Point Paper on Regulatory Over-Reach and Departures of Doctors from Pain Management Practice

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- Thousands of doctors are leaving pain management practice and deserting their patients throughout the US.
 - o Whole regions of US States now lack any pain management center.
 - o Patients overcome by pain are lapsing into disability. Some are committing suicide or seeking pain relief from dangerous street drugs.
- The main reason for physician departure is vast regulatory over-reach by DEA and State drug enforcement authorities
 - o A hostile regulatory environment leads doctors to fear financial ruin due to arbitrary "investigations" which often never go to court.
 - o Even if not investigated, doctors fear sanction or loss of license and livelihood if they prescribe opioid analgesics.
 - o The regulatory environment transcends specifics of any law self defense from sanctions is financially ruinous even when the doctor is right and regulators are wrong.
- The regulatory environment is driven by an unexamined and false mythology: the claim that America's "opioid crisis" was caused by doctors over-prescribing opioids to their pain patients.
 - Data published by CDC disprove this mythology conclusively.
 - o There has never been a cause and effect relationship between rates of prescribing versus rates of overdose deaths.
 - We have a Heroin and illegal Fentanyl crisis, not a prescription crisis. Any contribution of medically managed opioids is lost in the noise of street drugs.

- o People over age 62 are prescribed opioids six times more often than kids and young adults under 19. But kids and young adults overdose six times more often than people over 62. Prescribing is **NOT** the problem.
- Many US States have legislated limits on dose and duration of opioid prescriptions for acute or chronic pain. These limits must be repealed.
 - o There are no published trials demonstrating any benefit from mandated or coerced tapering of legacy patients treated with opioid pain relievers.
 - FDA has published safety warnings against rapid taper or unsupported discharge of legacy patients who have been treated with opioid analgesics.
 - o For many patients with severe pain, there are no effective alternatives to opioid pain relievers.
 - o In the absence of safe and effective alternatives, involuntary tapering of patients who are otherwise stable and whose quality of life is improved by opioid therapy becomes patient abuse and malpractice.
- The American Medical Association has repudiated the logic and criteria of the 2016 CDC guidelines on prescription of opioids to adults with chronic non-cancer pain.
 - o Some patients benefit from high-dose opioid pain relievers above levels recommended by CDC
 - o Guidelines were intended as advice for safety reviews, not mandates on dose limits -- but have been widely misapplied.
 - o No healthcare provider should fear sanction or loss of license solely because of the amounts or doses of opioid pain relievers that they prescribe for their patients.
- It is time to force regulators out of doctors' offices and return to the centrality of the doctor-patient relationship.