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Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?

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Abstract

Prescription opioids are an important tool for physicians in treating pain but also carry significant risks of harm when prescribed inappropriately or misused by patients or others. Recent increases in opioid related morbidity and mortality has reignited scrutiny of prescribing practices by law enforcement, regulatory agencies, and state medical boards. At the same time, the predominant 4D model of misprescribers is outdated and insufficient; it groups physician misprescribers as dated, duped, disabled, or dishonest. The weaknesses and inaccuracies of the 4D model are explored, along with the serious consequences of its application. This article calls for development of an evidence base in this area and suggests an alternate model of misprescribers, the 3C model, which more accurately characterizes misprescribers as careless, corrupt, or compromised by impairment.

I. Introduction

“Opioids play a unique role in society. They are widely feared compounds, which are associated with abuse, addiction and the dire consequences of diversion; they are also essential medications, the most effective drugs for the relief of pain and suffering.”¹

Physicians are understandably conflicted about how, when, and whether to prescribe opioids. On the one hand, relief from suffering is a primary obligation of physicians, and pain remains undertreated after decades of improvement efforts.² The inadequate treatment of pain was the subject of significant clinical and policy efforts in the 1990s;³ among those efforts were the increased use of opioids for acute pain and the use of long-term opioid therapy for patients with chronic pain.⁴ Although opioid prescriptions are only one aspect of effective pain treatment, the failure to utilize opioids in appropriate circumstances causes suffering and creates a barrier to effective pain care.⁵ According to Cheattle and Savage, “[o]ne of the barriers to effective pain management across the spectrum of pain conditions ... is the clinician’s fear of prescribing opioids beyond that merited by the actual risks.”⁶ Efforts in 1990s to lessen barriers to appropriate opioid use did result in decreased suffering for some patients.⁷

On the other hand, medicine's embrace of expanded opioid use and the influence by pharmaceutical companies on that use⁸ has had unintended consequences. Though many patients experience a newfound relief from suffering,⁹ the nonmedical use of opioids has also increased substantially.¹⁰ A small percentage of patients with underlying vulnerabilities to substance use disorders ("SUDs") may develop opioid use disorders from prescriptions to treat pain, while other individuals with SUDs¹¹ find a new drug of choice in diverted prescription opioids.¹² In 2010 alone, an estimated 16,000 individuals died from nonmedical use of prescription opioids, typically in combination with other drugs or alcohol.¹³ These deaths have garnered significant public attention.¹⁴

In limited instances, physicians may behave negligently or worse in prescribing opioids. Although any inappropriate prescription can have negative consequences for both physicians and their patients, those consequences are significant in the case of opioids.¹⁵ Opioid use disorders ("OUDs"), a subset of SUDs, are now the "second most common drug use disorder[]" in the United States, and prevalence has increased over the last two decades.¹⁶ In addition, the majority of individuals with OUDs do not receive treatment, despite the significant psychiatric co-morbidities and risk of overdose death.¹⁷ OUDs also carry societal and economic costs.¹⁸ Because opioids are regulated, prescription-only medications, dispensers, distributors, and physicians are all facing scrutiny.¹⁹ Although most of those with OUDs and those who suffer opioid related overdoses (OROs) do not obtain their opioids directly from their physician, some do.²⁰ Except for the opioids diverted in the supply chain before reaching dispensers, borrowed or stolen opioids originate as valid prescriptions.²¹ Additionally, about 27% of long-standing opioid abusers receive these drugs directly by prescription.²² Therefore, prescribing and patient education practices play a role in the availability of opioids for misuse²³ and the harms that flow from OUDs.²⁴

Physicians bear responsibility for careful and conscientious prescribing, which includes patient assessment, communication, and education.²⁵ In practice, that responsibility may be heightened in the case of opioids. Physicians can face serious legal sanctions for inappropriate prescribing, including malpractice liability, medical board discipline, and criminal convictions.²⁶

Physicians have an obligation to treat pain, and opioids remain one of the most broadly effective medications for many types of pain;²⁷ at the same time, physicians do not want to face legal entanglements related to prescribing opioids. In order to avoid the latter, it is important to understand when and why physicians face sanction for improperly prescribing opioids. Yet the reasons are currently confounding because of the paucity of trustworthy, current data, and the heterogeneity and inaccuracy of categories in the dominant "4D model" meant to explain such cases. Physician involvement ranges from clearly criminal behavior²⁸ (innocuously referred to as "dishonest") to falling victim to patient dishonesty ("duped").²⁹

Policy makers continue to rely on the 4D Model, which was developed over thirty years ago, to group physicians who abuse their prescribing privileges or disregard their professional obligations completely (misprescribers) into four categories: dated, duped, dishonest, or disabled.³⁰ The categorization, originally intended both to describe misprescriber characteristics and guide appropriate discipline,³¹ was subject to calls for refinement as early

as 1990.³² The descriptors are both over-inclusive and under-inclusive, leading to unpredictable and inconsistent enforcement. The duped category reflects patients' behavior, an inappropriate and misleading focus for regulatory oversight. Nonetheless, in its original form, the 4D Model continues to guide regulators as well as law enforcement.³³ A better model is urgently needed; one that consistently focuses on a *physician's* professional behaviors, not the patient's, and describes a physician's *choices*, not their length of time in practice.

Medicine is increasingly adapting to the complexity of opioid use, as well as the models of care needed for patients with multiple, complex chronic conditions such as those involving both pain and SUD. These already nuanced clinical choices should not be burdened with fear of unwarranted investigation. Such fear can exacerbate stigmatization and encourage patient avoidance of care.³⁴ Instead, a model is needed that allows physicians to prioritize each patient's well-being.³⁵ At the same time, the model must more accurately describe behaviors that rise to the level of misprescribing, thus guiding appropriate investigation and sanction.

This Article provides an overview of the regulation of opioid prescribing, the limitations and possible harms associated with the American Medical Association's (AMA) current 4D misprescribing framework, and draws attention to the need for ongoing research. The Article begins in Part II by reviewing the fundamental problems—the paucity of data and the limitations of the 4D model. Part III examines the legal regulation of medical practice and prescribing, and Part IV reviews cases in which physicians have been criminally prosecuted, presenting them within a 3C framework (Corrupt, Compromised by impairment, and Careless), which focuses on physician-related reasons for the misprescribing. Finally, this Article suggests that the 3C Model better reflects the causes of legal action and better guides the responses of regulators and law enforcement than the current 4D model because the 3C model focuses exclusively on the role of physicians in misprescribing.

II. Defining Misprescribing Amidst Incomplete Data and an Inaccurate Conceptual Framework

When physicians act and prescribe with integrity they enhance trust in the profession and allow for social disclosures and interactions that improve care.³⁶ In the context of opioid prescribing, courts have recognized that integrity may be challenged by uncertainty about which decisions most decrease suffering and promote well-being, especially when there is considerable pressure to act out of self-protection.³⁷ Nonetheless, “[p]hysicians are responsible for ... ‘providing the time, skill, and knowledge’” required for careful prescribing.³⁸

The label “misprescribing” should refer to a set of prescribing behaviors that demonstrably depart from the standard of care, such as issuing prescriptions without appropriate medical purposes or in inappropriate dosages or quantities given the characteristics of the patient to whom they are prescribed. Unfortunately, misprescribing is sometimes distorted and misused to describe an unfortunate outcome, such as when a patient who intends to sell his or her prescription successfully fools a physician or when a patient has an unexpected

adverse reaction.³⁹ The term misprescribing should be clear and should not include a physician who might follow standards of care and nevertheless write a prescription that does not serve a patient well for any number of reasons, such as an unknown allergic reactions, gene-drug interactions, or misinformation provided by a patient.

A. Incomplete Data

“It is one thing to cite statistics supporting the observation that opioid- related deaths have risen drastically in recent years. It is quite another matter to obtain and interpret specifics of how the deaths occurred so as to inform clinical practice going forward.”⁴⁰

The information available about physician misprescribing is in small supply. Existing studies tend to look at a broad set of behaviors that result in sanction, rather than just focusing on prescribing.⁴¹ Most confine their studies to cases from one state,⁴² from particular oversight boards,⁴³ or from specific types of sanctions.⁴⁴ Even these tend to cover data before 2007.⁴⁵ Results from those studies indicate that those sanctioned disproportionately are older,⁴⁶ male,⁴⁷ lack board certification,⁴⁸ and work in general practice, family practice, or specialize in psychiatry.⁴⁹

A few studies focus specifically on prescribing. Goldenbaum and colleagues studied opioid misprescribing and found the physician characteristics of those studied were similar to the more general studies of sanctioned physicians: older, male, non-board certified, general or family practitioners were more likely to face sanction.⁵⁰ Current work by DuBois and colleagues on misprescribing of controlled substances (primarily opioids) found similar patterns.⁵¹ Rather than studying physician demographics, Rich and Webster looked at underlying behavior patterns by analyzing medical records in malpractice opioid overdose cases from 2005 to 2009.⁵² They attributed the cause of overdose to physician error in seventy-five percent of the cases.⁵³ Those cases of physician error revealed a pattern of actions below the standard of care, including multiple medication errors in terms of dosing and conversion of doses between drugs.⁵⁴ None of the cases studied included physicians engaged in the criminal enterprise, but they did reveal concerns about careless prescribing habits.⁵⁵

In short, more misprescribing data are needed, including data from the investigation stage through to the sanction stage. Current data do not provide a comprehensive picture of the problem or reflect the increased enforcement and regulatory efforts of the last ten years.⁵⁶

B. A Harmful Model: 4Ds

“Language is more than just a vehicle for ideas: it shapes ideas—and the practices that follow from them.”⁵⁷

Decades ago, the AMA endorsed the 4D model to describe physicians who overprescribe. The four Ds are (1) dated, (2) duped, (3) disabled, and (4) dishonest.⁵⁸ The model grew out of addiction medicine experts’ work on physician prescribing practices courses in the late 1970s.⁵⁹ David E. Smith described the development of the 4D model as an evolution from work with physicians on disciplinary probation and other misprescribers.⁶⁰ The model was

included in a White House sponsored conference on prescription drug abuse and later endorsed by the AMA.⁶¹

Under the 4D model, a dated physician is described as “out of date regarding knowledge of pharmacology and the different diagnosis and management of chronic pain ...”⁶² A duped physician is “one who inadvertently supplies drugs to a drug abuser because the physician has been deceived by a drug abuser posing as a patient.”⁶³ Disabled physicians are impaired because of an SUD or other medical or psychiatric disability,⁶⁴ which may lead them to divert prescriptions for their personal use or to exhibit judgment so poor as to lead to patient harm. Finally, dishonest physicians are those who use their access to prescribing for personal gain (financial or otherwise).⁶⁵

The problem with the model, over time, is that the descriptors are not accurately aligned with the realities of opioid misprescribing, and accuracy matters when a framework is used to guide the adjudication of cases. While the framework suffers from several problems (e.g., “dishonest” is far too gentle a descriptor for the physicians who embrace a criminal identity and “dated” may be ageist), this Article focuses on the problem created by the “duped” category because it is the most severe.

1. The Problem with Duped

*“Good doctors have been and will continue to be deceived by patients, and undoubtedly there will be a few bad doctors who attempt to deceive others. In the end, however, we must not lose sight of the millions of patients who are suffering ...”*⁶⁶

The language of duped may cause unreasonable expectations for physicians from law enforcement, regulators, and even the medical field. A false narrative pervades medicine regarding physicians’ abilities to spot deceptive patients. Longo and colleagues suggest that physicians who try to help patients in pain and foster trust are “vulnerable to a manipulative patient.”⁶⁷ But this presumes that a less “therapeutic” physician would not be fooled. There is no evidence to support this assumption. Twenty-five years ago, Wesson and Smith understood this, explaining “[t]he term ‘duped’ is not always appropriate in these situations because it implies the physicians are careless, easily deceived, or foolish. It has an implied converse: that careful, competent physicians would ... recognize[] the deception.”⁶⁸ Karen Drummond explains this as the cultural narrative of the wily “drug-seeking” patient and naïve, “fooled” physicians: “[a]n unspoken clinical skill one is supposed to gain in the course of training is the ability to recognize ‘drug seeking behavior’ in order to not be ‘fooled’ by the drug seeking patient.”⁶⁹ She describes how this fallacy has taken hold of the culture through the media, such as “medical dramas” that depict experienced doctors and street wise nurses shaking their heads at “a bumbling new intern ... tricked by a ‘frequent flier’ patient.”⁷⁰

This fallacy pervades law enforcement attitudes as well. Testimony and press releases often focus on times when a physician prescribed medication for an undercover police officer posing as a patient.⁷¹ Jung and Reidenberg also noted this fact, with physician deception

alone offered as evidence of misprescribing.⁷² Zeigler has pointed out that those media reports negatively influence cultural attitudes and prescribing behavior.⁷³

Labeling physicians as misprescribers for merely being fooled is improper. While this has been acknowledged in the literature,⁷⁴ physicians have inappropriately faced sanctions simply for being fooled.⁷⁵ In fact, recent research found that even after training, people could not detect real versus faked pain more than fifty-five percent of the time.⁷⁶ Detection of patients with “fake” complaints by physicians may be even more difficult because of the presumption that patients come to them because of problems, sometimes called the “truth bias.”⁷⁷ This is also demonstrated by physicians’ poor rates of detection of actors or standardized patients in other studies.⁷⁸ Being fooled is no measure of malpractice, and certainly no measure of criminal behavior.⁷⁹ Holding physicians accountable for being fooled also resurrects paternalistic notions of wise physicians directing naïve patients.⁸⁰ Any physician who prescribes opioids is vulnerable to being duped by a deceptive patient; there is no degree of conscientiousness that can prevent it.⁸¹ There is also no justification for physicians to abandon their “truth bias” with patients; it is part of the relational trust the underscores a successful physician-patient relationship. In the context of pain, physicians may be motivated to abandon their truth bias out of fear of sanction for being duped.⁸² This fear may lead some to avoid opioids altogether, a position that is inconsistent with physicians’ obligations to the patients. Jung and Reidenberg describe the implications of the fear of deception:

[b]oth deception and fear of deception have consequences. Patients can get ... insufficient medical care when the doctor fears deception (disbelieving reports of pain when it exists). These consequences affect both the individual patient and society.⁸³

2. The Lie Detection Fallacy, Law Enforcement, and Physician Responses—

Law enforcement’s expectations that physicians will detect deception are unjustified but unsurprising in a field infected with overconfidence. Research with law enforcement demonstrates consistent unwarranted overconfidence by officers in their own lie detection abilities.⁸⁴ Part of this overconfidence probably stems from the backward looking nature of investigation and the bias that it engenders. Others have identified long-standing training techniques for law enforcement that focus on non-verbal cues and other behaviors that have proven empirically false.⁸⁵ Moreover, research has shown that exposure to these training techniques exacerbates overconfidence without improving the actual ability to detect deception.⁸⁶ Scores of research establishes the rate of lie detection at about fifty- four percent—a whisper above chance—regardless of training or confidence.⁸⁷ In fact, some research indicates that college students may even be better at detecting lies than police investigators.⁸⁸

Actors in the legal system are immersed in a culture saturated with lie detection mythology.⁸⁹ According to the U.S. Supreme Court, “[a] fundamental premise of our criminal trial system is that ‘the jury is the lie detector.’”⁹⁰ Juries are expected to determine, at a rate better than chance, which witnesses are trustworthy by virtue of their “natural intelligence and their practical knowledge”⁹¹ Given the pervasiveness of the lie detection

fallacy in law, it is not surprising that law enforcement and adjudicators are willing to assign blame to physicians who are deceived by patients despite due care.

Worse yet for physicians, recent research has found a connection between emotional intelligence and susceptibility to deception.⁹² Baker and colleagues found that empathy of emotionally intelligent individuals might impair their ability to discriminate between genuine and deceptive actors, thus making them more susceptible to deception than the average person.⁹³ This has serious implications for the many physicians conflicted by simultaneous obligations to trust their patients and to relieve suffering without further contributing to drug diversion and the harms of SUD. The medical literature is replete with evidence of the clinical value of emotional intelligence and its positive effect on physician patient relationships, patient outcomes, and physician satisfaction,⁹⁴ as well as its contribution to effective medical leadership.⁹⁵ In the context of pain, emotional intelligence and empathy are associated with the successful management of patients with multiple chronic problems, such as chronic pain.⁹⁶ Further, many programs exist to actually enhance emotional empathy in medicine to improve patient care.⁹⁷ What then, is a physician to do? Asking physicians to set aside the skills that facilitate effective patient care in an effort to prevent the occasional deceptive patient is contrary to the ends of medicine. A recent consensus statement by pharmacists on prescribing and dispensing controlled substances recommends trusting patients:

[T]he best clinical approach in most circumstances is *to assume the patient is reporting a true experience. Accepting a patient's complaint of pain as valid does not require clinical identification of a physical cause*, or demand the initiation of a specific treatment. It does, however, provide the foundation for assessment and the basis for developing an effective patient-physician dialogue⁹⁸

This position recognizes that there are disproportionate harms to encouraging suspicion of patients. The fear of deceit alone can compromise physician trust in patients, and that fear likely already contributes to avoidance of certain patient groups. Maia Szalavitz describes the tension this way: “[d]octors who would overlook a patient’s lies about, say, diet and exercise instead become personally affronted about painkiller misuse. It’s hardly surprising. Being fooled in this way can have severe legal consequences for the doctor.”⁹⁹ There have been several notable cases in which evidence of being fooled was the basis for arrest even though contextual information reveals a typical interaction.¹⁰⁰ While there is no way to completely eliminate the risk of a false or erroneous arrest,¹⁰¹ the use of the word “duped” may contribute to an increased risk of scrutiny based on being fooled. Those situations in which physicians are fooled because of their own carelessness are distinct and should be characterized in a way that reflects this distinction and level of culpability as well as the appropriate legal sanctions.

The language used to model misprescribing must not perpetuate this lie detection fallacy: “duped” as one of the 4Ds is not only inaccurate, it is harmful to physicians and to patients. Michael J. Brennan put it this way: “[w]e know we can not be 100% right all the time. Without an understanding of how right must we be, or how wrong are we allowed to be ... we will be floundering about with the issue of physician prosecution or the perception of such, forever.”¹⁰²

III. Regulation of Medical Practice and Prescribing

Law regulates medical practice both directly and indirectly.¹⁰³ Regulation of physician practice generally “orients itself around the few bad apples ... rules and enforcement efforts are targeted at finding, punishing, and deterring bad behavior on the part of a minority of the physician population.”¹⁰⁴ Yet, the investigation alone is burdensome and a driver of physician behavior: the “penalties of the process” produce physician avoidance of clinical activities that may place them in reach of investigation.¹⁰⁵ Physicians may find themselves embroiled in multiple legal and quasi-legal proceedings relating to the same prescribing events.¹⁰⁶ For example, physicians may face medical malpractice liability, medical board discipline ranging from reprimand to revocation of their medical license(s), exclusion from federal programs,¹⁰⁷ criminal charges ranging from misdemeanors to felonies, federal and state fraud charges for claims for services and prescriptions paid by the government on behalf of patients,¹⁰⁸ exclusion from participation in state programs,¹⁰⁹ breach of contract actions from private third party insurance providers, hospital peer review,¹¹⁰ and other proceedings by organizations to strip the physician of membership or special status.¹¹¹ An investigation alone can be devastating and a finding of liability can trigger a cascade of consequences that make it impossible to practice medicine. The most common actions related to misprescribing are reviewed below.

