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Research Article

In Defense of Doctors Who Treat Pain -- Questions and Answers for Judges, Juries ... and Journalists --

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As a US healthcare writer and patient advocate for almost 30 years, I read a lot. Recently, some of that reading is in court transcripts of doctors being persecuted out of medicine or into jail by various prosecutors and their hired "experts." I use the term "persecuted" intentionally. I believe that "medical experts" in many court or Medical Board proceedings are simply "hired guns" – clinical predators hired for large sums of money to tell stories whose details they do not themselves understand.

Most judges and juries -- and media reporters -- understand even less.

No lawyer likes to ask questions to which they don't already know the answers. But sometimes one must explore a witness's qualifications rigorously – and the Judge's qualifications as well. In my view, no judge or jury is competent to assess the credibility of a witness who testifies against a doctor unless *both* the witness and the judge understand not only the content of the medical literature but also its major weaknesses.

This principle was demonstrated glaringly in a US conference of the Florida Society for Interventional Pain Physicians (FSIPP) where I was invited to speak two years ago. Beginning my lecture, I asked an audience of about 100 doctors and nurse practitioners a series of questions for a show of hands. The last of the questions was "how many of you have recent training in the evaluation of clinical trials and study protocols?"

No hands went up.

As I suggested to the audience, "you realize of course, that without this exposure, when you read only the abstract of a published clinical paper, you have no idea whether the authors or peer reviewers knew what they were doing? You lack the skills to check their work."

You could have heard a pin drop as I continued with my lecture.

This reaction is similar to what I have heard separately from journalists whom I have challenged on grounds that "studies" they have lauded in their summary articles are rather frequently biased or wrong on basic science or methodology.

Problems with Scientific Peer Review

Even "experts" can fall victim to the burdens of their reading workloads or publication deadlines. They scan an abstract and come away believing incorrectly that they have done their duty of due diligence. However, we now know that the peer review process is failing in medical literature just as it is in psychology and psychiatry - and even physics. This failure is a dimension of what we call the "replication crisis" and relatively few judges, medical boards or journalists are even aware of the problem.

In many areas of science, when widely-praised studies are repeated by different investigators, results are different from the first time around. Even in studies where the same outcomes are observed, outcomes are frequently weaker or more ambiguous than in the original. Expectation bias and investigators' professional self-interest are likely involved in such failures. Also operating are the persistent biases of journal editors and peer reviewers, without whose approval nothing gets published.

This might be a modern example of "Extraordinary Popular Delusions and the Madness of Crowds," by Scottish journalist Charles Mackay, first published in 1841.

A reliable rule of thumb in such matters is the GIGO law: "garbage in, garbage out." Large numbers of papers in all areas of modern science now suffer from weak or unexamined assumptions, flawed methods, bias and cherry picked research. Many published papers, for instance, ignore the quality of studies that are combined for "meta-analysis." And if you write about healthcare and don't know what meta-analysis is, then you might be part of the problem.

Without probing the actual knowledge of "expert" witnesses, judges and juries cannot know whether they are hearing generally accepted principles and practices, or *not* -- even when clinical literature is quoted. Neither can journalists.

For a doctor who treats pain with opioid pain relievers, these errors can result in profound miscarriages of justice. US physicians have reported being targeted by drug enforcement agencies and medical boards for prescribing opioids, even when they have done so legitimately for chronic pain management. Doctors have experienced raids, had their medical records seized, and faced public scrutiny which has led to the ruin of their practices, and even patient suicides. Some have been denied adequate representation by law enforcement pre-trial asset seizures.

Questions for Medical Experts – and Answers

Thus, I suggest a few pertinent questions for any "subject matter expert" who testifies against a doctor concerning prevailing practice on opioid pain relievers – and for judges and journalists as well.

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• Questions: How many patients have you treated for pain during your career? How many of them died from all causes while under your care?

Answers: Patients treated for severe chronic pain often face <u>higher mortality rates</u> compared to the general population. Chronic pain can be associated with increased risk of death, particularly from causes such as cancer, diseases of the circulatory and respiratory systems, and suicide. None of these factors is a consequence of use of prescription opioid drugs approved for use by the US FDA.

• Questions: How many patients have you discharged or referred to an addiction specialist after they complained of inadequate pain care? Is this typical of other practitioners in your field? How do you know? What is the nature of "opioid dependence?" Are you familiar with the term "pseudo-addiction?

