IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

UNITED STATES OF AMERICA,

Criminal No. 03-0467-A

v.

WILLIAM ELIOT HURWITZ, M.D.
Defendant.

TRIAL BRIEF OF WILLIAM E. HURWITZ. M.D.

As counsel for Dr. Hurwitz, we submit this Memorandum to the Court for a better understanding, before the trial begins, of historical background of this case in terms of the treatment of chronic intractable pain, and Dr. Hurwitz's practice.

I. CHRONIC PAIN IS A SERIOUS MEDICAL CONDITION

"Pain is a more terrible lord of mankind than even death itself."[1] Pain can be debilitating.[2] Persistent pain can destroy the quality of life and erode the will to live.[3] Thus,

1 Statement of Dr. Albert Schweitzer, quoted in Stuart Davidson, Pain and Opiophobia, 40 Healthcare Forum J. 64, 64 (May/June 1997).

2 "Pain accounts for more than one quarter of workdays lost, increases health care utilization, and disrupts family and social functions." Breaking Down the Barriers at 3.

3 See Bernard Lo, Karen Rothenberg, & Michael Vasko, Appropriate Management of Pain: Addressing the Clinical, Legal, and Regulatorv Barriers, 24 J.L., Med., & Ethics 285, 285 (1996) (" [A]dequate palliation of pain may be likely to reduce requests for physician-assisted suicide."); Robin Bernhoff, How We Can Win the Compassion Debate, Citizen Magazine (June 24, 1996) (noting that "patients often want to die because of under treated pain" and arguing that the response is better palliative care rather than legalization of suicide); Kathleen M. Foley, The

IL

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA

Alexandria Division ?,hi\! 1:,::n.! - I ,(j", 10: 2 0

T

UNITED STATES OF AMERICA,

Criminal No. 03-0467-A

v.

WILLIAM ELIOT HURWITZ, M.D.
Defendant.

TRIAL BRIEF OF WILLIAM E. HURWITZ. M.D.

As counsel for Dr. Hurwitz, we submit this Memorandum to the Court for a better understanding, before the trial begins, of historical background of this case in terms ofthe treatment of chronic intractable pain, and Dr. Hurwitz's practice.

I. CHRONIC PAIN IS A SERIOUS MEDICAL CONDITION

"Pain is a more terrible lord of mankind than even death itself."! Pain can be debilitating.2 Persistent pain can destroy the quality of life and erode the will to live.3 Thus,

1 Statement of Dr. Albert Schweitzer, quoted in Stuart Davidson, Pain and Opiophobia, 40 Healthcare Forum J. 64, 64 (May/June 1997).

2 "Pain accounts for more than one quarter of workdays lost, increases health care utilization, and disrupts family and social functions." Breaking Down the Barriers at 3.

3 See Bernard Lo, Karen Rothenberg, & Michael Vasko, Appropriate Management of Pain: Addressing the Clinical. Legal. and Regulatory Barriers, 24 J.L., Med., & Ethics 285, 285 (1996) (" [A]dequate palliation of pain may be likely to reduce requests for physician-assisted suicide."); Robin Bernhoff, How We Can Win the Compassion Debate, Citizen Magazine (June 24, 1996) (noting that "patients often want to die because of under treated pain" and arguing that the response is better palliative care rather than legalization of suicide); Kathleen M. Foley, The

relieving pain and suffering has been a core duty of physicians since ancient times.

Modem medicine has the ability to relieve or reduce suffering caused by nearly all types ofpain.4 Nevertheless, the under-treatment of pain is a serious and wide-spread health issue.5 A lack of public understanding about the nature of pain therapy and overbearing actions of regulatory authorities have combined to impede access to pain treatment, deter physicians from practicing pain medicine,6 chill the legitimate prescription practices of physicians who do treat pain,7 and thereby

Relationship of Pain and Symptom Management to Patient Requests for Physician-Assisted Suicide. 6 J. Pain Symptom Mgt. 289 (1991). See also Washington v. Glucksberg, -U.S ----------, 117 S. Ct. 2258, 2273 (1997) (noting that "many people who request physician assisted suicide withdraw that request if their depression and pain are treated").

4 See Institute of Medicine Committee on Care at the End of Life, Approaching Death: Improving Care at the End of Life 132 (1997) [hereinafter Approaching Death]. The Institute of Medicine is an elite body of medical professionals "chartered in 1970 by the National Academy of Sciences to enlist distinguished members of the appropriate professions in the examination of policy matters pertaining to the health of the public." Id. at ii.

5 Approaching Death at 131.

6 See Hoover v. Agency for Health Care Admin., 676 So. 2d 1380, 1382 (Fla. App. 1996) (noting that physicians avoid treating pain patients "perhaps to avoid prosecutions"); id. at 1381 n.4 ("Many physicians avoid cating for patients who require Schedule II substances to relieve their suffering.").

7 There is a substantial and consistent body of research that indicates that clinicians are deterred from prescribing opioids out of concern that doing so will invite regulatory scrutiny. See, ~, Approaching Death at 195 ("There is still, it seems, an inappropriate sense of distrust on the part of the medical boards [regarding prescription of opioids for pain], which this committee believes has developed, in part, on the basis of misperceptions . . . about the nature and consequences of dependence and addiction. "); Breaking Down the Barriers at 1 0; Russell K. Portenoy, Opioid Therapy for Chronic Nonmalignant Pain: Clinicians' Perspective, 24 J.L., Med., & Ethics 296, 297 (1996); American Society of Addiction Medicine Position Statement (April 1997) ("[P]hysicians' concerns regarding possible legal regulatory, licensing or other third-party sanctions related to the prescription of opioids contribute significantly to the undertreatment of pain."); David Joranson & Aaron Gilson, Controlled Substances. Medical Practice. and the Law, in Psychiatric Practice Under Fire 188 (H. Schwartz ed., 1994); Shapiro, supra note 1, at 363 (noting "fear of legal penalties, especially disciplinary action," as important

I

deny patients in this country their constitutionally protected right to relief from unnecessary suffering. 8

The attitudes that deter the use of opioidanalgesics to treat pain stem from the *mistaken beliefs of the addictive potential* of opioids and our nation's commitment to eradicate drug addiction. While addiction is a hazard in the field of pain medication, it is important to differentiate between opioid addiction, dependence, and tolerance in order better to understand how trained physicians can provide effective treatment for pain while minimizing the risks that atterid opioid therapy.