A. Medical Malpractice

The general public is most apt to think of medical malpractice as a regulator of physician conduct although it is, at best, an extreme indicator of quality of care.¹¹² In reality, malpractice claims do not correlate well with the quality of physician practices;¹¹³ factors such as poor outcomes and the degree to which the patient likes the physician are more powerful predictors of malpractice suits.¹¹⁴ Incompetent but likable physicians may avoid the consequences of malpractice for some time. A malpractice action not dismissed in the early stages can be devastating for the provider’s reputation and reserves. This creates perverse incentives to avoid malpractice actions, which may lead to overtreatment.¹¹⁵ With regard to prescription opioids, however, there have also been a handful of cases in which physicians faced liability for undertreating pain.¹¹⁶

The outcome of malpractice cases often rests on the standard of care, which is a measure of “prevailing custom, with some substantial tolerance for ‘respectable minority’ views, [and] has been the gold standard for scrutinizing physician practice and treatment decisions in the malpractice context.”¹¹⁷ The standard of care is one of the most malleable elements of malpractice cases because it is not a fixed concept;¹¹⁸ there are usually multiple reasonable and appropriate standards, or “‘right ways’ of doing things for a patient.”¹¹⁹ For example, courts have held that failing to follow every recommendation of a state medical board prescribing policy is insufficient to establish a failure to meet the standard of care.¹²⁰ A number of factors—such as exam, dosing, patient education, and referrals—are relevant to a determination of breach in prescribing cases; they are considered in the context of the patient’s particular history and presentation.¹²¹ At the same time, one material and sufficient deviation from the standard of care may create liability.¹²² While malpractice might apply to

certain prescribing practices, without a pattern or other evidence, it is a poor barometer of competency.¹²³

B. State Boards of Medicine

*“Physicians should be aware that the legal system views medical licensure as an exclusive privilege. As such, physicians are held to a higher standard of moral and personal conduct than the general population ... actions that reflect poor judgment, flawed character, and sub-standard decision-making may trigger state medical board sanctions.”*¹²⁴

Medical practice is also regulated by state medical boards (“SMBs”)— regulatory agencies created by state medical practice act legislation.¹²⁵ The Federation of State Medical Boards’ Model Practice Act describes the purpose and function of SMBs:

The practice of medicine is a privilege granted by the people acting through their elected representatives [1)] [i]n the interests of public health, safety, and welfare, and [2)] to protect the public from the *unprofessional, improper, incompetent, unlawful, fraudulent and/or deceptive practice* of medicine, it is necessary for the government to provide laws and regulations to govern the granting and subsequent use of the privilege to practice medicine.¹²⁶

Thus, SMBs’ primary obligation is protection of health and safety of citizens through oversight of medical practice.¹²⁷ Vulnerable populations are especially in need of SMB protection.¹²⁸ SMBs regulate through a host of educational, practice, and fitness standards to ensure the basic competence physicians.¹²⁹ Although reactive by nature,¹³⁰ SMBs “have the statutory duty and authority to penalize or remove from practice physicians who provide substandard care.”¹³¹ They also have considerable latitude to investigate, adjudicate, and sanction physician behavior; sanctions can range from a reprimand to complete revocation of a license to practice.¹³² Although the research is limited, factors such as board certification, gender, country of training, and type of aberrant activity are associated with the likelihood of disciplinary proceedings.¹³³

A substantial number of SMB actions involve misuse and misprescribing of controlled substances, including opioid misprescribing.¹³⁴ In theory, SMBs can take action against physicians for underprescribing or undertreating pain,¹³⁵ although in reality these actions are rare.¹³⁶ Most cases involve excessive and unnecessary prescribing, and these cases reveal a variety of physician motivations and triggering conditions including financial gain, sexual favors, or impaired judgment secondary to disease or disability, none of which comply with the physician’s primary professional and ethical obligations to the patient.¹³⁷

Overall, the number of physicians disciplined has been historically low but may be currently increasing. In 2012, there were 878,194 actively licensed physicians in the United States,¹³⁸ 4479 of whom—about one-half of one percent of all licensed physicians—were disciplined by SMBs.¹³⁹ “A comparison of data from 2012 and 2008 shows most categories of board actions have experienced increases — particularly reprimands, restrictions, imposition of additional continuing medical education and suspensions of physicians’ licenses.”¹⁴⁰ In

Florida, the percentage of disciplinary actions per legally sufficient complaints rose from 16.8% from 2009 to 2010 to 28% in 2011 to 2012.¹⁴¹

“The disciplinary process is usually triggered by a complaint” to the SMB, such as a criminal charge or a disciplinary action by a hospital.¹⁴² All states allow voluntary complaints by individuals and institutions; however, they vary widely in when and by whom mandatory reporting to the SMB is required, as well as whether the SMB is obligated to communicate with boards in other states.¹⁴³ Allegations of misprescribing are one of the most common complaints.¹⁴⁴ Criminal investigations and charges are almost always reported to SMBs and criminal prosecutions are the most likely disciplinary trigger to lead to serious SMB action against a physician.¹⁴⁵ Conviction of a felony often results in automatic revocation of a license to practice medicine.¹⁴⁶ Convictions and successful complaints involving controlled substances lead to automatic revocation of a physician’s certificate of registration to prescribe controlled substances that is granted by the Drug Enforcement Agency (“DEA”).¹⁴⁷

C. Additional Regulation of Physician Prescribing

Regulation of prescription controlled substances sits at a volatile “clash” of cultures: between law enforcement and medicine.¹⁴⁸ Both professions seek to improve the overall health and safety of the public, but in drastically different ways. Physicians typically interact with an individual with a goal of improving the individual’s well being through a continuing relationship. One patient at a time, the physician hopes to meet a secondary goal of improving the public health and safety.¹⁴⁹ Trust is a critical tool in this enterprise. In an atmosphere of relational trust, physicians trust that patients are truthful, while patients trust that physicians are discreet and interested in improving their well being, thus allowing disclosure of deeply personal information to facilitate personalized care.¹⁵⁰

In contrast, law enforcement professionals tend to interact with individuals who may be engaged in illegal activities that they would rarely voluntarily disclose.¹⁵¹ One suspect at a time, law enforcement professionals aim to improve public safety by arresting criminal activity.¹⁵² An individual’s well being, at least in terms of freedom and reputation, is a sacrifice to improving public safety.

It is no surprise that there are continuing tensions between these professionals, especially in the context of drugs. Law enforcement inhabits a professional space in which drugs (including abused prescription drugs) are the enemy: dangerous, deadly, and harmful. Physicians inhabit a professional space in which prescription drugs are useful tools, often helpful, and rarely deadly.¹⁵³ These professional spaces converge at controlled substances, most of which have simultaneous potential for causing great harm and for providing great benefit, depending on the particular circumstances and contexts. It is in interpreting those circumstances where the clash is most profound.

Professionals have been negotiating this clash for a century.¹⁵⁴ Prior to 1914, all drugs were generally available without a prescription, and compounded for patients by pharmacists on their own initiative or upon a physician’s recommendation. The first legal foray into the domain of prescribing was the Harrison Narcotic Tax Act of 1914, a response to societal

concerns about substance abuse that required prescriptions for narcotics exceeding certain dosages.¹⁵⁵ The Act introduced some of the language that remains controversial today, allowing a physician to prescribe to a patient in “the course of his professional practice only.”¹⁵⁶ It resulted in the first wave of physicians facing criminal prosecution and license revocation for prescribing pain relievers.¹⁵⁷ Courts and law enforcement, embedded in the culture of prohibition, construed the language to prohibit maintenance prescriptions for those suffering from addiction.¹⁵⁸ Ghosts of those societal attitudes and of the Harrison Narcotic Act still linger today.¹⁵⁹ For example, the strict restriction of physicians authorized to provide medication-assisted therapy for those with an SUD acts as a barrier to treatment, despite the established benefits of pain reduction programs.¹⁶⁰ By all accounts, the law created far more social problems than it fixed.¹⁶¹ Nonetheless, it established precedents for prescribing medications as well as potential for physician criminal liability when their prescriptions did not meet the statutory requirement.¹⁶²

The Act also led to state and federal regulation of prescribing, particularly of controlled substances. While state licensure through SMBs authorizes the general practice of medicine and prescribing, authority to prescribe controlled substances is granted through state controlled substance authorities and by the DEA at the federal level.¹⁶³ Today, most states have agencies that regulate prescribing and dispensing of controlled substances, such as state boards of pharmacy or bureaus of narcotics.¹⁶⁴ Providers can face sanctions from both the state agency and the DEA, although a minority of states grant the DEA the power to sanction providers on their behalf.¹⁶⁵

1. The Food and Drug Administration—While the DEA enforces controlled substances law, the federal Food and Drug Administration (“FDA”) is responsible for the drug safety.¹⁶⁶ In 1938, the Federal Food, Drug and Cosmetic Act (“FDCA”) was passed to create standards of drug for protection of the public.¹⁶⁷ Not until the 1951 Durham-Humphrey amendments did a large group of drugs, rather than just narcotics, fall under the prescription only requirements.¹⁶⁸ The FDA, the federal administrative agency charged with enforcing the FDCA, is primarily a *consumer* protection agency and does not directly regulate physicians’ prescribing practices.¹⁶⁹ However, the FDA does determine which medications must be prescription only.¹⁷⁰

Since 1962, the FDA has required drug manufacturers to prove both the safety and effectiveness of new drugs before they enter the United States market.¹⁷¹ As part of the drug approval process, the FDA approves drug labels and labeling that include recommended indications and doses that strongly influence prescribing practices. Physicians, however, are free to use their medical judgment to prescribe approved drugs for conditions that are not part of the labeling (off-label prescribing).¹⁷² FDA approval of certain controlled substances, such as opioids, now include Risk Evaluation and Mitigation Strategies that mandate professional education, enhanced safety labeling and patient information, and other requirements for which the manufacturers are responsible.¹⁷³ The FDA also recommends the appropriate schedule or classification of controlled substances;¹⁷⁴ however, the DEA is ultimately responsible for scheduling drugs and enforcing the Controlled Substances Act (“CSA”).¹⁷⁵

Physicians charged with violations of the CSA for misprescribing often face companion FDCA violation charges; typically, these are charges of misbranding or adulterating a drug sold in interstate commerce,¹⁷⁶ the penalties for which range from civil monetary penalties to criminal misdemeanors or felonies.¹⁷⁷ These charges are based on the theory that the physician did not issue a valid prescription (not pursuant to legitimate medical practice) and therefore, introduced a “prescription only” drug into the market without a prescription, rendering it misbranded.¹⁷⁸

2. The Drug Enforcement Agency and the Controlled Substances Act—The

DEA is a federal law enforcement agency within the Department of Justice that enforces the CSA, which is a federal criminal drug law that prohibits illegal drug manufacturing and distribution.¹⁷⁹ Under the CSA, drugs are placed into one of five schedules based on their medical utility as well as the potential for abuse, misuse, physical and psychological dependence.¹⁸⁰ Schedule I drugs have “no ... accept[able] medical use” and “high potential for abuse”;¹⁸¹ Schedules II-V drugs have “accepted medical use[s]” with the potential for abuse and dependence ranging from high (Schedule II) to progressively less potential for abuse through Schedule V.¹⁸² Most opioids are Schedule II drugs, including morphine, oxycodone (the active ingredient in Percocet, Lorcet, and Oxycontin), hydrocodone (the active ingredient in Vicodin and Lortab), methadone, and Demerol.¹⁸³ With the recent inclusion of hydrocodone combination products, Schedule II drugs have become the most commonly prescribed opioids for pain (and the among the most commonly prescribed drugs overall in the United States).¹⁸⁴ Other drugs that may be useful for the treatment for pain and anxiety but subject to misuse are Schedule III drugs, such as codeine combination products,¹⁸⁵ and Schedule IV drugs which include benzodiazepines Ativan, Valium, and Xanax.¹⁸⁶

Under the CSA, it is “unlawful for any person to *knowingly or intentionally* ... manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance”;¹⁸⁷ conspiracy to do so is also a criminal offense.¹⁸⁸ Authorized individual providers with a certificate of registration who issue a valid written prescription¹⁸⁹ for a controlled substance “for a legitimate medical purpose ... in the usual course of his professional practice,”¹⁹⁰ are exempt from the CSA’s prohibition.¹⁹¹ Physicians acting outside that authority are in violation of the CSA.¹⁹² According to the Supreme Court, “the prescription requirement is better understood as a provision that ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, the provision also bars doctors from peddling to patients who crave the drugs for those prohibited uses.”¹⁹³ States generally have laws that mimic the language of the CSA, and state prosecutors may charge physicians under the state statutes.¹⁹⁴

a. Criminal Standard for Liability: Misprescribers may face criminal charges at both the state and federal levels. Criminal law violations require both a criminal act (*actus rea*) and a criminal intent or mental state (*mens rea*).¹⁹⁵ Violating the CSA requires a *mens rea* of knowledge and an *actus rea* of distributing, dispensing, possessing or manufacturing controlled substances.¹⁹⁶ For liability to attach to physicians, they must prescribe controlled

substances (1) knowingly; (2) without a legitimate medical purpose; and (3) outside the course of professional practice.¹⁹⁷ The knowledge requirement means physicians should not face CSA convictions for reckless or negligent prescribing. On the other hand, gross deviations from the standard of care can rise to the level of criminal culpability under state laws that include reckless or negligent *mens rea* requirements.¹⁹⁸ The required *mens rea* under state law actions for criminal negligence varies but generally entails “[g]ross negligence so extreme that it is punishable as a crime.”¹⁹⁹

Physician defendants in CSA actions must either have had “actual knowledge of the illegal activity or deliberately failed to inquire about it before taking action to support it.”²⁰⁰ Several physicians have been convicted under a theory of “willful blindness,” in which the mental state of the offender is equated to “knowing” because the physician intentionally buried her head in the sand to avoid knowing (it is also known as the “ostrich instruction[]” for the jury).²⁰¹ In other words, it took a knowing act to avoid learning that a prescription would be improper, and that knowing act substitutes for actual knowledge of the criminal endeavor.²⁰² Application of the willful blindness doctrine in CSA cases against physicians is typical when they have “ignored many warning signs and red flags and consciously eschewed performing the most rudimentary screening that would have revealed many ... patients’ ruses.”²⁰³ For example, in *United States v. Katz*, the physician “sought no patient medical history and never ordered diagnostic or laboratory tests for any of the patients ... [and] provided patients access to controlled substances by routinely refilling 30-day prescriptions when only two weeks had expired.”²⁰⁴ Knowledge must be determined from the context of the physician-patient encounter.

Law enforcement faces complex determinations of (1) the point at which a medical purposes becomes illegitimate; (2) the boundaries of usual practice; and (3) the extent at which crossing those boundaries warrants criminal liability.²⁰⁵ Context is critical in imposing criminal liability to physicians. The line between practice and criminality is a foundational question because criminal liability threatens individuals’ essential liberties far beyond those threatened by civil liability or professional discipline.²⁰⁶ The DEA has chosen not to further define the standards, and courts have not developed a precise definition.²⁰⁷ This is true, in part, because they depend on careful contextual evaluation.²⁰⁸ Courts have emphasized that it is essential to have evidence of the standard of care presented at trial, not because any deviation results in culpability, but because they need to establish a baseline from which to judge a gross deviation.²⁰⁹ According to the court in *United States v. Feingold*, “[k]nowing how doctors generally ought to act is essential for a jury to determine whether a practitioner has acted not as a doctor, or even as a *bad* doctor, but as a ‘pusher’ whose conduct is without a legitimate medical justification.”²¹⁰ The court in *United States v. MacKay* also explained that the criminal standard is far beyond a simple deviation from the standard of care (or a “bad doctor” standard in the language of the Feingold court):

[T]he case presented the jury with the difficult task of first deciding if MacKay’s prescriptions left the legal terrain of medically-helpful pain management. Then, if the jurors were persuaded there was such a departure, they faced the perhaps even more difficult task of deciding whether such behavior constituted a kind of medical malpractice, which, although negligent, is not criminal, or whether the doctor had

knowingly and intentionally left the field of medicine altogether to become a criminal drug dealer.²¹¹

Diane Hoffmann and other scholars, as well as many leaders of the pain management community, have pointed out the inherent dangers of imposing criminal liability by using the standard of care as a measure.²¹² Of course, extreme cases are more obvious, such as when a physician exchanges cash for prescriptions without forming a physician patient relationship.²¹³ In more nuanced cases, criminal penalties attach to a somewhat fuzzy degree of deviation from the standard of care.²¹⁴ Nonetheless, read carefully, the standard for criminality is at least two steps beyond that which would satisfy the breach requirement in malpractice: from a mistaken doctor (one breach in otherwise careful practice) to a bad doctor (pattern indicating carelessness) to a criminal doctor (pattern indicating knowledge or intention to violate law).

In addition, objective, reasonable, or good faith prescribing may protect physicians from liability; good faith in this context means “the honest exercise of good professional judgment as to a patient’s medical needs. Good faith connotes an observance of conduct in accordance with what the physician should reasonably believe to be proper medical practice.”²¹⁵ This coupled with the standard of care delineations implicates a contextual basis for any determinations of liability. Therefore, to avoid liability under the CSA, physicians must prescribe reasonably and carefully in context of the patient’s presentation.

b. Penalties: Penalties for CSA violations range from civil to criminal penalties, including mandatory incarcerations and monetary penalties.²¹⁶ “[I]f a patient dies from an overdose ... [of a prescribed drug,] the prescribing physician could face charges of manslaughter or even murder”;²¹⁷ death or serious harm come with an enhanced penalty of a mandatory minimum sentence of 20 years in jail under the CSA.²¹⁸ Some misprescribers have been sentenced under this provision,²¹⁹ which applies “if death or serious bodily injury results *from the use of* the unlawfully distributed substance.”²²⁰ A recent Supreme Court case, *Burrage v. United States*, clarified that under the CSA, the prescribed drug must be the *actual cause* of the victim’s death in order for the enhanced penalty to apply.²²¹ States can also bring criminal negligence charges against a physician independent of or in tandem with federal CSA charges after a patient overdoses.²²²

c. Loss of Authorization to Prescribe Controlled Substances: Absent or alongside criminal charges for violating the CSA, physicians may have their authority to prescribe controlled substances revoked or suspended;²²³ this is a regulatory process separate from criminal proceedings. These administrative adjudications, before administrative law judges, concern the DEA’s regulation of provider prescriptive authority for controlled substances.²²⁴ Grounds for denial, suspension, or revocation of a certificate of registration include: (1) material falsification of any applications to the DEA regarding controlled substances;²²⁵ (2) conviction of a state or federal felony related to controlled substances;²²⁶ (3) revocation or suspension of state license to practice medicine or state registration to prescribe controlled substances;²²⁷ (4) any acts that would make registration “inconsistent with the public interest”;²²⁸ or (5) exclusion from federal programs.²²⁹ Registration that is inconsistent with

the public interest is determined considering several factors,²³⁰ none of which is prioritized.²³¹

The conduct required for a certificate of registration action must deviate from the standard of care more than what is required for civil liability, but not to the extent required for criminal liability—perhaps in the range of the bad doctor standard described by the *Feingold* court.²³² At the same time, just one instance of diversion is sufficient to justify revocation.²³³ Opioid-related morbidity and mortality increases have led to more complex adjudications. According to a DEA administrative law judge:

[o]ne inexorable result of federal efforts to react reasonably to an immense growth in prescription medication dependence is *an increasingly complex and nuanced practice* of administrative law before the Drug Enforcement Administration.... The practice has morphed into a *more contested and complicated dynamic* that now requires litigation and academic skills that far exceed those previously demanded.²³⁴

Because physicians stand to lose so much from one investigation, it is more important than ever that data about misprescribers be updated and verified.

