMS should allow for payment for acupuncture services for cLBP by all provider types legally authorized by state law to treat that type of patient. Retrospective studies could then be undertaken to see if there were clear clinical effectiveness differences between provider types to guide future coverage.

Section Four: *Expert Opinion on Challenges Faced by CMS Reviewers and Policymakers Involved with Acupuncture Research and Acupuncture is Dose Dependent*

In preparing to submit these materials, we reviewed the October 10, 2003 Decision Memo the CMS issued on its findings regarding acupuncture for osteoarthritis (CAG-00175N). In that memo the Specific Decision Memorandum Question was listed as "Is there evidence of adequate methodological quality to conclude that the use of acupuncture significantly and reliably reduces pain in Medicare patients with osteoarthritis?" Although we sought this information, we were unable to verify the Specific Decision Memorandum Question that CMS seeks to address in this review. Absent that information, we can only assume the question CMS seeks to answer in this review will be similar to that in the osteoarthritis review except the condition will be on chronic low back pain (cLBP).

Having a clear question for a review of this nature is important for the evaluation of any medical intervention but, in our opinion, even more so for a review of the evidence behind acupuncture. We say that because one thing that has become clear to us is that deciding how to interpret findings of sham/placebo controlled acupuncture trials poses a challenge for anyone trying to undertake an unbiased review of acupuncture research. Knowing that the findings of these sham controlled trials are virtually the only negative findings that can be found on acupuncture for cLBP, we want to focus on offering information to CMS reviewers about how other reviewers have dealt with the issue of sham controlled studies. We also want to offer our expert opinion on why these studies are flawed and why they should be given little if any weight at all in a review of current evidence.

There is a large body of research conducted in places like China and Korea that consistently find impressively high effectiveness rates for acupuncture (90% or more) and, if compared to sham, will clearly outperform it. Yet those studies are seldom included in reviews undertaken in the West out of concerns that methodological quality

issues could lead to false positives. Remarkably, some have gone as far as to state that none of those trials are trustworthy, suggesting, in essence, a massive conspiracy to falsify evidence. Trails done in the West, on the other hand, while consistently finding acupuncture to be cost effective and clinically effective at least within a small to moderate degree, also find that "real" acupuncture may only outperform "sham" acupuncture in some but not a solid majority of trials. We know of no other therapy that has generated such a large body of evidence where that evidence is subject to such great heterogeneity and controversy.

There is no standard for just how much weight reviewers and policymakers should give to the findings of sham controlled acupuncture trials despite the critical role they often play in the policy decisions. We will highlight this by offering three examples of how different reviewers/policymakers dealt with the sham acupuncture conundrum.

The German Insurance Industry

In 2007, a three-arm RCT involving 1162 patients with a history of chronic low back pain for a mean of 8 years was published in the Archives of Internal Medicine. The trial was undertaken in Germany in 340 outpatient clinics and came to be known as the GERAC trial. The three arms of this trail were verum acupuncture (n = 387) according to principles of traditional Chinese medicine; sham acupuncture (n = 387) consisting of superficial needling at non-acupuncture points; or conventional therapy, a combination of drugs, physical therapy, and exercise (n = 388). It is believed this trail was the first to compare real and sham acupuncture with conventional therapy for chronic low back pain. This study was underwritten by the German private medical insurance industry as they attempted to decide whether or not to cover (pay for) acupuncture for chronic low back pain. The "acupuncturists" providing the acupuncture therapy were German M.D.s who had a minimum of 140 hours of acupuncture training. The results of this trial found that the real (verum) acupuncture did not significantly outperform the sham acupuncture but both the real and the sham were nearly twice as effective as conventional therapy. The 6 month response rate was 47.6% in the verum acupuncture group, 44.2% in the sham acupuncture group, and 27.4% in the conventional therapy group.

While acupuncture critics seized on these finding as proof that acupuncture was "only a placebo" it seems clear the policymakers for these German insurance companies decided to give less weight to the need for real acupuncture to surpass sham by a significant degree and more weight to overall effectiveness rates; i.e. that both real and sham acupuncture were nearly twice as effective as the conventional care those insurance companies had already been paying for. Although this study did not compare safety, acupuncture is known to be safer than most conventional care therapies for low chronic back pain especially the medications used (including opioids). Based on finding acupuncture to be nearly twice as effective and safer, these insurance companies decided to start covering acupuncture for chronic low back pain and still do to this day.

The GERAC researchers reached the following conclusions:

"Acupuncture, regardless of the technique, was significantly more effective than conventional therapy at all follow-up points. To our knowledge, this is the first time superiority of acupuncture over conventional treatment has been unequivocally demonstrated for the primary and secondary outcomes, including medication reduction, in contrast to studies with a usual care group."

"The results for conventional therapy were significantly poorer than those in the 2 acupuncture groups. This raises questions about qualitative and quantitative aspects of conventional therapy."

