

# **SURVIVING AMERICA'S WAR ON DRUGS**

## **A GUIDE FOR PAIN-TREATING PHYSICIANS**

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### **Why a survival guide?**

**Because once indicted, the only thing worse than winning  
your case is losing it!**

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**Disclaimer:** This document is offered tongue-in-cheek fashion. No physician possessed of good judgment and any instincts for self-preservation, who becomes cognizant of the menace represented by the current regulatory situation surrounding the management pain, would actually even consider prescribing opioids in the treatment of chronic pain conditions. In other words, **don't try any of this at home.**

# How To Use This Guide

## General Considerations

Opioids are believed as a matter of faith to be evil, and dangerous. As a result, engaging in pain treatment sets the stage for adversarial actions, in which doctors who prescribe these substances, and pharmacists who dispense them are vulnerable to administrative, civil, regulatory, and criminal prosecutions. A strategy is necessary to identify and educate potential litigants who may otherwise become adverse witnesses in such proceedings. Without such a strategy in place, the health care professional won't be aware of the existence of these potential adversaries until they appear on the witness stand to testify against him, accusing him of getting them addicted, or even of killing their relatives. One shouldn't assume that any part of the following strategy might actually prevent an assault by regulatory or law enforcement personnel. One should instead regard it as insurance, which may provide necessary ammunition with which to defend oneself against such an assault, should it occur.

The following strategy targets the population most likely to become adverse witnesses; the family members of chronic pain sufferers. This is also the population most in need of high quality information regarding opioids and the treatment of chronic pain.

## Logistics

- 1) During the initial visit, or whenever this survival strategy is introduced to your practice:
  - a. Have the patient fill out the "Family Tree" form.
  - b. *After* the form has been filled out, present the patient with an informed consent document for each family member named in the family tree. This sequence of events is essential, so that the purpose of the family tree form does not become apparent, to patients who might otherwise choose to conceal the existence of family members opposed to the use of opioids in the treatment of chronic pain. (These are exactly the individuals who must be identified, and educated.)
  - c. A tracking system must be implemented in order to assure that each consent form is returned, along with a copy of the relative's photo ID to verify that the signature is not forged.
- 2) Testimonial letters must initially be obtained from all identified family members, at monthly intervals. This interval can be lengthened after treatment has stabilized. Testimonial letters serve several purposes:
  - a. Every family member stays on board with the treatment.
  - b. Each member recommits himself to report any concerns to the practitioner.
  - c. Any problems that develop can be promptly addressed.

- d. The manufacturing of testimony after hostilities begin is thwarted.
- 3) This approach can be a double-edged sword, and care must be taken so that it doesn't backfire. Plaintiffs' attorneys and prosecutors will seize upon any perceived inconsistency. Consequently, any response to concerns expressed by a family member must be fully documented, along with whatever was done to resolve them. Otherwise, later it will appear that the practitioner ignored the problem. A letter from the concerned family member explaining that his concerns have been resolved must be obtained. Around this sort of occurrence, the interval between testimonial letters should revert to one month, and remain there until such time as the situation has again stabilized.
- 4) The urine screening and blood-testing program described below should be adopted.
- 5) Back up all records to another location, preferably on rented Web space, from which it can be retrieved if the originals are lost, destroyed, or seized.

### **Inconvenience**

Objections to this approach will arise, provoked by concerns about the amount of work it seems to entail. This effort will be well rewarded if a case ever ends up in the courtroom. Additionally, the strategy is implemented largely by clerical staff, and consists mainly of forms to be filled out on a regular basis, and of laboratory studies to be ordered periodically.

### **Ethical Considerations**

The strategy outlined above raises ethical questions around the issues of patient privacy, and autonomy. Acting out of purely idealistic considerations isn't realistic given the current regulatory climate. Only a practical approach, makes any sense, at least until society sees its way clear to repair the damage that the war on drugs has done to the physician-patient relationship, and to remove the threat of unwarranted prosecutions directed against conscientious professionals.

# THE FAMILY TREE

Relationship	Name	Age	Alive	Dead
Spouse				
Grandparents				
Parents				
Children				
Aunts/Uncles				
Cousins				
Friends				

# TESTIMONIAL LETTER

## CONCERNING THE PAIN TREATMENT

OF \_\_\_\_\_

I am writing to describe my impressions of the pain management in this patient whom I have had contact with \_\_\_ times over the last \_\_\_\_\_ .

1. Relationship to patient: \_\_\_\_\_.
2. Length of time known: \_\_\_\_\_.
3. Condition prior to treatment:  
Work: \_\_\_\_\_.  
Sleep: \_\_\_\_\_.  
Relationships: \_\_\_\_\_.  
Mood: \_\_\_\_\_.  
Mobility: \_\_\_\_\_.
4. Improvements noted with treatment:  
Work: \_\_\_\_\_.  
Sleep: \_\_\_\_\_.  
Relationships: \_\_\_\_\_.  
Mood: \_\_\_\_\_.  
Mobility: \_\_\_\_\_.
5. Comments:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_.

I agree to notify Dr. \_\_\_\_\_ if I become aware of any problems developing from the above patient's treatment such as abuse of medications or other substances, or if I change my mind, or develop any reservations about the benefits of this treatment. I also agree to notify the doctor if I become aware of any improper or illegal activity involving this patient's treatment, such as giving, lending, or selling of medications, or if I become aware of any such activity involving Dr. \_\_\_\_\_'s practice or any of his other patients.

