Dear Sirs:

I am writing to complain about Dr. Timothy Earl King's 2018 forensic patent and how it demonstrates overt bias when King testifies in court as a government expert in opioid pain management cases.

Dr. King applied for a patent (Provisional application No. 62/755,605, filed on Nov. 5, 2018) which purports to be "a forensic system and method, including a methodology, for analyzing medical and pharmacy data to determine the legitimacy of controlled substance prescription and use, and to detect fraud, abuse, and/or diversion of controlled substances. In one aspect, said method provides objective evidentiary data that shows with high certainty whether a suspected medical practitioner has been issuing controlled substance prescriptions "outside the usual course of medical practice" and/or "for other than legitimate medical purposes".

Later, King claims that his method is unique insofar as "Up to this time, there have been no objective published criteria that the Applicant is aware of to determine without reasonable doubt whether a prescriber of controlled substances is prescribing for legitimate medical use or not."

King provides background to support the need for his patent with a quote from the National Safety council stating, "A recent report from the National Safety Council states: "The opioid crisis is worsening. Over 42,000 Americans died of an opioid overdose in 2016, and government and public health officials are scrambling to find effective ways to reverse this frightening trend. As the death toll from opioid overdose increases, addressing the crisis becomes ever more urgent."

It is certainly disingenuous and false to opioid related deaths primarily or significantly to prescription opioids when it has been well known that the CDC miscoded fentanyl deaths as prescription opioid deaths when the vast majority were for illicit fentanyl.

https://pubmed.ncbi.nlm.nih.gov/33761120/

"The error, they said, was caused by miscoding deaths involving illicitly manufactured fentanyl (IMF) as deaths involving prescribed fentanyl. To understand what caused this error, the authors examined the CDC's methodology for compiling drug-related mortality data, beginning with the source data obtained from approximately 2.8 million death certificates received each year from state vital statistics registrars. "

Therefore, if the opioid overdose death crisis is primarily due to illicit fentanyl and other drugs, devoting resources to any purported problems with prescription opioid would have little positive impact on this crisis as a whole.

Further along, King provides some examples of what he views as illegitimate prescribing. King infers that certain conditions are risk factors for opioid use without providing evidence of causation. It's important to note that association is not causation especially when other co-morbidities are not properly factored in. The inference is that lack of consideration of these associations constitutes criminal prescribing.

"Applicant started specifically looking at which mental health illnesses were associated with addiction overdose and considering that mental health was a risk factor that a prescribing doctor should know about, from the patient's medical chart, and should take into account."

Another unsubstantiated conclusion without any supporting evidence to support it.

"So, it stood to reason that if a patient comes in to see the doctor and has COPD, and is a smoker, and has respiratory depression, then it is more likely that this patient will have fewer reserves, and thus is more liable to an overdose."

It should be understood that prescription opioids alone are not likely to be responsible for an increased death rate and that the cause is likely to be co-morbidities that may not be adequately controlled for in many studies.

https://pubmed.ncbi.nlm.nih.gov/31667741/

"In a nationally representative sample, opioid prescriptions were associated with increased short-term mortality only without adjustment for sociodemographics, health status, or utilization. The relationship between prescription opioid use and mortality risk is more complex than previously reported, meriting further examination."

In other instances, King demonstrates bias by only considering that the target physician is knowingly engaged in illegitimate prescribing.

"the target doctor has the ability to pull that patient's PDMP data, which means that the target doctor knows that the patient is getting narcotics elsewhere, yet the target doctor goes ahead and prescribes narcotics to the patient anyway, then it can be safely concluded that the target doctor is prescribing narcotics "outside the usual course of medical practice".

There may be several reasonable explanations. It often takes several days to input data into the PDMP so the target doctor may not know if there is another prescription. The PDMP information may not have been pulled by staff in time for the doctor's review. In many instances the patient may have needed an opioid for surgery, or an injury and it was prescribed by another treating physician. This cannot be considered a criminal violation under most circumstances but apparently King doesn't discuss any valid excuses.

Another example,

"For another example, a patient's data shows that the patient was positive for oxycodone that they were being prescribed, but the data was negative for benzodiazepine that they were also being prescribed, and was also negative for any oxycodone metabolites; what that usually means is that the patient has likely scraped off a tiny bit of the oxycodone while they were in the bathroom and added it to the urine sample, thus the sample showed positive for oxycodone but not for the metabolites, i.e., the patient was not taking the oxycodone, and the target doctor knew that there was a "medication inconsistency", or should have paid attention to that, but did not, because the data was in the chart! Yet, the next day the target doctor went ahead and issued another prescription."