reason for under-treatment of pain); Undertreatment of Pain Seen as Unintended Effect of Drug War, 9 Alcoholism and Drug Abuse Week 1 (June 23, 1997) (noting that "fear of professional censure by medical review boards and prosecution by the [DEA] . . . prevents doctors from adequately treating dying patients with chronic, severe pain.") (citing Dr. Christine Cassell); Davidson, supra note 5, at 64-67 ("Physicians who would depart from prevailing cultural prqctices [regarding opioid prescription for pain] are quickly penalized, adding fear of repercussions (legal and otherwise) to the list of reasons why physicians may withhold narcotic pain relief."); Sandra H. Johnson, Disciplinary Actions and Pain Relief: Analysis ofllie Pain Relief Act, 24 J.L., Med., & EtHics 319, 320 (1996); Shannon Brownlee & Joannie Schrof, The Quality of Mercy, U.S. News & World Rep. 54,56 (March 17, 1997) (noting doctors' fear of prosecution); Russell K. Portenoy and Richard Payne, Acute and Chronic Pain, in Substance Abuse, A Comprehensive Textbook 563, 582-84 (Joyce H. Lowinson et al. eds., 1997) [hereinafter "Comprehensive Textbook"]. See also Chris Hyman, Pain Management and Disciplinary Action: How Medical Boards Can Remove Barriers to Effective Treatment, 24 J.L., Med., & Ethics 338, 338 (1996); Christine Cassel, Narratives on Pain and Comfort: Dr. M's Story, 24 J.L., Med., & Ethics 290, 290-91 (1996) (discussing case of physician whose suspension from practice for pain medication was reversed).

8 See Robert A. Burt, The Supreme- Court Speaks: Not Assisted Suicide but a Constitutional Right to Palliative Care, 337 New Eng. J. ofMed. 1234, 1234 (1997) (stating that a majority of the Court in Washington v. Glucksberg - U.S. -' 117 S. Ct. 2258 (1997) "effectively required all states to ensure that their laws do not obstruct the provision of adequate palliative care. . . ."); Kathryn L. Tucker, The Death with Dignity Movement: Protecting Rights and Expanding Options after Glucksberg and Quill, 82 Minn L. Rev. 923, 935 (1998).

A. **Tolerance, Physical Dependence, and Addiction**

Tolerance, physical dependence and addiction are three separate terms with distinct medical meanings. Tolerance refers to the body's tendency to become accustomed to a substance such that, over time, more of the substance is needed to produce the same physical effect,9 an effect often observed with respect to the caffeine in coffee or tea, for example. 10 Physical dependence, by contrast, is defined solely in relationship to withdrawal: a person who suffers from withdrawal symptoms when she stops taking a drug is said to be physically dependent. 11 Again, caffeine is a commonplace example: regular tea- coffee-drinkers may experience withdrawal symptoms, typically headaches, if they are deprived of their morning brew. 12

Addiction is a wholly separate phenomenon. 13 Whereas "drug tolerance" and "physical dependence" focus on the pharmacological and physiological effects of drugs, "addiction" refers to the negative or harmful behavioral attributes of a drug user. The identifYing features of addiction are a craving for, compulsive use of, and fixation on, the drug or behavior in question, and

9 Portenoy & Payne, supra note 7, at 563 ("Tolerance is a pharmacologic property of opioid drugs defined by the need for increasing doses to maintain effects.") (footnotes omitted).

10 See *John* F. Greden & Adale Walters, Caffeine, in Comprehensive Textbook 294,295.

11 Portenoy & Payne, supra note 7, at 564 (Physical dependence "is defined solely by the occurrence of an abstinence syndrome (withdrawal) following abrupt does reduction or administration of an antagonist [which strips the drug from the body]."). Many substances, including cortiocosteroids (e.g., hydrocortisone antiinflammatory cream), as well as several of the medications that Appellant prescribed to his patients, can also produce the dual physical phenomena known as tolerance and physical dependence. See Approaching Death at 193; Physician's Desk Reference 1953-54 (51st ed. 1997).

12 See *John* F. Greden & Adale Walters, Caffeine, in Comprehensive Textbook 294,295.

13 See Approaching Death at 193 ("Neither physical dependence nor tolerance should be equated with addiction or substance abuse. ").

the negative personal and anti-social behavior exhibited to satisfy the addiction. 14

As these definitions make clear, tolerance to, and physical dependency on a drug do not necessarily lead to - in fact, seldom lead to - addiction. .Pain patients who undergo opioid treatment often develop tolerance and physical dependence but have little difficulty decreasing or stopping their opioid intake as the pain subsides or disappears. 15

B. Long-term Opioid Treatment for Chronic Pain Is Medically Accepted

The doctor's ethical and professional duty to alleviate pain and suffering must be balanced against the principle that the doctor shall "do no harm." 16 Over the years, practitioners have struck the balance at different places when it comes to prescribing potentially addictive opioids to alleviate pain. For instance, for most of the previous century, surgeons refused patients anesthesia

14 See Portenoy & Payne, supra n.7, at 564 (characterizing addiction as "a psychological and behavioral syndrome in which there is drug craving, compulsive use, and a strong tendency to relapse after withdrawal, [combined with] rumination about the drug and an intense desire to secure its supply"); .id. ("[A]ddiction is a chronic disorder characterized by 'the compulsive use of a substance resulting in physical, psychological or social harm to the user and continued use despite that harm.") (citing AMJ.\ task force). See also 21 U.S.C. § 802(1) ("The term 'addict' means any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction."); Approaching Death at 192-94; Mark S. Gold et aI., Eating Disorders, in Comprehensive Textbook 319; Sheila B. Blume, Pathological Gambling, in Comprehensive Textbook 330 (discussing eating disorders, compulsive gambling, and other non-drug addictive-type disorders).

15 Portenoy & Payne, supra note 7, at 564; Institute of Medicine, Federal Regulation of Methadone Treatment 10 (Richard Rettig & Adam Yarmolinsky eds. 1995) ("The pain patient . . . . will develop tolerance and physical dependence but will not exhibit the illicit or inappropriate drug-seeking behavior."); Joranson & Gilson, supra n. 11, at 182-83; American Pain Society, Principles of Analgesic Use in the Treatment of Cancer Pain (3d ed. 1992).

16 See Shapiro, supra note 1, at 363 (discussing duty to treat pain); Rich, supra note 1, at 235-37 (same); Tom L. Beauchamp & LeRoy Walters, Contemporary Issues in Bioethics 25 (4th ed. 1994) (discussing duty to "do no harm").

during surgery,17 a practice that would today be condemned as barbaric. The perceived harm of opioid therapy for pain patients stemmed from the possibility that the prolonged use of opioid analgesics can lead to the patient's physical or psychological dependence upon the medication, or perhaps even to a full-blown drug addiction. Today, however, there is a strong medical consensus that opioid therapy is a responsible and highly effective method for relieving chronic pain, and that the risk of opioid addiction among pain patients has been greatly overstated. In order to understand the paradigmatic shift in recent decades, a brief history of pain medicine is instructive.