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(Signature)

# INFORMED CONSENT DOCUMENT

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## Basic Information

### Chronic Pain

Chronic pain is a progressive disease of the nervous system, caused by failure of the body's internal pain control systems. The disease is accompanied by changes in the chemical and anatomical makeup of the spinal cord. Chronic pain is a malignancy, in the sense that when it goes untreated, it increases in intensity and spreads to areas that weren't previously affected, damaging the sufferer's health and functioning.

### Goals of Treatment

Lowering of pain levels.

Reducing suffering through restoration of functioning in life activities, as close to normal as possible.

Arresting and reversing the damage done by chronic pain to the nervous system and overall health of the patient.

### Opioids

Opioids are substances naturally produced within the body to regulate pain. The public knows them as endorphins, which produce a state of euphoria called the runner's high. Chronic pain victims, who can't produce enough of these substances within their own bodies, often benefit from supplementation with pharmaceutical opioids.

Opioid analgesic medications are recognized by medical boards around the

country as the cornerstone of treatment in chronic pain. Unfortunately, their use is limited by widely held, but mistaken, beliefs about their dangers, most of which are wildly overstated.

The principal opioid medications are: Morphine, Oxycodone (OxyContin), Hydrocodone (Vicodin, Lortab), Hydromorphone (Dilaudid), Methadone, Fentanyl (Duragesic, Actiq), and Codeine.

### Addiction

Addiction is defined as, cravings for a substance, compulsive use, and *continuing use in spite of harm*. It is widely feared that exposure to opioids will lead to addiction. Research projects, such as the Boston Collaborative Study, involving over 10,000 patients treated with opioids, reveal that this is not the case, and that addiction to opioids in pain patients is rare.

It is apparent when a chronic pain victim is addicted to opioids. If the drugs make the patient's life better by controlling his pain, he is a pain patient. If they make his life worse, and use continues, addiction may be suspected. This distinction is not subtle.

### **Dependence**

Dependence occurs in most patients who regularly use opioids, but is not a sign of addiction. It is a physical reality, signifying that a patient using opioids is likely to have a flu-like withdrawal reaction if he discontinues the medication abruptly. If opioids are to be discontinued, gradually tapering the dose, rather than stopping the medication suddenly can prevent this syndrome.

### **The Therapeutic Trial**

An implication of the above information is that opioids can be tried in the treatment of chronic pain, and safely withdrawn if they are not useful, or if problems arise.

### **Respiratory Depression & Tolerance**

When an individual unaccustomed to opioids, ingests too large a dose it can slow or even stop breathing. But when a patient's dose of opioids is raised gradually utilizing a process known as titration, tolerance builds, and he can eventually take amounts that would kill a person not accustomed to these dosages. Pain stimulates breathing, making respiratory depression even more unlikely in pain sufferers.

Tolerance also quickly develops to the "high" caused by opioids. Within a couple of days, or weeks the patient returns to feeling completely normal, although he may be taking enormous doses of medication.

### **Getting High**

Government sponsored research at the National Institute of Drug Abuse has determined that the majority of normal volunteers do not enjoy opioids.

### **Titration to Therapeutic Effect**

This phrase describes the process of gradually increasing the dose of opioids until pain is controlled, and the patient reaches his best level of functioning. In patients who have been debilitated by pain for months or years, this process may go on over an extended period of time.

Many patients require a variation in their dosage from day to day, depending on their pain levels and activities. In this sense, pain is a moving target, which requires ongoing mini-titrations both upwards and downwards. Once a general dosage range is established, it is likely to remain stable over long periods of time.

### **Dosage**

The range of possible doses needed to control pain varies from one patient to another, more than it does with any other drug in the entire field of medicine. This means that some patients will require dosages of a size that is staggering to the uninformed observer. Dosage has nothing to do with addiction, and does not increase any risk that might be associated with opioid treatment.

The amount of medication that allows optimal functioning is the correct dose. **There is no upper limit to the dose of opioids that can be safely used**, as long as the medicine is increased gradually.

### **Safety**

Overall, opioids are the safest analgesics a doctor can prescribe. When they are used as directed serious problems are rarely encountered.

### **Toxicity**

Opioids are not toxic to any organ system in the body. They do no damage, even with long-term use. A possible exception is the suspicion that high dose methadone may provoke cardiac arrhythmias in susceptible individuals.

### **Side Effects**

Opioid medications may cause a variety of side effects, including, but not limited to, nausea, vomiting, dizziness, constipation, sedation, dry mouth, fluid retention, weight gain, weight loss, suppression of the immune system, suppression of thyroid function, suppression of menstrual cycle, suppression of male hormone, itching, and allergic reactions.

### **Diversion**

Opioids are dangerous when they are diverted into the hands of non-patients who intend to abuse them. These individuals are not protected against the respiratory depressant effects of opioids, by either tolerance or pain, and are likely to combine them with respiratory depressants, including alcohol and tranquilizers. The results can be tragic. The majority of deaths attributed to opioids occur in non-patients who have deliberately abused a combination of the above substances.

### **Security**

For the above reasons, the bulk of a patient's supply of opioids must be kept locked in a safe and never given, sold, or traded to anyone else.