As far as oxycodone is concerned, a positive UDS for oxycodone without metabolite can result for several reasons not discussed by King. For one, the patient may have been taking the medications inconsistently and metabolites may not have been seen if the patient restarted the medication and the UDS was done before metabolites accumulated. Secondly, UDS does not necessarily detect all metabolites of oxycodone and some people have different metabolic pathways. Oxycodone

glucuronides are not routinely tested on UDS for example. Thirdly, some patients more rapidly metabolize opioids than others. And lastly of course, laboratory error from improper laboratory procedures (cleaning, maintenance and calibration of equipment etc.) or sample custody problem should be considered.

As far as giving the patient another prescription, it would be important to note that if the prescriber believed that the patient was taking some of their medications, it would be important to slowly taper the opioid in prefer to avoid the dangers of a precipitous withdrawal which could result in an MI, stroke, suicide, street medication use.

Kings patent is little more than a means of organizing data derived from medical records, PDMP and arrest records. The bizarre claim that his system can objectively determine whether a prescription is legitimate or not is ludicrous bordering on the insane.

In making a diagnosis, King claims that causes of certain conditions can be conclusively determined.

"Is the back pain caused by musculoskeletal factors, such as, for example, the patient being overweight, a smoker, aerobically deconditioned, presence of social stresses in the home or workplace, or marital stressors. The physician would be expected to look at these factors and determine that the patient's problem may not require the use of chronic narcotics."

More often, when there are many factors involved, one specific cause for a condition cannot be precisely determined. This is typical in patients with chronic pain.

King appears to make recommendations that are mere personal opinion, and not based on scientific studies but nonetheless can be determined by a chart review. Does this constitute criminal activity via illegitimate use?

"If the patient, for instance, has not been cooperative with the treatment plan, e.g., has not lost weight, continues to eat unhealthily, and nothing has changed in their habitus, etc., then it is not appropriate for the doctor to prescribe narcotics. Very often a medical chart may show that the physician apparently does not care"

King does not provide any medical articles or studies that prove illegitimate use in any of the examples he cited.

King goes to ridiculous extremes when he claims that he can divine the thoughts of a physician by simply reviewing a medical record. "Very often a medical chart may show that the physician apparently does not care: the patient demands a narcotic, and they get it which is totally inappropriate"

King also claims that his "invention" is effective.

"The invention has been field tested for efficacy and legal foundation and improved incrementally. It has been recently highly modified to meet the requirements of legal prosecution, court acceptability, and medical accuracy, and has evolved into its current format."

If so, in view of the claims he has made as to the "invention's" ability to determine whether a prescription is legitimate, he should be required to immediately divulge this information and show exactly how it was collected and proven to be effective.

King also makes claims that his patented system can detect fraud. "Key concepts are objectively and clearly defined by his method, such as: ... (c) Is there evidence of fraud?"

Although Dr. King is a highly credentialed physician, there are serious questions as to whether he meets criteria as a qualified expert as required in Federal rule of evidence 702. Specifically, King's reliability of testimony must be called into question. As listed in the 2 complaints against Dr. King by Roger Pellmann, King has made numerous false and misleading statements in federal court in his testimony on opioid pain management. Furthermore, as was revealed in the US v Campbell case, King admitted to using his patented system as discussed above when analyzing cases as a government expert. Although King claims that his patent has been tested for efficacy, we find no evidence of studies or peer reviewed articles to support this claim. King's examples that he cites in the patent application appear to be speculations, not based on scientific evidence, and incorrect. His statement that he could determine by the chart whether a target physician "cared" is prejudicial and forms a negative opinion of a defendant's intent. His claim that his system can detect fraud is untested and, in a field, where he lacks credentials, training and experience.

For all intents and purposes, King's patent is a means of defining "illegitimate purpose" as it is used in the Controlled Substance Act. King is in effect making law, secret law.

At this time, I urge that the medical board suspend Dr. King's ability to act as an expert witness in federal court cases. He has clearly demonstrated bias and has a clear financial motivation to find the "target" physicians guilty of illegitimate prescribing. I would also think that the board should review King patients' medical records and practices and determine whether indeed King himself would pass his own "objective" standards.

Sincerely,