Medicine has understood since the beginning ofthe 20th century that opioids such as morphine can relieve pain but also can also produce tolerance, physical dependence, and addiction in patients. For its part, law enforcement has closely policed the dispensing of opioid drugs to protect against diversion. Physicians who abused their prescribing privileges and acted outside of the legitimate scope of medical practice have traditionally been sanctioned harshly by state and federal authorities. 18 As a result, for much ~fthis century, physicians were quite conservative in their use of opioids to treat even the most obviously needy pain sufferers: terminal cancer patients. Consequently, many cancer victims endured excruciating pain during their final days, weeks, and even years,19 even though doctors had at hand the means to alleviate such pain. In recent decades,

17 See Davidson, supra note 1, at 64-67.

18 See David F. Musto, Historical Perspectives, in Comprehensive Textbook 1, 3-5. See also United States v. Jin Fuey Moy, 241 U.S. 394 (1916); see generally Annotation, Federal Criminal Liability of Licensed Physician for Unlawfully Prescribing or Dispensing "Controlled Substance" Or Drug in Violation of the Controlled Substances Act (21 Uscs & 801 et seq.), 33 A.L.R. Fed. 220 (1997).

19 This state of affairs persisted at least into the mid-1980s. See Astrid James, Painless Human Right: Treatment of Cancer Pain in Developing Countries, 342 Lancet 567,567 (1993) ("In the developed world in 1985 more than 50 percent of cancer patients has unrelieved pain.

however, the tide has turned such that there is firm consensus within the medical profession that the risk of addiction does not justify the withholding of adequate pain treatment for patients facing imminent death.2O

At the same time that this consensus was developing, researchers were growing increasingly adept at fighting cancer through early detection, chemotherapy, radiation therapy, and surgical techniques, all of which dramatically extended the life expectancy of cancer patients.21 These medical advances, however, did not necessarily remove the pain caused by cancer; indeed, some of these treatments themselves - such as chemotherapy - cause considerable pain. The medical community meanwhile was shedding much of its prejudice against treating cancer pain patients with opioids, and so became more willing to provide *non-terminal* cancer patients with opioid therapy, including high doses over extended periods. As the medical community learned that such pain treatment was safe and effective, it was forced to reassess some of its old assumptions regarding opioid therapy.22 First, it became clear that people in pain react differently to opioids than do persons who use opioids to feed a drug habit or addiction. Specifically, pain patients rarely, if ever, experience the sense of euphoria that recreational users do; to the contrary, powerful opioid

Yet cancer pain can be relieved in 75-90 percent of patients with appropriate analgesia."); see generallv John P. Morgan, American Opiophobia: Customary Underutilization ofOpioid Analgesics, in Controversies in Alcoholism and Substance Abuse 163 (B. Stimmel, ed. 1986).

20 See Portenoy & Payne, supra note 7, at 567 ("Opioids are accepted treatment in cancer pain. . . .").

21 See Approaching Death at 34 ("The dying process today tends to be more extended, in part, because medical treatments can control pneumonia, kidney failure, and other immediate causes of death that accompany cancer, heart disease, and other It, slow killers.' It).

22 Russell K. Portenoy, Opioid Therapy for Chronic Nonmalignant Pain: Clinicians' Perspective, 24 lL., Med., & Ethics 296, 296 (1996).

treatment most often produces dysphoria in pain patients. 23 Second, pain patients did not become addicted even after receiving long-term, high-dose opioid therapy.24 In fact, it was found that once the source of the pain was removed, patients voluntarily decreased or stopped altogether their use of opioids, notwithstanding any tolerance or physical dependence they may have developed to the opiates.25 Third, clinicians came to understand that behavior that might suggest drug abuse or addiction in a non-pain patient was not necessarily cause for alarm when exhibited by a pain patient.26 Indeed, a pain patient may exhibit identical behaviors for entirely different (and understandable) reasons: for example, the patient may quite reasonably have learned through experience that one medication works better and has fewer side effects than another; or, the patient may be so apprehensive at the thought of being without pain medication in the event of an acute or prolonged bout that he or she sets aside medication for a future emergency.27

Finally, it is important to bear in mind that non-malignant pain can be just as

23 Portenoy & Payne, supra note 7, at 581.

24 Approaching Death ~t 193 ("Research indicates that addiction in patients appropriately receiving opioids for pain is very small, ranging from roughly 1 in 1,000 to less than 1 in 10,000.") (citations omitted); Portenoy & Payne, supra note 7, at 581; Morgan, supra note 23, at 171. See Samuel Perry & George Heidrich, Management of Pain During Debridement: A survey of U.S. Bum Units, 13 Pain 267,274 (1982); Jane Porter and Hershel Hick, Correspondence, Addiction Rare in Patients Treated with Narcotics, 302 New Eng. 1. of Med. 123 (1980). These numbers are comparable to the rates of addiction in American society as a whole. See Portenoy & Payne, supra note 7, at 581. See also Davidson, supra note 1 (reporting that the evidence to support the "fear that dosages large enough to relieve pain will cause addiction" is merely anecdotal).

25 See Approaching Death at 193.

26 Id. at 194 ("[S]ome behaviors suggestive of addiction may be confused with those resulting from inadequately managed pain or anxiety about the reliability of pain management.")

27 See id.

excruciating and debilitating as cancer pain. Although it is today widely accepted that opiates are appropriate for long-term treatment of non-cancer pain, some physicians view cancer pain as unique and discount the quality and severity of other types of pain.

Yet, as experience makes clear, the etiology of the pain does not necessarily determine the magnitude of the pain or the degree to which the sufferer is debilitated: pain is pain, whether caused by neurological problems, a car crash, or bums. And, although, as mentioned above, drug abuse and addiction are real risks that physicians must try to avert, a fear of these risks rarely justifies withholding opioid therapy from patients where, as in the patients here at issue, their pain is serious and persistent, and office policy and procedures are in place to manage any patient who are diverting or misusing their meds.