Importantly, this GERAC study was followed-up in 2009 by a similar multi-arm study in the U.S. lead by researcher Daniel Cherkin that found similar results; real and sham acupuncture were both about 1 ½ times to2 times more effective as conventional care:

"At 8 weeks, mean dysfunction scores for the individualized, standardized, and simulated acupuncture groups improved by 4.4, 4.5, and 4.4 points, respectively, compared with 2.1 points for those receiving usual care ($P < .001$).

"Participants receiving real or simulated acupuncture were more likely than those receiving usual care to experience clinically meaningful improvements on the dysfunction scale (60% vs 39%; $P < .001$)."

"Symptoms improved by 1.6 to 1.9 points in the treatment groups compared with 0.7 points in the usual care group ($P < .001$)."

Summary: These two head to head trials compared conventional care to real and sham acupuncture for chronic low back pain and found both forms of acupuncture to be nearly twice as effective. Because these two trials are considered to be of relatively high methodological quality, they frequently make the inclusion criterial of many reviews of acupuncture trials on chronic low back pain. Yet, when reviewers decide to give the greatest weight to the outcomes of how real acupuncture compares to sham, these two trials will be judged to be "negative" and will count against finding acupuncture effective.

NICE 2016

The U.K.'s National Institute for Health and Care Excellence (NICE) is an agency that preforms reviews of research to advise the U.K. government on what their National Health Institute (NHI) insurance should or should not cover. In November 2016 they released their review of therapies for treating low back pain and sciatica that included a review of acupuncture. In April, 2016, NICE had released their draft findings of this review process and that included information on how their advisory committee had decided to undertake their review of acupuncture research. They made the decision (see below) that if they did not find real acupuncture to outperform sham in the RCTs they

selected by a predetermined amount, they would then not consider any other research findings on clinical or cost effectiveness or comparisons with usual care.

NICE had done a pervious review of acupuncture for low back pain in 2009 and found enough evidence of effectiveness to recommend it to be approved and covered by the NHI insurance. Unlike that 2009 review, in the 2016 review NICE decided to employ a concept they called a "minimum clinically important difference" (MCID) criteria. They set this MCID at what would be the equal on a 0-10 visual analogue pain scale as a difference of 1.0, which also had to be statistically significant. The difference between acupuncture versus sham in the 2016 review was documented by NICE as 0.8, falling just short of the clinical difference they had chosen even though it was statistically significant. For this reason, acupuncture was not recommended [18].

While requiring real acupuncture outperform sham by a score of 1 on and 1-10 pain scale may not seem like too much to ask, having this as a must-pass requirement is problematic in many ways. First, if you look at what the Cherkin 2009 study we detailed above found in their multi-arm trial, conventional care was found to only improve symptoms (pain) by 0.7 points. That would mean that NICE found that real acupuncture outperformed sham by more than conventional care was found to relieve low back pain in total but they still considered this insufficient. Second, of the nearly 30 trials NICE selected to compare real to sham acupuncture, 2 of the trials used only one acupuncture treatment! Obviously those trials were not intended to be used for an acid test of if real acupuncture outperforms sham. They should not have been included in NICE's review that was demanding a no wiggle-room MCID. In fact, there were several studies that NICE selected for their review that employed sub-optimal numbers of treatments and these trials were most likely never intended to be a test of acupuncture's ultimate potential for reducing low back pain.

Quotes from February NICE 2016 draft: "Low back pain and sciatica: Management of non-specific low back pain and sciatica. Assessment and non-invasive treatments" pages 493-495.

"The GDC first discussed the necessity of the body of evidence to show specific intervention effects, that is, over and above any contextual or placebo effects. It was therefore agreed that if placebo-controlled evidence (or sham acupuncture) is available, this should inform decision making in preference to contextual effects, but that the effect sizes compared with usual care would be important to consider if effectiveness relative to placebo, or sham, has been demonstrated."

"For the usual care comparison in people with low back pain without sciatica, the GDG agreed that clinically important benefits in terms of improvements in quality of life were observed in evidence from a number of studies."

This following quote references the cost per QALY (quality adjusted life year). NICE sets a threshold for the cost of a QALY at £20,000 to £30,000. If a therapy can provide 1 QALY for less than £20,000 to £30,000, it is considered cost effective. Acupuncture was

found to provide 1 QALY at £3,598, more than 5 times below that threshold in all measurements at no worse than a 97% probability.

"This within-trial analysis found that the addition of acupuncture to usual care increased costs and improved health (increased QALYs) with an incremental cost-effectiveness ratio of £3,598 per QALY gained. Uncertainty was not reported in the analysis using EQ-5D but in the analysis using SF-6D (which had a similar ICER) the probability of acupuncture being cost effective was around 97%".