Answers: Opioid dependence in medical practice is <u>a purely physical reaction</u> in which patients who have been treated with opioid pain relievers may experience withdrawal symptoms if they are tapered too rapidly off their medications. The concept reflects fundamental principles of pharmacology that were well established in the 1970's.

Dependence is not addiction.

<u>Pseudo-addiction</u> is an affliction of doctors, not patients. It reflects <u>a misinterpretation</u> of patient requests for better pain control. This misperception is complicated by institutional bias introduced by legal counsels who are loathe to risk practice exposure to censure on grounds of "violating" dose limits in poorly researched government prescribing guidelines.

• Question: In your opinion, how frequently do patients treated for pain by a doctor die of a prescription drug overdose?

Answer: Incidence of overdose-related mortality in clinical patients is <u>too low to confidently estimate</u> within confounds imposed by <u>poor doctor training</u> and limited observation times in clinical encounters. Moreover, <u>definitive large-cohort studies</u> indicate that combined near-term incidence of suicide events or hospitalization for overdose in clinical patients treated with opioids is on the order of 2% or less.

In all probability, opioids are actually innocent bystanders in the causation of these tragedies.

As noted by the Director of the US National Institute on Drug Abuse, "unlike tolerance and physical dependence, addiction is not a predictable result of opioid prescribing. Addiction occurs in only a small percentage of persons who are exposed to opioids — even among those with preexisting vulnerabilities".

Dr Volkow is also on record questioning the prevailing emphasis on "abstinence only" policies in treatment of addiction.

• Question: What are the best indicators in a patient's medical records that they may experience bad outcomes from pain treatment using prescription opioids?

Answer: A history of attempted suicide, hospitalizations for overdose, or severe psychiatric disorders are <u>four to twenty times more significant</u> in risk of near-term overdose or suicide than treatment with opioids.

• Question: Is there a widely accepted consensus standard of opioid prescribing that definitively limits dose levels due to patient risks?

Answer: No there is not. The 2022 US CDC <u>Clinical Practice Guideline</u> is not a "consensus" standard for the treatment of pain. The CDC itself indicates that their guidelines are "intended as recommendations to guide clinicians in making informed, patient-centered decisions about pain care, including opioid therapy..."

Indeed, CDC guidelines are widely rejected by practicing clinicians on multiple grounds:

- Weak medical evidence and gross over-emphasis on risk and non-consensual tapering of legacy patients, many of whom have been stable for years on high-dose opioid therapy.
- Anti-opioid bias, cherry-picked research, and faulty methodology, including scientifically unjustifiable claims that non-opioid approaches, including non-pharmacological approaches, are "preferable" to opioids in the absence of trials that demonstrate any such thing.
- Failure to address or embrace the implications of highly variable opioid metabolism between individuals, due to genetics a failure reflected in almost all published drug trials.

Conclusions:

However uncomfortable this reality may be for medical boards, prosecutors or judges – or for political decision makers -- there is presently no consensus standard by which a doctor's prescribing practices can be determined to lie outside usual and accepted conditions of practice. The central and arguably *only* pertinent judgment of potential benefits and harms for each patient is the doctor's clinical experience and training.

The misinformed or biased testimony of a paid professional witness is simply not enough to establish guilt "beyond a reasonable doubt.{

If a doctor or pharmacist harms patients by inattention, negligence, or unprofessional conduct, then Medical Boards and Boards of Pharmacy are charged with revoking their licenses. If a doctor prescribes or a pharmacist dispenses large volumes of opioids in the absence of face-to-face doctor-patient relationships, medical testing and ongoing patient monitoring, then we recognize indicators for referral to law enforcement (In the US, pill mills are thankfully rare these days, due to better State oversight).

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But de-licensing clinicians, placing them on probation or sending them to jail for occasional errors in record keeping is simply ludicrous. US practice of medicine has been grossly criminalized by government overreach. It is past time for such overreach to end and for political interference in the practice of evidence-based medicine to end with it.

Even in cases in which prescribing practices are questionable, the <u>burden of proof must be on law enforcement</u> to demonstrate beyond a shadow of doubt that the doctor knew they were prescribing narcotics outside the usual course of professional practice. Unless evidence is verified for harms suffered by patients due to dangerous behavior on the part of a doctor, there can be only one legally or ethically justified outcome in prosecutions of clinicians:

Case Dismissed!

Author Note: Richard A Lawhern, PhD, is author or co-author of over 250 papers, articles, and interviews in a mixture of peer-reviewed clinical journals and mass media. His work focuses on the intersection of public health policy with regulation of pain medicine. The present paper has also been accepted for publication in a widely read and cited US healthcare newsletter.

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