II. FACTUAL BACKGROUND OF DOCTOR HURWITZ

Dr. William E. Hurwitz is a well-known practitioner in the medical treatment of patients suffering from chronic intractable pain. It is important to understand that chronic pain patients are not those suffering from transitory or easily treatable causes of pain; they are suffering from long-term pain syndromes that either have been treated unsuccessfully by other methods, or can not practicably be treated by alternative approaches. Only such patients met the screening criteria at Dr. Hurwitz's practice. The vast majority of Dr. Hurwitz's pain patients had previous diagnoses of chronic pain and long histories of treatment by other methods and by other physicians, including other physicians specializing in pain treatment, without success. Examples of patients in his practice were: a multiple amputee suffering from "phantom limb" pain, injury victims suffering from neuropathic (nerve damage) pain, facial disfigurement, or irreparable skeletal injuries, people with multiple back surgeries or implanted appliances that failed to resolve or exacerbated their pain,

people suffering from daily intense headaches, and people suffering from various systemic diseases causing pain, such as fibromyalgia, multiple sclerosis, reflex sympathetic dystrophy, and AIDS. These are chronically and in many cases severely ill people, who have exhausted their other options in the medical system before coming to Dr. Hurwitz. Given their previous medical histories, these patients are candidates for the type of medication therapy used by Dr. Hurwitz, which often involves high dosages of opioid drugs.

A. Previous Regulatory Proceedings

Although ruled inadmissable by the Court, a brief history of Dr. Hurwitz's pain practice is in order in the event this evidence becomes admissible over defense objection. Ironically, much of Dr. Hurwitz's recognition in the field of chronic pain treatment stems from previous regulatory proceedings brought against him by the Virginia Board of Medicine in 1996. In May 1996, the Virginia Board brought disciplinary charges against Dr. Hurwitz alleging that he had "indiscriminately and excessively" prescribed high dosages of opioid drugs to some 29 enumerated patients. The resulting hearings, taking place in June, July, and Au.gust of 1996, attracted extensive local and national media attention, and were the longest disciplinary hearings in the history of the Virginia Board of Medicine to that date.28 Those hearings also proved to be a watershed in changing medical and regulatory attitudes toward the use of high-dose opioid therapy to treat chronic pain.

At the 1996 hearings, Dr. Hurwitz's practice was supported strongly by four nationally-prominent experts in the treatment of chronic pain: (1) Dr. James Campbell of the Johns

28 One reason for the length of the 1996 hearings was that some 50 patients and their family members, out of approximately 220 pain patients at that time, came to Richmond at their own expense to testify on behalf of Dr. Hurwitz, describing Dr. Hurwitz's care and its favorable effects on their quality of life.

people suffering from daily intense headaches, and people suffering from various systemic diseases causing pain, such as fibromyalgia, multiple sclerosis, reflex sympathetic dystrophy, and AIDS. These are chronically and in many cases severely ill people, who have exhausted their other options in the medical system before coming to Dr. Hurwitz. Given their previous medical histories, these patients are candidates for the type of medication therapy used by Dr. Hurwitz, which often involves high dosages of opioid drugs.

A. Previous Regulatory Proceedings

Although ruled inadmissable by the Court, a brief history of Dr. Hurwitz's pain practice is in order in the event this evidence becomes admissible over defense objection. Ironically, much of Dr. Hurwitz's recognition in the field of chronic pain treatment stems trom previous regulatory proceedings brought against him by the Virginia Board of Medicine in 1996. In May 1996, the Virginia Board brought disciplinary charges against Dr. Hurwitz alleging that he had "indiscriminately and excessively" prescribed high dosages of opioid drugs to some 29 enumerated patients. The resulting hearings, taking place in June, July, and Au"gust of 1996, attracted extensive local and national media attention, and were the longest disciplinary hearings in the history of the Virginia Board of Medicine to that date.28 Those hearings also proved to be a watershed in changing medical and regulatory attitudes toward the use of high-dose opioid therapy to treat chronic pain.

At the 1996 hearings, Dr. Hurwitz's practice was supported strongly by four nationally-prominent experts in the treatment of chronic pain: (1) Dr. James Campbell of the Johns

28 One reason for the length of the 1996 hearings was that some 50 patients and their family members, out of approximately 220 pain patients at that time, came to Richmond at their own expense to testify on behalf of Dr. Hurwitz, describing Dr. Hurwitz's care and its favorable effects on their quality of life.

Hopkins Medical School in Baltimore; (2) Dr. Mitchell Max of the National Institutes of Health; (3))

Dr. Russell Portenoy ofthe Memorial-Sloan Kettering Hospital in New York; and (4) Dr. C. Stratton **Hill** of the M.D. Anderson Cancer Clinic at the University of Texas. Even the two opposing pain experts-Dr. Stephen Long of the Medical College of Virginia and Dr. James Manning of the University of Virginia -did not question Dr. Hurwitz's therapeutic intent or good faith, but only the details of his practice and documentation.

All six of those pain experts, on both sides, unanimously agreed on one critical point: that, as a matter of medical science and good medical care *there is no such thing as an "excessive" opioid dosage in the context of chronic pain treatment.* This fact is due to the inherent chemical properties of opioid drugs and the individually variable physiology of the human body. Unlike most other prescription drugs, the commonly-used opioid medications have no known toxic effect on major organs systems, *at any dosage.29* Furthermore, opioids are well-known to produce a "tolerance" effect, which means that dosage must be increased over time to maintain pain-relieving effect. 30

Finally, for reasons not yet fully understood by medical science, there is a huge range

29 Even many common over-the-counter medicines have toxic effects. For example, acetominophen (Tylenol), which is often used in combination with opioid drugs in such products as Percocet or Lorcet, causes liver damage above a certain dosage. Most pure opioid pharmaceuticals do not have such organ-toxicity effects.

30 Along with tolerance comes physical dependence, which refers to the intense withdrawal syndrome suffered by most patients when opioid drugs are stopped or significantly reduced. A popular misconception equates dependence with "addiction," but these are two different things. Dependence is a chemical and physiological fact; addiction is a psychological disease. Thus, while most chronic pain patients are physically dependent, very few are "addicts." *See Virginia Opioid Guidelines* ("Physical dependence is a predictable sequelae of regular, legitimate opioid or benzodiapine use, and does not equate with addiction.")

of variability among individual patients in terms of dosages that will produce adequate pain-relieving effect or limiting side-effects. The upshot ofthese factors is that therapeutic dosage levels of opioid medications are subject to extremely wide ranges of variation, up to 1 ,OOO-fold or more.3l There is no doubt about any of these facts; they have been established by numerous scientific studies over the years, and are now textbook statements of medical science.32 Their implications for standards of medical care also are well-accepted: pain-treating physicians are to follow the principle of "titration to effect," meaning that dosage is increased, without limit, until the patient reports adequate pain controt33 or unacceptable side effects appear; and there is no general ceiling to therapeutic dosage.

31 This does not mean that there cannot be an "overdose" of opioid drugs, but it does mean that whether a given dosage of an opioid drug is too much depends upon the prior experience of a given patient and the patient's established tolerance to the particular drug being used. In an "opiate naive" patient (little or no prior exposure to opioids), relatively modest dosages can be life-threatening by inducing respiratory depression, whereas those same dosages, or many multiples of those dosages, have no adverse effect on a patient who has been consistently taking that drug. Furthermore, tolerance tends to be drug-specific. Although there is some "cross-tolerance" among the opioids, taking one opioid generally does not confer the same degree of tolerance to a different opioid.