3. Increased Opioid Prescribing Scrutiny—There are continued concerns about the chilling effect of investigations on legitimate physician prescribing.²³⁵ According to one health law attorney, “[a]s prescription drug overdoses rise nationwide, attorneys are seeing more physicians held liable Doctors make easy targets ... because they often are seen as placing would-be weapons into patients’ hands”²³⁶ Any unexpected patient death may attract scrutiny and legal difficulties;²³⁷ those involving opioids are almost certain to do so, with physicians occasionally facing criminal murder charges after a patient’s death.²³⁸ Some commentators have noted that physicians are more readily prosecuted after a patient overdoses on opioids, as opposed to other kinds of drugs.²³⁹ This may be a consequence of the level of cultural concern surrounding opioids, or alternatively because a death involving controlled substances simply offers additional causes of action through state and federal controlled substances laws.

The DEA has the authority to investigate for any reason,²⁴⁰ but also asserts that they do not target physicians or prescribers for investigation.²⁴¹ The agency has stated that the “types of cases in which physicians have been found to have dispensed controlled substances improperly under federal law generally involve facts where the physician’s conduct is not merely of questionable legality, but instead is a glaring example of illegal activity.”²⁴² While isolated examples of overreaching prosecutors exist,²⁴³ there are no recent data regarding prosecutors’ decisions to charge physicians. A 2003 study revealed a number of prosecutors surveyed understood the complexity of misprescriber situations;²⁴⁴ however, the majority of prosecutors did not regard physicians as effective self-regulators.²⁴⁵ The prosecutors ranked deceptive patients as the largest source of diversion, followed by impaired, dated, and dishonest doctors, respectively.²⁴⁶ The group did significantly over-estimate the risk of addiction resulting from therapeutic treatment with opioids as moderate to high; the extent of that belief was positively correlated with willingness to investigate and charge physicians.²⁴⁷ Along with beliefs about the risks of addiction, the most relevant factors in

the decision to charge were beliefs about the actions of the SMB and whether the doctor prioritized her own financial interests over patient care.²⁴⁸ Many prosecutors have been willing to rely on SMBs to determine appropriate physician behavior.²⁴⁹ At the same time, their own beliefs about addiction or the appropriateness of SMB action influenced their decisions to charge, which highlights the need for education to correct mistaken beliefs and to develop effective working relationships between law enforcement and SMBs.²⁵⁰

There are some indications that law enforcement scrutiny of physicians has grown recently in reaction to the rise in prescription drug abuse. Beginning in 2008, the DEA aggressively added agents and resources to the tactical diversion squads that investigate providers and pharmacies; these groups conducted several highly publicized operations, such as “Operation Pill Nation I” and “Operation Pill Nation II.”²⁵¹ According to high-ranking officials at the DEA, the squads increased investigations, inspections, and administrative actions significantly.²⁵² The number of criminal malpractice prosecutions in this area has also risen.²⁵³ Others have alleged that certain SMBs are eager to sanction physicians who they believe too generously prescribe opioids.²⁵⁴

This may not be unwarranted: although they are a small percentage, misprescribers not only contribute to the drug abuse problem, they do so in a way that hurts both individuals with SUD and patients in pain. Opioids, especially when combined with other drugs such as benzodiazepines and alcohol, are particularly dangerous.²⁵⁵ While the majority of these prescriptions are appropriate, all physicians are obligated to carefully select and assess the patient’s candidacy and response to prescription medications.

Law enforcement is obligated to conduct informed and contextual investigations; overreach can destroy the professional and personal lives of wrongfully prosecuted physicians and cause additional harms to patients in pain by worsening the chilling effect.²⁵⁶ Some have suggested that it can also create “[e]xcessive skepticism toward patients reporting chronic pain can promote stigmatization, opiophobia, and undertreatment of legitimate problems, not to mention counterproductive adversarial tone in doctor-patient communications.”²⁵⁷ It also creates a culture of “suspicion of patients reporting intense pain, itself already a problem, for the subjectivity of pain already creates an air of distrust between the between the doctor—who relies upon objective measures—and the patient—who claims to be suffering but yet cannot ‘prove’ it objectively.”²⁵⁸

Creating a culture of avoidance can also prevent physicians from appropriately diagnosing and treating (or referring for treatment) those patients with a SUD.²⁵⁹ This only worsens the underlying cultural narratives about SUD that characterize those with addiction as social deviants rather than people with a serious medical condition.²⁶⁰ This social narrative is powerfully active in physicians as well and may be more powerful at times than the lessons during medical training. Drummond describes the struggles of residents in a palliative care rotation treating terminal, self-identified addicts for pain at the end of life.²⁶¹ She writes about the frustration of residents who “feel like ... [drug] dealer[s]” and the permeability of the line between social and medical values.²⁶² According to Drummond, three underlying narratives are evident:

an American cultural narrative about addicts as social deviants, a medical cultural narrative about “drug seeking” patients, and a third narrative which is shared by both medical culture and American culture: the story of the deviant physician who complies with such a patient’s request, thus becoming the addict patient’s “dealer.”²⁶³

Those that practice pain management also face a guilt-by-association label because so many illicit drug diversion groups branded themselves as “pain clinics” as a front for illegal activities.²⁶⁴ This led to numerous additional state imposed restrictions on pain clinics and the practice of pain medicine and possibly increased scrutiny from law enforcement.²⁶⁵ As a result, pain physicians, in particular, fear investigations and false arrest. Lynn Webster, the President of the American Academy of Pain Medicine, faced a four-year long DEA investigation of his prescribing practices but was not charged.²⁶⁶ Dr. Webster explained the reluctance of pain physicians to use opioids: “[p]hysicians practicing in good faith who use opioids to treat some types of chronic pain face negative judgments, [and] ... clinical judgments retrospectively can be viewed as reckless and willful intent to cause harm.”²⁶⁷ At the same time, he emphasizes that there are “unsavory physicians who dispense pills for profit without a legitimate medical need. Crossing the line in this manner has disrupted the ability of real doctors to treat patients with real pain when opioids are involved.”²⁶⁸

Although existing research does not show a correlation between pain specialization and legal sanction for misprescribing,²⁶⁹ the perception that this correlation exists remains among pain specialists, and a number of high profile cases have added to those fears.²⁷⁰ There is also a paucity of literature on false accusations.²⁷¹ The consequences of false accusations are serious, “ranging from an unearned loss of trust to an unearned deviant label, as well as other losses such as money and freedom.”²⁷² False labeling, because of criminal operations converting the pain-management moniker, may contribute to increased scrutiny as well.²⁷³

The case against Dr. Debra Roggow, a pain management physician who is board certified in physical medicine and rehabilitation, seemed to focus only on the amount of opioids prescribed.²⁷⁴ She was swept up in the federal “Pill Nation II” operation, described as a “drug dealer[] wearing [a] white coat[],”²⁷⁵ but ultimately was acquitted of charges.²⁷⁶ According to Dr. Roggow’s attorney:

The government looks at [medical pain management] as if there’s something wrong when a physician hits a certain quantity (or dosage) or hits a certain timeframe of prescribing. [This type of assessment] should be a concern for all physicians. In this case, however, the physician kept very good medical records and regularly performed physical examinations and monitored her patients for functional improvements and drug side effects. Had this not been the case, you might be better able to understand how the case could be brought.²⁷⁷

To the extent Roggow’s case is illustrative of a false accusation, it ended in the same way most reported overreaching cases do: with an exoneration of the accused through acquittal or dismissal.²⁷⁸ Having a favorable result does not erase the serious reputational, financial, personal, and professional harm to those wrongly accused.²⁷⁹ It is not surprising that fear of false accusation drives those physician behaviors that do not prioritize patient well-being.²⁸⁰

At the same time, there are misprescribers whose practices range from careless to criminal; SMBs alone cannot meet the demands resulting from such practices.²⁸¹ Instead, collaboration and cooperation between SMBs and law enforcement is essential. An improved model of opioid prescribing behavior that warrants investigation could facilitate the collaboration of SMBs and law enforcement, and provide much needed guidance to physicians who wish to treat pain adequately while managing the risk of investigation.

IV. Careless, Corrupt, and Compromised Physician Misprescribers

“[P]hysicians, like all people, are subject to temptations, aversions, errors in judgment, and missteps.”²⁸²

There are multiple categories of physician behavior that warrant discipline of some kind for misprescribing. Refining the basic model of physician misprescribing based on updated evidence is a modest, macro level step. Part II.B offered a critique of the current 4D model, focusing on the problem of the “duped” category, which unfairly blames physicians for believing patients.²⁸³ A better approach is to focus consistently and explicitly on physician traits that contribute to the misprescribing behavior, such as the 3C model of misprescribers: Careless, Corrupt, and Compromised. This Article argues that this approach better aligns with determinations of culpability.

A. Careless Physicians

For reasons other than impairment, physicians in this category are practicing below the appropriate standard of care and causing harm to others. In this category, the behavior is taking place within the practice of medicine—that is, there is no intent to engage in criminal activity—but the practice patterns are careless and even reckless. These misprescribers fail to attend to basic procedural requirements for competent and careful practice.²⁸⁴

In this category, carelessness does not warrant criminal charges unless it rises to the level of recklessness required for state charges such as manslaughter. In general, sanctions by SMBs are most appropriate. The misprescribing in the careless category typically consists of procedural failures under conditions with no or limited physician oversight.²⁸⁵

The case of Dr. Jarrott is illustrative:²⁸⁶ he was disciplined by the Louisiana SMB for a pattern of misprescribing in the late 1990s and early 2000s.²⁸⁷ For one patient, Jarrott repeatedly prescribed increasing doses of opioids and benzodiazepines without adequately documenting any history or continued evaluation of the medications’ effectiveness.²⁸⁸ Worse yet, he prescribed without consulting the patient’s other doctors, previous records, or hospital records. All of these sources would have revealed that the patient was hospitalized for medication overdoses once or twice per year for four years.²⁸⁹ In two of the instances, Dr. Jarrot issued prescriptions just days after the patient’s discharge from opioid overdose hospitalizations.²⁹⁰ All of this occurred without referral to or consultation with other physicians and despite the warnings of the patient’s mother.²⁹¹ The last interaction Dr. Jarrott had with this patient was when he refilled her multiple prescriptions just two weeks after she was issued a month’s supply; the patient died the next day.²⁹² Thus, the court found:

Dr. Jarrott's failure to order or failure to follow through on a drug screen for the patient, failure to create a treatment plan properly including non-addictive modalities, failing to consult or refer to an appropriate specialist(s), ... follow up on psychiatric care, ... understand or control the patient's supply of controlled substances, and failure to address the family's warnings ... demonstrated ongoing breaches of medical standards and medical incompetence.²⁹³

Similar patterns emerge in other cases of careless misprescribing and include repeated failures to follow-up on information critical to the patient's well being or to engage with the patient on their current state of health; failures to consult other physicians or seek help and advice; continued willingness to fill prescriptions early and repeatedly; and failure to attend to the concerns of others (such as pharmacists or family members).²⁹⁴

Opioids are often prescribed in doses or combinations inappropriate to the patient's presentation.²⁹⁵ But careless misprescribers are consistently inattentive to patients' medical needs and continue to prescribe opioids even when ample evidence indicates opioids are not advancing patient well-being.²⁹⁶ They are not merely "duped" or "dated,"²⁹⁷ rather they are clearly not practicing medicine in a responsible manner. Thus, subjecting them to disciplinary action is fair and serves to protect the public. At the same time, there is no evidence that such careless prescribers personally benefit from their negligence and it would be hard to prove that their failure to practice up to the standard of care is due to a willful blindness or a willing embrace of criminal identity.

B. Corrupt Physicians

*"What makes a man 'bad'—his actions, his motives, or his conscious decision to be a bad person?"*²⁹⁸

It is hard to understand why some physicians become corrupt despite the high bar to enter the profession and the benefits of the professional reputation; nonetheless, physicians do sometimes break with any semblance of professional care.²⁹⁹ Common factors in misprescribing cases, particularly those involving outlaw physicians, include motivations of greed, such as accepting cash only or cash in excess of fair market value. Other common factors include dispensing from within the clinic (rather than sending patients to a pharmacy), solo practice or practice with non-licensed personnel, prescribing doses and combinations of medications that no level of tolerance could account for, and leaving reports of concerned patient family members, friends, other physicians, and pharmacists unaddressed.³⁰⁰

The most common scheme involving corrupt physicians is (or was) "pill mills," in which cash is exchanged for prescriptions without medical care.³⁰¹ Sadly, according to one convicted pill mill operator, "you need somebody to write the prescriptions [and] ... [h]iring doctors to sell drugs is easy."³⁰² Other research has revealed that there are indeed outlaw doctors willing to betray professional obligations in favor of criminal rewards.³⁰³ Rigg and colleagues' research with individuals in prescription OUD recovery is revealing.³⁰⁴ Participants told stories of taking other people's MRIs to visits with the name crossed out with a magic marker; of physicians just asking them what drugs they wanted outright; and of

being directed to the doctor's pharmacy only; the participants also reconstructed the identity of the prescriber from a doctor to a "legal drug dealer[]" or "candy man."³⁰⁵

Some physicians enter the criminal enterprise despite prestigious credentials. At one time, Dr. David Brizer was a successful academic physician with a record of publications and a faculty appointment at New York University.³⁰⁶ In 2013, the New York psychiatrist and addiction specialist admitted to outright selling prescriptions to non-patients for \$300 a script, including writing prescriptions in fictitious names for a cumulative profit of nearly half a million dollars.³⁰⁷ He eventually entered a plea deal with New York to resolve the over fifty felony charges against him and voluntarily surrendered his license.³⁰⁸

Dr. Brizer was an active scholar in the 1980s and 1990s, publishing a number of articles on psychiatry, addiction, and violence.³⁰⁹ By 1998 he left academia and was director of adult inpatient psychiatry at a New Jersey facility;³¹⁰ later he served as chair of psychiatry at Norwalk Hospital.³¹¹ But by 2009, he no longer listed any institutional affiliations in his publications³¹² and was working in a solo practice when charged.³¹³ His last publication, a co-edited text on addiction psychology was published in 2010,³¹⁴ the first year he admitted to selling prescriptions.³¹⁵ It is unclear what led to his break with professional identity.³¹⁶ Less than two years after his conviction and surrender of his license, Dr. Brizer appears to be working as a life coach;³¹⁷ he also is soliciting work as a house sitter and a writer.³¹⁸ Nonetheless, his ability to reach an agreement with prosecutors and to voluntarily surrender his license displayed some degree of acceptance of responsibility and willingness to change.³¹⁹

Other corrupt physicians have shown an unfortunate abundance of hubris. A notable example is that of Paul Volkman,³²⁰ a former emergency medicine and pediatric physician.³²¹ In 2003, a series of medical malpractice cases made him uninsurable and unemployable in traditional medical pursuits.³²² His complete lack of humility and inability to seek help are evident even in earlier records of his practice. In one case, a toddler with epiglottitis died in his pediatric office after Volkman insisted on attempting to intubate her in the office without emergency equipment and despite clinical contraindications, close proximity of multiple emergency departments, and the objections of hospital and emergency personnel.³²³ Even after forbidding paramedics to assist and multiple failed attempts to obtain an airway, Volkman refused to move the child to an emergency department no less than five times before an emergency team from the pediatric hospital took over.³²⁴ Although they resuscitated and intubated her, she died.³²⁵

In the aftermath of this and other malpractice cases, Volkman began working as the sole physician at a health clinic owned by non-physicians in Ohio in 2003.³²⁶ His practice soon drew questions from pharmacists and distributors.³²⁷ After pharmacies in the area refused to fill his prescriptions, Dr. Volkman applied for a distributor license and the clinic began directly dispensing controlled substances.³²⁸ Between 2003 and 2005, he was often among the top purchasers *in the nation* of Schedule II and Schedule III drugs, such as oxycodone and hydrocodone (schedule III until 2014); distributors from across the nation contacted the DEA out of concern at the size of his orders.³²⁹ The Ohio Board of Pharmacy inspected

several times and issued violations, once noting a “Glock handgun, two night sticks, and a four-foot club with leather straps—all in the area where the clinic dispensed drugs.”³³⁰

The clinic operated on a cash only basis and required hundreds of dollars from each patient, without exception, before Dr. Volkman would see them.³³¹ Patient after patient reported receiving massive quantities and doses of medication without an examination; one patient reported receiving 900 Percocet and 180 Lorcet (oxycodone/acetaminophen and hydrocodone/acetaminophen combinations) on the first clinic visit.³³² An audit of the drug inventory in the dispensing side of the clinic found shortages of nearly 50,000 10mg pills of diazepam (a strong benzodiazepine) as well as hundreds of thousands of oxycodone and hydrocodone combination products.³³³ Federal investigators in 2005 noted, “[u]rine specimen cups, filled with urine, were scattered all over the floor. The clinic has no equipment to view X-rays and MRI results. Miscellaneous pills were strewn all throughout the clinic premises.”³³⁴

Soon thereafter, the clinic owner fired Volkman, citing his inability to work with others and lack of oversight; Volkman then opened his own “clinics” in two locations for the same practices.³³⁵ In 2006, Volkman’s certificate of registration and distributor registration were revoked.³³⁶ He was also sued for wrongful death after he tripled the oxycodone dose for a patient on his second visit and initiated high doses of both Valium and Xanax; the patient died the next day of an overdose.³³⁷ In 2007, Volkman wrote a self-promotional comment to a *New York Times* story, claiming persecution by the DEA even though he was an “extremely careful” physician.³³⁸ His hubris, distorted justifications, and perhaps narcissistic tendencies are evident in his statements:

why the vicious DEA campaign against doctors? It wont [sic] save us all from the evils of drug addiction. In fact, the DEA is a vicious, criminal organization, corrupt from top to bottom. In fact, the DEA has no desire to stop drug diversion. In fact, the *DEA fosters and controls drug diversion, taking a healthy cut of the cash flow from the sale of illegal drugs on the street.* The DEA brings bogus charges and stages sham trials to cover up their own criminal role, and to put doctors out of business. *Pain doctors, after all, make it possible for patients to obtain pain medicine legally from pharmacies, instead of having to buy it on the street,* thus taking business away from the DEA.³³⁹

