New guidelines were adopted expanding the use of these medications to less life threatening conditions; doctors were often forced to change treatment plans in favor of increasing medication management, and the pills started flowing. In the years that followed, BILLION of scripts for Vicodyn, Oxycontin, Percoset just to name a few were handed out based on research largely funded by drug manufactures which said time and time again: **Opioids work, Opioids are safe, "addiction is rare".** In 2011 alone, 131 Million scripts of Vicodyn were written nationwide. That's more than 1 Script for every 3 living Americans today. The problem: The Golden Rule. He who has the gold, makes the rules. At the center of this issue, almost all of the research studies published and later quoted to create this new paradigm were financed by those companies who wanted to increase sales on their created and patented medications. The studies had an inherit research bias, and that bias then shaped policy. This research bias is true in all fields of health care today, not just in pharmaceutics. We currently watch the unfolding of a nationwide opioid addiction epidemic, crippling US families and the economy. Today we have a very different picture on how those pain management guidelines panned out:

"Pennsylvania leads the nation in drug overdose deaths among young adult men, according to a new analysis, raising the level of urgency about an epidemic that over the last decade has killed more than twice as many Americans as homicide."[2]

"From 2000-2014, hospitalizations for pain medication overdoses increased 225 percent statewide, while those for heroin overdoses jumped 162 percent, according to the report from the Pennsylvania Health Care Cost Containment Council."[3]

"Opioids are essentially legal heroine," says Lewis Nelson, who served on an FDA panel to revise the Risk Evaluation and Mitigation Strategy (REMS) associated with the prescription drugs."[4]

Just this month alone, the Federal Government and the PA State Government each convened task forces to tackle this growing problem or opioid \ heroin use, which all experts agree started from the over use of medications. In fact the Society of Human Resource Management (SHRM) in its March 2016 magazine even made this the cover article, since the problem is costing so much toll on business in the US over the past few years. (Graphic #1)

They profited from biased research, and the taxpayer is left to clean up the mess. This sadly is the same type of industry driven and company funded evidence that also showed that Avandia, Vioxx, Celebrex **and so many other medications** in the past few years that were miracles when they were released... but would eventually be pulled off the market. A decade later showing scandalous misrepresented studies that were biased & misleading on the benefits, all the while downplaying the risks and side effects.

The Washington post did an expose on this increasing issue of research bias for financial gain in 2012 and in its indictment of Pharma and concluded the most prestigious medical journal in the world, the New England Journal of Medicine regularly features articles over which pharmaceutical companies and their employees can exert significant influence. Over a year-long period ending in August of that year, NEJM published 73 articles on original studies of new drugs, encompassing drugs approved by the FDA since 2000 and experimental drugs. Of those articles, 60 were funded by a pharmaceutical company, 50 were co-written by drug company employees and 37 had a lead author, typically an academic, who had previously accepted outside compensation from the sponsoring drug company in the form of consultant pay, grants or speaker fees. [5]

I fear as we go into this brave new world of EBMT cookie cutter, one size fits all medicine based on boxes checked and flow charts of predetermined care followed, that again the EBMT guidelines will be created and rules made based on the same financial only incentive driven models largely driven this time by the Insurance industry.

The major downfall of EBMT is the ASSUMPTION all evidence and research used is solely for the benefit of patient outcomes, and that financial motives are not actually the single largest dominating elephant in the room in the selection of all patient care protocols. In the past decade the British Medical Journal (BMJ) has been bringing a lot of attention to this process for EBMT in its criticism of the current peer review model of research publishing. "Publishing medical journals is not a charitable venture, even when the owners are non-profit making medical societies. Considerable financial resources are needed to publish high quality journals, and owners and editors are vulnerable to economic pressures that may threaten the intellectual integrity of their journals. The medical community should objectively and dispassionately investigate whether this concern is a reality" [6] In fact the recently retired 25 year editor, Richard W. Smith, of the world renown and prestigious BMJ wrote in an editorial about this common place problem of the flawed peer reviewed medical system when he said, "Sadly we also know—from hundreds of systematic reviews of different subjects and from studies of the methodological and statistical standards of published papers—**that most of what appears in peer-reviewed journals is scientifically weak.**"[7]

