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STATEMENT

OF

JOHN P. FLANNERY, II, Esq.

[Former federal drug prosecutor (S.D.N.Y.), and former Special Counsel to the U.S. Senate and U. S. House Judiciary Committees; currently in private practice (www.CMZLaw.com)]

BEFORE THE

SUBCOMMITTEE ON CRIME, TERRORISM, AND HOMELAND SECURITY

OF THE

COMMITTEE ON THE JUDICIARY

U.S. HOUSE OF REPRESENTATIVES

CONCERNING

"THE DRUG ENFORCEMENT ADMINISTRATION'S REGULATION OF MEDICINE"

PRESENTED ON

JULY 12, 2007 AT 10 AM, IN 2237 RHOB

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Mr. Chairman, the Honorable Members of this Subcommittee, the Staff, respected members of this distinguished panel, and those attending this crucial hearing, I want to thank you for the opportunity to address this Crime Committee on an aspect of the "DEA's Regulation of Medicine" that I find among the most troubling incursions into our constitutional "right to be let alone" by our government.

There are 40 to 75 million patients across America (according to various statistical surveys) who suffer from terrible chronic pain that never leaves them, not even when they

sleep, and it has shattered the normal lives that they once enjoyed with their families at home and their colleagues at work.

The source of this pain should be well known as, with greater frequency, our friends and our family members suffer from this chronic non-malignant pain.

It's not the kind of pain that hurts for a day or so and heals itself. It abides and courses through your body like a raging fire, for six months or more, often for years, driven on by an unseen wind, stealing your sleep, your ability to stay awake during the day, and it replaces your even disposition with anger, and it tempts you to suicide. It is a Joycean nightmare from which one may not awake.

Surgery, therapies, various medicines may help for a time but the pain persists undiminished in many who consider alternative remedies. The modest amount of natural opioids that our bodies produce to block the pain receptors are overrun by the pain.

Congress specifically identified certain controlled substances in the Controlled Substances Act for the treatment of such pain. In recent years, physicians have discovered that by a combination of fast-acting and long release opioids that they can restore some semblance of normalcy to many patients who previously despaired at their suffering.

You might presume that the government was doing all that it could to redress this pandemic of pain.

Instead our government is daily making it worse, creating a public health crisis when it should be easing our pain.

Our Justice Department, and the DEA as its agent, is exceeding the authority granted by the U.S. Congress under Title 21, United States Code, Section 841(a)(1), that empowered the

Executive Branch to prosecute physicians for illicit drug dealing when the physicians acted with the specific intent to push drugs rather than to treat patients. *United States v. Moore,* 423 U.S. 122, 143, 96 S.Ct. 335 (1975); *see also* Title 21, United States Code, Section 802(21).

1. The Supreme Court created a standard in 1975

In 1975, the Supreme Court examined the Controlled Substances Act to decide whether it applied to physicians at all -- as the Act did not plainly include physicians who prescribed pain medication; indeed, it appeared to exempt physicians from its coverage.

The Supreme Court in *Moore* did the best that it could with a collection of imprecise statutory provisions and regulations to conclude that physicians are covered insofar as physicians may not push drugs.

The Supreme Court's formulation was that a physician had to act "outside the course of professional medical practice" with the "intent" to act as a drug pusher, rather than as a treating physician.

Congress has not re-visited the statute to clarify what conduct by physicians may be criminal – not since the Supreme Court in *Moore* cobbled together its holding.

Since *Moore*, much mischief has been done.

2. The Justice Department has been re-defining the standard

The Justice Department has been deciding on a case by case basis, by its charging documents, by its testifying experts at trial, by the extraneous evidence it offers, and by the wrong-headed jury instructions that it proposes to the court, what is permissible medical practice, and judges have been led into error by the Justice Department, allowing these prosecutions to modify and restrict pain medicine in this nation to a dangerous degree, and

according to a malpractice standard, that is civil in nature, although, in every respect, the consequences of these trials are criminal including the stigma of conviction, of mandatory sentences, levied fines, forfeited property, and confinement in federal prisons for decades – when not for life.