### **Driving**

When opioids are taken on a regular schedule tolerance quickly develops and the psychological "high", if there ever was one, vanishes leaving the user feeling completely normal. Long-term opioid users as a group have driving records for accidents and violations that are the same as everyone else's.

### **Pain Relief & Functioning**

Opioids reliably reduce pain levels in chronic pain sufferers, however they seldom make the pain go away completely, as regularly occurs in patients with acute pain. Patients can endure this residual pain, as long as their dose of opioids is titrated up to a level where they can function. Improved functioning is the major benefit derived from the effective treatment of chronic pain. This reduces suffering.

### **Death and Opioids**

Deaths caused by opioids, among patients who take them as prescribed are virtually unheard of.

# CONDITIONS FOR TREATMENT

## Social, Financial, and Legal Issues

I understand that my involvement with opioid treatment will expose me to the following medical, financial, social, and legal risks, and possibly other unstated risks as well.

Patients relying on insurance reimbursement for medication expenses are subject to denial of coverage based on allegations that the treatment is not medically necessary, or that it is unconventional

Chronic pain and opioid therapy may lead to family disagreement regarding the propriety or economic value of treatment, possibly resulting in divorce or estrangement from family members.

Employers or regulatory authorities may view opioid therapy as a disqualification for certain kinds of work.

Pharmacists and other health care workers may stigmatize patients on opioid therapy as addicts. Possession of opioid medications may make patients a target for robbery or police investigation.

I understand that Dr. \_\_\_\_\_ 's practice operates at the discretion of the regulatory authorities and that his licenses to practice medicine and to prescribe controlled substances may be suspended without warning. Under such circumstances, there may be no medical facility willing to continue treatment as prescribed by Dr. \_\_\_\_\_, and patients may then be subject to the risk of acute opioid withdrawal.

## Addiction

I am aware that opioids have some potential to be addictive and am willing to take that risk, as long as I feel the benefits of treatment in my situation outweigh the risks. I understand that if I do become addicted, this is a treatable condition, and I have the right to request and be referred for treatment. I am aware that addiction is defined as the continuing use of a drug or activity in spite of harm, cravings, and a decreased quality of life. I am aware that the chance of becoming addicted to my pain medicine is very low. I agree to tell my doctor my complete and honest personal drug history and that of my family to the best of my knowledge. I agree to immediately report any psychological cravings I may experience for the substances with which I am being treated, as well as to report any adverse consequences or side effects of their use. I agree to report to Dr. \_\_\_\_\_ any use or desire to use controlled substances for other than their intended purpose. This could include recreation, relief of stress, or getting high.

### **Dependence**

I understand that physical dependence is an expected consequence of using opioids, and is not a sign of addiction. I understand that physical dependence on opioids means that I may have a flu-like withdrawal reaction if the medication is ever abruptly discontinued. This withdrawal reaction is preventable by tapering the dose of medication gradually, should it become necessary or desirable to discontinue treatment.

Abrupt opioid withdrawal means that I may suffer from any or all of the following: increased pain, depression, muscle cramps, irritability, nausea, vomiting, sweats, chills, runny nose, yawning, large pupils, goose bumps, abdominal pain and cramping, diarrhea, irritability, aches throughout my body and a flu-like feeling. I am aware that opioid withdrawal is uncomfortable but not usually life threatening. In some individuals, severe withdrawal reactions may be life threatening.

I understand that these medications may be safely discontinued, when tapered slowly and that even gradual discontinuation may lead to increased sensitivity to pain. I understand that if I am pregnant or become pregnant while taking opioid medications, my child would be physically dependent on opioids at the time of birth, and withdrawal could be life threatening for the baby, if not properly managed medically.

### **Side Effects**

I understand that opioid medications may cause a variety of side effects, including, but not limited to, nausea, vomiting, itching, dizziness, constipation, sedation, dry mouth, fluid retention, weight gain, weight loss, suppression of the immune system, suppression of thyroid function, suppression of menstrual cycle, suppression of male hormone, itching, and allergic reactions. High dose methadone is

suspected of causing irregular heartbeat, which can be life threatening.

### **Titration/Tolerance/Safety**

I understand that with gradual titration and continued use I may develop tolerance, which will allow me to take dosages of opioids that would most likely kill an opioid naïve individual, and I understand that these large dosages are safe, as long as they are not combined with overdoses of alcohol or tranquilizers.

I understand that if I do not take opioids for a period of time, possibly as short as a few days, this tolerance can be lost, and returning directly to my previous dose can be lethal. Another gradual titration may be required.

I am aware that tolerance to analgesia means that I may require more medicine to get the same amount of pain relief. If tolerance occurs, increasing doses may or may not be effective, and may cause unacceptable side effects. On the other hand, titration is very often effective in controlling pain. The most common reason for needing a higher dose is increased physical activity. Greater pain may also signal the progression of an underlying disease.

### **Other Medical Conditions**

I understand that certain chronic medical or psychiatric conditions, such as insulin-dependent diabetes, inflammatory bowel disease, sleep apnea, epilepsy, depression, and panic disorder, among others, may increase the risk of opioid therapy and complicate the process of opioid withdrawal.

### **Drug Interactions**

I am aware that certain other medicines such as nalbuphine (Nubain™), pentazocine (Talwin™), buprenorphine (Buprenex™), and butorphanol (Stadol™), may reverse the action of the medicine I am

using for pain control. Using any of these other agents while I am taking my pain medicines can cause symptoms like a bad flu, called a withdrawal syndrome. I agree not to take any of these medicines, and to tell any other doctors that I am taking an opioid as my pain medicine, and as a result can't take any of the medicines listed above.