EBMT is designed to make doctors nothing more than rubber stamps for a few carefully selected research articles, regardless of common sense or the experience of the physician. Not all care plans fit all circumstances. In the article, **The Real World Failure of Evidence-Based Medicine** the author states, "EBM is therefore an *ad hoc* construct

and is not a valid basis for medical decision-making. This is further demonstrated by its exclusion of relevant scientific and probative real-world decision-making evidence and processes. It draws upon a narrow evidence base that is itself inherently unreliable. It fails to take adequate account of the nature of causation, the full range of evidence relevant to its determination, and differing approaches to determining cause and effect in real-world decision-making. EBM also makes a muddled attempt to emulate the scientific method and it does not acknowledge the role of experience, understanding and wisdom in making medical decisions." [8]

In the paper entitled: **How evidence-based medicine is failing due to biased trials and selective publication** the authors just barely fall short of using the words fraud when discussing how research is used and wielded in decision making. "Evidence-based medicine (EBM) was announced in the early 1990s as a 'new paradigm' for improving patient care. Yet there is currently little evidence that EBM has achieved its aim. Since its introduction, health care costs have increased while there remains a ***lack of high-quality evidence suggesting EBM has resulted in substantial population-level health gains***. In this paper we suggest that EBM's potential for improving patients' health care has been thwarted by bias in the choice of hypotheses tested, manipulation of study design and selective publication. Evidence for these flaws is clearest in industry-funded studies. We argue EBM's indiscriminate acceptance of industry-generated 'evidence' is akin to letting politicians count their own votes. Given that most intervention studies are industry funded, this is a serious problem for the overall evidence base. Clinical decisions based on such evidence are likely to be misinformed, with patients given less effective, harmful or more expensive treatments. More investment in independent research is urgently required. Independent bodies, informed democratically, need to set research priorities. We also propose that evidence rating schemes are formally modified so research with conflict of interest bias is explicitly downgraded in value."[9]

Other recent Journal articles exploring this topic do in fact call it outright fraud and document their proof of this ascertain. In the 2013 research paper, **Fraud and misconduct in clinical research: A concern**, the author writes, "Scientific fraud reappears with alarming consistency from paleontology to nanotechnology. Several studies have found that more than 40% of surveyed researchers were aware of misconduct but did not report it. Sheehan *et al.* reported in 2005 that 17% of surveyed authors of clinical drug trials reported that they personally knew of fabrication in research occurring over the previous 10 years. Quality at sites is usually judged by audits and inspections. There has been as high as 23% (official action indicated) for cause inspections conducted by US Food and drug Administration (USFDA) over the last several years. These kinds of results indicate that there exists a substantial problem. Fraud/misconduct can lead to study losing its entire credibility. **Moreover, it can lead to ineffective or harmful treatment being available or patients being denied of effective treatment.**" [10]

In fact this level of research bias and misuse of studies in EBMT to drive the new health care paradigms is so wide spread, that the United States **Center for Disease Control** (CDC) published a Editor's Choice paper on this topic just recently in June 2015 with cautions on using research in EBMT: **How Do You Know Which Health Care Effectiveness Research You Can Trust? A Guide to Study Design for the Perplexed**:

"Evidence is mounting that publication in a peer-reviewed medical journal does not guarantee a study's validity. ***Many studies of health care effectiveness do not show the cause-and-effect relationships that they claim. They have faulty research designs. Mistaken conclusions later reported in the news media can lead to wrong-headed policies and confusion among policy makers, scientists, and the public.*** Unfortunately, little guidance exists to help distinguish good study designs from bad ones, the central goal of this article.

Another pattern in the evolution of science is that early studies of new treatments tend to show the most dramatic, positive health effects, and these effects diminish or disappear as more rigorous and larger studies are conducted. As these positive effects decrease, harmful side effects emerge. Yet the exaggerated early studies, which by design tend to inflate benefits and underestimate harms, have the most influence.