VA Evidence Map of Acupuncture 2014

In 2014 the Department of Veterans Affairs Veterans Health Administration Quality Enhancement Research Initiative Health Services Research & Development Service published a review of acupuncture prepared by their Evidence-based Synthesis Program (ESP) Center West Los Angeles VA Medical Center titled "Evidence Map of Acupuncture" [19].

This review was a "systematic review of systematic reviews" and drew on reviews published from 2005 to March 2013. The reviewers classified the evidence found into four categories: "evidence of no effect," "unclear evidence," "evidence of a potential positive effect," and "evidence of a positive effect." While chronic pain was found to have the highest rating of "evidence of a positive effect" the rating for the evidence at that time for low back pain was "unclear evidence". However, the back pain category included both acute and chronic low back pain and the research up to that point was less positive for acupuncture's role in treating acute low back pain than it was for chronic low back pain. It is not clear what the Evidence Map rating system would have found for chronic low back pain alone.

What we find of such value in the Evidence Map of Acupuncture study to the current CMS review is in their section on "Future Research". This review summarized data from all passive controlled RCTs to determine the effectiveness of acupuncture including "no treatment, waiting list assignment, acupuncture as add-on treatment to a treatment plan received by both treatment groups, and placebo control such as sham acupuncture" with no breakdown given to any control. That being the case, it is impossible to know just how much weight the sham controlled studies had although considering that most trials on acupuncture done in the West tend to include sham controls, it is likely they had a significant weight in this review. However, the reviewers discuss in some detail the issue that sham acupuncture controls can play in acupuncture research.

Many reviewers of acupuncture trials find significant heterogeneity in effectiveness results and this has long been seen as a negative finding and one that tends to make policymakers hesitant to endorse the use or expansion of acupuncture services. However, the Evidence Map reviewers point out that an "overarching theme and source of heterogeneity in results appeared to be the selection of the comparator against which the

treatment effects of acupuncture was compared" and that "clinical effectiveness estimates may depend on the chosen comparator".

They then go on to detail that the so-called "sham" acupuncture used as a comparator (control) is not a single comparator but can be any one of 5 different types of "sham acupuncture" and that "the type of sham acupuncture may already be a source of heterogeneity among studies assessing the effectiveness of acupuncture." They cite several authors who have argued that different sham acupuncture methods are not "non-specific" or "inert" controls but may actually stimulate some of the mechanisms the active treatment/real acupuncture is intended to stimulate. In other words, sticking needles almost anywhere to any depth or even stimulating needle penetration may cause the body to produce helpful natural pain modulating or anti-inflammatory chemistry and not just a placebo effect. This no doubt explains why there are at least five different types of sham acupuncture controls; because each control attempted was suspected to be flawed so researchers kept trying different ones.

The Evidence Map reviewers then make a provocative statement and one that shows they were not at all convinced that the finding of real acupuncture not clearly outperforming sham is due to the placebo effect:

"If the explanation for the observation of little difference in effectiveness between true and sham acupuncture is that both true and sham acupuncture have positive effects, then the specific implication for the VA could be that there is no need for training in acupuncture and for VA to hire licensed acupuncturists, since the sham acupuncture could be performed by a technician with minimal training."

We don't know what impact this advice about hiring untrained technicians to preform sham acupuncture had on VA policymakers although we do note that the VA recently developed a set of official employee designations for hiring Licensed Acupuncturists and that they have been expanding their use of acupuncture services significantly in the last 1-2 years.

Conclusion

We detailed how three different sets of policymakers and/or reviewers approached the subject of how much weight to give sham controlled trials. The Germany insurance industry decided the significantly superior clinical effectiveness of acupuncture over conventional care found in the GERAC trial trumped concerns over non-specific results. NICE reviewers and policymakers decided just the opposite; deciding that the finding of effectiveness over sham controls must pass a pre-determined threshold before they would even consider evidence of clinical effectiveness, cost effectiveness or comparative effectiveness. The VA Evidence Map reviewers, while considering sham controls in their review by pooling those studies with studies using other types of passive comparator's, actually suggested that taking advantage of the positive clinical results of sham acupuncture might have a place in the large VA healthcare system.

The question CMS reviewers and policymakers will need to answer is: How much weight will be given to sham controlled studies and why? Considering all the problems that have been found with sham controls as well as problems with clinical quality controls found in real acupuncture arms of trials, we at the Acupuncture Now Foundation believe the only ethical decision to reach is to place the highest weight on considering the benefit-to-harm ratio of applying acupuncture for cLBP. We also believe it would be constructive for CMS to share how they came to determine how much weight was afforded sham controlled trials in this review and respectfully request CMS do so.