The Justice Department's impermissible re-definition of medicine, on a case by case basis, has so narrowed what is acceptable medical practice that it is fair to say that the Justice Department disapproves of a physician treating a patient with any substance containing an opioid component.

a. Constitutional Notice

We presume constitutional notice, say it's a necessary predicate, before we may hold anyone accountable for his bad acts. But the Justice Department has resisted all demands to state what precisely constitutes the offending misconduct. The Department prefers confusion over notice as this uncertainty effectively deters physicians from treating chronic pain.

b. the Department's varying "norm"

I represented a physician, Dr. Ron McIver of South Carolina, and the Justice Department prosecuted him for failing to conform with a "professional norm" that the Executive Branch defined for the first time at his trial after Dr. McIver had treated his pain patients.

Dr. McIver's case was so troubling that the ***New York Times Magazine*** featured a cover story, written by ***Times*** correspondent Tina Rosenberg, aptly titled, "When is a Pain Doctor a Drug Pusher?"

Dr. McIver's prosecution is illustrative of these prosecutions and underscores what's

gone awry. In McIver's case, the government insisted that Dr. McIver didn't do what the "average" physician might do when treating pain patients. Dr. McIver didn't conform to "the norm" - as defined by the Justice Department's paid expert at trial. But this "norm" was not the standard formulated by the Supreme Court in *Moore, supra.*

Dr. Stephen Storick, the Justice Department's expert at the McIver trial, conceded these norms were an "ever-changing modality" and that what Dr. McIver did as a treating physician, according to Dr. Storick, "[we] did it five years ago."

Dr. Storick explained that his "professional norms" were not "outside the bounds of professional conduct" but that "he [Dr. Storick] wouldn't do" what Dr. McIver did -- as it violated his "professional norms".

DEA Agent Rene Crowley conceded, for example, that neither Title 21, United States Code, Section 841, nor the Code of Federal Regulations, limited the number of pills a physician could prescribe. Dr. Storick also admitted that there was no maximum dosage for opioids that was prohibited. He acknowledged the finding of the University of Wisconsin Pain Management Study that "[o]pioids should be titrated by a percentage of the current dose based on the intensity of pain." Dr. Storick agreed that "titration" (increasing the dosage) was an apt approach for cancer patients, but he dismissed the study as "academic" and claimed to know better because, he said, "I work for a living." It wasn't outside the bounds of professional medical practice; but it didn't meet his standard.

Dr. Storick said that the highest daily dose that he would prescribe to a non-cancer patient with chronic pain was 160 mg OxyContin (80 mg OxyContin twice a day); Storick said

he was unfamiliar with the fact that Medicaid allows a daily dose of up to 960 mg of OxyContin (or eighty tablets).

Thus, you have some idea of the elusive norm applied to Dr. McIver.

c. The Department's jurisdictional competence – or authority.

The Department has been replacing its "judgment" of medical science without the lawful authority to do so.

The Supreme Court found that the Department exceeded its jurisdictional competence when it sought to defeat a state legislature's preference to allow assisted suicide. *Gonzales v. Oregon*, 546 U.S. 243, 126 S. Ct. 904, at 922 (2006). Justice Kennedy said, if the Attorney General enjoyed this authority to criminalize what it saw fit, then it would enjoy the unrestrained power to criminalize "the conduct of registered physicians whenever they engage[d] in conduct [that] he [the AG] deem[ed] illegitimate." *Id.*, at 920.

While our judicial branch decried the Department's unauthorized interference with assisted suicide, it has not yet seen fit to restrain the Department's interference with physicians who treat those in pain so that they may avoid suicide.

d. The Jury is not much help in protecting physicians.