Scientists, journalists, policy makers, and members of the public often do not realize the extent to which bias affects the trustworthiness of research. We hope this article helps to elucidate the most common designs that either fall prey to biases or fail to control for their effects. Because much of this evidence is easily displayed and interpreted, we encourage the use of visual data sets in presenting health-related information.

These design principles have implications for the tens of billions of dollars spent on medical research in the United States each year. Systematic reviews of health care intervention studies show ***that half or more of published studies use weak designs and are untrustworthy***. The results of weak study design are flawed science, misconstrued policies, and potentially billions or trillions of wasted dollars.

This article and these case reports barely break the surface of what can go wrong in studies of health care. If we do not learn and apply the basics of research design, scientists will continue to generate flip-flopping studies that emphasize drama over reality, and policy makers, journalists, and the public will continue to be perplexed." [11]

If this is the *TRUE* belief published by the Center for Disease Control of the United States of America, how are we to guarantee a true unbiased system in PA at this time? Given the current climate? Aren't we jumping the gun with HB1800 maybe a decade too early in this process?

In the BMC Medical Ethics Journal this October 2015 article, The importance of values in evidence-based medicine, the publication assess, "EBM has generated substantial advances in methodology that have allowed us to distinguish between helpful and harmful treatments, identify the major problems with publication bias, and surface and address industry conflicts of interest. **Unfortunately, the predominance of technical progress has also served to support the myth that EBM is value neutral.** The focus on technical methodologies has obscured the equally important issue of values and, in turn, the way values impinge on judgments and the processes of interpretation of all steps in the EBM process. While technical progress must continue, at least some effort in the next decades should be given to exploring questions of value. This is not just a philosophical or methodological point; it is of profound practical importance."12

Given all of these facts of the true realities of EBMT emerging in the academic community as well as at the highest levels of the Federal Government, we at the PCA feel that it is too early to adopt rigid EBMT policies and use the injured worker's of the commonwealth as Guinea pigs in a this new post ACA social experiment on patients.

There may come a day in the future that the PCA can stand behind to support a change in the WC guidelines to use EBMT, ***but that moment is not today*** and not on HB1800 in its current form. If and when a new bill is introduced several years from now, after all of these concerns are addressed on a nationwide level and national standards have been adopted that removes and makes more transparent all financial motives of the large industry players that stand to benefit the most from this reform, then maybe the PCA would be willing to look a more flesh out bill with more protections against abuse by the Worker's compensation insurance industry.

This new bill should consider many items that were just mentioned this weekend at the Workers' Compensation Research Institutes annual meeting for 2016, the largest policy driver on Worker's compensation statistics in the US. At the meeting held just this March 10th & 11th, these are some of the take away points.

1) In PA, with claims of at least 7 days lost time from work 15% of the injured employees never returned to the job. State by state varied from 9% to 19%. First point of contact provider type makes a large difference on total outcome. (more details below)
2) In PA, 13% of injured workers had a "big problem" obtaining a treatment \ the care that was needed. 36% of injured employees were "discouraged" from seeing a provider they wanted to see. 14% were dissatisfied with the care they received. Trust was a big issue. The less trust there was at the workplace the more problems were experienced. These numbers appear to be growing with the increase of case management, and will no doubt continue to rise in EBMT.
3) PA workers compensation claims for back injuries had surgery rates of slightly more that 10%. States varied from California at about 7% to Oklahoma near 20%. States that had easier \ higher access to Chiropractic care early in their treatment, tend to have lower back surgery outcomes (see below for more details).
4) For every 1% increase in spinal surgeons in an area spinal surgery went up 2.7%. Increases in conservative care providers in a region leads to a decrease in overall spine surgery rates.
5) 75% of injured workers receive opioid medications. LA, NY, and PA were the **highest prescription areas**. Opioid prescription rates are trending down between 2012 and 2014.
6) ***The Effects of Provider Choice on Workers Compensation Costs***, found a 13 to 18% savings for those states that allowed provider choice compared to those states that made the employer/insurer choose the provider. EBMT will often limit provider choices.