### **Other Medications**

I understand that opioids may be prescribed alone or in combination, and that they may be supplemented with other classes of medications, such as stimulants, tranquilizers, muscle relaxants, laxatives, anti-histamines, anti-nausea medications, or anti-depressants.

I understand that the effects of sedatives, muscle relaxants, and mind-altering medications or chemicals may be dangerously increased when administered to a patient on opioid medications. I agree to inform other physicians as to which medications I am taking and to request that they consult with Dr. \_\_\_\_\_ or his associates, regarding the co-administration of medications that may affect alertness or consciousness.

I will check with Dr. \_\_\_\_\_ before taking any over the counter medications. Some are known to have adverse interactions with the medications I may be taking.

### **Unused Medication**

I agree to bring any medication I will not be using; in for destruction under observation by Dr. \_\_\_\_\_ or his staff and that this event will be noted in my chart. Medications will never actually be returned to the doctor.

### **Tylenol**

I am aware that there is a risk of liver and possibly kidney damage associated with the use of Tylenol (acetaminophen), and I

understand that the risk is small except in individuals who deliberately overdose. Periodic liver function testing of GGTP can determine if there is a potential problem in patients using Tylenol regularly.

### **Alcohol & Overdose**

I agree not to drink alcohol to excess, with the understanding that the majority of deaths caused by so called opioid overdoses actually occur in combination with overdoses of alcohol and other central nervous system depressants such as Valium, Xanax, and barbiturates.

### **Marijuana (In states where this applies)**

I agree not to use marijuana without the approval or recommendation of a licensed physician, and then only for medicinal purposes.

### **Pharmacy**

I agree to fill all my prescriptions at only one pharmacy, whenever this is possible, because this promotes a better quality of care.

### **Other Providers**

I agree to report any contact with other health care providers to Dr. \_\_\_\_\_, including visits to the emergency room and encounters with mental health care providers.

### **Storage of Medications**

I agree to keep my medication in a safe, except for what I may carry to be used throughout the day. I will provide proof of this in the form of a receipt for the purchase of a safe, or a picture of the safe itself. This provision is to keep medication from falling into the wrong hands, where it can be dangerous.

### **Social Responsibility**

With the understanding that opioid treatment for chronic pain remains controversial, I agree to represent the issue well by being a good and productive citizen. If I remain too disabled to maintain or return to full time employment I will at least engage in some socially productive activity, such as volunteer work.

### **Senate Bill 402 (California Patients)**

I have been informed as a patient with chronic intractable pain, in accordance with California law, that if Dr. \_\_\_\_\_ chooses not to treat my pain with opioid analgesics, there may be other doctors who will.

### **(Females Only)**

If I plan to become pregnant or believe that I have become pregnant while taking this pain medicine, I will immediately call my obstetric doctor and this office to inform them. I am aware that, should I carry a baby to term while taking these medicines, the baby may be physically dependent upon opioids. I am aware that the use of opioids is not generally associated with a risk of birth defects, however birth defects can occur whether or not a mother is using medications.

### **(Males only)**

I am aware that chronic opioid use has been associated with low testosterone levels. This may affect my mood, stamina, sexual desire, physical, and sexual performance. I

understand that my doctor may check my blood in order to determine if my testosterone level is normal.

### **Illicit Drug Use & Reporting**

I agree not to participate in the use of, or in any activity involving illegal drugs, and to inform Dr. \_\_\_\_\_ if I become aware that any of his other patients are involved in these activities. If I happen to use illegal drugs or abuse any substance I will inform Dr. \_\_\_\_\_ immediately, so that appropriate treatment can be arranged.

### **Drug Screening**

I agree to random drug screening. I authorize this clinic to test my blood, urine, or hair, for the presence of illicit substances and for non-prescribed medications, without prior notice, and agree to submit to psychiatric or drug abuse evaluation should the clinic staff request it.

### **Diversion**

I agree not to sell, give, trade, or otherwise transfer any controlled substance to any other individual, as this activity constitutes a sale of drugs, and is a felony. I further understand that if someone were to die as the result of such a transaction I could be charged with manslaughter or even murder, as well as drug dealing.

### **Snitching**

I am aware that the government routinely engages patients to testify against pain doctors whom they suspect of being drug kingpins. I agree to immediately disclose any concerns to Dr. \_\_\_\_\_, if I suspect that he is simply prescribing drugs for profit, or doing anything else improper, and to leave his practice immediately if I am not satisfied that he is engaged in the good faith practice of medicine. In agreeing to this, I am making it clear that if I attempt to make such assertions at a later date, I have simply been set up to do this because

of other trouble I have gotten myself into, and that whatever I say along these lines is likely to be entirely contrived and self serving.

### **Treatment Adherence**

I agree to comply with all orders for lab testing, x-rays, and treatment, and to notify Dr. \_\_\_\_\_ if there is some reason I cannot follow through with any aspect of my care in a timely fashion.

### **Pill Counts**

I agree to unannounced counts of my medication.

### **Law Enforcement**

I agree to report any arrests, convictions, or other contact with law enforcement to Dr. \_\_\_\_\_.

### **Integrity**

I agree not to lie to Dr. \_\_\_\_\_ or to withhold any information, which might impact my treatment or his practice.