Therapeutic response als9 tends to be drug-specific within the opioid group, as the drugs are chemically similar but not identical. Thus, one patient may respond well to a given drug, whereas an otherwise similar patient may received either inadequate pain relief or intolerable side-effects from that drug, but do well with a different opioid.

32 For example, the *Oxford Textbook of Palliative Medicine* § 4.2.3 (Opioid Analgesic Therapy), at 169, contains the following discussion of the prototypical opioid drug morphine:

"[D]ose is tailored to each patient, doses are repeated at regular intervals so that the pain is prevented from returning, and there is no arbitrary upper limit. . .. The dose of morphine may range from 2.5 mg 4-hourly to 2500 mg 4-hourly (or the equivalent in controlled-release tablets) and there are anecdotal reports of much higher doses. This dose range of a thousand-fold or more to achieve the same end-point is remarkable and is not seen in any other area of therapeutics. Dose is titrated against effect, either until control of pain is achieved or limiting side-effects develop."

33 Obviously, medical science has yet to develop an objective "pain meter," so that physicians must rely upon the reports of their patients as to pain relief and many side effects.

The 1996 hearings involving Dr. Hurwitz also called attention to the fact that, as a matter of Virginia state law, there also is no such thing as an "excessive" opioid dosage per se in the context of chronic pain treatment, because the Virginia General Assembly has explicitly so enacted, on several occasions. These statutes are found in both the Virginia Drug Abuse Control Act, Va. Code § 54.1-3408.1, originally enacted in 1988 and amended in 1990 and 1995 to strengthen its protections, and in provisions regulating the practice of medicine in Virginia, Va. Code § 54.1 2971.01, enacted in 1995 to profile the Assembly's intent to protect practicing physicians. These statutes are designed to provide a safe-harbor protection to physicians who prescribe in good faith what the statutes themselves refer to as "excess" dosages of pain-relieving drugs in cases of chronic intractable pain. They are a very explicit statement of the legislated public policy of Virginia that physicians treating chronic pain are not to be criticized for prescribing high dosage levels of opioid drugs.

By the close of the 1996 hearings, the Virginia Board of Medicine accepted these principles of medicine, and Virginia state law. The Board found certain deficiencies in the details of Dr. Hurwitz's practice and documentation, and ordered a 90-day revocation of his license, followed by probation under various conditions, including continuing medical education on several topics and a restriction of his controlled-substance prescribing privileges for a minimum of one year. (Virginia Board Order, August 10, 1996). Over the next year, Dr. Hurwitz worked to satisfy the various conditions of the Board's 1996 order, and he did more. At his follow-up hearing in August 1997, Dr. Hurwitz presented the Board with a written Pain Practice Protocol and accompanying patient consent form, which set forth in detail the standards under which he proposed to re-enter

chronic pain practice. Following extensive consideration on the record at that hearing,34 the Board approved Dr. Hurwitz's Pain Practice Protocol, with some additional requirements, and made it a condition of Dr. Hurwitz's continuing probation that he follow that protocol upon re-entering pain practice. On that basis, the Virginia Board restored Dr. Hurwitz's full prescribing rights under Virginia law, by an order dated August 8, 1997.

In the meantime, however, other developments had intervened to expand the scope of the regulatory proceedings. At the close of the first day of the Virginia Board hearings on June 20, 1996, a dispute had arisen regarding the completeness of the Commonwealth's exhibits purporting to represent Dr. Hurwitz's medical records. In response, the Board, which had entered a summary pre-hearing suspension of Dr. Hurwitz's medical license, ordered that the hearing be adjourned indefinitely, and the summary suspension continued indefinitely.

On June 28, 1996, Dr. Hurwitz and several of his patients commenced a civil action

34 For example, Dr. Karen Knapp, who was then President of that Board and the presiding officer in both the 1996 and 1997 hearings, explained the 1996. order on the record in 1997 as follows:

> "I never felt that. . . there was anything wrong with your intent. I think I felt that there was a problem with your process, that you got overwhelmed, that you got a lot of patients, that you were really trying to help, and along the way, the documentation, the contact, you know, the process effort - I think you laid out a really good process here [in the 1997 Pain Practice Protocol] ... that can benefit a lot of people"

(1997 Conference Tr. 95). This same sentiment independently had been expressed by the judge to whom the state judicial review proceedings were assigned, Hon. Paul F. Sheridan of the Arlington County Circuit Court. *(See* Transcript of Proceedings before the Hon. Paul F. Sheridan, May 8, 1997, at 80-81) ("[I]n . . . total review of the record, the maximum level of factual accusation against the doctor can't be said to reach a bad faith. . .. So one would be hard pressed on a review to find by the burden of proof any standard violation of good faith. . .. Had this just been a good faith argument, I would have granted Summary Judgment [in favor of Dr. Hurwitz].")

in the United States District Court for the Eastern District of Virginia, alleging, inter alia, that the indefinite adjournment violated the Due Process Clause. *Hurwitz, et at.* v. *Hasty, et at., and Three Unknown Named Agents of the Federal Drug Enforcement Administration,* Case No.3: 96CV523 (E.D. Va., Richmond Division). In addition to the state officials, that complaint also named as anonymous defendants three individual employees of the federal DEA, as the evidence already adduced in the regulatory hearing had shown that the Board's disciplinary proceedings had been instigated by those individuals.35 Dr. Hurwitz moved with the complaint for a TRO lifting the summary suspension, and that application was heard on July 3, 1996, by Judge Robert Merhige, who had been assigned to the case for all purposes. Following argument, Judge Merhige gave his preliminary view in Chambers that: "I don't think that the doctor has been treated fairly. . . you can't take people's licenses away from them and not give them a prompt hearing. . . . If you [the Commonwealth] do not give him his hearing by [a date certain], I am going to order his license returned to him." (Transcript of Proceedings before Hon. Robert Merhige, E.D. Va., July 3,1996, at 41-42). On that basis, Judge Merhige temporarily abstained from deciding the TRO application. The state hearing resumed at the promised date, and so that aspect of the case was mooted. However, Judge Merhige also denied motions to dismiss the underlying claims, and stayed the federal case pending completion of the state regulatory proceedings and state judicial review.