You might presume that a jury could serve as a corrective for the government's excesses in these cases but you would be mistaken as the jurors' fear of addiction accommodates the government's prosecutions.

The Mayday Fund, in the 90's, asked Mellman Lazarus Lake, Inc., to conduct a public opinion poll of 1004 adults that would reflect the nation's views, so that we might "understand people's underlying assumptions about pain and its treatment." The research concluded that

Americans "would rather bear pain than take action to relieve it." Americans "withstand pain because they fear that too much medication will cause them to become addicted or dependent." When we select a jury, if there are more blue-collar workers or lower income Americans, the Mayday survey data indicates that they "are more likely to avoid medication than are professional or higher income Americans."

A high proportion of the population experience surgical pain (63%), or chronic back aches (49%). But Americans generally respond that they don't give in to pain. 92% say "it's a part of life". 71% wouldn't call the doctor when in pain. 66% said the last time they felt fairly serious pain, they withstood it. 46% tried to avoid medication unless the pain got "bad." 35% waited "until the pain [was] unbearable before they would take medication."

What explains this tolerance for pain?

It's our fear of medication and drug addiction.

87% believe "it is easy to become too reliant on pain medication." And Americans believe this to be true of any medicine, not just prescription drugs. 72% believe they will develop a tolerance to medication, if they use it, and it won't work when they need it. 41 % believe physicians give too much medication.

In an America, in which the citizens fear pain medication and addiction, and "tough it out," the Government is unconcerned about jury selection.

e. The jury doesn't have to find the physician "intended" to push drugs.

It is a bedrock principle that you may be held responsible for the natural consequences of what you intend to do.

But the Department does not prove in these pain cases that the defendant "knew" he was practicing "outside the course of professional medical practice" in order to push drugs, or that he did "intend" to push drugs.

In the McIver case, when it was on appeal before the U.S. Court of Appeals for the Fourth Circuit, the government said at oral argument that it was not sure that the government was required to prove "specific intent."

Circuit Judge James Harvie Wilkinson, III, pressed the prosecution, asking whether "specific intent was required" or whether, by adding it, was the court writing a "gloss" onto the statute?

The prosecution said, "I don't know."

Judge Wilkinson said, "Why not? That's part of the case!"

The prosecution then said, "The case did not go to the jury on specific intent."

Judge Wilkinson replied, "But he's now claiming [for Dr. McIver] it's an error, and I'm asking you, if we make this into a specific intent crime, are we adding or not to what Congress has set forth?"

Circuit Court Judge Allyson Kay Duncan asked the prosecution to explain what takes a malpractice claim to a criminal level and how was that dividing line articulated for the jury's consideration.

The prosecution said because the jury had been given an instruction that Dr. McIver could not be willfully blind as to what was happening, thus had the jury been instructed as to intent.

Judge Duncan then asked if that response meant the prosecution was then conceding that there was a specific intent standard?

In response, the prosecution said, "I do acknowledge there is an intent standard and it was proven and it was more than amply charged to the jury."

Judge Wilkinson expressed concern as to how the expert testimony and the jury instructions interlocked seamlessly around a violation of "professional norms" at the expense of criminal intent. Congress, Judge Wilkinson noted, did not express the critical element of proof for the jury as "a reasonable physician" standard or "a violation of professional norms" Congress had said "outside the course of professional practice."

Judge Wilkinson asked the prosecution if what Congress prescribed "wasn't something textually different from a 'norm of professional practice'." Judge Wilkinson asked, "doesn't 'outside the course' mean 'you just shuck professional practice to one side' and 'set yourself up as a drug dealer' and put all your medical training to one side?" Judge Wilkinson asked the prosecution if there wasn't a difference between "professional norms" and "outside the course of professional practice"?

The prosecution responded that there was "a difference."

But when the three-judge panel wrote its decision upholding Dr. McIver's conviction, the "difference" was considered as inconsequential as Dr. McIver's intent. (The colloquy is available on CD from the U.S. Court of Appeals for the Fourth Circuit.)