When that day comes, that the house does release an updated version of an EBMT bill, we would like to see this bill include a **"Conservative Care First"** approach as the method of policy. We as Chiropractors often see patients that could be more easily, treatment effectively and cost efficiently in our clinic statewide. However, by the time they have reached out offices, often as the doctor of last resort, they have had 4 tests, given 3 drugs, six months of atrophy and scar tissue as set in... but one one has addressed or even attempted treatment that the root cause of the condition.

As Doctors of Chiropractic, we see large volumes of real evidence and studies often buried and ignored as it pertains to a conservative care first approach by Chiropractors. Why? Because Chiropractic doesn't have the Media draw, Big Pharma cash and preferential treatment by the insurance industry that some of our fellow practitioners receive. We currently see abuses of EBMT s in third party major medical administrators that cut care plans for all patients in ubiquitous EBM care plans for 6-8 visits of care then forced release, regardless if the patient's back pain was caused by a muscle strain or a bulging disc. We see it in URO and PRO reports that point to the same citation to flip and flop to prove or disprove care by convenience.

All the while published studies that show patient satisfaction, efficacy and cost savings for care administered by a DC is beneficial to the entire system. For example the study in JMPT that studied the Tennesee Blue Cross Blue Shield one year treatment cost average for all patients with a diagnosis in the family of lower back pain care. The Study compared whether it was first initiated by a DC vs an MD. The study found, "Paid costs for episodes of care initiated with a DC were almost 40% less than episodes initiated with an MD. Even after risk adjusting each patient's costs, we found that episodes of care initiated with a DC were 20% less expensive than episodes initiated with an MD." 13 (see Graphic #2) Or the study in the Journal of Spine published in February 2015 that shows that lower back pain initiated and treated through spinal manipulation versus typical medical care showed at four weeks, the two groups compared patients that reported symptoms of 30% or greater improvement by reduction in objective pain scales. The Manipulation group was 94% better versus the medical group that was only 56% improved during the same 4 week period. 14 (See Graphic #3)

And lastly, when we compare the category that really creates long term disability and the HIGHEST average patient cost: patients that end up with back surgery. In a 2013 Study published on Worker's Compensation patients entitled, **Early predictors of lumbar spine surgery after occupational back injury: results from a prospective study of workers in Washington State,** that the most surprising finding of the study was that if the first point of first point of contact for their injury was with a ***Chiropractor, only 1.5%*** of those patients EVER received surgery "Baseline variables associated with surgery ($P < 0.05$) in the multivariate model included higher Roland-Morris Disability Questionnaire scores, greater injury severity, and surgeon as first provider seen for the injury. Reduced odds of surgery were observed for those younger than 35 years, females, Hispanics, **and those whose first provider was a chiropractor.** Approximately 42.7% of workers who first saw a surgeon had surgery, **in contrast to only 1.5% of those who saw a chiropractor**. The area under the receiver operating characteristic curve of the multivariate model was 0.93 (95% confidence interval, 0.92-0.95), indicating excellent ability to discriminate between workers who would versus would not have surgery." 15 (See Graphic #4) 42.7% versus 1.5%, that is a HUGE difference in outcomes, just by choice of first provider. Yet, most workers' compensation panels in the Commonwealth still *do not even have DCs on their panels*. These studies alone should be great cause for consideration with any new attempt at a rewrite of HB1800 in the future to make sure that EBMT MANDATEs conservative care first, with Chiropractic.

I will close with one last study, opioid use by provider type as discussed in the Journal of the American Academy of Orthopedic Surgery from May of 2015, **The opioid epidemic: impact on orthopaedic surgery**. The article breaks down opioid distribution by specialist type.16 (See Graphic #5) One more thing to note in this breakdown, where they note Orthopedic Surgeons were he 3rd highest by number of scripts written... is that Chiropractors over the same period ***wrote ZERO scripts nationwide*** for these medications. And that is a prescription for thought.

Respectfully Submitted,

Keith M. Miller DC.