35 Though named in the complaint anonymously, the identities of at least two of those three individuals ultimately were revealed and were known to the DEA's management at the time that the subsequent 1998 settlement agreement was reached. These were Kathryn Daniels, and Mary Johnson-Rochee. To the extent that these same individuals, whose personal liability was released as a part of that 1998 settlement negotiated on their behalf by Kord Basnight, Esq., of the DEA's office of General Counsel, had any involvement in initiating the current investigation, we suggest that there is at least the appearance of personal interest, bias, or animus against Dr. Hurwitz.

The federal action remained pending in that same posture in mid-1997, when Dr. Hurwitz applied to the federal DEA for a restoration of his full prescribing rights under federallaw,36 in parallel with the restoration of his prescribing rights under Virginia law by the August 1997 Virginia Board order. During lengthy negotiations over the ensuing months, the DEA linked its action on Dr. Hurwitz's application for an unrestricted federal registration to a settlement of the pending federal action against its employees. That settlement ultimately was reached in June 1998, when Dr. Hurwitz entered into a new agreement with the DEA. **In** addition to dismissing the pending claims against the individual agents, that 1998 agreement laid down certain regulatory conditions under which Dr. Hurwitz would resume and conduct his practice over the three-year term of the agreement, and these conditions should be given particular weight in the United States Attorney's current evaluation of this case. There were three major conditions of significance:

(1) The 1998 DEA agreement incorporated by reference all of the terms and conditions of the August 1997 Virginia Board order, "as if said terms and conditions. . . were fully set forth herein," (1998 DEA Agreement, ~ 1. a), and gave special attention to Dr. Hurwitz's adherence to his approved Pain 'Practice Protocol (and associated patient consent form), and the provisions applicable to out-of-town patients, which were to survive any subsequent dissolution or modification by the Virginia Board of its own order and continue for the full three-year term of the DEA Agreement *(id.)*

36 By an agreement executed in January 1997, Dr. Hurwitz's federal DEA registration had been restricted in parallel with the restrictions imposed by the August 1996 Virginia Medical Board order (prohibiting Schedules II-IV), which were dissolved in August 1997 by the Virginia Board.

(2) The 1998 DEA agreement provided that Dr. Hurwitz's office records were open to inspection by DEA personnel at any time, "without an administrative inspection warrant and without prior written notification" (1998 DEA Agreement, ~ 1.e).

(3) The 1998 DEA agreement required Dr. Hurwitz to submit a quarterly report to the DEA of all of his Schedule II controlled substance prescriptions, "incJuding the date, patient name and address, and the name, quantity and medical purpose" (1998 DEA Agreement, ~ 1.b), and copies of all signed Patient Consent Forms, which included a waiver of patients' medical confidentiality with respect to the regulatory authorities.

As a result of these extraordinary arrangements, Dr. Hurwitz was placed in a unique position as perhaps the most closely scrutinized and governmentally supervised practitioner of medicine in the United States. They certainly show that Dr. Hurwitz provided a very comprehensive degree of openness to and cooperation with federal drug abuse control officials. Every 90 days, the DEA received a log of Schedule II prescription written by Dr. Hurwitz for every pain patient in his practice, replete with names, addresses, dates, quantities, and so forth. The DEA could come to Dr. Hurwitz's office whenever it w~ted and look at whatever it wanted. One would expect-and Dr. Hurwitz had every reason to believe and every right to expect-that this information, together with other information available to the DEA from pharmacy records and other sources, would be used responsibly by the DEA to carry out its mission of preventing drug diversion, and that information gathered by the DEA would be used forthrightly and cooperatively to assist Dr. Hurwitz in preventing patient misbehavior.

Pursuant to the provisions of the 1998 DEA Agreement, Dr. Hurwitz re-entered chronic pain practice on or about July 1, 1998. At that point, Dr. Hurwitz was still on state probation

under the August 1997 Virginia Board order, and both the federal action and state judicial review proceedings remained pending against the state officials and agencies. By the end of 1998, all of these matters were settled. In connection with that resolution, Dr. Hurwitz's resumed medical practice was inspected by a medical board probation officer, who issued a favorable report to the Virginia Board. In its order thereon, dated December 15, 1998, the Board found that Dr. Hurwitz had complied with all terms and conditions of his probation, and had "taken appropriate steps to address all problems identified in the Board's Order of August 10, 1996" (1998 Virginia Board Order, at 2), and accordingly terminated his probation and issued him a full and unrestricted license to practice medicine in the Commonwealth *(id.* at 3-4).

B. **General Developments Affecting Pain Treatment**

During 1996-98, Virginia took a national leadership role, acting together with other states, as well as national organizations, to strengthen the emerging national consensus in favor of high-dose opioid therapy for chronic pain treatment. In 1997, the Medical Society of Virginia issued its *Guidelinesfor the Use ofOpioids in the Management of Chronic, Non-Cancer Pain* (hereinafter the *"Virginia Opioid Guidelines';*. In 1998, those guidelines were approved by ajoint resolution of the Virginia General Assembly, Sen. 1. Res. No. 165, and endorsed by the Virginia Board of Medicine pursuant to a new statute enacted for that purpose, as "providing an appropriate standard of care," Va. Code § 54.1-2912.2. The *Virf5.inia Opioid Guidelines* served as a prototype for other states, and were followed closely by the *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain,* adopted by the National Federation of State Medical Boards in 1998 (copy included as Addendum 6 to Dr. Hurwitz's preliminary memorandum to the Virginia Medical Board).

National professional organizations also had issued similar guidelines.37 All of these guidelines were intended to encourage physicians to treat chronic pain in appropriate cases with high-dose opioid therapy, "without fear of discipline, excessive scrutiny, or remunerative or restrictive legal penalties," *Virginia Opioid Guidelines;* Preamble; *see also* American Medical Association, House of Delegates Resolution H-120.960 ("physicians who appropriately prescribe and/or administer controlled substances to relieve intractable pain should not be subject to the burdens of excessive regulatory scrutiny, inappropriate disciplinary action, or criminal prosecution.")

The movement toward a more enlightened regulatory and legal environment was dealt a temporary setback in 2000, when widespread press reports of OxyContin abuse raised both public attention38 and physicians' concerns of untoward legal action. National groups representing patients and health care professionals joined with senior Justice Department officials in an attempt to allay those concerns.

Finally, and just recently, in August 2004, the DEAjoined with numerous health care groups in issuing a new consensus statement - that is, the DEA Frequently Asked Questions or

.

37 These include a joint consensus statement by the American Academy of Pain Medicine and the American Pain Society, which are the two premiere professional organizations in the United States concerned with the treatment of pain. We note that this statement was approved by the AAPM on June 29, 1996-nine days after the commencement of the Virginia Board hearings involving Dr. Hurwitz-and by the APS on August 20, 1996-ten days after the Virginia Board's 1996 order in Dr. Hurwitz's case.

