

## Non-Negotiables in the DEA FAQ Redux

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The DEA is interfering with medical practice. They probably wish they were not doing this (they consistently tell us that this is not their purpose), and surely they must know that they have no legal authority to do this. But they are doing it nonetheless. Withdrawal of the meticulously developed “Prescription Pain Medication” Frequently Asked Questions document, only weeks after it was posted to their website with great fanfare, sends a frightening message that the agency is in disarray. Doctors and pharmacists, whose careers depend on level-headed responses by regulators, are worried about what new surprises may be in store if they continue to meet the needs of their chronic pain patients. Irrational flip-flops on the rules for prescribing and dispensing provide convincing evidence that the DEA has no clear understanding of either medicine or pharmacy. Uncertainty and inconsistency in regulation interferes with medical practice.

In the aftermath of this fiasco, there will be many efforts to reach out to the agency and help them. They need help. They must be terribly embarrassed. We should be embarrassed for them. Any time other people stub their toe so publicly and so completely, caring human beings develop a natural feeling of compassion and understanding toward them. Yet, the DEA is a tough agency to have warm feelings for. Their statements do not make sense and they do not listen well to those who offer assistance. It is a hard situation to deal with. Perhaps it is impossible.

If there is to be any re-negotiating with the agency on rules for dispensing opioid analgesics, there are two core statements in the now-withdrawn FAQ that must be retained and strengthened. These two statements have nothing to do with whether multiple prescriptions can be issued on the same day with instructions to fill on different dates (although DEA now denies that this can be done, they are clearly wrong under the law, and they themselves encouraged this practice until recently). The core statements are unrelated to the number of patients in a practice receiving opioids, the number of dosage units prescribed and the duration of therapy (DEA insists that these are red flags for diversion, although anyone with any knowledge of pain management knows that these factors are the hallmarks of a successful practice).

Here are the two non-negotiable core statements from the withdrawn document:

- “Although the FAQs reflect a consensus view of an expert panel, lack of strict adherence to these suggestions does not imply that a particular practice is outside

the scope of legitimate medical practice.” (Page 3)

- “A ‘universal precautions’ approach to the prescribing of controlled prescription drugs does not mean that all patients who have the capacity to engage in abuse or diversion will be identified, or prevented from these behaviors over time.” (Page 23)

The first statement illustrates the crucial distinction between acts that are outside the usual course of professional practice (legitimate medicine) and acts that are within medicine but fall below the standard of care (the consensus of experts). Acts that are outside the usual course of professional practice are not medical acts at all. They occur when a doctor does not bother with pain assessment, the development of a treatment plan, necessary follow-up, and appropriate documentation. To authorize access to opioids outside the usual course of professional practice is illegal. It is drug trafficking. It is not any kind of medicine. Doctors who sell drugs or prescriptions without any attempt at medical practice have committed a crime.

In contrast, acts that fall below the standard of care occur when a doctor conducts a medical practice inconsistent with standards developed by those who are competent in the field. This is potentially malpractice. It is not illegal. It is medicine, although perhaps not very good medicine. Drug trafficking necessarily is below the medical standard of care, but actions below the medical standard of care are not necessarily drug trafficking. The withdrawn FAQ reiterates (page 28) that “prescribing opioids (referred to as narcotic drugs in federal regulations) for pain, including ‘intractable’ pain, is lawful when there is a physician-patient relationship established by an examination, a treatment plan, and medical records.” Some doctors may not be prescribing opioids according to the best practice standards (it is a tautology that half of doctors are below average in skill), but they are not criminals merely because their clinical skills are subject to challenge.

The withdrawn FAQ speaks the truth by saying that there is not even the implication of criminality in medical practices that fail to follow suggestions made by a consensus of pain management experts. This is a tough truth for the DEA, because many prosecutions of doctors have been based on allegations of substandard practice. The statement in the withdrawn FAQ is a truth that is non-negotiable. Evidence that a doctor has practiced below the standard of care in prescribing opioids is irrelevant in a civil or criminal drug diversion case where the allegation is that the doctor was not practicing medicine at all.

The second non-negotiable statement is even more fundamental. It reflects the widely understood phenomenon of human error. Even the most careful doctors, who use recommended precautions to prevent diversion by their patients, cannot completely prevent diversion. Some diversion is inevitable and is the necessary cost of compassionate treatment that meets the needs of chronic pain patients. A doctor who completely shuts out drug diverters will shut out suffering pain patients as well.

Consider the similar situation of a news reporter who must accept the risk that some reported facts will occasionally be untrue, despite the reporter’s best efforts to assure the

truth of all facts. If the standard were that the reporting of an untrue fact is a crime punishable by imprisonment, then newspaper and magazine pages would be empty. The news that the public deserves would not be reported. Because the public needs the news, the public is willing to accept the risk that some reported facts will not be truthful. Likewise, the public is willing to accept the fact that some prescriptions will be issued to drug diverters, because the public needs to have pain medications prescribed when they are appropriate.

The withdrawn FAQ speaks the truth when it says that even the most cautious prescribing of opioids cannot altogether prevent diversion and abuse. This truth is tough for the DEA, because many of their prosecutions of doctors have cherry-picked evidence about a tiny few criminal diverters from a practice that was generally meeting the needs of a large number of legitimate patients. Those criminal diverters cannot be eliminated without also eliminating many of the legitimate patients. The statement in the withdrawn FAQ is a truth that is non-negotiable.

If the DEA insists on negotiating these non-negotiable truths, then all efforts at collaboration with them must cease. Confrontation will be the only option. Interference in medical practice by a federal agency is intolerable. If the agency insists on an approach to diversion prevention that misunderstands medical practice and victimizes pain patients, it has outlived its usefulness.

Regulation of medical practice is best left to state governments, where traditionally it has occurred. As state regulatory agencies review the quality of medical care within the practices of their licensees, they will occasionally discover activities that are outside medical practice. These activities can be referred to the DEA for criminal or civil action because they are not medicine. In the absence of that referral, the DEA is not needed.

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