Dr. Keith M. Miller

Co-Chairperson PCA Legislative Committee

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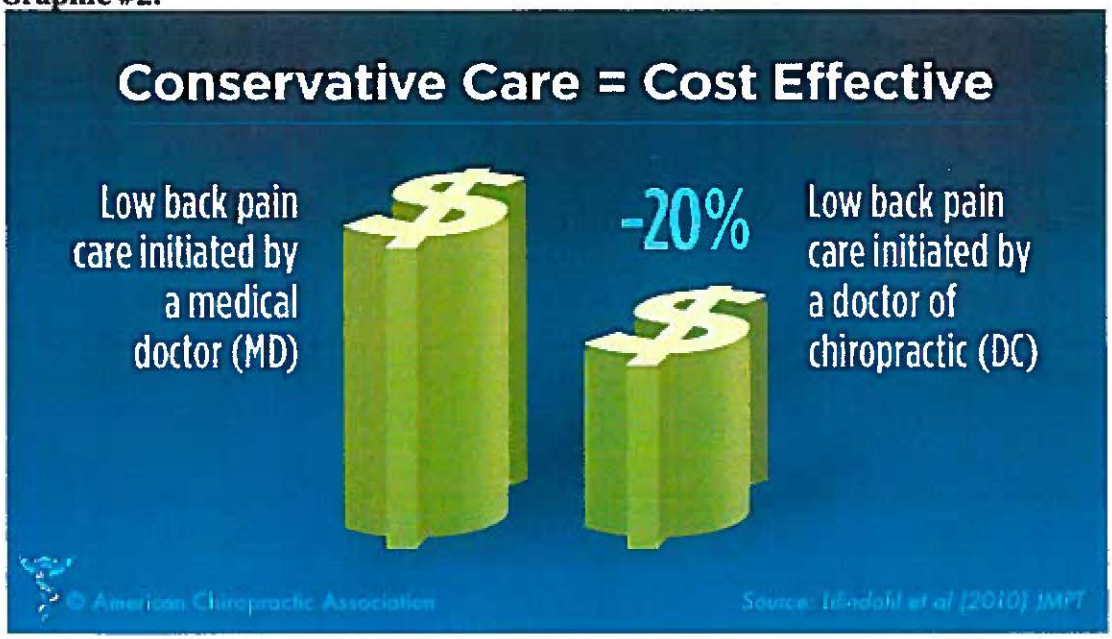
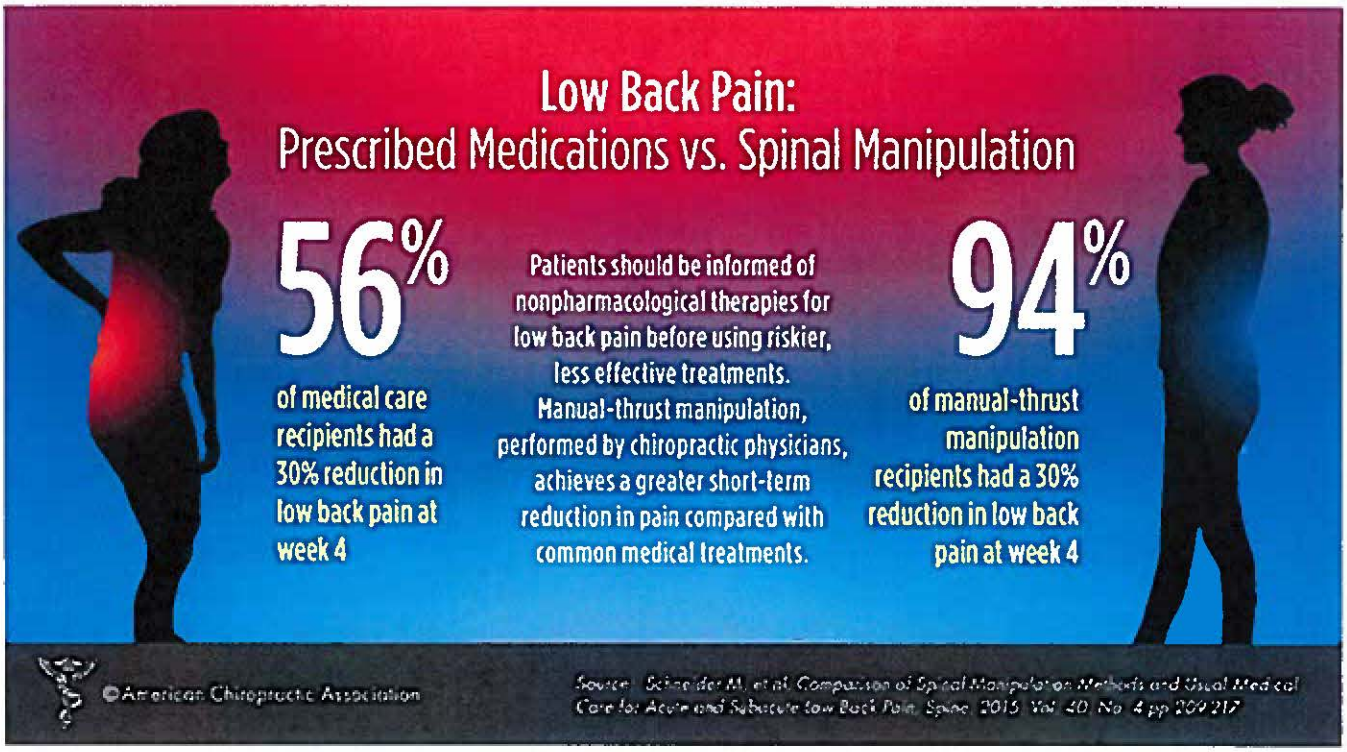
Graphic #1