### **Dangers & Driving**

I understand that the medications used to treat pain may impair alertness and coordination, primarily during the days following the introduction of a new medication, or when a dose has been recently increased.

I will not be involved in any activity that may be dangerous to me or to someone else, if I feel drowsy, or am not thinking clearly. Such activities include, but are not limited to using heavy equipment or a motor vehicle, working at unprotected heights, or being responsible for another individual who is unable to care for himself or herself.

It is illegal to operate a motor vehicle while the ability to drive is impaired by

medication, and I agree to comply with such prohibition.

### **Privacy**

I give my consent for Dr. \_\_\_\_\_ to discuss my care with other practitioners and pharmacists who are, or who have been involved in my treatment. This consent will be in force until revoked in writing.

With the understanding that pain and its treatment are issues that involve entire families, I give consent for Dr. \_\_\_\_\_ to discuss my treatment with my family members. This consent will be in force until revoked in writing.

### **Nature of the Treatment Alliance**

I understand that I am entering into a progressive doctor patient relationship, based on the concepts of teamwork and shared decision making, and that such a relationship requires my informed participation. I will do my best to remain informed, and to continue to learn about all aspects of pain management in order to participate actively and productively in my care.

### **Exclusivity**

I agree not to obtain pain medications from any provider other than Dr. \_\_\_\_\_, except on an emergency basis. If this occurs I will notify Dr. \_\_\_\_\_ at the first opportunity.

### **Reciprocity**

I understand that the above clause conversely entitles me to pain management sufficient to assure my optimum functioning. I will be expected to report accurately on the effects of my treatment. This will include level of functioning, side effects, and whether or not I am receiving enough pain medication to achieve treatment goals.

### **Understanding**

I have read this form or have had it read to me, and I understand all of it. I have had all of my questions regarding this treatment answered to my satisfaction.

### **Termination**

Either party may terminate this agreement at any time and for any reason.

# PATIENT AGREEMENT

I have suffered from chronic pain for \_\_\_\_ years.

The decision to attempt this form of treatment was made because my condition is serious, and other approaches have not cured my pain. These include:

Surgery \_\_, Physical Therapy \_\_, TENS \_\_, Biofeedback \_\_, Pain Clinic \_\_, Implantable Device \_\_, Relaxation Techniques \_\_, Other Modalities \_\_\_\_\_

\_\_\_\_\_.

I understand that opioid treatment for chronic pain is the subject of social controversy. There is significant disagreement regarding the propriety and morality of this treatment, in spite of the fact that the scientific literature on this subject makes it clear that there is at least a subset of patients suffering from chronic pain who appear to do quite well on this treatment, but no other. I believe that I am among those who can benefit from this treatment.

I understand that the doses of medication prescribed are likely to be significantly higher than doses customarily prescribed for short-term pain management, and that other physicians, pharmacists, and medical facilities unaccustomed to this treatment may object, and refuse to continue this treatment, should I choose or need to seek it elsewhere.

By signing this agreement, I voluntarily give my informed consent for the treatment of chronic pain with opioid analgesic medications.

Signatures:

\_\_\_\_\_  
(Patient)

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(Doctor)

\_\_\_\_\_  
(Date)

# SPOUSES & FAMILY MEMBERS AGREEMENT

1. I have read and understood the above information concerning treatment of chronic pain with opioid analgesic medications.
2. I am in agreement with of the conditions of treatment listed above, and further agree to inform Dr. \_\_\_\_\_ immediately if I become aware that any of them are being violated.
3. I specifically understand that chronic pain is a disease of the nervous system, which carries serious and progressive adverse health consequences for the victim, when allowed to progress unchecked.
4. I understand that addiction is a psycho-behavioral disorder involving cravings for a substance or activity, along with self-destructive behavioral manifestations including repeated use of the substance in spite of adverse consequences. I am particularly aware of the low incidence of addiction to opioid medications among pain patients, and I understand the difference between dependence and addiction.
5. I am also aware of the low incidence of respiratory depression in pain patients who use opioids, and aware of the facts that patients are protected against this occurrence by their pain, which stimulates respiration, as well as by tolerance developed through regular exposure to opioids. I understand that if a patient combines their opioid medication with overdoses of alcohol or tranquilizers, there is significant risk of respiratory depression and death, and that the vast majority of opioid related deaths occur in this fashion, in non-patients.
6. I am aware that Dr. \_\_\_\_\_ is available to answer any questions or concerns not fully explained by the above information, and I have availed myself of that opportunity to my own satisfaction prior to signing this document.
7. I agree to notify Dr. \_\_\_\_\_ immediately if any problems occur or if I develop any reservations or questions about this treatment in the future.
8. With the above facts and conditions in mind, I am comfortable with the idea of \_\_\_\_\_ participating in a comprehensive pain management program which may include the use of opioids, as well as a variety of other medications and treatment modalities.
9. A copy of my photo ID accompanies this document.