3. Few pain patients become addicted.

Dr. Mark Sullivan, Professor of Psychiatry and an Adjunct Professor of Medical History and Ethics at the University of Washington, confirmed that only 2% of chronic pain patients

may become addicted and that there is a 98% chance that a patient who claims that he has chronic pain is "on the level." *See* Pain, Opioids and Addiction: "An Urgent Problem for Doctors and Patients", 3/5/07, NIH Conference (http://videocast.nih.gov/PastEvents.asp?c=1.)

4. Detecting patients who are lying is difficult – if possible at all.

Knowing who is deceiving the physician is hard to uncover, according to a recent study conducted by Drs. Beth Jung and Marcus Reidenberg:

> "Physicians operate with what *Burgoon et al.* call a *truth bias.* That is, they presume that patients' presentation of themselves are true, complete and accurate. Their assessment of patients' pain complaints are based both on current information (obtained in the interview and physical examination) and on the starting point, or anchoring point for the assessment. Doctors assume that patients come to see them because they have a problem for which they want treatment. Law enforcement personnel appear to have a different assumption when they interview some people." *See* Jung G, Reidentbert M, DECEIVING PHYSICIANS, In Press (2006).

5. Nor is it easy to confirm a patient's pain.

It is good that patients are "on the level," according to Dr. Sullivan, because there is almost no way to confirm that a person has pain; the Center for Disease Control statistics reveal that "80% of lower back pain cannot be identified with imaging" whether it's an fMRI, PET, CT-scan or x-ray. *See* Pain, Opioids and Addiction: "An Urgent Problem for Doctors and Patients", *supra*.

Dr. Storick criticized Dr. McIver for not considering certain tests to confirm his diagnosis but also admitted that there are people who have pain who have a negative MRI. J.A. 564.

The medicial community is of one mind that "[i]t is sometimes a difficult medical judgment as to whether opioid therapy is indicated in patients complaining of pain because

objective signs are not always present." *See* "Rights and Responsibilities of Physicians in the Use of Opioids for the Treatment of Pain" (Public Policy Statement on the Rights and Responsibilities of Healthcare professionals in the use of Opioids for the Treatment of Pain – a consensus document of - the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine).

While cancer "is a symptom of a disease bearing a direct relationship predominantly with tissue pathology[,] … there is only a *weak association* between reported pain and objective findings of disease in chronic pain not associated with cancer" (italics supplied). See Loeser, BONICA'S MANAGEMENT OF PAIN, 3rd ed., Lippincott Williams & Wilkins (2001).

Dr. Storick confirmed on cross-examination that "pain is a subjective amount of discomfort" and "there's no way to really measure it." Despite this observation, Dr. Storick, the government's expert, said he wouldn't prescribe opioids for any patient unless he could find objective signs of pain. In other words, he would purposefully fail to treat patients with lower back pain, migraine headaches, fibromyalgia, reflexive sympathetic dystrophy disorder (RSD), and various neuropathic disorders if he couldn't find "objective signs of pain". That was his "norm" or standard.

Incidentally, Dr. Storick couldn't know what Dr. McIver's patients had to say or how they presented themselves as patients as he never talked to or examined any of them.

6. Dependence is not addiction .

Physicians patiently explain that a dependence on a medical regimen that is an effective remedy to endless days of mind-altering pain is not an addiction, not some sort of obsession that is unrelated to medical need. It is indeed a medical remedy attacking a disease.

7. Physicians are discouraged from treating.

Physicians have made a decision, and are conducting the kind of triage that you might find in an emergency room, treating those that they can help as best as they can - but not going so far as to risk going to jail for treating a pain patient too aggressively – if at all.

Medical conferences in recent years add this issue -- "pain treatment" -- to their agendas to warn physicians against treating patients with controlled substances for fear of federal or state prosecution.

Unsurprisingly, given this direction by the leaders in their own medical profession, physicians are refusing to treat lest they be jailed.