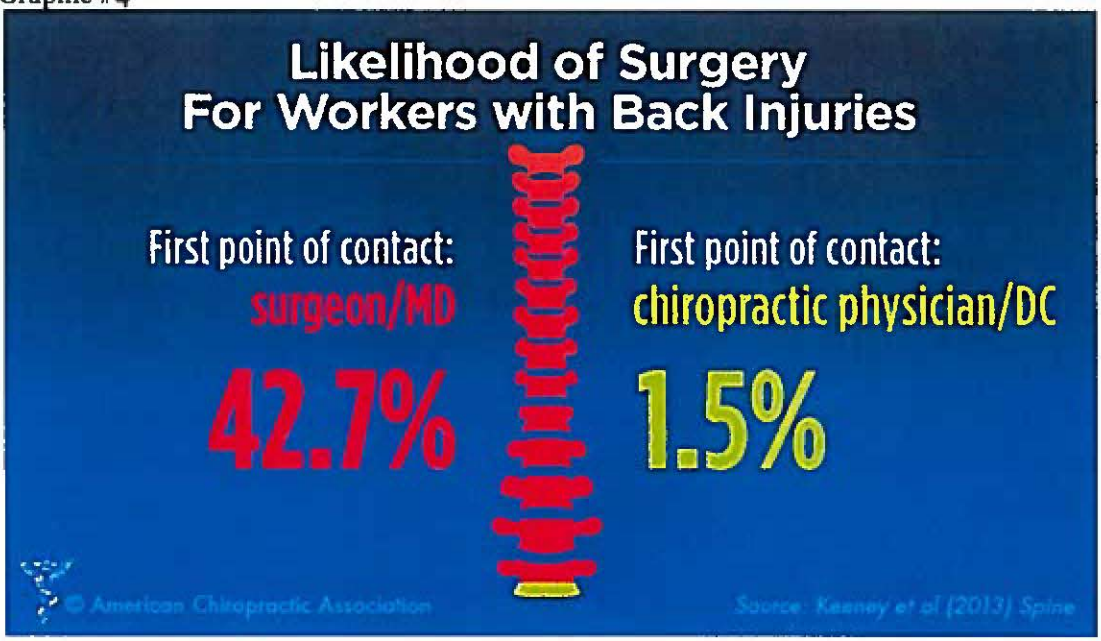
Graphic #2:



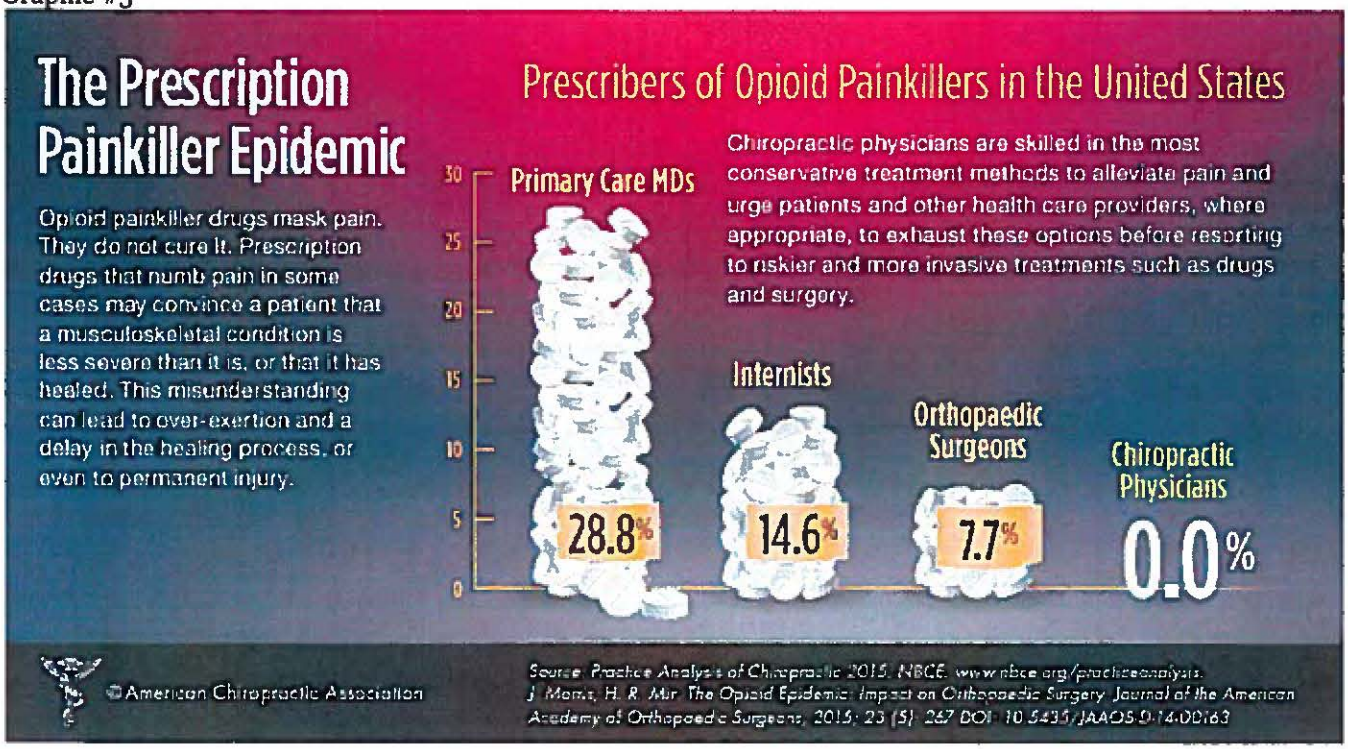
Graphic #3:



Graphic #4



Graphic #5


The Prescription Painkiller Epidemic
Opioid painkiller drugs mask pain. They do not cure it. Prescription drugs that numb pain in some cases may convince a patient that a musculoskeletal condition is less severe than it is, or that it has healed. This misunderstanding can lead to over-exertion and a delay in the healing process, or even to permanent injury.
Prescribers of Opioid Painkillers in the United States
Chiropractic physicians are skilled in the most conservative treatment methods to alleviate pain and urge patients and other health care providers, where appropriate, to exhaust these options before resorting to riskier and more invasive treatments such as drugs and surgery.
30
25
20
15
10
5
0
Primary Care MDs
28.8%
Internists
14.6%
Orthopaedic Surgeons
7.7%
Chiropractic Physicians
0.0%
©American Chiropractic Association
Source: Practice Analysis of Chiropractic 2015. NBCE. www.nbce.org/practiceanalysis.
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