Acupuncture is Dose Dependent

We agree that the inability to find a truly inactive control that does not cause positive physiologic changes in the body similar to that in real/verum acupuncture is a serious flaw in acupuncture research and is a source of heterogeneity. However, we believe a likely bigger flaw and source of heterogeneity is on the active/real acupuncture side of many multi-arm studies. The biggest reason sham controlled acupuncture trials are prone to false negatives is due to the fact that there are no published clinical practice guidelines (CPGs) that have been vetted by the acupuncture profession to help assure clinical quality in the practice of acupuncture. Without such CPG's, researchers have no way of knowing how to establish the clinical criteria that will be applied in their studies. The ANF has been working with others in the acupuncture profession to start to produce such guidelines but until they become available researchers and reviewers have no choice but to be left to their own devices to figure out clinical quality in acupuncture trials.

When reviewers of acupuncture trials (such as CMS reviewers for this NCA) set about the task of developing their inclusion criteria for the trials they will include and exclude for their review, the lack of CPGs mean those reviewers have no profession vetted guidance on issues of acupuncture clinical quality. This being the case, the clinical protocols seen in acupuncture trials in the West vary greatly. The problems created by the lack of CPGs are most readily seen in the great disparity in the number of acupuncture treatments that pervades acupuncture trials.

As with most therapies, those with expertise in the clinical application of acupuncture will tell you that acupuncture is "dose dependent"; the spacing and number of treatments over time has an impact on acupuncture's effectiveness. This will be true regardless of what points are chosen or needling techniques used. Yet appreciation of this this simple clinical fact is typically not reflected in how acupuncture research is conducted or reviewed.

It is also common knowledge within the acupuncture community that in China, acupuncture treatments are typically done on a daily or every other day basis in the first stage of the treatment process and that dozens of treatments may be utilized in total, especially in the treatment of chronic conditions. Yet the vast majority of acupuncture

trials conducted in the West use far fewer treatments in total and at a substantially less frequent interval.

Trials in the West often begin treatment at once a week and may only undertake 4 to 10 treatments in total. Some trials only use 1-3 treatments! Rarely will Western trials employ more than 2 treatments a week or beyond 20 treatments in total. The higher treatment frequencies/total numbers employed in East Asian trials are utilized by highly experienced acupuncturists to help achieve the highest effectiveness rates (MTB). Yet, despite this great disparity in treatment frequency/total numbers, no clinical rational is offered to explain why Western researchers have confidence that their treatment frequency/total numbers are clinically justified. Researchers often go to great lengths to explain why their trial design is adequate – blinding methods, sample sizes, control protocols, etc., but the rationale behind clinical protocols is given far less consideration. It would be hard to imagine such a great disparity in drug dosages being accepted in drug trials without researchers offering some clinical rational for using those different dosages.

Two trials on osteoarthritis of the knee, one done in the U.S.A. and the other in Israel [20-21] and one trial done in the U.S. on carpal tunnel syndrome [22], all utilized a higher treatment frequency (at least twice a week for 8 weeks) and total treatment numbers than is usually the case in Western acupuncture trials. Both of these trials found that the effectiveness rates for the real acupuncture did not start to significantly surpass the sham until 12 weeks – a longer timeframe than most Western studies allow for. Other studies have found similar trends with higher numbers of treatments leading to higher effectiveness rates [23-24]. One has to wonder how many trials that did not find real acupuncture to outperform sham may have done so if they had utilized more frequent treatments carried-out over longer periods of time.

The implications for CMS reviewers regarding acupuncture dosage is that they should look closely at the number of trials undertaken in studies for cLBP. Unless a minimum of 2 treatments a week for 8 weeks have been done and then effectiveness rates monitored for several weeks after 8 weeks, you may not get a clear picture of acupuncture's effectiveness. We are not saying it will always take at least 16 treatments over 8 weeks to get near MTB with acupuncture but that it may well take that many treatments for some patients.

The other implication for CMS policymakers is with regard to how many treatments should be authorized for payment for acupuncture services for treating Medicare patients with cLBP. Authorizing enough treatments to allow a patient to achieve MTB while guarding against overuse of acupuncture services and contain costs is a delicate balance to strike. We believe a possible cost effective way to reduce over usage/ over billing for acupuncture services would be to develop an informed consent document that patients would be required to read and sign that would explain how many treatments may be needed. The Acupuncture Now Foundation would be happy to work with the CMS in drafting such a document as we have expertise in acupuncture "utilization/medical necessity management.

Appendix A

A sample of quotes from comments sent to the CDC regarding the problem of lack of guidelines and limited insurance coverage for non-pharmacologic therapies as compiled by The Acupuncture Now Foundation.

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."

American Society of Anesthesiologists:
"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 nonpharmacological therapies (all modalities available), and payers should reduce patient co-insurance and co-pays to encourage the use of non-pharmacological therapies."