With fewer physicians prescribing controlled substances, chronic pain patients daily consider the dilemma of choosing endless days of extraordinary pain without surcease or surrendering to suicide.

8. The bias of settled habits.

The federal government has wrongly and artfully cast the prosecutions of physicians as if it were a part of this nation's never-ending "war on drugs".

In this never-ending "war", that is never won either, the government invokes its drug speak, to mis-characterize physicians as "drug dealers", medicines as "drugs", and patients as "users" or "addicts".

Our critical faculties have failed to question the language we've grown accustomed to accepting. Thorsten Veblen called this the "bias of settled habit."

We must resolve to re-consider this "war" on physicians and patients, and the language we suffer in silence, because the extension from the street and "street drugs" to professional

medical offices and "prescriptions" is a quantum leap that has adversely affected the quality of debate and of our national health.

9. Stand-ins – red flags – that mislead.

The Justice Department has created an array of what they call "red flags" that are "stand-ins" for actual proof as to whether the physician did anything criminal. These flags are confounding in their logic. They consider how far a patient travels to see his physician, and the fact that the patient knows what prescriptions helps his condition. But, isn't it the case that a patient has to travel further because fewer physicians treat pain? Shouldn't we expect that a person in pain has the experience to know what makes a difference to ease his pain?

10. Why don't we limit ourselves to detecting crime, rather than creating it?

The Justice Department authorizes its agents to pretend to have pain, often lower back pain, and, if the physician doesn't catch on that they are pretending, then the Department may claim that the physician was drug dealing. No matter that you can't confirm back pain by any imaging device in 80% of the cases. No matter that physicians are by nature and necessity trusting of the patients they see.

11. We have lost our innocence – at least its presumption.

We have statutes in drug cases that presume guilt -- upon the government's say-so.

What follows upon the government's say-so, whether by indictment or search warrant, is the seizure of the physician's entire practice (taking his charts and the medical histories needed to practice), cutting off the patients, leaving patients to fend for themselves, denying the physician the right to write prescriptions, and maybe even confining the physician while he awaits trial.

Some physicians who have never gotten a traffic ticket before they run afoul of the government ask why they aren't presumed innocent. Is our answer really that the offense is so serious, you are just going to have to wait until you prove to us you are innocent?

12. We require more restraint in these prosecutions.

The media always knows more about these cases than the physician or his counsel when a search or indictment issues.

When the Accused gets to trial, the government offers a blizzard of information, an ambush, in an exercise that is less judicial and more like a political campaign.

The rules of evidence are applied without much rigor as all manner of prejudicial hearsay is offered in the jury's presence.

13. Confined pending sentencing and appeal.

If the physician is convicted, he is confined pending sentence, and, after sentence, he is confined pending his appeal.

This presumption is harsh when the physician was at large for years following the alleged misconduct, presented no danger to himself or his community, and always showed up at court.

But this denial of bail is presumed and hard to rebut.

The trial judge has to say that he made an error at law to justify releasing the defendant pending sentence or appeal.

Or the prosecutor has to agree that he doesn't expect the physician to receive any jail time.

This is as unjust and unfair as anything that is happening in modern criminal jurisprudence – and not just in these chronic pain cases. It diminishes the significance of any appeal.

14. The sentencing guidelines appear arbitrary.

When we sentence a physician for prescribing pain medication, we pretend that the pills that were prescribed are not oxycodone but that they were marijuana instead. There is no sentencing guideline for oxycodone itself. There is one, however, for marijuana. Why is that you might ask? There is no explanation. We treat as equivalent the medicine (oxycodone) and the substance (marijuana) that we insist has no medical use. We also multiply the weight of the oxcodone by 100s and 1000s, depending on when the offense occurred, to find an "equivalent" amount of marijuana and the corresponding offense level (for marijuana) under the sentencing guidelines. No one can give you any cogent reason for this bizarre and arbitrary sentencing exercise. It should be struck down.