Volkman was arrested later that year and charged with multiple federal offenses, including violations of the CSA leading to the deaths of four patients.³⁴⁰ In 2008 his license to practice medicine was revoked, and it remains permanently revoked despite two subsequent appeals.³⁴¹ In 2011, he was convicted on every federal charge by a jury, and in 2012 he was sentenced to four life sentences under the enhanced penalty provision of the CSA and ordered to forfeit 1.2 million dollars.³⁴² As he stood before the judge for sentencing, instead of expressing remorse, he “demanded [he] be released from jail.”³⁴³ He lost an appeal of that decision in 2013;³⁴⁴ however, his sentence enhancement under the CSA for causing the deaths of his patients will be reviewed by the Sixth Circuit following the Supreme Court’s remand for review of causation in light of the Court’s 2014 decision in *Burrage*.³⁴⁵

Dr. Dewey MacKay's case is another in which negligent practice goes beyond what we categorize as "careless." His willful blindness, which the courts recognize as equivalent of knowingly or intentionally distributing controlled substances for nonmedical purposes, differentiates his case. Dr. MacKay was an orthopedic surgeon until 2001, when his health problems led him to switch to pain management, and he soon began practicing out of an office as a solo practitioner.³⁴⁶ McKay's prescribing practices went far beyond a "bad doctor" standard of care and revealed a sustained pattern of: (1) egregiously overscheduling patients (e.g. sometimes seeing 100 patients in less than eight hours); (2) conducting no or only cursory examinations with entire visits lasting between two to five minutes; (3) complete omissions in charting; (4) reflexive prescribing of controlled substances without evaluation or consideration of alternatives; and (5) other negligent practices.³⁴⁷ In several instances, he continued to prescribe to patients who reported to him that they were receiving multiple prescriptions from other doctors (doctor shopping) and prescribed to patients despite knowing the patients had existing prescription agreements with other physicians.³⁴⁸ He repeatedly refilled prescriptions "early" after prescriptions were reported as lost or stolen.³⁴⁹ In 2011, a federal jury convicted him on forty counts, thirty-seven of which were for unlawful distribution of controlled substances.³⁵⁰ In upholding those convictions, the court looked to facts such as his: (1) failure to record important information regarding prescription, diagnosis, and functional improvement; (2) prescribing quantities and dose of opioids without a relationship to function; (3) superficial or absent examinations; and (4) other information that indicated an "overwhelming[] ... disregard" for proper prescribing.³⁵¹ He was sentenced to twenty years in prison based on the enhanced penalty provision connected to the overdose death of a patient,³⁵² which was later reduced to thirty-six months.³⁵³ In describing MacKay's conduct and criminal conviction, the district court acknowledged there was no proof that the doctor decided to "become a criminal."³⁵⁴ Instead, "[t]here was evidence that showed him to be inattentive to the conditions of his patients to the point that criminal culpability could rationally be found, as it was."³⁵⁵ We would also note that Dr. MacKay benefitted from his behavior in the same way that other "corrupt" physicians benefit because seeing 100 patients per day is extremely profitable.

These are just a few examples of corrupt physicians. A recent review of 100 cases of improper prescribing of controlled substances found a clear pattern among physicians who fit what this Article calls the "corrupt" physician profile: they were motivated by financial gain and sometimes sex; worked in solo or small private practices that provide little oversight; and prescribed to patients who suffered from chronic pain or SUDs, providing them with demand.³⁵⁶ Many of them also evidenced self-centered personality traits.³⁵⁷

The bigger questions are how and why do these individuals cast aside the obligations of their professional identity? In most cases, financial reward provides a clear motive for the deviation from professional standards.³⁵⁸ A sense of self-efficacy, the "belief that one can perform successfully at a given task or endeavor," may also be a motivator for criminal activity.³⁵⁹ In contrast to those whose crimes "stem from need, desperation, or impulsive behavior," the ability to plan and succeed in the criminal enterprise using special abilities or skills may help construct or maintain a successful image and frame the meaning offenders attach to the crimes.³⁶⁰

A common but disturbing phenomenon among criminals is their capacity to rationalize their actions and maintain their own self image. According to Banja,

most human beings perceive themselves as good and decent people, such that they can understand many of their rule violations as entirely rational and ethically acceptable responses to problematic situations. They understand themselves to be doing nothing wrong, and will be outraged and often fiercely defend themselves when confronted with evidence to the contrary.³⁶¹

Although not studied in physician offenders, non-physician criminals use rationalization techniques both before and after commission of crime.³⁶² These techniques may be related to the problems identified by attorneys who represented physicians facing criminal or disciplinary proceedings. Heumann and colleagues reported that attorneys were most frustrated by the inability of many of the physicians to admit or display any remorse at all; many preferred “to continue to argue their innocence” instead.³⁶³ “They elaborated upon what they saw as exculpatory considerations which removed their responsibility” and “were frequently unable to show sincerity in admitting contriteness for their actions; the egos of many physicians interfered with their acceptance of responsibility and expressions to the court.”³⁶⁴

C. Compromised by Impairment

In contrast, some physicians misprescribe because their abilities are compromised by impairment. Impairment is the “inability of a licensee to practice medicine with reasonable skill and safety” due to mental or physical illness or condition that adversely affect cognitive, motor, or perceptive skills, or habitual or excessive use or abuse of controlled substances, alcohol or other substances that impair ability.³⁶⁵ Of these, drug and alcohol impairments are the most common reasons for discipline.³⁶⁶ SMBs have worked to provide access to rehabilitation for impaired physicians, who are more likely to have their licenses restored than those disciplined for reasons unrelated to impairment.³⁶⁷ This group, however, also has the highest risk of repeat disciplinary actions,³⁶⁸ probably because of the chronic and relapsing nature of addiction.³⁶⁹

Although physicians are somewhat healthier overall as compared to the general population, their rates of overall SUD are higher than the general population; in fact, the rates of opioid and benzodiazepine misuse are up to five times higher.³⁷⁰ In addition, SUD increases an individual’s risk of suicide, which is an even more pressing concern for physicians because they already experience a much higher rate of suicide than the general population.³⁷¹ Why physicians have better health habits than the general population but higher rates of SUD is unknown.³⁷² There are a number of theories, ranging from a higher rate of family history of SUD, a higher rate of diagnosable SUD or mental health disorders as medical students, stressful work environments, personality traits that attract individuals to medicine, second-hand exposure, and the easy access to drugs of abuse.³⁷³ Impaired physicians risk financial loss, legal problems, loss of license to practice medicine, and significant health threats.³⁷⁴ Consequences extend beyond the personal harms to the physician’s family, co-workers, employers and especially patients.³⁷⁵

Physicians as a professional group were one of the first to acknowledge the problems of impairment and created impaired physician programs, which Morrow calls both a practical activity and “a symbolic expression of the basic professional beliefs and values that underlie medical practice and influence colleagues’ relations with each other, with patients, and with the public.”³⁷⁶ This acknowledgment marked a change in self-regulation and disciplinary methods, which were previously either “educational[]” or “punitive” in nature.³⁷⁷ It created a zone of blame mitigation, in which the behavior is understood as a product of the impairment, and for which treatment offers restoration of the capacity for professional, ethical behavior.³⁷⁸

Impaired physicians are also not a significant source of diverted drugs: they more often misappropriate drugs for their own use than engage in practices more likely to lead to direct harm to patients.³⁷⁹ Cummings and colleagues found that impaired physicians typically diverted by stealing opioids from the workplace, writing fraudulent prescriptions for personal use, using medication samples, or by misusing valid prescriptions.³⁸⁰ These findings were consistent with previous work by Parran, who found that impaired physicians did not have significantly different prescribing practices for their patients in comparison to non-impaired physicians.³⁸¹

There is evidence that physicians with SUD can return to practice after intensive treatment, follow up and monitoring. McLellan and colleagues studied the outcomes of nearly 1,000 physicians treated in such programs between 1995 and 2001; they found that at five years after completing a comprehensive program, seventy-eight percent of the physicians were practicing in good standing.³⁸² Every state has a support system in place to treat the impaired physician through Physician Health Programs, which evaluate and treat impaired physicians voluntarily or involuntarily.³⁸³ For those who resist voluntary treatment, the threat of the loss of their medical license is often successful; in fact, treatment outcomes are similar for those treated voluntarily and involuntarily.³⁸⁴ A “combination of medical, psychosocial, support group interventions, combined with extensive posttreatment monitoring and drug testing, generally results in sustained recovery among the physicians who attend specialized treatment programs.”³⁸⁵

Thus, at least when underlying impairments contribute to misprescribing, there is hope that evidence-based remediation programs can prevent future deviations. These programs exhibit both compassion for the affected professional and concern for the well being of the patients. Underlying contributing causes of misprescribing, however, have not been nearly as well studied. Until that deficit is rectified, SMBs and law enforcement must continue playing catch-up and risk both over and under-reaching with their investigations and responses.

V. Conclusion: A Modest Proposal and Implications for Research

The problem of misprescribing opioids requires further study to understand its frequency, the factors that influence misprescribing, and its impact on patients, particularly those suffering pain and those with SUDs. The dominant model of misprescribers, the 4D model, is inaccurate and may perpetuate mistaken beliefs and even harmful practices as a result. Significant research into identifying and mitigating misprescribing and the associated harms

is warranted; however, based on existing evidence, the 4D model should be replaced with a 3C model (Careless, Corrupt, and Compromised) (See Table 1). The 3C model (1) consistently focuses on the behavior of physicians (rather than patients), and (2) better matches behaviors with culpability and thus appropriate responses by SMBs and law enforcement.

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References

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2. *See, e.g.*, Institute of Medicine, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research* 1–4 (2011) (hereinafter IOM, *Relieving Pain in America*) (“*The 2010 Patient Protection and Affordable Care Act* required the Department of Health and Human Services (HHS) to enlist the Institute of Medicine (IOM) in examining pain as a public health problem.”). This is true over time, across clinical setting, patient age, and diagnosis. *See generally id.*
3. *See, e.g.*, Rosenblum, *supra* note 1, at 406 (“During the 1990s, a major change occurred [t]he use of opioids for legitimate medical purposes has been accompanied by a substantial increase in the prevalence of nonmedical use of prescription opioids.”) (citation omitted).
4. Rosenblum, *supra* note 1, at 406. Opioids are only a small part of the overall treatment of pain and the public health problem of insufficient and inadequate treatment of pain is only somewhat related to the availability and appropriate use of prescription opioids. Goldberg, Daniel S., McGee, Summer J. Pain As a Global Public Health Priority. Oct.2011 at 3. 11 *BMC Public Health* (“Thinking about global chronic pain as a public health priority implies immediately that the global focus on access to essential medicines like opioids is insufficient as a primary police strategy.”) In addition, evidence for the long term effectiveness for opioids in chronic pain is lacking. Chou, Roger, et al. The Effectiveness and Risks of Long-Term Opioid Therapy for Chronic Pain: A Systematic Review for a National Institutes of Health Pathways to Prevention Workshop. 2015; 276:276. 162 *Annals Internal Med* (“[M]ost opioid trials do not extend beyond 6 weeks and are of limited relevance to long-term opioid use.”).
5. *See* Cheatle, Martin D., Savage, Seddon R. Informed Consent in Opioid Therapy: A Potential Obligation and Opportunity. 2012; 105:106. 44 *J. Pain & Symptom Mgmt* It is a barrier but one of many and should not be conflated with the inadequate treatment of pain altogether. *See, e.g.*, Goldberg, Daniel S. On the Erroneous Conflation of Opiophobia and the Undertreatment of Pain. 2010; 20:20. 10 *Am. J. Bioethics*
6. Cheatle & Savage, *supra* note 5. This is a problem that has existed for probably as long as physicians had opioids at their disposal. *See, e.g.*, Marks, Richard M., Sachar, Edward J. Undertreatment of Medical Inpatients with Narcotic Analgesics. 1973; 173:173. 78 *Annals Internal Med* (“Physicians who exaggerated the dangers of addiction were more likely to prescribe lower doses of drugs, even for patients with terminal malignancy.... causing much needless suffering....”). Wesson and Smith described the tendency of the “legitimate” needs of some patients for access to be “overlooked” and overshadowed by the focus on curbing prescription drug abuse. *See* Wesson, Donald R., Smith, David E. Prescription Drug Abuse: Patient, Physician, and Cultural Responsibilities. 1990; 613:613. 152 *W. J. Med*
7. *See* Dickson, Barry D., et al. Use of Opioids to Treat Chronic, Noncancer Pain. 2000; 107:109. 172 *W. J. Med* (“Reports [on the effect of opioid use on pain] encompassing more than 1000 patients have described favorable outcomes in selected samples of patients.”).

8. See, e.g., *United States v. Purdue Frederick Co.*, 495 F.Supp.2d 569, 576 (W.D. Va. 2007) (accepting the plea deals between Purdue, three of its executives, and the United States). Purdue Pharmaceuticals and associated companies engaged in flagrant dissemination of patently untrue information about Oxycontin, ultimately resulting in over 600 million dollars in fines. Between 1995 and 2001, the company advanced that Oxycontin was “less addictive” and more abuse deterrent than immediate release versions of oxycodone. *Id.* at 571–72. These claims were both untrue and noted as such in the scientific evaluation of the drug during FDA approval. Emily Chasan, *Pursue Frederick Pleads Guilty in OxyContin Case*, Reuters (May 10, 2007, 2:27 PM), <http://www.reuters.com/article/us-oxycontin-misbranding-idUSWBT00695020070510> [perma.cc/ARZ4-CCVH]. Griffin, O Hayden, III, Miller, Bryan Lee. OxyContin and a Regulation Deficiency of the Pharmaceutical Industry: Rethinking State-Corporate Crime. 2010:213.19 *Critical Criminology* Lexchin, Joel, Kohler, Jillian Clare. The Danger of Imperfect Regulation: OxyContin Use in the United States and Canada. 2011:233.23 *Int’l J. Risk & Safety Med*
9. See, e.g., de Leon-Casasola, Oscar A. Opioids for Chronic Pain: New Evidence, New Strategies, Safe Prescribing. 2013; S3:S9.126 *Am. J. Med* (“Opioids are a viable treatment alternative in patients with pain....”); Cheattle & Savage, *supra* note 6 (“There is growing consensus that opioid treatment agreements ... or contracts are an important component of clinical management of opioid therapy for pain.”) (citation omitted).
10. Dart, Richard C., et al. Trends in Opioid Analgesic Abuse and Mortality in the United States. 2015; 241:242.372 *New Eng. J. Med*
11. The Diagnostic and Statistical Manual, Fifth Edition (DSM-V) combines previous definitions of substance abuse and substance dependence into a substance use disorder spectrum ranging from mild to severe. *Am. Psychiatric Ass’n Substance Related and Addictive Disorders* 1–2 (2013) <http://www.dsm5.org/Documents/Substance%20Use%20Disorder%20Fact%20Sheet.pdf> [perma.cc/9UQA-XCL9].
12. See, e.g., Rigg, Khary K., Murphy, John W. Understanding the Etiology of Prescription Opioid Abuse: Implications for Prevention and Treatment. 2013; 963:965.23 *Qualitative Health Res* (identifying themes of opioid misuse emerging after heroin or cocaine use as well as some who initially took opioids as prescribed but switched to abuse after experiencing euphoric effects); See, e.g., Ling, Walter, et al. Prescription Opioid Abuse, Pain and Addiction: Clinical Issues and Implications. 2011; 300:300.30 *Drug & Alcohol Rev* (addressing the increasing public health problem of opioid misuse).
13. Dart, *supra* note 10; Harold Pollack, *100 Americans Die of drug Overdoses Each Day. How Do We Stop That?*, Wash Post. (Feb. 7, 2014), <https://www.washingtonpost.com/news/wonk/wp/2014/02/07/100-americans-die-of-drug-overdoses-each-day-how-do-we-stop-that/> [perma.cc/4QFR-P76B]. The majority of those involved polysubstance ingestion or Methadone. Pollack, *supra* note 13. See HHS, Substance Abuse & Mental Health Services Administration, Drug Abuse Warning Network, 2011: National Estimates of Drug Related Emergency Department Visits, HHS Publication No. (SMA) 13–4760, DAWN Series D-39 (2013) [hereinafter Drug Related Visits Study].
14. The attention was certainly more than the problem of suffering and pain garner. See, e.g., Peter Eisler, *Seniors and Prescription Drugs: As Misuse Rises, So Does the Toll*, USA Today (May 22, 2014), <http://www.usatoday.com/story/news/nation/2014/05/20/seniors-addiction-prescription-drugs-painkillers/9277489/> [perma.cc/S8QU-T7MY] (arguing that the “medical community ... is often quick to offer narcotic painkillers ...”); Aaron Glanz, *Opiates Handed Out Like Candy to ‘Doped Up’ Veterans at Wisconsin VA*, *Reveal* (Jan. 8, 2015) <http://www.revealnews.org/article-legacy/opiates-handed-out-like-candy-to-doped-up-veterans-at-wisconsin-va/> [perma.cc/Q5PG-NUA9] (noting that veterans refer to the VA medical center in Wisconsin as “candy land”); Lynn Webster, *NFL Players Reveal Nation’s Poor Treatment of Chronic Pain*, *Chicago Sun Times* (August 26, 2014), http://espn.go.com/nfl/story/_/id/10958191/nfl-illegally-supplied-risky-painkilling-drugs-former-players-allege-suit [perma.cc/7ARU-D242] (arguing that more must be done to treat chronic pain); Graeme Wood, *Doctors Without Moral Borders: What Makes This Drug Crisis Different From All Other Drug Crises?*, *The New Republic* (March 24, 2014) (“[M]odern medicine hasn’t yet figured out a universally effective way to wean abusers off long-term addiction; some will be sliding up to a methadone-clinic window every morning for the rest of their lives. And their addictions will continue the way they began, just as the doctor ordered.”).