Relationship to Patient: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Age: \_\_\_\_

DOB: \_\_\_\_ \_\_\_\_ \_\_\_\_

SS#: \_\_\_\_\_

Signatures: \_\_\_\_\_  
(Family Member)

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(Doctor)

\_\_\_\_\_  
(Date)

# Pain Evaluation Interval Form

1. Are you experiencing any side effects from your medication? Please circle. Constipation Nausea Itching Somnolence Other:

\_\_\_\_\_

2. Please rate your pain numerically since your last visit:

Average: 1 2 3 4 5 6 7 8 9 10

Maximum: 1 2 3 4 5 6 7 8 9 10

Minimum: 1 2 3 4 5 6 7 8 9 10

3. Please rate your functioning in these aspects of your life as they may be compromised by pain:

Sleep: 1 2 3 4 5 6 7 8 9 10

Exercise: 1 2 3 4 5 6 7 8 9 10

Social: 1 2 3 4 5 6 7 8 9 10

Mood: 1 2 3 4 5 6 7 8 9 10

4. Please give a percentage to rate the overall effectiveness of you pain control: \_\_\_\_\_%

5. Are you receiving enough pain medication?

6. Are you aware of anyone diverting or abusing their medication?  
\_\_\_\_\_Yes \_\_\_\_\_No (Your responses will be kept confidential)

7. Do you have any suggestions or questions concerning your pain care?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Name)

\_\_\_\_\_  
(Date)

# BLOOD AND URINE TESTING OF PAIN PATIENTS

## Introduction

Lab testing of pain sufferers has become widespread because doctors have been recruited into the role of drug diversion investigators. Surprisingly, when a doctor is prosecuted, the presence of a testing program is not accepted as evidence that he attempted to detect addiction, and limit diversion. Instead, lab results are nitpicked by government experts, whose testimony is then employed by prosecutors, intent on demonstrating that the testing program was a sham, intended to disguise the doctor's drug dealing behind a veneer of medical practice.

Interpretation of test results is complicated, and failure to do so competently can result in disaster for the legitimate patients whose treatment may be terminated as a result. Additionally, if not executed perfectly, the presence of a drug-testing program may unwittingly assist prosecuting attorneys in convicting a doctor they have mistakenly targeted for prosecution as a drug dealer.

## Interpreting Laboratory Results

Every result returning from the laboratory should be reviewed with skepticism regarding its accuracy, and each value must be interpreted in the context of the patient's entire clinical picture. Results departing from the expected should receive scrutiny, with consideration given to any pharmacological, metabolic, or laboratory variables that may have influenced the outcome.

## Quantitative Variations

Because of individual variation in absorption and metabolism of opioids, it is impossible to know what a patient's blood level of a particular medication should be, without performing repeated testing. Quantitative levels are only meaningful if a patient is *observed* taking a known dose of medication, prior to obtaining a sample.

The key to sorting out quantitative errors is repetition of any suspect value, while maintaining as much control over the circumstances as possible.

## False Negatives and False Positives

In addition to the possibility of being too high or too low, lab results can also be completely wrong. Urine drug screens negative for opiates often occur, because this test is fairly sensitive for opiates such as morphine, codeine, and heroin, but is not specifically designed to pick up the synthetic opioids, such as hydrocodone, oxycodone, and meperidine.

Many legitimate pain patients have been unfairly excluded from pain treatment because of a false negative on a urine drug screen for opiates.

A negative screen for opiates exposes the treating physician the risk that it will later be used against him in a courtroom. The accusation will be that he continued to prescribe opioids, and in doing so contributed to drug diversion, by supplying a patient whom he should have known wasn't taking the prescribed medication.

The way to prevent the above accusation is by obtaining concurrent blood opioid levels every time a urine drug screen is ordered. This serves as a cross check, which dramatically reduces the rate of false negatives.

It should be kept in mind that negative urine opiate screens frequently result from under treatment of pain. This occurs because the current standard of care for pain management requires pain patients who run out of medication "early" to suffer in silence, so as not to appear to have engaged in unsanctioned dosage escalation.

## Prodrugs

Certain opioids are not effective in the form in which they are taken, and must be converted within the body into substances that treat pain. Codeine and hydrocodone are the most common examples. Codeine is converted primarily to morphine, and hydrocodone is converted to hydromorphone. Not every patient has the enzymes required to perform these metabolic conversions. This must be kept in mind, as it carries implications for what substances will be detected upon testing.

### **Metabolic Conversion**

A patient taking codeine can be expected as a result of metabolic conversions, to have both morphine and hydrocodone in his urine and blood. As a consequence, if an unexpected substance appears on testing it is necessary to consider the metabolic pathways that may have produced it, prior to accusing the patient of stepping outside of the therapeutic relationship, and imposing sanctions against him for a transgression that may turn out to be imaginary.

The body converts carisoprodol (Soma) to meprobamate. This is significant, because carisoprodol is a common and effective neuromodulator, often used as an adjuvant in the treatment of chronic pain.

The presence of any substance, other than what the doctor prescribed, or the absence of any substance he did prescribe, must be fully explained in the medical record. Otherwise, this apparent failure will be offered in the courtroom as evidence of drug diversion, about which the treating physician either knew, or should have known.

### **Urine Opioid Levels**

Urine opioid levels are nearly worthless, because these substances tend to be concentrated in the urine. High urine opioid levels say more about the duration of treatment and the concentration of the urine, than they do about the dose of medication taken, or blood levels achieved.

### **Recommended Strategy**

In the current climate of regulatory oppression, the sane response is not to prescribe controlled substances, but if one feels ethically obligated to do so, these are some suggestions:

Order blood levels for every drug prescribed, as well as for that drug's known metabolites

Obtain urine drug screens concurrently.