15. The mandatory minimum is harsh and illogical.

If a patient has died, and this does happen in medical practice, and, if that patient was receiving an opioid, then it is presumed that the patient died as "a result" of the prescription and the physician faces a twenty year minimum up to a life sentence.

In the case of Dr. McIver, he had a patient, Lawrence Shealy, who had relentless chronic pain from crippling arthritis, back and knee pain, heart disease, depression, sleeplessness, and, unsurprisingly, he had tried to commit suicide.

At the time of his death, Mr. Shealy had an enlarged heart, an enlarged spleen and liver from congestive heart failure, severe coronary artery atherosclerosis, hardening of the arteries,

90% blockage of his left anterior descending artery, a 50% blockage of the left circumflex arterial branch, a scarred heart from an earlier heart attacks, and congested organs, meaning, that, as the blood backed up into the system, it backed up into the organs.

There is every reason to believe that Mr. Shealy died because of the complications involving his heart disease, having nothing to do with the medication that he was taking. Indeed, sudden death is the commonest presenting symptom of cardiovascular disease. *See* Zipes D.P., Wellens H.J.J., Sudden Cardiac Death. Circulation. 1998:98:2334-2351; available at http://circ.ahajournals.org/cgi/content/full/98/21/2334 .

While Mr. Shealy had various medications available to him at the time of his death, there was every indication that he had taken the appropriate medication that he had been prescribed for 16 days without suffering any adverse side effects. If the prescription was as harmful as the Department argued, then why hadn't the OxyContin caused Mr. Shealy's death sooner?

Yet, Dr. McIver was held responsible for the "resulting" death and was sentenced to 30 years, ten above the mandatory minimum of 20 years, and he is serving that sentence at the federal facility in Buttner, NC..

16. We have a right to be let alone.

We have a right to be "let alone", to enjoy our constitutional "right of privacy", the penumbral emanations of those basic rights enumerated in our Constitution.

The government may not muzzle a physician's unquestioned right to advise his patient confidentially or to write prescriptions or to associate with other physicians who seek to treat

chronic pain patients. That's violative of the right of free speech and to associate and to assemble guaranteed physicians and patients by the First Amendment.

The government may not compromise a physician's livelihood, by which it "takes" what is his property, in violation of the constitutional guarantee that no "taking" by the government of a person's property shall occur without due process, meaning unless it is fundamentally fair.

The government may not abridge the health and well-being of patients, for what could be more clearly an infringement of the constitutional guarantee of life and liberty?

The government may not set apart chronic pain patients as different than other patients, denigrate them in word and deed, stigmatize them as addicts when they should be healed, and thus deny patients the equal protection of our laws.

The government may not punish patients in violation of the constitutional prohibition against cruel and unusual punishment.

I represent Richard Paey, a chronic pain patient, who was the focus of a ***Sixty Minutes*** piece because he is serving a twenty-five year sentence in the state of Florida for possessing medicine – Percocets – to treat his chronic pain. Although he only "possessed" these medications, he was convicted of "trafficking." While in custody, Richard Paey is receiving more pain medication, a morphine pump, than was the subject of his alleged "trafficking." The State Court of Appeals agreed that the 25 year sentence was unjust but also said that only the Governor – by his clemency powers – may set the matter right in a clemency petition.

17. Congress must act!

Plainly, the "system" we have is not working well – if it can be said to be working at all..

For some, it may be tempting to think that chronic pain does not concern them.

But the difference between being pain-free today and being in chronic pain tomorrow may be a rush-hour rear-end collision at a congested intersection. Or a discovered illness that partners with chronic pain.

If we do not help those who are hurting today, there may be no one to help us tomorrow.

May this hearing commence a much-needed dialogue to clarify the law, and to improve the flawed process we have (if not to replace it entirely).

Thank you for your time and kind attention to my remarks.

# # #