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17. Blanco et al., *supra* note 16, at 144 (estimating that the lifetime probability of seeking treatment for those with OUDs is 42%). This fact is even more shocking considering the recognition of SUD as a disease is more than a century old; Willcox WH. Norman Kerr Memorial Lecture on Drug Addiction. Brit Med J. 1923:1013–16. ("The only treatment that gives a hopeful prospect of complete cure is one which recognizes that drug addiction is a disease, and as such requires the same careful attention to detail [as] any other disease").
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22. Christopher Jones et al., *supra* note 20, at 803 (“Among nonmedical users reporting 200 to 365 days of use, opioid pain relievers were most often obtained via prescription from physicians (27.3%).”).
23. In March 2015, the Secretary of Health and Human Services announced a new three-part initiative to address opioid use disorders. *See HHS, Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths*, ASPE Issue brief, 1 1 (2015), <http://www.hhs.gov/news/press/2015pres/03/20150326a.html> [perma.cc/9SSL-B99K]. Prescribing practices are the third part of the initiative. *Id.*
24. *See supra* notes 8–18 and accompanying text.
25. See Barnes, Michael C., Sklaver, Stacey L. Active Verification and Vigilance: A Method to Avoid Civil and Criminal Liability when Prescribing Controlled Substances. 2013; 93:100.15 DePaul J. Health Care L. This too, is a multifaceted problem, in part because physicians are so poorly trained in recognizing and appropriately treating or referring patient with SUDs alone much less those who also have complex comorbid conditions. *See McLellan, A Thomas, et al. Can Substance Use Disorders be Managed Using the Chronic Care Model?: Review and Recommendations from a NIDA Consensus Group*. 2014; 1:6–7.35 Pub. Health Rev
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27. *See, e.g., Cheatle & Savage, supra* note 6 (“[M]any pain expert agree that opioids remain the most effective analgesics available.”).
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30. *See* Donald R. Wesson & David E. Smith, *supra* note 6, at 614. The 4D model was adopted by the Amer. Medical Ass’n (AMA) in the 1980s following the 1980 White House Conference on Prescription Drug Abuse. *Id.*
31. *Id.* at 614 (describing the framework as intended to “stimulate educational alternatives for the dated or duped physicians” and as being “pragmatically useful” because several state boards of medicine did begin offering educational strategies and other “alternatives to discipline”).
32. *See, e.g., id* at 616 (Wesson and Smith urged refinement of the model, especially the duped category in 1990).
33. *See, e.g., Hoffmann ... Tarzian, supra* note 29 (board of medicine members struggle with the idea of being duped as a measure, one said “[i]t’s the standard of care to take care of people’s pain just like it’s the standard of care not to be duped”) Spickard, Anderson, Jr, et al. Changes Made by Physicians Who Misprescribed. 2002; 110:110.88 J. Med. Licensure ... Discipline (“Physicians cited for prescribing by a state medical board generally fall into two distinct groups: those who abuse (disabled) and/or sell drugs (dishonest), and physicians whose misprescribing results from a variety of other causes (dated, duped).”). Voth, Eric A. Prescribing Controlled Substances Reconsidered. 2008 2 J. Global Drug Pol’y ... Practice (discussing the meaning of “Dated”, “Duped”, “Disabled” and “Dishonesty”)

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37. *See, e.g.,* United States v. Ilayayev, 800 F.Supp.2d 417, 436 (E.D. N.Y. 2011) (explaining that physicians are in a “precarious position when considering prescribing opioid[s]”).
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41. *See, e.g.,*Khaliq, Amir A., et al. Disciplinary Action Against Physicians: Who Is Likely to Get Disciplined?. 2005:773.118 Am. J. Med(exploring the “spectrum of characteristics of physicians by the Oklahoma Board of Medical Licensure and Supervision since its inception in 1922)Kohatsu, Neal D., et al. Characteristics Associated with Physician Discipline: A Case-Control Study. 2004:653.164 Archives Internal Med(studying California Board of Medicine cases between 1998 and 2001).
42. *See, e.g.,*Heumann, Milton, et al. Prescribing Justice: The Law and Politics of Discipline for Physician Felony Offenders. 2007:1.17 B.U. Pub. Interest L. J(studying discipline and felony convictions of physicians in New Jersey through 2006); Kohatsu et al., *supra* note 41Morrison, James, Wickersham, Peter. Physicians Disciplined by a State Medical Board. 1998:1889.279 J. Am. Med. Ass’n(studying discipline by the California medical board from 1995 to1997)
43. *See, e.g.,*Arora, Kavita Shah, et al. What Brings Physicians to Disciplinary Review? A Further Subcategorization. 2014:53.5 Am. J. Bioethics Empirical Bioethics(acknowledging that studying data from the AMA eliminates most physicians because the majority of U.S. physicians are not members of the AMA)
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46. Kohatsu et al., *supra* note 41, at 655; Jung et al., *supra* note 44, at 343;
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48. Kohatsu et al., *supra* note 41, at 655
49. Khaliq et al., *supra* note 41, at 775; Kohatsu et al. *supra* note 41, at 655Jung et al., *supra* note 44, at 341.
50. Goldenbaum et al., *supra* note 44, at 742.
51. DuBois, James M., et al. A Content Analysis of Reports on 100 Cases of Improper Prescribing of Controlled Substances. J Drug Issues. 2015 forthcoming.
52. Rich & Webster, *supra* note 40.
53. *See id.* at S60–62 (physician errors included 1) starting “opioid-naïve patients” on excessive and dangerous doses of drugs, 2) inaccurately converting the doses from one opioid to another and resulting in too high of dose, and 3) directing too rapid an escalation in doses and 4) failing to screen for comorbidities while patient behaviors were self-medication, self-escalation of doses, and polysubstance abuse).
54. *Id.* at S61–62.

55. *See generally id.* (exploring the effects of physician error in the context of prescribing opioids).
56. For example, many states have seriously restricted physicians' ability to practice as pain specialists, created detailed practice standards for prescribing, or similar actions. *See, e.g.*, Tenn. Code. Ann. § 63-1-301 (2010 & Supp. 2015) (including a definition for "[p]ain management clinic"); Fla. Stat. § 459.0137 (2007 & Supp. 2016) (detailing specific requirements for "[p]ain-management clinics"). The DEA has also invested significant resources into new tactical diversion squads charged with investigating doctors and pharmacies as potential sources of diversion. *See* Joseph T. Rannazzisi, Deputy Asst. Administrator, Drug Enforcement Agency, U.S. Dep't of Justice, *Statement for the Record: Responding to the Prescription Drug Abuse Epidemic*, U.S. Senate Caucus on International Narcotics Control (July 18, 2012), <http://www.dea.gov/pr/speeches-testimony/2012-2009/responding-to-prescription-drug-abuse.PDF> [perma.cc/C3RP-9LLK].
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62. Lance P. Longo et al., *supra* note 58.
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64. *Id.* at 615.
65. *Id.* at 615–16. Two additional Ds were later suggested but never adopted: dismayed (careless because of "time constraints", external pressures) and dysfunctional (unable to say no to anyone because of psychological or personality traits. Brown, Martha E., et al. Searching for Answers: Proper Prescribing of Controlled Prescription Drugs. 2012; 79:80–81.44 J. Psychoactive Drugs We focus on the AMA's 4D model and recommend changes because while these two additional categories provided some further explanations, but still are under-inclusive.
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67. Longo et al., *supra* note 58.
68. Wesson & Smith, *supra* note 6, at 616 ("Drug abusers ... may create the illusion ... that they are seeking medical attention for a disease or illness for which the desired drug would be appropriate. Scams for medications can be quite sophisticated, innovative, and impossible to unravel in the time available for the physician-patient interaction.").
69. Drummond, Karen L. I Feel Like His Dealer: Narratives Underlying a Case Discussion in a Palliative Medicine Rotation. 2012; 124:134.30 Literature & Med
70. *Id.*
71. *See, e.g.*, Jung, Beth, Reidenberg, Marcus M. Physicians Being Deceived. 2007; 433:433.8 Pain Med ("Our review of [DEA] ... actions against physicians who prescribed opioids found that some of these actions were based on prescriptions given to undercover agents. In several high-profile prosecutions of physicians for prescribing opioids, prosecutors claimed that the doctors should have known the individuals were feigning pain solely to obtain the prescriptions.") (citation omitted) Reidenberg MM, Willis O. Prosecution of Physicians for Prescribing Opioids to Patients. 2007; 903:904.81 Clinical Pharmacology & Therapeutics (finding that in many of the cases they reviewed between 2004 and 2005, the focus was on the fact that undercover officers had "fooled" the physician); Hailey Branson-Potts, L.A. Times Blog (June 15, 2012, 6:11 PM), <http://latimesblogs.latimes.com/lanow/2012/06/doctor-charged-with-murder-supplied-addict-with-hundreds-of-addictive-pills-each-week-former-patient.html> [perma.cc/U5B2-6WB9] ("In two weeks of testimony, prosecution witnesses have said they exaggerated or lied to [the doctor] about suffering pain and walked away with their desired prescriptions after little or no examination.").
72. Jung & Reidenberg, *supra* note 71.
73. Ziegler, *supra* note 66, at 445.

74. See, e.g., Hellman, Deborah. Prosecuting Doctors for Trusting Patients. 2009; 701:702. arguing that physicians should trust their patients. 16 George Mason L. Rev
75. See Reidenberg & Willis, *supra* note 71, at 905 (identifying being deceived as one of three groups of physicians investigated for misprescribing); see generally Jung & Reidenberg, *supra* note 71 (describing many DEA actions focusing on deception of physicians).
76. Bartlett, Marian Stewart, et al. Automatic Decoding of Facial Movements Reveals Deceptive Pain Expressions. 2014; 738:738, 740.24 Current Biology (finding computer vision system was more accurate, at 85%, than humans)
77. Jung & Reidenberg, *supra* note 71, at 434. There are also well documented problems with disbelief of patient reports of pain, but this could be worsened in part by the language of duped. See *id.* at 435.
78. See, e.g., *id.* at 434–35 (reviewing the results of six studies on standardized patients and physician detection).
79. See Rich & Webster, *supra* note 40, at S64.
80. See Johnson, Sandra H. Regulating Physician Behavior: Taking Doctors' "Bad Law" Claims Seriously. 2009; 973:988. noting that physician decisions were historically accorded deference because of the paternalistic relationship between doctor and patient. 53 St. Louis U. L.J
81. Jung & Reidenberg, *supra* note 71, at 436.
82. See Reidenberg & Willis, *supra* note 71, at 903. There is continuing evidence that patients in pain face discounting and sometime outright suspicion by physicians. The language of duped may underlie or exacerbate this problem. See, e.g., Jung & Reidenberg, *supra* note 71, at 436 ("When portions of the medical press describe cases of physicians accused of diverting controlled substances because they were deceived, suspicion of patients with chronic pain complaints increases.").
83. Jung & Reidenberg, *supra* note 71 at 435.
84. See Kasson, Saul M., et al. Police Interviewing and Interrogation: A Self-Report Survey of Police Practices and Beliefs. 2007; 381:393–94.31 L. & Hum. Behav (finding survey participants estimated their lie detection abilities at 77% but reality is about 54%).
85. See, e.g., Vrij, Aldert, et al. Pitfalls and Opportunities in Nonverbal and Verbal Lie Detection. 2010; 89:97–98.11 Psychological Science Pub. Int For example, as opposed to not making eye contact, liars will work to maintain eye contact while truth tellers scanning their memories may often shift their gazes. *Id.* at 96.
86. See Saul M. Kasson et al., *supra* note 84 at 382–383. See also Vrij, Aldert, Granhag, Pär Anders. Eliciting Cues to Deception and Truth: What Matters Are the Questions Asked. 2012:110.1 J. Applied Res. Memory & Cognition (recommending deception researchers "stop ... trying to find good lie detectors, teaching people to focus on cues that are not really diagnostic, or designing yet another gadget based on the anxiety assumption").
87. Saul M. Kasson et al., *supra* note 84, at 393–94.
88. Kasson, Saul M., et al. I'd Know a False Confession if I Saw One: A Comparative Study of College Students and Police Investigators. 2005; 211:221–22.29 L. & Hum. Behav (finding students more accurate than police, and police more confident and prone to judge confessors as guilty).
89. See, e.g., United States v. Magallanez, 408 F.3d 672, (10th Cir. 2005) (examining whether a witness is credible if there is a significant motive to lie); see also Meixner, John B. Liar, Liar, Jury's the Trier? The Future of Neuroscience-Based Credibility Assessment in the Court. 2012; 1451:1464. Comment. 106 Nw. U. L. Rev ("It would be wonderful if judges and jurors were able to determine the credibility of witnesses by carefully staring at the witnesses' shoulders and lower lips during testimony, but an abundance of research into laypeople's and trained individuals' ability to detect lies has shown that people are simply not very good at detecting lies by analyzing demeanor. Additionally, training individuals to look for certain demeanor-based cues does not significantly improve accuracy; in fact, it increases misplaced confidence in one's own abilities to detect lies and leads to a bias toward suspecting others' untruthfulness.") (footnotes omitted).
90. United States v. Scheffer, 523 U.S. 303, 313 (1998) (citing United States v. Barnard, 490 F.2d 907, 912 (9th Cir. 1973))

91. *Scheffer*, 523 U.S. at 313 (citing *Aetna Life Ins. Co. of Hartford v. Ward*, 140 U.S. 76, 88 (1891)) (internal quotations omitted).
92. Baker, Alysha, et al. Will Get Fooled Again: Emotionally Intelligent People Are Easily Duped by High-Stakes Deceivers. 2013; 300:308–09.18 *Legal & Criminological Psychology*
93. *Id.* at 309. This is preliminary research but could represent a significant hurdle for already taxed physicians trying to straddle the competing interests and pressures of treating pain and not contributing to diversion.
94. *See, e.g.*, Paul Burcher, *Emotional Intelligence and Empathy: Its Relevance in the Clinical Encounter*, 3 *Patient Intelligence* 23, 27 (2011) (“For physicians, both emotional intelligence and empathy are crucial.”) *see also* Stanton, Clive, et al. Comparison of Emotional Intelligence Between Psychiatrists and Surgeons. 2011:124.35 *Psychiatrist* (finding psychiatrists and surgeons had similar composite EI scores but that psychiatrists were significantly higher on emotional awareness and empathy subcategories while surgeons scored higher on self-regard subcategory)
95. *See, e.g.*, Mintz, Laura Janine, Stoller, James K. A Systematic Review of Physician Leadership and Emotional Intelligence. *J Graduate Med Educ.* 2014; 1:21, 22–25. (“Eighty-three articles addressed the theme that EI is a key component of developing medical leaders”) Serio, Catherine D., Epperly, Ted. Physician Leadership: A New Model for a New Generation. *Fam Practice Mgmt.* 2006; 51:52. (“[S]uccessful leadership stems not from one’s IQ but from one’s EQ, or emotional intelligence”)
96. *See, e.g.* Bellon, Juan Angel, Fernandez-Asensio, Maria Eugenia. Emotional Profile of Physicians who Interview Frequent Attenders. 2002; 33:38.48 *Patient Educ. & Counseling* (studying the emotional responses of physicians during patient interviews, and finding that 37% of participants responded felt that “I think this person really needs me”) Elder, Nancy, et al. How Respected Family Physicians Manage Difficult Patient Encounters. 2006; 533:535, 538–39.19 *J. Amer. Board Family Med* (“The physician participants discussed management strategies that we [re] classified into three categories: collaboration, empathy, and the appropriate use of power.”)
97. *See, e.g.*, Murinson, Beth B., et al. A New Program in Pain Medicine for Medical Students: Integrating Core Curriculum Knowledge with Emotional and Reflective Development. 2011; 186:192.12 *Pain Med* (“[T]he need for improved medical education in pain and pain care is clear”)
98. Letter from James L. Madara, Exec. Vice Pres., CEO, American Medical Association, to Thomas Frieden, Dir., CDC (Jan. 12, 2016), <http://www.painmed.org/files/ama-letter-to-cdc-proposed-2016-guidelines-for-prescribing.pdf> [perma.cc/K9W3-WFQC] (emphasis added).
99. *See* Maia Szalavitz, *Here’s What’s Wrong with How U.S. Doctors Respond to Painkiller Abuse*, *Pacific Standard* (Apr. 22, 2015), <http://www.psmag.com/health-and-behavior/heres-whats-wrong-with-how-us-doctors-respond-to-painkiller-misuse> [perma.cc/DT5Z-Q96B]. *See also* Bok, Sissela. Lying: Moral Choice in Public and Private Life. 1978:20. (“Those who learn that they have been lied to in an important matter ... are resentful, disappointed and suspicious [t]hey see that they were manipulated, that the deceit made them unable to make choices for themselves according to the most adequate information available, unable to act as they would have wanted to act had they known all along.”).
100. *See, e.g.*, Pate Law & Johnson, *Page Pate Successfully Resolves Case for Doctor Charged with Operating “Pill Mill”*, *Our Blog* (May 3, 2013), <http://www.pagepate.com/our-firm-successfully-resolves-case-for-doctor-charged-with-operating-pill-mill/> [perma.cc/B2CK-2TSM] (“The patient files included MRI reports, patient questionnaires, patient charts, and drug tests. The results were clear: Dr. Mintlow was engaged in the legitimate practice of medicine. Our firm also found numerous patients who were more than willing to testify that Dr. Mintlow was an excellent doctor who cared deeply about their health and quality of life.”); *see also* U.S. Dep’t of Justice, Drug Enforcement Agency, Docket No. 13–37, Samuel Mintlow, M.D.: Decision and Order (Dec. 30, 2014), http://www.deadiversion.usdoj.gov/fed_regs/actions/2015/fr0123_2.htm.
101. *See, e.g.*, Pollock, Wendi, Menard, Scott. It Was a Bum Rap: Self-Reports of Being Erroneously Arrested in a National Sample. 2014; 325:325.39 *Crim. Just. Rev.* (“Arrests that are erroneous for any reason are a serious concern in the United States, for both individuals and police departments. For individuals, these actions could cause harms in the form of the possibility of being falsely labeled as a criminal, the loss of family trust, job loss, high financial costs, incarceration, and so on.”) (citation omitted).