Obtain blood levels of opioids at every step in titration.

Test often.

Conduct your drug-testing program by ambush.

### **Ambush**

Prosecuting attorneys will argue that positive blood and urine tests are worthless in the detection of diversion, because the patient who was diverting all along, only took their medication to fool the testing program. For this reason, it is necessary to conduct a testing program by ambush. Preferably samples are obtained in the office. A second option is to require the patient to go immediately to the lab following their appointment.

Blood levels obtained in this surprise fashion can be later crosschecked by having the patient bring in their medications, so that they can be observed taking their prescribed dose, followed by testing for blood levels. If a rise occurs, don't jump to any conclusions concerning malfeasance on the part of the patient, because experienced patients typically don't use their medications in the exact way it is prescribed.

### **Test Everyone**

If only part of the patient population is tested, a prosecutor may assert that this is evidence that the provider knew these patients shouldn't have been treated in the first place.

### **Decision Making & Follow-up**

All decision making, and the resulting plan of action must be clearly documented in the medical record. Otherwise, it will be second-guessed by prosecuting attorneys, and the experts they hire to nitpick through every element of the medical record. One must assume that the expert who will be reviewing your charts is completely ignorant about the meaning of lab test results, but that he will think he knows everything. Guys like this are dangerous.

# Applying The Standards

## Overview

One must understand that investigators and prosecutors do not have your best interests at heart. Never underestimate their power. They are good at what they do, and once you are targeted for prosecution, your conviction becomes their work product. Their job is to put you in prison for as long as possible. In order to accomplish this, they require evidence. Law enforcement typically obtains this evidence by hiring an expert to review medical records with an eye for deviations from the standard of care.

For this reason, it is essential to be intimately familiar with the standards, because any perceived deviation can result in being targeted for prosecution, and will be employed as evidence of criminal intent in the ensuing matter. The standard of care includes the following elements, from which one must be careful not to deviate. These elements include aberrant drug-related behaviors, red flags, and a mandate to exhaust non-opioid treatment options before prescribing opioids.

The issue underlying all of these elements of the standard of care is opioid addiction. In the courtroom, any deviation from the standards becomes evidence that the provider either knew, or *should have known*, that he was providing drugs to addicts, or in other words dealing drugs, rather than practicing medicine.

## Aberrant drug-related behaviors

The following behaviors are widely believed to indicate opioid addiction in pain patients.

Borrowing another patient's drugs

Obtaining prescription drugs from non-medical sources

Unsanctioned dosage escalations.

Aggressive complaining about need for higher doses.

Drug hoarding during periods of reduced symptoms.

Requesting specific drugs.

Acquisition of similar drugs from medical sources.

Prescription Forgery.

Stealing Another Patient's Drugs.

Recurrent Prescription Losses.

Concurrent use of related illegal drugs.

## Red Flags

Law enforcement officials rely on a system of red flags to alert them to criminal prescribing, and to be employed as evidence in the courtroom. The admissibility of many of the following red flags has been confirmed in federal appellate court decisions. Some red flags are directly borrowed from the standard of care in the form of aberrant drug-related behaviors, and others have been developed independently. Regardless of their source, the cautious professional is well advised to regard red flags as an element of the standard of care.

A number of red flags are listed below. They are sorted according to categories:

### The Clinic:

The clinic is rumored to be a "candy store", or "pill mill".

The practice has a "swinging door".

Has an extraordinary volume of patients.

A line forms outside the clinic, "like one would see at a crack house."

Suspicious looking individuals are seen arriving at the clinic.

“Obscene”, or “staggering” quantities of opioids are prescribed.

**The Pharmacy:**

Pharmacy sells the same number of controlled cough syrup prescriptions in the summer as in the winter.

Substantial time passes between issue/presentation of prescription and pick up, but prescription involves a controlled substance for severe pain.

Pharmacy employees pre-count pills and pre-fill prescriptions.

**The Patient**

Patient asks for something stronger or more pills.

Went to multiple doctors.

Has seen an expert.

Traveled a long distance to see the doctor.

Waited more than 4 hours to see the doctor.

Told the doctor he or she was a drug addict.

Had insurance, but paid cash for visits or prescriptions.

Quality of life did not improve.

Failed a urine or blood screen.

Asks physician for drugs using street name.

Failed a pill count.

Has a criminal history for drug offenses.

Told staff he was a drug addict or dealer.  
Was convicted of a crime.

Was a “frequent flyer”.

Keeps coming back or calling in early for refills.

Several members of the same family get drugs.

Appeared to be under the influence of alcohol or drugs.

Patients ask for drugs by name.

Patients fake symptoms to feed addiction.

The patient uses a Medicaid taxi, but pays cash for visits or prescriptions

**The Physician:**

Performs perfunctory physical examinations.

Tells patients he can't give them pain medicine unless they tell him they're in pain.

Asks patients to sign release forms acknowledging addictive potential and dangers of drugs prescribed.

Does not indicate re fills on prescriptions for Schedule III drugs.

Chart notes are written in different colored ink but by same person.

Physician or [Pharmacist] learns that patient is getting controlled drugs from other doctors.

Does not follow up or prescribe different drugs or courses of therapy after initial encounter with patient, but still sells them the same prescriptions for the same nebulous complaints (i.e., headaches, neck aches, backaches, etc.)