American Pain Society:
"We agree that non-pharmacologic therapies are important tools in the management of many types of chronic pain. Unfortunately, many non-pharmacological therapies, are not reimbursed by Medicaid, Medicare or third-party payers. Support for such therapies in the guidelines might be useful for implementation of this recommendation. We believe that patients should have both pharmacological and non-pharmacological approaches available and reimbursed, as well as the availability of specialists when appropriate, for the management of their chronic pain."

American College of Physicians:
"The College also suggests that the Guideline document call for payment policy changes both within the public and private sector that will facilitate access to nonpharmacological therapies."

American Academy of Pain Management:
"We suggest adding a paragraph specifically acknowledging and addressing all of these coverage challenges, adding suggestions for how providers can assist patients in obtaining these types of care if not covered by their insurance plans." "We further urge CDC to issue recommendations to the third-party payer community, listing the minimum benefits that should be offered in this context. The letter from the American Medical Association in response to the first draft of this guideline also mentioned this need. At a bare minimum, recommendations that payers provide universal coverage for the five types of nonpharmacologic care mentioned in the DoD/ VA pain guideline (physical manipulation, massage, acupuncture, biofeedback, and yoga) should be issued.
To fully support an integrative pain management model, providers such as acupuncturists, chiropractors and naturopathic physicians should be part of health insurance provider panels. These providers are well trained in non-pharmacologic approaches to treating chronic pain and can effectively collaborate with other providers on pain management teams to help reduce the use of opioids for initial treatment as well as to help with discontinuation of opioids in patients who have been on long-term opioid therapy."

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."

American Academy of Addiction Psychiatry and American Osteopathic Academy of Addiction Medicine:
"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? In many parts of the country, referral resources to

behavioral health providers, those offering complementary and alternative medicine, pain management specialists etc. are not available."

Providence Health:
"While we support the reference to nonpharmacologic therapy, we agree with other stakeholder comments that reforms to payment policy are needed to address barriers to access because services may not be covered by health insurance or coverage may be limited."

Alliance for Patient Access:
"For example, the CDC identifies non-pharmacological treatment as "preferred" despite the fact that many health plans have weak or nonexistent coverage for alternative pain management treatments."

Trust for Americas Health:
"Furthermore, many insurers don't adequately cover or reimburse for non-pharmacologic therapies such as acupuncture, biofeedback, relaxation, and other interactive, multimodal therapies. Payer policies—both public and private—would need to be fundamentally changed to support this recommendation."

Appendix B

Mechanisms of acupuncture in pain management

Mechanisms underlying acupuncture analgesia have been extensively researched for over 60 years [13, 27]. In animal models and human studies acupuncture and/or electroacupuncture has been shown to be effective for the alleviation of inflammatory, neuropathic, cancer, and visceral pain [13, 28].

a. Neural pathways

Ascending neural pathways involving Aδ Aβ and C sensory fibers have been mapped, the mesolimbic loop of analgesia in the brain and brain stem has been identified and descending pathways have also been mapped [25].

b. Endogenous opioid & non-opioid mediators

Numerous mediators have been identified including opioid and non-opioid neuropeptides, serotonin, norepinephrine, dopamine, cytokines, glutamate, nitric oxide, and gamma-amino-butyric-acid (GABA) [13, 25]. Acupuncture analgesia has been shown to involve several classes of opioid neuropeptides including enkephalins, endorphins, dynorphins, endomorphins and nociceptin (also known as Orphanin FQ) [25-27]. Among the non-opioid neuropeptides, substance P (SP), vaso-active intestinal peptide (VIP) and calcitonin gene-related peptide (CGRP) have been investigated for their roles in both the analgesic and anti-inflammatory effects of acupuncture [13, 29]. Adenosine has also been shown to play a role in acupuncture's effects on pain [30].

c. Neuroplasticity

Adverse neuroplasticity can present a challenge in pain management as neuroplastic changes can be associated with chronic severe pain that is resistant to treatment. There is evidence that acupuncture has the capacity to reverse adverse neuroplastic changes in the spinal dorsal horn as well as in the somatosensory cortex in chronic pain [31-33]. This suggests that acupuncture may have an important role in treating chronic pain that involves adverse neuroplastic changes.

Appendix C

National Association of Attorneys General

1850 M Street, NW
Twelfth Floor
Washington, DC 20036
Phone: (202) 326-6000
http://www.naag.org/

September 18, 2017

Marilyn Tavenner
President and CEO
America's Health Insurance Plans
601 Pennsylvania Avenue, NW
Washington, DC 20004

Re: Prescription Opioid Epidemic

Dear Ms. Tavenner,

The undersigned State Attorneys General are sending you this letter to urge America's Health Insurance Plans (AHIP) to take proactive steps to encourage your members to review their payment and coverage policies and revise them, as necessary and appropriate, to encourage healthcare providers to prioritize non-opioid pain management options over opioid prescriptions for the treatment of chronic, non-cancer pain. We have witnessed firsthand the devastation that the opioid epidemic has wrought on our States in terms of lives lost and the costs it has imposed on our healthcare system and the broader economy. As the chief legal officers of our States, we are committed to using all tools at our disposal to combat this epidemic and to protect patients suffering from chronic pain or addiction, who are among the most vulnerable consumers in our society.