102. Brennan, Michael J. Letter to the Editor. 9 Pain Med. 2008; 379:380.
103. Health care in general is one of the most highly regulated industries and all facets of its operation are subject to federal, state, and local law. *See* Field, Robert I. Why is Health Care Regulation So Complicated?. 2008; 607:607.33 Pharmacy & Therapeutics; *see, e.g.,* Bryden, Daniele, Storey, Ian. Duty of Care and Medical Negligence. 2011:124.11 Continuing Educ. Anesthesia (regulating physicians through private negligence actions); *Anti-Kickback & Stark Compliance*, Am. Acad. of Family Physicians, <http://www.aafp.org/practice-management/regulatory/compliance/stark.html> (regulating contracts between physicians and other entities) [perma.cc/S7TN-Y3L4]; *A Roadmap for New Physicians: Fraud and Abuse Laws*, HHS, Office of the Inspector General, <http://oig.hhs.gov/compliance/physician-education/01laws.asp> [perma.cc/DV6B-SCTA] (regulating the sector with fraud and abuse laws); *Emergency Medical Treatment & Labor Act (EMTALA)*, Centers for Medicaid & Medicare Services, <https://www.cms.gov/Regulations-and-Guidance/Legislation/EMTALA/> [perma.cc/JQ6K-XHN8] (regulating treatment); *The HIPAA Privacy Rule*, HHS, <http://www.hhs.gov/hipaa/for-professionals/privacy/> [perma.cc/NM9D-MBUM] (regulating the transmission of health information to ensure confidentiality). This article makes no attempt to cover even a fraction of these but will focus primarily on the regulation of the individual provider professional behavior by state medical boards, law enforcement, and the Drug Enforcement Agency, a division of the Department of Justice and the Federal Bureau of Investigation.
104. Johnson, *supra* note 80.
105. *Id.* at 999–1000 (describing the impact of the penalties of the process as a category of bad law claims that should be taken seriously) (internal quotation marks omitted).
106. *See, e.g.,* Barnes & Sklaver, *supra* note 25, at 96 (“When a patient dies of a prescription drug overdose, the physician may face legal actions ranging from civil liability to first-degree murder.”)
107. *See, e.g.,* Schneider v. CMS, DAB No. CR3066, 2014 WL 265780 (Departmental App. Bd. Jan. 7, 2014) (affirming CMS’s exclusion from participation through revocation of enrollment and billing privileges for failing to report a short term suspension by the Wyoming medical board after a patient died of a mixed drug overdose involving transdermal fentanyl patches prescribed by Dr. Schneider). Conviction of a felony related to controlled substances triggers automatic exclusion from federal and state health care programs and the physicians is thereafter an excluded provider. 42 U.S.C. 1320a-7(a)(4)(2012). In addition, any suspension of a medical license requires the provider to report to the Centers for Medicare and Medicaid Services. 42 C.F.R. § 424.516(d)(1)(ii) (2015).
108. Conviction or guilty pleas of felonies related to controlled substances trigger a cascade of consequences that make it impossible to practice medicine, from excluded provider status to automatic revocation of a DEA certificate of registration to automatic suspension of a medical license. *See* 42 U.S.C. 1320a-7(a)(4).
109. *See, e.g.,* Agency for Health Care Administration v. Meek, C.I. No. 13-1101-000, at *2-3 (Fla. Div. Admin. Hearings Apr. 7, 2014) (suspending physician’s participation in the Florida Medicaid program for ten years after his federal indictment).
110. Meyer, Donald J., Price, Marilyn. Peer Review Committees and State Licensing Boards: Responding to Allegations of Physician Misconduct. 2012:193.40 J. Amer. Acad. Psychiatry L (describing the “peer review” process).
111. *See, e.g.,* Arora et al., *supra* note 43, at 54 (describing the process by which a physician could lose AMA membership as a disciplinary measure).
112. For a basic overview of medical malpractice, including the elements and standard of proof required, *see* Bal, G Sonny. An Introduction to Medical Malpractice in the United States. 2008:339.467 Clin. Orthopedics Related Res
113. *See, e.g.,* Fed’n of St. Med. Bds., U.S. Medical Regulatory Trends and Actions 7 (2014), https://www.fsmb.org/Media/Default/PDF/FSMB/Publications/us_medical_regulatory_trends_actions.pdf [perma.cc/J26J-47KE] [hereinafter U.S. Medical Regulatory Trends] (“[M]alpractice claims are not always reliable measures of a physician’s competence or a violation of the law. Issues such as a physician’s time in practice, the nature of his or her specialty, the types of patients treated, and geographic location can have a significant

influence on the number and amounts of malpractice judgments and settlements. Malpractice settlements are sometimes handled by insurance companies who opt for settlement based on the terms of coverage, not the validity of the underlying claim. These terms may also authorize settlement of a claim without any consultation of the physician involved or an ultimate determination of fault.”).

114. *See, e.g.*, Stelfox, Henry Thomas, et al. The Relation of Patient Satisfaction with Complaints Against Physicians and Malpractice Lawsuits. 2005; 1126:1131.118 Amer. J. Med(“[P]hysicians who received low patient satisfaction ratings were more likely to have complains from patients and malpractice lawsuits than those with high ratings. Physicians with high rates of complaints from patients were also more likely to have malpractice lawsuits than were physicians with low rates.”).
115. *See, e.g.*, Hermer, Laura D., Brody, Howard. Defensive Medicine, Cost Containment, and Reform. 2010; 470:470.25 J. Gen. Internal Med(arguing that fear of medical malpractice results in “defensive medicine”).
116. *See e.g.*, Mayer, Gilah A. Why an Elder Abuse Case is a Stride in the Direction of Civil Culpability for Physicians Who Undertreat Patients Suffering from Terminal Pain. 2002:313. Comment, Bergman v. Chin: 37 New Eng. L. Rev(discussing *Bergman v. Chin*, one of the most notable cases where a physician has been found liable for undertreating that resulted in a \$1.5 million jury verdict).
117. Johnson, Sandra H. Customary Standards of Care: A Challenge for Regulation and Practice. 2013; 9:9–10.43 Hastings Center Rep.(noting the difficulty in the reliance on the majority practices and how it can incentive physicians to practice in the “safety of the middle of the herd” rather than employ new evidence based practices or engage in innovation).
118. *See id.* at 9; *see also* Zitter, Jay M. Physician’s Liability for Patient’s Addiction to or Overdose from Prescription Drugs. 2009; 391:402–03. Annotation. 6th. 44 A.L.R.(describing the standard of care, in general terms, as “standard of skill and learning ordinarily possessed and exercised under similar circumstances by physicians in good standing in the same or similar localities”).
119. Brushwood, David B. Debunking Myths of Negligence in Pain Management Practice. 2007; 47:48.21 J. Pain & Palliative Care Pharmacotherapy
120. *See, e.g., id* at 50–52 (discussing a Florida case in which the physician was not found liable for failing to include every possible action listing in the state guideline but showing reasonable attention to the benefits and harms to the patient). There are at least some indications that the legal system governing malpractice is able to discern when medical care is individualized and that it need not include every possible option to protect against liability. *See, e.g.*, Dallaire v. Hsu, No. CV075004043, 2010 WL 2822494, at *7 (Conn. Super. Ct. 2010) (holding failure of physician to follow guidelines to contact previous doctors and pharmacies before prescribing opioids did not constitute a deviation from the standard of care); *see, e.g.*, Brushwood, *supra* note 119 (discussing a case where the Thir District Court of Appeal of Florida recognized that “pain management practice requires doing ... things that are appropriate for each patient”).
121. Jay M. Zitter, *supra* note 118. These include whether (1) doses were excessive in relationship to the patient’s history, (2) prescriptions were written with minimal or no physical exam, (3) the physician warned the patient of dangers, such as polysubstance ingestion, (4) the physician failed to refer the patient to specialty care, (5) the physician failed to give proper weight to the opinions of others, and (6) the physician failed to keep appropriate records. None of them are dispositive alone. *See general id.*
122. *See, e.g.*, Rich & Webster, *supra* note 40, at S62 (“A failure to modify practices recently proven to be ineffective or to pose unacceptable risks to patients can provide the basis of a finding of medical malpractice”).
123. In fact, SMBs often weigh the import of malpractice cases based only on patterns. *See* U.S. Medical Regulatory Trends, *supra* note 113. One case usually does not warrant action or concern.
124. Bal, Amrit K., Bal, B Sonny. Medicolegal Sidebar: State Medical Boards and Physician Disciplinary Actions. 2014; 28:31.472 Clin. Orthopaedics & Related Res
125. *See* Meyer & Price, *supra* note 110, at 195, 199 (explaining that state boards are oversight agencies, charged with protecting the public and that the “board’s client is the public,” not physicians who are privileged to practice under their authority).

126. Fed'n of State Med. Bds., Essentials of a State Medical and Osteopathic Practice Act 3 (2012) [hereinafter, FSMB, Essentials], http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/GRPOL_essentials.pdf [perma.cc/YTC5-PX4N] (emphasis added, numbers added for clarity).
127. *See id.* at 3–4.
128. Vulnerable populations in this article means “groups that are not well-integrated into the healthcare system because of ethnic, cultural, economic, geographical, or health characteristics, and whose isolation from health care puts them at risk....” Ellen Lawton & Megan Sandel, *Investing in Legal Prevention: Connecting Access to Civil Justice and Healthcare through Medical-Legal Partnership*, 35 J. Legal Med. 29, 30 (2014).
129. *See* Fed'n St. Med. Bds., 2014 Annual Report: Connecting for Success 4–5 (2014), <http://www.fsmb.org/Media/Default/PDF/Publications/fsmb-annual-report2014.pdf> [perma.cc/7LYF-CNGX]; *see also* FSMB, Essentials, *supra* note 126, at 4 (“‘Competence’ means possessing the requisite abilities and qualities (cognitive, non-cognitive, and communicative) to perform effectively within the scope of the physician’s practice while adhering to professional ethical standards.”).
130. *See, e.g.*, James N. Thompson & Lisa A. Robin, *State Medical Boards: Future Challenges for Regulation and Quality Enhancement of Medical Care*, 33 J. Legal Med. 93, 104 (2012) (noting that “boards cannot function as police overseeing the practice of medicine. The boards are set up to respond to complaints from individuals or organizations within the state.”).
131. *See* Johnson, *supra* note 117, at 9.
132. *See* U.S. Medical Regulatory Trends, *supra* note 113, at 6–7.
133. *See, e.g.*, Khaliq et al., *supra* note 41, at 776 (indicating the results from their study on which physicians are more likely to be disciplined).
134. *See, e.g.*, *Recent Actions*, Arizona Board of Osteopathic Examiners in Medicine and Surgery, <http://www.azdo.gov/GLSPages/RecentActions.aspx> (listing cases of prescribing issues or physicians with substance abuse issues, such as driving under the influence convictions or appearing to work impaired); *see Recent Actions*, Arizona Board of Allopathic Medicine, *Recent Actions*, <http://www.azmd.gov/GLSPages/RecentActions.aspx>.
135. For example, the Federation of State Medical Boards Model Policy on Opioid Use in the Treatment of Chronic Pain emphasizes that “inappropriate treatment [of pain] includes non-treatment, inadequate treatment, overtreatment, and continued use of ineffective treatments.” FSMB, Model Policy on the Use of Opioids, *supra* note 15, at 7.
136. Hoffmann & Tarzian, *supra* note 29, at 22.
137. *See, e.g.*, Heumann, Milton, et al. Bad Medicine: On Disciplining Physician Felons. 2009; 133:153–167.11 Cardozo J. Conflict Resolution (“present[ing] the first-ever comprehensive analysis of the legal and political disciplinary processes for physician felony offenders in the state of New York”).
138. Young, Aaron, et al. A Census of Actively Licensed Physicians in the United States, 2012. 2013; 11:14.99 J. Med. Reg.(reporting that three-quarters of licensed physicians are board certified).
139. *See* U.S. Medical Regulatory Trends, *supra* note 113, at 19 (using the reported numbers of disciplined physicians divided by the total number of licensed physicians in 2012 results in a rate of 0.00510).
140. *Id.* at 20.
141. *See* Fla. Dept. of Health, Division of Medical Quality Assurance, 2011–2012 Annual Report and Long Range Plan 18 (2012) http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/annual-report-12a.pdf [https://perma.cc/4WSB-9C9Q] (reporting 35/208 complaints resulted in discipline in 2009–10 and 58/207 (28%) in 2011–2012).
142. Bal & Bal, *supra* note 124, at 29.
143. *See* U.S. Medical Regulatory Trends, *supra* note 113, at 57–58. For example, SMBs must report certain actions to the National Practitioner Databank (NPDB). *See About Us*, National Practitioner Databank, <http://www.npdb.hrsa.gov/topNavigation/aboutUs.jsp> [perma.cc/G4H2-ANQN].
144. U.S. Medical Regulatory Trends, *supra* note 113, at 9.

145. *See, e.g.*, Kim, Christopher J. The Trial of Conrad Murray: Prosecuting Physicians for Negligent Over-Prescription. 2014; 517:519.51 Am. Crim. L. Rev. (“[W]hen a doctor over-prescribes medication, he exposes himself to the danger of criminal liability.”).
146. *See, e.g.*, Mo. Rev. Stat. § 334.103(1) (2008) (creating an automatic revocation upon conviction and conclusion of proceedings for felony involving the practice of medicine, dishonestly, fraud, and moral turpitude, among others).
147. *See* 21 U.S.C. § 822(a)(2) (2012) The COR is issued by the Attorney General, who heads the Department of Justice, the federal department in which the DEA is situated. *See id.* The Attorney General is also empowered to deny, revoke, suspend, or limit them through the DEA. 21 U.S.C. § 824 (2012).
148. *See, e.g.*, Hoffmann, Diane. Treating Pain versus Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws and Policies. 2008; 231:236, 256–57.1 St. Louis U. J. Health L. & Pol’y (“discuss[ing] the ‘culture clash’ ... between physicians and drug enforcement personnel”).
149. *See id.* at 257.
150. *See id.*
151. *See id.* at 256–57.
152. *See id.*
153. *See id.* Of course, opinions on the utility of opioids vary by physician and by practice area. For example, surgeons generally see opioids as an important component of post-operative acute pain management while those who specialize in addiction medicine may have different views. *See, e.g.*, C. J. Arlotta, *Orthopedic Surgeons Largely Contribute to Opioid Epidemic, Study Reveals*, Forbes (May 12, 2015), <http://www.forbes.com/sites/cjarlotta/2015/05/12/orthopaedic-surgeons-largely-contribute-to-opioid-epidemic-study-reveals/#45eed665636c> (“Even though emergency physicians are not likely to prescribe opioids to discharged patients, doctors from other medical fields are contributing to the opioid epidemic at a higher rate.”)
154. For a fascinating account of the early efforts to regulate drugs with the potential for abuse for the benefit of the public health, see Acker, Caroline Jean. *Addiction and the Laboratory: The Work of the National Research Council’s Committee on Drug Addiction, 1928–1939*. 1995:167.86 Isis
155. Harrison Narcotics Tax Act, Pub. L. No. 63-223, 38 Stat. 785 (codified as amended at 26 U.S.C. § 4701 et. seq.); *see also*, C.E. Terry, *The Harrison Anti-Narcotic Act*, 5 Amer. J. Pub. Health 518, 518 (1915) (criticizing the act as insufficient).
156. §2(a), 38 Stat. at 786 (requiring new recordkeeping and charting requirements as well). The language of the Controlled Substances Act allows for prescriptions for a “legitimate medical purpose” in the usual course of professional practice, a standard that continues to confound many experts. Controlled Substances Act, Pub. L. 91-513, § 101, § 102, 84 Stat. 1242, 1244 (1970) (codified at 21 U.S.C. § 801 et. seq.).
157. *See* Cantor, Donald J. The Criminal Law and the Narcotics Problem. 1961; 512:514.54 J. Crim. L. & criminology
158. *See, e.g.*, King, Rufus G. The Narcotics Bureau and the Harrison Act: Jailing the Healers and the Sick. 1953; 736:736–38.62 Yale L. J. (“Our grievous error was in allowing the narcotics addict to be pushed out of society and relegated to the criminal community.”).
159. *See*, for example, Herrick, Walter R. Second Annual Report of the Narcotic Drug Control Commission. 1920:17. (partly attributing addiction to the fact that “without dispute that the rank and file of medical practitioners in the State are employing narcotics vastly in excess of ... legitimate therapeutics”), for an interesting view into the historical attitudes surrounding opioids and substance abuse. *See also* Stanley LL. Morphinism. 1916; 586:588.6 J. Crim. L. & Criminology (“Physicians of the last decade have been too eager to allay pain merely by slight injection of morphine ... with the result that people... have been unwittingly put under the defiling influence of the drug.”).
160. *See, e.g.*, Volkow, Nora D., et al. Medication-Assisted Therapies—Tackling the Opioid–Overdose Epidemic. 2014:2063.370 New Eng. J. Med. (describing the difficulties in treating opioid addiction); *see also* Suzanne Neilsen et al., *Buprenorphine Pharmacotherapy and Behavioral Treatment: Comparison of Outcomes Among Prescription Opioid Users, Heroin Users and Combination Users*, 48 J. Substance Abuse Treatment 70 (2015) (studying the effectiveness of

buprenorphine in prescription opioid uses); Jennifer Sharpe Potter et al., *The Multi-Site Opioid Addiction Treatment Study: 18-Month Outcomes*, 48 J. Substance Abuse Treatment 62 (2015) (studying “long-term response to treatment of opioid addiction”).

161. See King, *supra* note 158. Even in the early 1950s, scholars acknowledged that criminal punishment was an insufficient deterrent to drug crimes. See, e.g., Pescor MJ. The Problem of Narcotic Drug Addiction. 1953; 471:478.43 J. Crim. L. & Criminology
162. See King, *supra* note 158, at 738.
163. Some states require newly licensed providers to obtain authority through a separate state agency such as a state board of pharmacy. In those states, the DEA requires proof that such state authorization exists before issuing a COR. See, e.g., *DEA Form 224- New Application for Registration*, U.S. Dep’t of Justice, Drug Enforcement Agency, Division of Diversion Control, http://www.deadiversion.usdoj.gov/drugreg/reg_apps/224/224_instruct.htm [perma.cc/6L3L-9UG6] (Section 4 addresses the interaction between the DEA and the state).
164. See U.S. Medical Regulatory Trends, *supra* note 113, at 74.
165. See *id.*
166. *Infra* Part III.C.1.
167. Federal Food, Drug, & Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 301 et seq.) (2014)) [hereinafter FDCA].
168. See FDA, *A History of Drug Regulation in the United States* 7 (2006), <http://www.fda.gov/downloads/AboutFDA/WhatWeDo/History/ProductRegulation/PromotingSafeandEffectiveDrugsfor100Years/UCM114468.pdf> [perma.cc/CH59-Q3ZZ] [hereinafter History of Drug Regulation] (The Durham Humphrey Amendments of 1951 “identified fairly clear parameters for what constitutes a prescription drug”).
169. *Id.* at 2.
170. See *id.* at 14.
171. Drug Amendments of 1962, Pub. L. No. 87-781, § 102(a)(1), 76 Stat. 780, 782-83 (Oct. 10, 1962).
172. See, e.g., *Understanding Investigational Drugs and Off Label Use of Approved Drugs*, FDA. (Feb. 5, 2016), <http://www.fda.gov/forpatients/other/offlabel/default.htm> [perma.cc/9KRV-CFJT] (providing information about the labeling and use of off-label drugs).
173. See, e.g., FDA, Extended-Release (ER) and Long-Acting (LA) Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS) 2 (2015), <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM311290.pdf> (“The goal of this REMS is to reduce serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse of extended-release or long-acting (ER/LA) opioid analgesics while maintaining patient access to pain medications. Adverse outcomes of concern include addiction, unintentional overdose, and death.”). The FDA’s ability to impose REMS was the result of the 2007 Food and Drug Administration Amendments Act. *FDAAA Implementation – Highlights One Year After Enactment Summary*, FDA (Apr. 27, 2009), <http://www.fda.gov/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCA/FoodandDrugAdministrationAmendmentsActof2007/ucm083161.htm> [perma.cc/A5AE-YYNS].
174. See 21 U.S.C. §§ 811-12 (2012); see also *Scheduling of Drugs Under the Controlled Substance Act*, FDA, <http://www.fda.gov/newsevents/testimony/ucm115087.htm> [perma.cc/QVP4-YDGU] (discussing the FDA’s role in the scheduling process and specifically addressing three drug substances of interest at the time of the statement’s release).
175. Controlled Substances Act, Pub. L. No. 106-172, §§ 6, 7, 114 Stat. 11 (2000) (as amended by Pub. L. 111-8, div. G, title I, § 1301(d), 123 Stat. 829 (2009)). The Comprehensive Drug Abuse and Prevention & Control Act of 1970 established requirements related to the manufacture, prescription, and distribution of any controlled substance. 21 U.S.C. § 801. It also provides procedural requirements for the Attorney General to follow regarding scheduling of drugs. 21 U.S.C. § 811.
176. 21 U.S.C. § 331.
177. *Id.* § 333(a)(1).