38 As is often the case with sensational press reports, it now appears that much of the concern over OxyContin was unfounded. Not only did both the FDA and DEA subsequently reaffirm the safety and efficacy of medical OxyContin use, but later scientific research has found that OxyContin abuse in itself was not the exclusive or primary factor in most drug-abuse deaths. *See* Edward 1. Cone, et aI., "Oxycodone Involvement in Drug Abuse Deaths: A DAWN-Based Classification Scheme Applied to an Oxycodone Postmortem Database Containing over 1000 Cases," *Journalof Analytical Toxicology,* Volume 27, pp. 57-67 (March 2003).

"FAQ's," that the Court has ruled are admissible evidence - reaffirming the legitimacy of the use of OxyContin and other opioids to treat chronic pain.

III. DR. HURWITZ'S RESUMED PAIN PRACTICE, 1998-2002

Dr. Hurwitz's resumed pain practice continued for 4-112 years, from July 1998 through December 2002. During that time, he treated a total of 400+ patients for chronic pain. His patients represent a wide demographic spectrum and a variety of underlying medical conditions. They ranged in age from 18 to 74, with a mean and median age of 42. They were about equally divided between women and men. Half of his patients were residents of either Virginia (36%) or Maryland (14%). Slightly less than half(44%) were "local" patients within the meaning of the 1997 Virginia Board order (residing within 50 miles of his office in McLean, Virginia); the remainder were considered "out-of-town" patients, and were required to have local physicians in their home areas. However, many of the local patients also had primary care physicians or co-treating specialists, as Dr. Hurwitz's practice was focused on the medical treatment of chronic pain.

Dr. Hurwitz's practice was based upon the standards articulated in his 1997 Pain Practice Protocol, which had bee'n approved by the 1997 Virginia Board order and incorporated into the 1998 DEA Agreement. In this respect also, Dr. Hurwitz's practice represents an unusual and perhaps unique instance in which both state and federal regulatory authorities had endorsed specified written standards of medical care by a particular physician.

The 1997 protocol and accompanying consent form cover a number of issues, including patient screening and monitoring, patient responsibilities, initiation of therapy, adjustment of dosage, communication with local physicians, and documentation. There was no material deviation by Dr. Hurwitz from the 1997 protocol. Of course, no protocol can be implemented to a

standard of perfection, particularly when its implementation depends in part on the cooperation of others. For example, out-of-town patients' compliance with the local physician requirement was not 100% at all times, in part due to difficulties created by the DEA's "auditing" efforts (discussed below). Furthermore, some issues arose in the course of Dr. Hurwitz's practice that were not resolved definitively by the 1997 protocol, and in those cases Dr. Hurwitz was required to rely upon his best medical judgment in the circumstances as then known to him.

As indicated by the 1997 protocol and in accordance with the medical literature, Dr. Hurwitz's practice involved a wide range of therapeutic dosage levels of opioid drugs and individualized determinations of the drug or combination of drugs that worked best for each particular patient.39 Sufficient data are available to estimate the highest stable dosage for 377 of his patients.40 Those data show that daily dosage levels, expressed in morphine-equivalent units, ranged from a low of 55 milligrams to a high of 12.6 grams, with a mean of2.61 grams and a median of 1.82 grams.41 **In** accordance with the known chemical properties of opioid drugs, dosage adjustment and the development of tolerance tended to be exponential rather than linear.

.

39 Many of Dr. Hurwitz's patients were on a regimen that combined both a "long-acting" drug (such as Methadone, MS Contin, or OxyContin) with a "short-acting" drug (such as oxycodone, hydromorphone, or morphine), in order to optimize overall pain control. This treatment method was considered controversial or at least "unconventional" at the time of the 1996 Virginia Board hearing, but is now accepted and standard medical practice in chronic pain treatment.

40 The remaining patients were either in treatment too briefly to develop a stable dosage estimate, or were not prescribed opioid drugs for their pain.

41 Thus, the upper end of dosages prescribed to Dr. Hurwitz's patients of 12.6 grams per day of morphine-equivalent is about 15% lower than the upper end of the daily dosage range of 15 grams (2.5 grams every 4 hours) of morphine reported in the *Oxford Textbook of Palliative Medicine* (see note, above).

Dr. Hurwitz's practice included extensive efforts to prevent drug abuse and diversion by patients. All patients were instructed, both orally and in writing, on the prohibition of transfer of their medications. By signing the approved Patient Consent Form, patient.s agreed to abide by that condition, among others, and also acknowledged their awareness of the supervision of Dr. Hurwitz's practice by regulatory authorities and their waiver of confidentiality as to those authorities. All patients were monitored on a follow-up and prescribing interval of approximately one month. In accordance with the 1997 protocol, out-of-town patients were permitted to report in writing, on an Interval Report Form, for 2 of each 3 months, and were required to be seen in the office in the third month. Local patients generally were seen monthly or bi-monthly.

When Dr. Hurwitz uncovered definite signs of patient dishonesty or unreliability, he discharged those patients from his practice. Some 17 of his patients were discharged from Dr. Hurwitz's practice on this basis. In accordance with the 1997 protocol, drug abuse, in the sense of urine or blood test results indicating use of illicit substances, was treated differently than diversion. In cases of illicit substance use, patients initially were placed on enhanced supervision and counseled on drug abuse, either by Dr. Hu~witz or by referral to another practitioner. If follow-up testing indicated that illicit substance use had ceased, then the patient generally was retained, with more frequent monitoring. If the initial intervention did not resolve the problem, then the patient would be discharged, referred for drug abuse treatment, or subjected to heightened monitoring.

In other cases, signs of suspected diversion were more ambiguous. This occurred in the cases of four patients who were arrested and charged by authorities with prescription-drug diversion, in three separate episodes. The first two patients, Kevin Fuller and Cindy Horn, were a cohabiting couple, who were arrested and charged in a Virginia state court in Fauquier County,

following the execution of a search warrant at their home in January 200 1. According to the information available to Dr. Hurwitz at the time, the items seized in the search were the patients' own prescriptions and prescribed drugs, and the charges were in the nature of possession with intent to distribute, based upon the quantity of drugs seized from the home of these high-dose patients.

The patients were briefly detained following arrest, and then released on bail. The patients denied any wrongdoing, and Dr. Hurwitz believed them. However, he did not rely only on their word. In addition to his information on the circumstances of the search and pre-trial release, Dr. Hurwitz previously had given these patients blood tests, which showed that they actually were taking high doses of the prescribed medication. Following their pre-trial release, the patients were suffering from withdrawal syndrome, thus indicating that they continued to take the medication. He had treated the patients for over two years without any significant problems, and he believed that the patients would be unlikely to engage in misconduct while charges were pending against them. On that basis, he decided to continue treating these patients pending the disposition of the charges. He did not ignore the pending charges. Instead, he placed both patients on enhanced scrutiny by reducing their follow-up office-visit intervals to 1-2 weeks, attempting to taper their dosage levels, and repeatedly questioning the patients concerning the status of the pending case. Following a continuance in April 200 1, the charges against both patients were dropped by the Commonwealth's attorney at the preliminary hearing stage in May 200 1.