The opioid epidemic is the preeminent public health crisis of our time. Statistics from the Surgeon General of the United States indicate that as many as 2 million Americans are currently addicted to or otherwise dependent upon prescription opioids.[1] Millions more are at risk of developing a dependency—in 2014, as many as 10 million people reported using opioids for nonmedical reasons.[2] The economic toll of the epidemic is tremendous, costing the U.S. economy an estimated $78.5 billion annually.[3] State and local governments alone spend nearly 8 billion dollars a year on criminal justice costs related to

[1] Surgeon General of the United States, *Opioids*, https://www.surgeongeneral.gov/priorities/opioids/index.html (last updated June 1, 2017); Nora D. Volkow, M.D., *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, National Institute on Drug Abuse (May 14, 2014), https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse.

[2] *See* Surgeon General, *supra* fn. 1 (citing *National Survey on Drug Use and Health*, Substance Abuse and Mental Health Services Administration, 2014).

[3] Healthday News, *Opioid Epidemic Costs U.S. $78.5 Billion Annually: CDC* (Sept. 21, 2016), http://www.health.com/healthday/opioid-epidemic-costs-us-785-billion-annually-cdc.

opioid abuse.[4] The human cost is even more staggering: Opioid overdoses kill 91 Americans *every single day*.[5] More than half of those deaths involve prescription opioids.[6]

The unnecessary over-prescription of opioid painkillers is a significant factor contributing to the problem. Although the amount of pain reported by Americans has remained steady since 1999, prescriptions for opioid painkillers have nearly quadrupled over the same timeframe.[7] This four-fold increase in prescriptions has contributed to a commensurate increase in the number of opioid overdose deaths.[8] The dramatic increase in supply has also made it relatively easy to obtain prescription opioids without having to resort to the black market: Over 50% of people who misuse opioids report that they obtained them for free from a friend or relative, while another 22% misused drugs that they obtained directly from a doctor.[9] While illegal opioids like heroin remain a serious problem that also must be addressed, the role played by prescription opioids cannot be ignored. While there is no panacea, any comprehensive effort to address and end the opioid epidemic must tackle the ever-increasing number of prescriptions for opioid painkillers.

Reducing the frequency with which opioids are prescribed will not leave patients without effective pain management options. While there are certainly situations where opioids represent the appropriate pain remedy, there are many other circumstances in which opioids are prescribed despite evidence suggesting they are ineffective and even dangerous. For example, the American Academy of Neurology has explained that while the use of opioid painkillers can provide "significant short-term pain relief," there is "no substantial evidence for maintenance of pain relief or improved function over long periods of time."[10] Another recent study concluded that the use of opioids to treat chronic, non-cancer related pain lasting longer than three months is "ineffective and can be life-threatening."[11] When patients seek treatment for any of the myriad conditions that cause chronic pain, doctors should be encouraged to explore and prescribe effective non-opioid alternatives, ranging from non-opioid medications (such as NSAIDs) to physical therapy, acupuncture, massage, and chiropractic care.

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[4] *Id. See also Costs of US Prescription Opioid Epidemic Estimated at $78.5 Billion*, Wolters Kluwer (Sept. 14, 2016),http://wolterskluwer.com/company/newsroom/news/2016/09/costs-of-us-prescription-opioid-epidemic-estimated-at-usd78.5-billion.html

[5] *Understanding the Epidemic: Drug overdose deaths in the United States continue to increase in 2015*, Centers for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/epidemic/ (last updated Dec. 16, 2016).

[6] *Prescription Opioid Overdose Data*, Centers for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/data/overdose.html (last updated Dec. 16, 2016).

[7] See *Surgeon General*, supra fn. 1; *Opioid Addiction 2016 Facts and Figures*, American Society of Addiction Medicine (2016), https://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf.

[8] Vivek Murthy, *The Opioid Crisis: Our Solution*, TIME (Oct. 13, 2016), http://time.com/4521562/2016-election-opioid-epidemic/

[9] *Opioids*, Substance Abuse and Mental Services Administration, https://www.samhsa.gov/atod/opioids (last updated Feb. 23, 2016).

[10] Gary M. Franklin, MD, MPH, *Opioids for chronic noncancer pain: A position paper of American Academy of Neurology*, 83 Neurology 1277 (2014).