178. 21 U.S.C. § 353(b). *See also*, United States v. Nazir, 211 F. Supp. 2d 1372, 1377 (S.D. Fla. 2002) (“[T]he word ‘prescription’ cannot be defined as mere piece of paper signed by a doctor for drugs, no matter how fraudulent.”).
179. *Id.* §§ 801–904
180. *Id.* § 812(b).
181. *Id.* § 812(b)(1)(A)–(B). Schedule I drugs can only be used by providers subject to specific permissions for use in research and include drugs such as heroin, LSD, and crack cocaine. *See* 21 C.F.R. § 1308.11 (2015).
182. 21 U.S.C. § 812(b)(2)–(5).
183. 21 C.F.R. § 1308.12. Until October 2014, hydrocodone with Tylenol was a schedule III drug also. *See also* Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II, 79 Fed. Reg. 49,661, 49,662 (Aug. 22, 2014) (to be codified at 21 C.F.R. pt. 1308).
184. *See*, e.g. Zhong, Wenjun, et al. Age and Sex Patterns of Drug Prescribing in a Defined American Population. 2013; 697:704.88 Mayo Clinic Proc
185. 21 C.F.R. § 1308.13.
186. 21 C.F.R. § 1308.14. It is worth noting, however, that benzodiazepines are implicated in almost a third of prescription drug overdoses. *Prescription Drug Overdose Data: Deaths from Prescription Opioid Overdose*, CDC (Oct. 16, 2015), <http://www.cdc.gov/drugoverdose/data/overdose.html> [perma.cc/C79H-CXM8].
187. 21 U.S.C. § 841(a) (emphasis added).
188. *Id.* § 846; *see Id.* § 841(b) for the penalties of such an offense.
189. *Id.* § 829. Although not directly applied to in-person prescribing, a 2008 Amendment to the CSA added that “[t]he term ‘valid prescription’ means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by ... a practitioner who has conducted *at least 1 in-person medical evaluation* of the patient....” Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Pub. L. No 110–425, § 309, 122 Stat. 4820 (2008) (emphasis added).
190. 21 C.F.R. § 1306.04(a).
191. *See* 21 U.S.C. §§ 353(b), 802(21), 829(b).
192. *See, e.g.*, United States v. Boccone, 556 F. App’x. 215, 228 (4th Cir. 2014) (explaining that conviction under CSA requires the government to show that a practitioner “distributed or dispensed a controlled substance ... acted knowingly and intentionally, ... [and that the practitioner’s] actions were not for legitimate medical purposes in the usual course of his professional medical practice or were beyond the bounds of medical practice”) (internal quotation marks omitted). *See, e.g.*, United States v. Moore, 423 U.S. 122, 131–33 (1975) (holding that the possession of a COR is not a protection either).
193. *Gonzales v. Or.*, 546 U.S. 243, 274 (2006).
194. *Barnes & Sklaver*, *supra* note 25, at 103.
195. *See, e.g.*, Model Penal Code § 2.01, 2.02(2) (Am. Law Inst., Proposed Official Draft 1962) (containing four types of *mens rea*: (1) purposely (conscious and intentional acts with hope of result); (2) knowingly (knowledge that act is criminal and is practically certain of result); (3) recklessly (conscious disregard and gross deviation from law abiding standard of conduct); and (4) negligently (failure to perceive a risk such that it is a gross deviation from law abiding conduct)).
196. 21 U.S.C. § 841(a).
197. 21 C.F.R. § 1306.04 (2015).
198. *See, e.g.*, Kim, *supra* note 145, at 527–28 (discussing *United States v. Wood*, and its effect of increasing “government interest in prosecuting doctors for involuntary manslaughter”).
199. *Id.* at 532 (quoting *Criminal Negligence*, Black’s Law Dictionary (10th ed. 2014)).
200. *United States v. Katz*, 445 F.3d 1023, 1031 (8th Cir. 2006).
201. From, Justin C. Avoiding Not-So-Harmless Errors: The Appropriate Standards for Appellate Review of Willful-Blindness Jury Instructions. 2011; 275:281. Note. 97 Iowa L.

Rev(furtherdiscussing that the willful blindness theory is not limited to the CSA as it applies to many criminal causes of action (including other white collar crimes), and that it is sometimes it is used to equate one's mental state to recklessness and sometimes to knowledge.

202. *See, e.g.,* Hellman, *supra* note 74, at 716 (describing a case in which the government relied on circumstantial evidence to argue that a physician willfully blinded himself). A common example of willful blindness in CSA violations is a drug runner who demands not to be told what is contained in the transported packages. Frans J. von Kaenel, *Willful Blindness: A Permissible Substitute for Actual Knowledge Under the Money Laundering Control Act?*, 71 Wash. U. L. Q. 1189, 1199 n.61 (1993).
203. *Katz*, 445 F.3d. at 1031.
204. *Id.* (upholding the willful blindness jury instruction as proper).
205. *See generally* Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716 (Sept. 6, 2006) (responding to questions related to the role of the DEA in regulating the prescribing of controlled substances and the ways in which law enforcement may find that a physician prescribed or dispensed controlled substances for other than a legitimate medical purpose).
206. Recall that civil liability in medical malpractice can result from even one deviation from the standard of care and professional discipline usually requires some degree of pattern of inappropriate practice. *See* *McCourt v. Abernathy*, 457 S.E.2d 603, 607–08 (S.C. 1995) (holding physicians liable for failing to diagnose and treat patient within standard of care). Civil liability, however, involves loss of money and status but not loss of basic civil rights and freedoms. *See, e.g., id.* (affirming the jury's determination of damages).
207. *See, e.g.,* Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52, 716, 52, 719 (Sept. 6, 2006) ("Throughout the 90 years that this requirement has been a part of United States law, the courts have recognized that there are no definitive criteria laying out precisely what is legally permissible, as each patient's medical situation is unique and must be evaluated based on the entirety of the circumstances. DEA cannot modify or expand upon this longstanding legal requirement through the publication or endorsement of guidelines."). *See also*, Barnes & Sklaver, *supra* note 26, at 95–97; Brushwood, David B. Defining Legitimate Medical Purpose. 2005; 306:307.62 Am. J. Health-Sys. Pharmacy (arguing that the standard should be understood as without a "medical purpose" to properly protect physician good faith treatment decisions from criminal scrutiny).
208. *See, e.g.,* *United States v. Boccone*, 556 Fed. App'x. 215, 229 (4th Cir. 2014) (holding that "'there are no specific guidelines concerning what is required to support a conclusion that an accused acted outside the usual course of professional practice,' and that the court 'must engage in a case-by-case analysis of evidence to determine whether a reasonable inference of guilt may be drawn from specific facts.'") (quoting *United States v. Singh*, 54 F.3d 1182, 1187 (4th Cir. 1995)).
209. *See, e.g.,* *United States v. Feingold*, 454 F.3d 1001, 1007 (9th Cir. 2006) ("[O]nly after assessing the standards to which medical professionals generally hold themselves is it possible to evaluate whether a practitioner's conduct has deviated so far from the [standard of care]").
210. *Id.* (emphasis in original).
211. *United States v. MacKay*, 20 F. Supp. 3d 1287, 1297 (D. Utah 2014).
212. *See* Hoffmann, Diane E. Physicians Who Break the Law. 2009; 1049:1079–84.53 St. Louis U. L.J. *See also* Diane E. Hoffmann, *supra* note 148 at 239–42 (citing to cases such as the one against Dr. Frank Fisher, who spent 5 months in jail before his charges were reduced).
213. *See, e.g.,* *United States v. Kaplan*, 895 F.2d 618, 620–21 (9th Cir. 1990) (issuing numerous prescriptions for controlled substances without a documented physical exam of the patients is evidence of conduct "outside the course of usual professional practice"); *United States v. Nelson*, 383 F.3d 1227 (10th Cir. 2004) (physician convicted for selling prescriptions over the internet); *United States v. Rosen*, 582 F.2d 1032 (5th Cir. 1978) (noting that no physical examination, large numbers of amphetamine prescriptions, and use of "street slang" in reference to the drugs was sufficient to determine the doctor acted without a legitimate medical purpose).
214. *See* Brief for Defendant at 8, *United States v. MacKay*, 2011 WL 10723623 (D. Utah 2011) (No. 110CR00094) ("It is dangerous in close cases to require juries to determine if a physician is a criminal based on a deviation of undefined measure from a civil standard."); Hoffmann, *supra*

note 213, at 1080 (“In addition to the arrests and prosecutions of physicians for fraud, scores of physicians are being arrested and prosecuted for drug abuse and diversion based on a standard that is ‘uncomfortably close’ to a civil malpractice standard.”). *But see* Barnes & Sklaver, *supra* note 25, at 104 (“Physicians can meet these duties under the CSA by abiding by the medical standard of care. Although the CSA test is used for criminal liability, it is consistent with the medical standard of care, and courts have applied both the reasonable, prudent physician and medical customs tests in CSA cases.”) (footnote omitted).

215. *See* United States v. Schneider, 704 F.3d 1287, 1301 (10th Cir. 2013) (holding the good faith instruction at the trial level was not in error) (internal quotation marks omitted); *see also* Goodman, Katherine. Prosecution of Physicians as Drug Traffickers: The United States’ Failed Protection of Legitimate Opioid Prescription Under the Controlled Substances Act and South Australia’s Alternative Regulatory Approach. 2008; 210:214. Note. 47 Colum. J. Transnat’l L. (“[I]n most circuits, a physician’s good faith in treating his patients presents no bar to conviction unless he purposely complied with objectively accepted, standard medical guidelines.”).
216. 21 U.S.C. § 841(b) (2012); *see also* United States v. Ilayayev, 800 F. Supp. 2d 417, 434–43 (E.D.N.Y. 2011) (providing an excellent overview of the pressures faced by physicians and the obligations of law enforcement).
217. *Ilayayev*, 800 F. Supp. 2d at 434.
218. 21 U.S.C. 841(b).
219. *See, e.g.*, United States v. Paul Volkman, 736 F.3d 1013 (6th Cir. 2013) (affirming a physician’s sentence of four consecutive life terms for violations of the CSA leading to the deaths of four patients); United States v. Joseph, 709 F.3d 1082 (11th Cir. 2013) (affirming one doctor’s thirty-year prison sentence for “unlawfully dispensing or distributing controlled substances and causing death or serious bodily injury”); United States v. Webb, 655 F.3d 1238 (11th Cir. 2011) (affirming several concurrent life sentences for misprescribing leading to patient deaths).
220. *See. Joseph*, 709 F.3d at 1092.(emphasis added)(internal quotation marks omitted) (quoting 21 U.S.C. § 841(b)(1)(C)).
221. *Burrage v. United States*, 134 S. Ct. 881, 887 (2014). Previous to the *Burrage* decision, physician defendants faced the twenty-year mandatory sentence if the prescription contributed to the patient’s death. *See* United States v. MacKay, 20 F. Supp. 3d 1287 (D. Utah 2014) (reducing MacKay’s sentence on remand following the *Burrage* decision from 240 months of incarceration to 36 months).
222. *See* Kim, *supra* note 145 (providing a comprehensive overview of criminal medical negligence actions for over-prescription).
223. *See, e.g.*, Samuel Mintlow, M.D.; Decision and Order, 80 Fed. Reg. 3,630, 3,631 (Jan. 23, 2015) (revoking his DEA COR even though the SMB did not take action against him). Most states have state boards of pharmacy or bureaus of narcotics that authorize prescribing of controlled substances at the state level. *See, e.g.*, Joint State Government Commission: General Assembly of the Commonwealth of Pa., House Resolution 659: Report of the Task Force and Advisory Committee on Opioid Prescription Drug Proliferation 76 (2015) (“The Advisory Committee supports passage of House Bill 75 of 2015 (P.N. 66), which would require nonresident (out-of-state) pharmacies to register biennially with the State Board of Pharmacy to be permitted to fill prescription orders for Pennsylvania residents.”) An administrative action at one level will often automatically trigger parallel proceedings to sanction, suspend, or revoke the prescriber’s authority. *See e.g.*, Barbara Anderson, *Fresno Psychiatrist Faces Disciplinary Action by Medical Board in Second Patient Death*, Fresno Bee (Feb. 21, 2015), <http://www.fresnobee.com/news/local/article19536294.html> [perma.cc/6ZYV-QW44] (after being accused of gross negligence by the Medical Board of California, the physician’s license was revoked).
224. *See generally* Mulrooney, John J., II, Hull, Andrew J. Drug Diversion Administrative Revocation and Application Hearings for Medical and Pharmacy Practitioners: A Primer for Navigating Murky, Drug-Infested Waters. 2015:327.78 Alb. L. Rev.(providing an excellent and detailed description of the administrative process and the standards by which actions for revocation are measured).
225. 21 U.S.C. § 824(a)(1) (2012).

226. *Id.* § 824(a)(2).
227. *Id.* § 824(a)(3).
228. *Id.* § 824(a)(4).
229. *Id.* § 824(a)(5).
230. *Id.* § 823(f) (Factors include the recommendations of the SMB, the physician's experience with controlled substances, convictions of any laws related to controlled substances, compliance with controlled substances laws, or any other conduct that threatens public health.).
231. See Mackay, Dewey C, MD. Revocation of Registration. Aug 16.2010 49,956, 49,973. 75 Fed. Reg. ("I 'may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether a registration should be revoked'") (quoting Robert A. Leslie, M.D., 68 Fed. Reg. 15,227, 15, 230 (2003)).
232. *United States v. Feingold*, 454 F.3d 1001, 1007 (9th Cir. 2006). The DEA must find that "the practitioner's conduct went 'beyond the bounds of any legitimate medical practice, including that which would constitute civil negligence.'" Samuel Mintlow, M.D.: Decision and Order, 80 Fed. Reg., at 3648 (quoting Laurence T. McKinney, 73 Fed. Reg. 43,260, 43,266 (2008) (quoting *United States v. McIver*, 470 F.3d 550, 559 (4th Cir. 2006))) (internal quotation marks omitted).
233. See Dewey C. MacKay, M.D.; Revocation of Registration, 75 Fed. Reg., at 49,977 ("[T]he Agency has revoked other practitioner's registration for committing as few as two acts of diversion, and the Agency can revoke based on a single act of intentional diversion.") (citation omitted).
234. Mulrooney, II & Hull, *supra* note 225, at 327–28 (emphasis added) ("The prevalence of prescription controlled substance abuse has grown exponentially over the past decade. State and federal regulatory agencies have struggled to adjust to the changing realities of a new challenge and a new dynamic between the regulators and the regulated community.... [T]hese efforts have also left many responsible professionals in the regulated community scrambling to understand new realities").
235. The chilling effect was described as a myth by the DEA and researchers have asserted that the risks are very small. Press Release, DEA, The Myth of the "Chilling Effect" (Oct. 30, 2003), <http://www.dea.gov/pubs/pressrel/pr103003.html> [perma.cc/ZTX6-RAJ3]. Nonetheless, providers continue to report fears of investigation and prosecution. See, e.g., Marcus M. Reidenberg & O. Willis, *supra* note 71 (finding a reduction in the prescription of opioids due to fear of legal action).
236. Alicia Gallegos, *Physician Liability: When an Overdose Brings a Lawsuit*, Am. Med. News (Mar. 4, 2013), <http://www.amednews.com/article/20130304/profession/130309978/4/> [perma.cc/28N4-3BMD] (quoting health law attorney Michael A. Moroney)
237. See, e.g., Anderson, *supra* note 224 (describing the story of a physician who "was placed on probation six years ago for a patient death [who] now faces new disciplinary action by the Medical Board of California for a second death.").
238. See, e.g., FoxNews, *CA Doctor Ordered to Trial in 3 Drug Deaths* (June 26, 2012), <http://www.foxnews.com/us/2012/06/26/trial-decision-due-for-ca-doctor-in-drug-deaths/> [perma.cc/XD8E-KMVL] (describing the story of a physician who was charged with second-degree murder after "prescribing pain killers to three young me who died").
239. See, e.g., Reidenberg & Willis, *supra* note 71, at 905 (explaining that these prosecutions "contribute[] to physicians' fear of prescribing opioids"). This may, of course, also simply be a function of the CSA and the specific provisions regarding death or serious harm, which provide prosecutors with an explicit statutory violation to pursue.
240. *United States v. Morton Salt Co.*, 338 U.S. 632, 642–643 (1950) ("[An administrative agency's power] is more analogous to the Grand Jury, which does not depend on a case or controversy for power to get evidence but can investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not.").
241. See, e.g., Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716, 52,719 (Sept. 6, 2006) (citing the rate at which physicians in the United States have lost their DEA registration status at 0.01% in any year, fewer than 1 out of 10,000 physicians).
242. *Id.* at 52,717.