Dr. Hurwitz believed, and continues to believe, that his response in this case, based upon the circumstances as known to him, was correct as a matter of medical ethics and medical care, and fully in accordance with law. His response certainly was honest and above-board. Dr. Hurwitz's decision and rationale in this instance were openly and thoroughly discussed with a representative

of the Virginia Medical Board at a meeting in April 2001, which was attended by a representative of the federal DEA.

The two other episodes were similar. In August 2001, a third patient, Bret McCarter was arrested and charged by state authorities for possession of his own prescribed medications. In this instance also, Dr. Hurwitz had previous blood test results showing that this patient actually was taking very high doses of the prescribed drug, and this patient's physically debilitated condition spinal stenosis, metal rods in his back - is quite unambiguous. Dr. Hurwitz followed the same enhanced-scrutiny protocol in this instance, and this charge also was dropped at the preliminary hearing. A third episode involving the patient Tim Urbani occurred in or about March 2002. In this instance, the patient initially reported a theft of medications from his vehicle. Dr. Hurwitz's approach to such reports was to require the patient to make a police report of the theft. According to the patient's statements to Dr. Hurwitz, he later was arrested by the same officer to whom he had reported the theft, and charged on the basis of the presence in a family vehicle of prescription drugs belonging to his wife, Mary. Shortly after that episode, the patient reported being re-arrested by federal authorities based on the same event. In that instance also, Dr. Hurwitz followed the same protocol of enhanced supervision that he had followed in the previous cases, until the patient was again arrested and detained by federal authorities in June 2002.

In all of these instances, Dr. Hurwitz acted honestly, reasonably, and openly. He hid nothing. These events were recorded in his medical notes, and were discussed openly with regulatory authorities. So far as the circumstances were known to Dr. Hurwitz, in none of these cases was there even an allegation of actual sale or transfer of medications, but only charges of possession-with-intent, based on the quantities of drugs actually prescribed to these patients.

Furthermore, unlike some other cases where police authorities contacted Dr. Hurwitz to verify a patient's status, in none of these instances was Dr. Hurwitz approached by law enforcement personnel with supplementary information or a request for his cooperation. Had he been approached, he could have cooperated with them to ascertain whether the suspicions were founded or unfounded, just as he had cooperated very extensively with the state and federal regulatory authorities.

A. **Cooperation with Authorities, and Non-Cooperation from Authorities**

As discussed above, throughout this period, Dr. Hurwitz had a very close relationship of cooperation with and supervision by both federal and state regulatory authorities, or he thought that he did. For the first six months of his practice, Dr. Hurwitz remained under state probation, and his practice was examined by a medical probation officer before that probation was terminated in December 1998.42 From the. inception of his resumed practice in July 1998, Dr. Hurwitz was performing his duties under the 1998 DEA Agreement, including his quarterly reports to the DEA of each and every Schedule II controlled substance prescription written and his extensive productions of medical records to the DEA at their request.43 He expected that the DEA would use this

42 Although Dr. Hurwitz thus had been granted a full and unrestricted license to practice medicine in Virginia as of January 1999, it now appears that a new investigative file was opened on him by the Virginia Department of Health Professions in or about April 1999, just 4 months later, though this fact was not made known to Dr. Hurwitz until February 2000.

43 The DEA came to Dr. Hurwitz's office in both 2000 and 2001 to request copies of medical records. The 2000 request alone amounted to some 6,000 pages of records regarding some 32 patients, which created an enormous burden on Dr. Hurwitz's small office staff consisting of a receptionist and two nurses, That request was accompanied by a further request that Dr. Hurwitz provide a summary listing of all local and co-treating physicians for all patients in his practice, which he did. In both 2000 and 2001, the DEA representative was accompanied by a representative of the Virginia Medical Board, who in 2000 purported to be investigating complaints received by the Board from pharmacists, regarding 3 or 4 of Dr. Hurwitz's patients, but nonetheless made overlapping document requests of similar scope and volume. Dr. Hurwitz also complied fully with the Virginia Board's requests. A similar scenario occurred in 2001, and

information to assist him in monitoring his patients and prevent drug abuse and diversion. And yet, in this entire period, there is not one single instance in which the DEA provided any feedback of any kind to Dr. Hurwitz regarding the diversion or misuse of his patients' medications.

IV. CONCLUSION

Dr. Hurwitz office was searched by the DEA pursuant to a federal search warrant in November 6,2002. Because of the expected criminal charges, Dr. Hurwitz closed his practice at the end of 2002. He did so under the continued threat of government intervention in the treatment of his patients.

Despite Dr. Hurwitz's best efforts to transfer his current patients to other physicians, many patients were unable to obtain adequate continuity of care, perhaps because of the unfounded stigma that continues to be attached to chronic pain patients treated with opioid drugs, despite years of efforts by regulatory authorities and professional organizations to dispel the prejudice against such treatment in both the public mind and some quarters of the medical profession. Those patients now join the millions of other Americans-estimated by medical literature to range between 30 and 80 million Americans-who are suffering with untreated or under-treated chronic pain, mainly because physicians are in fear of untoward legal action against them if they prescribe therapeutic levels of opioids. This is not a good result for the overwhelming majority - upwards of 90% - of Dr. Hurwitz's patients who are honest and upright citizens who have never misused their prescription drugs, or any drugs, and who simply suffer the misfortune of chronic pain, for which there are safe, effective, and lawful drugs that most physicians are afraid to prescribe.

in 2002. Although the 1998 DEA agreement expired of its own terms in June 2001, Dr. Hurwitz continued to operate under equivalent terms, including an expanded quarterly report, under an agreement with the D.C. Board of Medicine that extended those terms into mid-2003.

This case will highlight the government's overreaching goal- to deny the science of treating chronic pain, and to reinforce the prejudice and mythology surrounding high dose opiod treatment.

RESPECTFULL SUBMITTED,

Patrick S. Hallinan (CSB #33838)
Kenneth H. Wine (CSB #142385)
Hallinan & Wine
345 Franklin Street
San Francisco, CA 94102
(415) 621-7400

Marvin D. Miller (VSB #1101) 1203
Duke Street
Alexandria, VA 22314
(703) 548-5000

Attorneys for Defendant DR.
WILLIAM HURWITZ