[11] Eric Scicchitano, *Geisinger doctors: Opioids ineffective for chronic pain put patients at risk*, The Daily Item (Dec. 7, 2016), http://www.dailyitem.com/news/local_news/geisinger-doctors-opioids-ineffective-for-chronic-pain-put-patients-at/article_2d66014f-511e-554f-bed5-768886b48616.html (citing, generally, Mellar P. Davis & Zankhana Mehta, *Opioids and Chronic Pain: Where is the Balance?* 18 Current Oncology Reports 71 (2016), *available at* https://link.springer.com/epdf/10.1007/s11912-016-0558-1)

Insurance companies can play an important role in reducing opioid prescriptions and making it easier for patients to access other forms of pain management treatment. Indeed, simply asking providers to consider providing alternative treatments is impractical in the absence of a supporting incentive structure. All else being equal, providers will often favor those treatment options that are most likely to be compensated, either by the government, an insurance provider, or a patient paying out-of-pocket. Insurance companies thus are in a position to make a very positive impact in the way that providers treat patients with chronic pain.

Adopting an incentive structure that rewards the use of non-opioid pain management techniques for chronic, non-cancer pain will have many benefits. Given the correlation between increased supply and opioid abuse, the societal benefits speak for themselves. Beyond that, incentivizing opioid alternatives promotes evidence-based techniques that are more effective at mitigating this type of pain, and, over the long-run, more cost-efficient.[12] Thus, adopting such policies benefit patients, society, and insurers alike.

The undersigned Attorneys General serve an important role in combating the opioid epidemic. As the chief legal officers of our States, we are charged with protecting consumers, including patients suffering from chronic pain and opioid addiction. Among other things, we are committed to protecting patients from unfair or deceptive business practices and ensuring that insurers provide consumers with transparent information about their products and services.

We are thus committed to utilizing all the powers available to our individual offices to ameliorate the problems caused by the over-prescription of opioids and to promote policies and practices that result in reasonable, sustainable, and patient-focused pain management therapies. In the near future, working in conjunction with other institutional stakeholders (such as State Insurance Commissioners), we hope to initiate a dialogue concerning your members' incentive structures in an effort to identify those practices that are conducive to these efforts and those that are not. We hope that this process will highlight problematic policies and spur increased use of non-opioid pain management techniques. The status quo, in which there may be financial incentives to prescribe opioids for pain which they are ill-suited to treat, is unacceptable. We ask that you quickly initiate additional efforts so that you can play an important role in stopping further deaths.

We look forward to having this discussion with you.

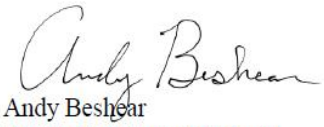
Sincerely,

Leslie Rutledge
Arkansas Attorney General

Pamela Jo Bondi
Florida Attorney General

[12] Harrison Jacobs, *Pain doctors: Insurance companies won't cover the alternatives to opioids*, Business Insider (Aug. 10, 2016), http://www.businessinsider.com/doctors-insurance-companies-policies-opioid-use-2016-6 ("If you look at the long-term cost of [opioids], plus monitoring, office visits and drug screenings . . . it's cheaper long-term to do the more advanced therapy,") (quoting Dr. Timothy Deer, co-chair, West Virginia Expert Pain Management Panel).

Derek Schmidt
Kansas Attorney General



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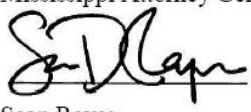
Hector Balderas
New Mexico Attorney General



Sean Reyes
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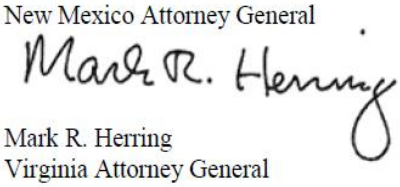

Mark R. Herring
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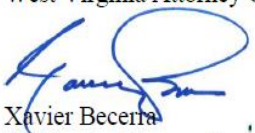
Patrick Morrisey
West Virginia Attorney General

Mark Brnovich
Arizona Attorney General



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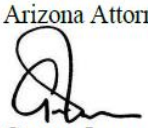
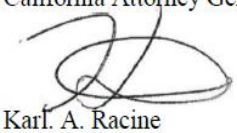
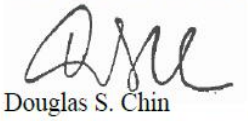


George Jepsen
Connecticut Attorney General



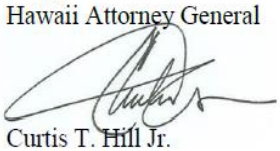
Karl A. Racine
District of Columbia Attorney General