Allows patient to perform yard services, etc. In exchange for prescriptions writes prescriptions for dosages that a physician acting in the ordinary course of professional conduct would only write for opioid tolerant individuals.

Directs patients to more than one pharmacy.

Prescribes more than one kind of controlled substance.

Continues to prescribe addictive drugs to his patients after he became aware (or should have become aware) of their addictions.

Prescribes narcotics to treat cluster headaches.

Does not make professional appointments, but receives callers on a first-come, first-served basis.

Gives priority based on the order of signature on a clipboard chart, instead of medical priority.

Charges \$\$\$ for first visit, and \$ for subsequent visits.

Gives out post-dated prescriptions.

Conducts meaningless physical examination.

Issues unusually large quantities in separate prescriptions with separate dates to same patient on same day.

Over a two-year period, only examines patient four or five times, or less.

Defense was that “she was a TRUSTING DOCTOR.”

### **A Mandate To Exhaust All Other Treatment Alternatives**

Practitioners are required to exhaust all other treatment alternatives prior to committing a patient to a long-term course of opioids. This element of the standard of care is dictated by medical board guidelines in states that have them, and assumed to be the standard of care by experts hired by the prosecution, in states where guidelines haven't been adopted.

### **Conflicting Elements Within The Standard Of Care**

Elements within the evidence-based standard of care exist, which conflict with the above-mentioned items, in the sense that they promote the compassionate treatment of chronic pain. These elements are not discussed here, as they are virtually never enforced. In fact adherence to the elements of the standard of care, which mandate aggressive treatment of chronic pain is likely to result in prosecution based on the elements of the standard that conflict with this approach.

It must be noted that rather than indicating addiction, aberrant drug-related behaviors often signal the presence of under treated pain. In a similar fashion, the red flags mentioned above, are all characteristics expected when observing practices where effective pain management is being provided. The mandate to exhaust non-opioid therapeutic options is, in the case of many patients, also misguided, as it treats opioid therapy as if it were a dangerous and undesirable last resort in the treatment of pain, rather than an option to be weighed, based on the benefits it might provide to the individual patient under consideration.

### **Conclusion**

While it is fascinating to examine how conflicts within the standard of care for pain management contribute to the ongoing public health crisis, which is the under treatment of pain, this exercise is of no practical value to those who wish to stay clear of entanglements with the regulatory system. A rational approach to this issue entails maintaining a familiarity with medical standards, and knowing which elements of those standards are enforced, combined with steering a wide path around any patient or situation that would seem to represent a departure from the standards.

# WINNING YOUR CASE

## Choosing a Lawyer

Assume you have adhered to the approaches discussed above, and you find yourself facing prosecution anyway. You are now facing the single most important decision of your life; the only one more important than choosing who you marry. You have to pick a lawyer, and lacking experience with the legal system, having never been accused of a crime before, you don't have a clue about how to go about this.

An analogy closer to home might be useful. If you found out you needed major surgery in order to save your life, you would shop around for the best surgeon. You would find out how many of your kind of cases he has done, and what his complication and mortality rates are. When your life is on the line in the criminal justice system, you are well advised to take the same measured approach to finding a lawyer. What you have to find out is, **who wins these cases?** The following page recommends a lawyer who combines an extensive knowledge of opioid pharmacology and pain management with a winning record.

## Financial Realities

There is no insurance available for this sort of eventuality, so the defendant either shoulders the cost himself, or the court appoints an attorney. The second option dramatically increases the chances of conviction, loss of license, and a long stay in prison.

You will need to have money in some sort of trust where it can't be seized at the time of your arrest, either as evidence, or confiscated as if it were proceeds from drug dealing. The following is an estimate of the expenses for which one should be prepared, if engaged in the prescription or dispensing of controlled substances.

A minimum of \$500,000 – 1,000,000 for representation and expenses.

A minimum of \$200,000 for appeal expenses, in case you lose.

A minimum of 100,000 for professional board representation, which will follow your criminal case.

A minimum of 5 years living expenses. (Assume you will be prevented from working)

# Patrick S. Hallinan



Mr. Hallinan is a trial attorney specializing in the litigation of complex criminal cases in state and federal court. He has practiced law in San Francisco for thirty-eight years and, throughout his career, has been active in high-profile legal and political issues involving the conflict between the exercise of governmental power and individual liberty. He was named the leading criminal defense lawyer in “Bay Area Surveys”, by the *San Francisco Examiner*, and Attorney of the Year, by California Attorneys for Criminal Justice, as well as by the Drug Policy Commission of Washington, D.C.

Mr. Hallinan has represented author Ken Kesey, San Francisco District Attorney Joe Freitas, California Court of Appeal Justice William Newsom, Congressman John Burton, Black Panther author Eldridge Cleaver, the Soledad Seven, San Francisco Sheriff Richard Hongisto, Federal District Court Judge Robert Aguilar, and former California Schools Superintendent William Honig. Mr. Hallinan was also featured in the PBS series *Frontline: Snitch*, a documentary about the harmful effects of the government's use of paid informants in the federal criminal justice system.

Mr. Hallinan successfully represented Dr. Frank Fisher against multiple murder, drug dealing, and conspiracy charges, arising from his legitimate practice of chronic pain management. Dr. Fisher's co-defendant, a pharmacist Stephen Miller, was cleared as well, as a result of this representation. Mr. Hallinan is currently representing a number of physicians in similar high profile cases around the country.

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