Christopher M. Carr
Georgia Attorney General

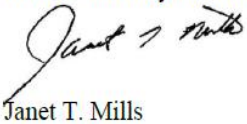


Douglas S. Chin
Hawaii Attorney General

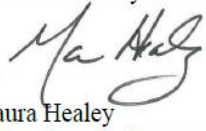
Lisa Madigan
Illinois Attorney General



Curtis T. Hill Jr.
Indiana Attorney General

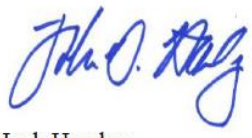


Janet T. Mills
Maine Attorney General



Maura Healey
Massachusetts Attorney General

Bill Schuette
Michigan Attorney General



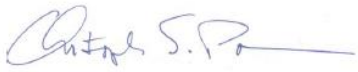
Josh Hawley
Missouri Attorney General

Tim Fox
Montana Attorney General

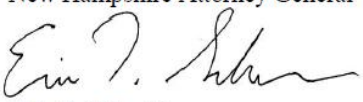
Douglas Peterson
Nebraska Attorney General

Adam Paul Laxalt
Nevada Attorney General

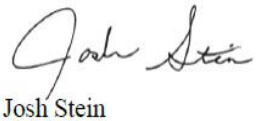
Gordon MacDonald
New Hampshire Attorney General



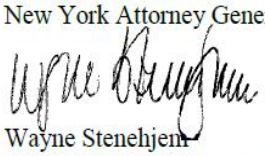
Christopher S. Porrino
New Jersey Attorney General



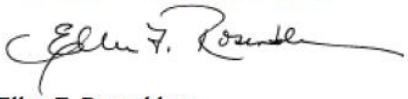
Eric T. Schneiderman
New York Attorney General



Josh Stein
North Carolina Attorney General

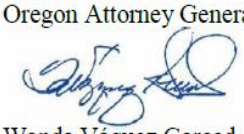


Wayne Stenehjem
North Dakota Attorney General



Ellen F. Rosenblum
Oregon Attorney General

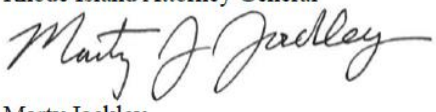
Josh Shapiro
Pennsylvania Attorney General



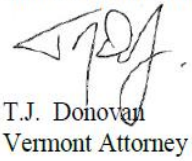
Wanda Váquez Garced
Puerto Rico Attorney General

Peter Kilmartin
Rhode Island Attorney General

Alan Wilson
South Carolina Attorney General



Marty Jackley
South Dakota Attorney General



T.J. Donovan
Vermont Attorney General

Brad Schimel
Wisconsin Attorney General

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Biography

Matthew Bauer, L.Ac., began his full-time practice of acupuncture and Chinese Medicine in 1986 and began working with several acupuncture organizations in the U.S. In 2014 Matthew founded the "Acupuncture Now Foundation" (ANF), a U.S. based international non-profit dedicated to offering reliable information regarding the practice of acupuncture. By drawing on the combined knowledge of acupuncturists the world over, the ANF hopes to help guide the development of the practice of acupuncture from an ancient art to an evidence-based modern healthcare resource. Having served as a consultant in the managed care industry since 1998, Matthew helped to create the first managed care acupuncture-based credentialing and utilization guidelines and since 2013 has served on the Board of Directors of American Specialty Health Group, Inc. As a managed care consultant, Matthew took part in a think-tank with a dozen experienced Acupuncturists from the U.S., Mainland China, Taiwan, and Korea. That experience convinced Matthew of the need to find ways to gather experienced Acupuncturists together to share their knowledge to further the understanding of this ancient healing system. Matthew has authored dozens of articles and two books and has particular interest addressing problems with acupuncture research and the practical issues involved with bringing acupuncture into mainstream medicine.

Dr. John McDonald, PhD commenced acupuncture studies in Australia in 1971, clinical practice in 1975 and teaching acupuncture in 1977. John has been a pioneer in developing acupuncture education in Australia in curriculum development and as a Dean, Department Head, senior lecturer and course coordinator in a number of colleges and universities. In 2006 John participated in the finalizing of the World Health Organization Western Pacific Region Standard for Acupuncture Point Locations. Among John's publications are the textbook "Zang Fu Syndromes: Differential Diagnosis and Treatment" co-authored with Dr Joel Penner from Los Angeles, seven peer-reviewed journal papers, 19 other journal papers, more than 30 health magazine articles and four videos. Recently John has, with Stephen Janz, co-authored a comparative literature review, The Acupuncture Evidence Project, sponsored and published by the Australian Acupuncture and Chinese Medicine Association of Australia Ltd (AACMA).

Currently John is an Adjunct Senior-Lecturer in the School of Medicine at Griffith University (where he conducted his PhD research into the immunological mechanisms underpinning the effects of acupuncture in allergic rhinitis). John is also Vice-President for Research of the Acupuncture Now Foundation, a lecturer and member of the Curriculum Advisory Committee at the Endeavour College of Natural Health and a reviewer for various peer-reviewed journals including Nature, BMJ, Evidence-Based Complementary and Alternative Medicine and Journal of Acupuncture and Meridian Studies. John has also recently been appointed to the Editorial Board of Digital Chinese Medicine at Hunan University of Chinese Medicine.