243. *See, e.g.*, Hoffmann, *supra* note 148 at 239–256 (profiling cases in which prosecutions were inappropriate).
244. Ziegler, Stephen, Lovrich, Nicholas P, Jr. Pain Relief, Prescription Drugs, and Prosecution: A Four- State Survey of Chief Prosecutors. 2003:75, 79, 83. at Table 2. 31 J.L., Med. & Ethics(studying prosecutor attitudes in Connecticut, Maryland, Oregon, and Washington regarding pain medication prescriptions and diversion).
245. *Id.* at 86.
246. *Id.* at 82–83 Table 3.
247. *Id.* at 88. Data regarding the rate of addiction within the population of patients receiving opioids on a chronic basis is extremely variable and context dependent. *Id.* Exposure alone to opioids does not create addiction, as is evidenced by the thousands of tons of unused opioids collected in medication take backs across the country. Lewis et al., *supra* note 21. That is also evidence that physicians generally prescribe more pain pills than most people need for acute pain.
248. *Id.* at 87 (explaining that decisions about charging depended upon whether the board handled it appropriately, failed to take appropriate action, or whether they are currently investigating the case).
249. *Id.* at 93–94.
250. *See, e.g.*, Fed’n St. Med. Bds., Policy Brief: Balance, Uniformity and Fairness: Effective Strategies for Law Enforcement for Investigating and Prosecuting the Diversion of Prescription Pain Medications While Protecting Appropriate Medical Practice (2009), http://www.fsmb.org/Media/Default/PDF/Publications/pub_bbpi_policy_brief.pdf [perma.cc/WF2G-KCJF] (providing information “to ensure that patients who need pain medications have access, and to prevent these drugs from becoming a source of harm and abuse”).
251. *See* Rannazzisi, *supra* note 56, at 8–9.
252. *Id.* (noting at page 8 that between 2008 and 2011, inspections increased 528% and administrative actions increased 87%).
253. *See* Kim, *supra* note 145, at 535.
254. *See* United States v. Ilayayev, 800 F. Supp. 2d 417, 434 (E.D.N.Y. 2011) (citing Christine Gorman et al., *The Case for Morphine*, Time (Apr. 28, 1997) (“identifying Tennessee, West Virginia, and New York as those states whose review boards are ‘notorious’ for revoking ... licenses”).
255. Pollack, *supra* note 13.
256. *See, e.g.*, Robert J. Gatchel, *Is Fear of Prescription Drug Abuse Resulting in Sufferers of Chronic Pain Being Undertreated?* 10 Expert Rev. Neurotherapeutics 637, 638 (2010) (citing to physician surveys to conclude that “many physicians have their limited pain medication prescriptions due to fear of regulatory investigation.”); *see also* Maia Szalavitz, *supra* note 99.
257. William B. Millard, *Grounding Frequent Flyers, Not Abandoning Them: Drug Seekers in the ED*, 49 Annals of Emergency Med. 481, 481 (2007); *see also* Reidenberg & Willis, *supra* note 71, at 905 (discussing physicians’ fear of prescribing opioids due to criminal prosecutions).
258. Karen L. Drummond, *supra* note 69, at 134; *see* McLellan, et al., *supra* note 25, at 2–3.
259. This is a significant problem already because the treatment of SUD has been unfortunately walled off through practice and regulation leaving many, if not most, physicians untrained or undertrained in recognizing possible SUD and unequipped to guide patients in this area. For an excellent discussion of this underlying problem, *see* Weber, Ellen M. Failure of Physicians to Prescribe Pharmacotherapies for Addiction: Regulatory Restrictions and Physician Resistance. 2010:49.13 J. Health Care L. & Pol’y
260. *See* Drummond, *supra* note 69, at 134 (“[E]ven within the medicalization narrative, the active addict, and to a lesser degree, the recovering addict, is still a socially deviant figure, morally suspect whilst operating under the influence and a dangerous figure even in recovery because of the risk of ‘relapse.’”).
261. Drummond, *supra* note 69.
262. *Id.* at 126.
263. *Id.* at 131.
264. *See, e.g.*, Anna Phillips, *Tampa Pill Mill Owners, Manager Sentenced to 30 Years, Get Huge Fines*, Tampa Bay Times (Sept. 19, 2014), <http://www.tampabay.com/news/courts/criminal/pain->

[clinic-owners-sentenced-to-30-years-in-prison/2198509](http://www.justice.gov/usao-ndfl/pr/pain-clinic-owner-and-two-physicians-sentenced-prescription-drug-conspiracy-and-money) [perma.cc/WS57-FN7G] (discussing the prosecution of a “couple [who allegedly] use[ed] their licensed pain clinic as a front to sell thousands of prescriptions to opioid addicts”); Press Release, United States Attorney’s Office Northern District of Florida, Pain Clinic Owner and Two Physicians Sentenced for Prescription Drug Conspiracy and Money Laundering Conspiracy (Jan. 18, 2013), <http://www.justice.gov/usao-ndfl/pr/pain-clinic-owner-and-two-physicians-sentenced-prescription-drug-conspiracy-and-money> [perma.cc/9F3D-GH53] (discussing the sentencing of physicians for “running illegal pill mill pain clinics”).

265. *See, e.g.*, Brown v. CVS Pharmacy, L.L.C., 982 F. Supp. 2d 793, 802–03 (M.D. Tenn. 2013) (detailing the recent history of Tennessee’s restrictions on opioid prescribing and pain management clinics as evidence that prescribing controlled substances is a matter of public concern); Webster, Lynn. When Prosecution Replaces Prescription. Pain Med News. Aug 5.2014 1:1.(noting that “the federal government has moved aggressively to regulate, restrict and monitor the use of painkillers”).
266. *See* Stephanie Smith, *Prominent Pain Doctor Investigated by DEA After Patient Deaths*, CNN (Dec. 20, 2013), <http://www.cnn.com/2013/12/20/health/pain-pillar/>.
267. *DEA Ends Investigation of Pain Doctor*, DrLynnWebster, <http://www.lynnwebstermd.com/dea-ends-investigation-of-pain-doctor/> [perma.cc/XJ88-2NWQ].
268. *Id.* (“Actions like these clearly create a chilling effect. There is no false narrative.”).
269. *See e.g.*, Donald M. Goldenbaum, et al., *supra* note 44 (pain specialty not disproportionately represented); James M. DuBois, et al., *supra* note 51 (“[t]his article advances understanding of improper prescribing of controlled substances”).
270. Notable cases such as that of Dr. William Hurwitz and Dr. Frank Fisher are described in multiple articles. *See* Hoffmann, *supra* note 148; Hoffmann, *supra* note 213. A more recent case is that of Dr. Daniel Baldi, a pain specialist who was ultimately acquitted on all criminal charges. *See* Tony Leys, *Baldi, Acquitted on All Charges, Wants to Return to Work*, Des Moines Register (May 2, 2014), <http://www.desmoinesregister.com/story/news/crime-and-courts/2014/05/01/baldi-verdict-jury/8576229/> [perma.cc/5HTV-QCAF]; Iowa Bd. Med., *In the Matter of Daniel J. Baldi, D.O., Respondent, Stipulated Order-Agreement not to Practice Medicine*, <http://medicalboard.iowa.gov/Legal/Baldi,DanielJ.,D.O.-03-09-653,03-12-041.pdf> [perma.cc/U3R8-69YL].
271. What does exist focuses on either sex crimes or capital crimes. *See* Menard, Scott, Pollock, Wendi. Self Reports of Being Falsely Accused of Criminal Behavior. 2014; 5:378. 378. 35 Deviant Behav
272. *Id.* at 379.
273. *See* Menard & Pollock, *supra* note 272, at 378–79 (explaining that false labeling can lead to false accusations and even eventual actual deviance as a result of the continued stigmatization).
274. Dept. of Health v. Roggow, CASE NO. 2009–22381 (State of Fl. Bd. of Osteopathic Med. Jan. 11, 2011) (administrative complaint) (“On or about March 9, 2010, the Department received information from a pharmacist in the Fort Myers area that Respondent appeared to be prescribing excessive quantities of controlled substances. The allegations were supported by pharmacy records indicating numerous patients of Respondent were receiving large quantities of controlled substances.”); *see also* Dr. Acquitted by Federal Jury Speaks to NBC2, NBC-2 News (June 29, 2012), <http://www.nbc-2.com/story/18918407/dr-acquitted-by-federal-jury-speaks-to-nbc2> [perma.cc/29CF-SQBU] (“the government’s evidence centered mainly on the volume of pills prescribed by Dr. Roggow”).
275. This was an operation by the tactical diversion squad of the DEA. Tom Brennan, *Attorney General in Florida to Discuss Prescription Drug Abuse*, Tampa Tribune (Oct. 28, 2011), <http://tbo.com/news/crime/attorney-general-in-tampa-to-discuss-prescription-drug-abuse-298876> [perma.cc/XP9H-KGPN].
276. NBC-2 News, *supra* note 275; *see* Aisling Swift, *South Fort Myers Doctor Acquitted of Illegally Prescribing Pain Killers*, Naples News (June 28, 2012), www.naplesnews.com/news/local/south-fort-myers-doctor-acquitted-of-illegally-prescribing-pain-killers-ep-388531341-342486082.html [perma.cc/D3EB-WEMJ]

277. Jennifer Bolen, *Board Certified Doctor Cleared of Criminal Charges for High-Dose Opioid Prescribing*, Practical Pain Mgmt. (Aug. 31, 2012), <http://www.practicalpainmanagement.com/resources/ethics/board-certified-doctor-cleared-criminal-charges-high-dose-opioid-prescribing> [perma.cc/SV4C-XFYH].
278. While those outcomes are favorable, the charge and embroilment with the legal system can still effectively end a practice. *See, e.g.,* Leys, *supra* note 271 (case of Daniel Baldi, who was acquitted).
279. *See, e.g.,* Hoffmann, *supra* note 148, at 233 (“In a number of troubling cases, however, the physicians arguably were wrongly charged. While some of these providers ultimately were exonerated through acquittal or appeal, their careers, and in many cases their personal lives, were destroyed.”).
280. *See* Gatchel, *supra* note 257, at 639. (explaining that opiophobia can lead to undertreatment of pain medication).
281. Kim, *supra* note 145, at 537 (explaining that relying on SMBs and civil actions have proven inadequate and, “physician self governance has not risen to the occasion”).
282. Heumann et al., *supra* note 137, at 134, 161 (reporting on qualitative research with attorneys for physicians accused of felonies and reporting an upward trend in drug related felonies between 1990 and 2007 in New York).
283. *Supra* Part II.B.
284. For example, the FSMB’s Model Policy on Opioid Use lists several procedural failures that should be considered inappropriate practice, including: failures to adequately assess the patient, failure to monitor response, and inadequate patient education. FSMB Model Policy, *supra* note 12 at 5–6.
285. *See, e.g.,* United States v. Volkman, 797 F.3d 377, 384 (6th Cir. 2015) (explaining that a physician whose license was ultimately revoked for misprescribing had little to no oversight). Physicians in this category are often practicing in solo practices or in small groups and not in academic centers in which, for example, residents would also be involved in patient care. DuBois, *supra* note 51.
286. In this and the other examples we use in the remainder of the paper, we relied on facts as presented in published court or administrative agency opinions and sometimes in news reports. We acknowledge these sources do not include a full accounting of the story surrounding the events in question.
287. Jarrott v. La. St. Bd. of Med. Exam’rs, 19 So. 3d 526 (4th Cir. 2009) (affirming the civil district court’s decision to uphold the decision of the board for a two year suspension, prohibition of practice in pain management, and \$5,000 fine).
288. *Id.* at 529–31. These kinds of procedural care failures match the kinds of guidelines often used by SMBs such as those listed in the FSMB’s Model Policy. *See* FSMB Model Policy, *supra* note 15, at 14.
289. Jarrott, 19 So. 3d at 540–41.
290. *Id.* at 541–46.
291. *Id.* at 530–31.
292. *Id.* at 545.
293. *Id.* at 531.
294. *See, e.g.,* David A. Ruben, M.D.; Decision and Order, 78 Fed. Reg. 38,363, 38,370 (June 26, 2013) (suspending physician’s COR for one year after a pattern of prescribing to patients with positive drug screens, after being informed they had completed opioid addiction treatment, were under the care of another physician for addiction, and for failing to document appropriate physical, histories, or prescriptions).; *see also* Jerry Germroth, M.D., No. 0101-034309, 2013 WL 7205090 (Va. Bd. Med. Dec. 17, 2013) (permanently prohibiting physician from prescribing schedule II-III controlled substances and ordering physician to complete continued medical education).
295. *See, e.g., id.*; *see also* Nibedita Mohanty, No. 0101-045978, 2013 WL 5592614 (Va. Bd. Med. Sept. 25, 2013) (co-prescribing high doses of Oxycodone products and Dilaudid).
296. These are typically not failures that rely on sophisticated medical judgments or behavior that might be described as judgment calls. These are failures to conform to basic procedural care

requirements such as taking histories, checking medical records from recent hospitalizations, and documenting responses to medications.

297. *See supra* Part II.B.
298. Chuck Klosterman, *Bad Decisions: Why AMC's Breaking Bad Beats Mad Men, The Sopranos, and The Wire*, Grantland (Aug. 2, 2011), <http://grantland.com/features/bad-decisions/> [perma.cc/9R9R-9B7E].
299. *See, e.g., PA Psychiatrist Arrested for Over-Prescribing, Trading Opioid-Addiction Treatment Drugs for Sex*, Gant News (Aug. 20, 2013), <http://gantdaily.com/2013/08/20/pa-psychiatrist-arrested-for-over-prescribing-trading-opioid-addiction-treatment-drugs-for-sex> [perma.cc/L486-939L] (reporting psychiatrist who exchanged sex for controlled substances, charged only cash but also double billed insurance companies); Michael Sadowski, *Accused Prescription-Selling New Cumberland Doctor Faces New Drug Charges*, Cent. Pa. Bus. J. (Dec. 16, 2014), <http://www.cpbj.com/article/20141216/CPBJ01/141219783/Accused-prescription-selling-New-Cumberland-doctor-faces-new-drug-charges> [perma.cc/X3JL-38SF] (reporting new drug charges against a physician selling prescriptions at convenience stores, his house, and other public areas); Press Release, The United States Attorney's Office Southern District of Georgia, Georgia Doctor Sentenced To 20 Years In Prison For Operating Pill-Mill Clinics (Aug. 8, 2014), <http://www.justice.gov/usao-sdga/pr/georgia-doctor-sentenced-20-years-prison-operating-pill-mill-clinics> [perma.cc/6D9X-NEE4] (doctor collected half a million dollars in cash for prescriptions, used proceeds, in part to buy himself a Ferrari).
300. *See, e.g., United States v. Bourlier*, No. 11-15268, at *5 (11th Cir. 2013) (along with other evidence that the physician knew or should have known of patients with SUD was the fact that "some family members had called ... to ask [the physician] to stop writing prescriptions for addicted patients.").
301. *E.g., Paula McMahon, South Florida Pill Mill Trial Stars Hidden Cameras, Security Video, Doctors' Own Words*, Huffpost Miami (Jul. 6, 2013, 3:32 AM), http://www.huffingtonpost.com/2013/07/06/south-florida-pill-mill_n_3553196.html [perma.cc/8C4V-8KQB] (explaining that undercover federal agents went to "pill mills" and "posed as patients").
302. Joanna Shepherd, *Combating the Prescription Painkiller Epidemic: A National Prescription Drug Reporting Program*, 40 Amer. J. L. & Med. 85, 96 (2014) (quoting Felix Gillette, *American Pain: The Largest U.S. Pill Mill's Rise and Fall*, Bloomberg Businessweek (June 6, 2012), <http://www.bloomberg.com/bw/articles/2012-06-06/american-pain-the-largest-u-dot-s-dot-pill-mills-rise-and-fall> []) (interviewing a former pill mill operator) (internal quotation marks omitted).
303. *See, e.g., Rigg, Khary K., et al. Prescription Drug Abuse & Diversion: The Role of the Pain Clinic*. 2010; 681:686–87.40 J. Drug Issues (quoting a "pill mill" participant as saying that "[the physicians] are there for the money").
304. *See generally id.* (interviewing prescription drug abuses in South Florida to better understand pain clinics).
305. *Id.* at 687–90 (internal quotation marks omitted).
306. See Brown, Richard P., et al. Adrenocortical Function and Suicidal Behavior in Depressive Disorders. 1986; 317:317.17 Psychiatry Res (listing David Brizer, M.D., as a "Research Assistant Professor of Psychiatry, New York University Medical Center at Manhattan Psychiatric Center.")
307. *See Dr. Feel Good Fesses Up*, Rockland County Times (Mar. 1, 2013), <http://www.rocklandtimes.com/2013/03/01/dr-feel-good-fesses-up/> [perma.cc/3FFS-BKWG].
308. Searching for David Brizer on the New York Professional Misconduct & Professional Discipline web site shows that he voluntarily surrendered his license on July 29, 2013. *Physician Information*, N.Y. State Dep't of Health, Office of Prof'l Med. Conduct, <http://w3.health.state.ny.us/opmc/factions.nsf/58220a7f9eeafab85256b180058c032/e569462f71b4cbe785257a700050f866?OpenDocument> [perma.cc/58LT-AALB]. The surrender supersedes the Interim Order in the matter. *See In the Matter of David Allen Brizer, M.D., Interim Order*, N.Y. State Dep't of Health (Sept. 15 2012), [http://w3.health.state.ny.us/opmc/factions.nsf/58220a7f9eeafab85256b180058c032/e569462f71b4cbe785257a700050f866/\\$FILE/BRD%20144516.pdf](http://w3.health.state.ny.us/opmc/factions.nsf/58220a7f9eeafab85256b180058c032/e569462f71b4cbe785257a700050f866/$FILE/BRD%20144516.pdf) [perma.cc/9KEA-4VZJ] [hereinafter *Order*]

309. *See, e.g.*, Brown et al., *supra* note 307 (discussing the effect of adrenocortical function on psychiatric condition); Brizer, David A. Religiosity and Drug Abuse Among Psychiatric Inpatients. 1993; 337:337.19 *Amer. J. Drug & Alcohol Abuse* (discussing “treatment outcomes of chemically dependent patients”); Brizer, David A., et al. Treatment Retention of Patients Referred by Public Assistance to an Alcoholism Clinic. 16 *Amer J Drug & Alcohol Abuse*. 1990:259. [PubMed: 2288324] (discussing treatment for alcoholics) Brizer, David A., et al. A Rating Scale for Reporting Violence on Psychiatric Wards. 1987:769.38 *Hosp. & Community Psychiatry* (discussing the incidence of violence in psychiatric institutions).
310. David Brizer, Book Review, 49 *Psychiatric Servs.* 1104 (1998) (reviewing Joel Paris, *Social Factors in the Personality Disorders: A Biopsychosocial Approach to Etiology and Treatment* (1996)) (original pagination unavailable), <http://ps.psychiatryonline.org/doi/full/10.1176/ps.49.8.1104> [perma.cc/FEK3-Y8WC].
311. By 2003, he is listed as chair of psychiatry at Norwalk Hospital in Norwalk, Connecticut. David Brizer, Book Review, 54 *Psychiatric Servs.* 1174, 1174 (2003) (reviewing Daniel Wegner, *The Illusion of Conscious Will* (2002)).
312. *See, e.g.*, David Brizer, Book Review, 28 *J. Addictive Diseases* 280, 280 (2009) (reviewing Susan Cheever, *Desire: Where Sex Meets Addiction* (2008)) (listing only a city in New York under author affiliations).
313. *See* U.S. v. MacKay, 715 F.3d 807, 813 (10th Cir. 2013); Press Release, Federal Bureau of Investigation, Salt Lake City Division, Brigham City Doctor Indicted on Drug distribution Charges (Aug. 5, 2010), <https://www.fbi.gov/saltlakecity/press-releases/2010/slc080510.htm> [perma.cc/DE72-74TU].
314. The book is *Clinical Addiction Psychiatry* (David Brizer & Ricardo Castaneda eds., 2010).
315. Steve Lieberman, *Former Nyack Psychiatrist Gets Probation for Selling Oxy Scripts*, Lohud (Feb. 7, 2014), <http://www.lohud.com/story/news/local/westchester/2014/02/07/former-nyack-psychiatrist-gets-probation-for-selling-oxy-scripts-/5283221/> [perma.cc/HD4L-SGAF].
316. *See* Stephen Rex Brown, *Midtown doc David Brizer was like a one-man Pfizer, selling prescriptions for Oxycodone and other pills, authorities said*, *Pfizer*, N.Y. Daily News (Feb. 11, 2013, 3:40 PM), <http://www.nydailynews.com/new-york/doc-drug-dealer-article-1.1261132> [perma.cc/U6UJ-7WYK].
317. *See* David Brizer, *Psychology Today*, https://therapists.psychologytoday.com/rms/prof_detail.php?profid=132469&sid=1428614767.156_7324&county=Queens&state=NY&spec=13&tr=ResultsName [perma.cc/4HEE-MPKY].
318. *See* David Brizer: *Responsible Reliable Housesitter, Single Male, Physician & Writer*, CareGuide, <http://housesitter.com/responsible-reliable-housesitter-single-male-physician-writer-house-sitter-new-york-ny> [perma.cc/WAR6-HJW8]; *David Brizer: Writer*, MeetAWriter, <http://meetawriter.com/david-brizer-writer-new-york-ny> [perma.cc/YP2D-KDYX] (The pictures of Mr. Brizer and his self- description match the stories on his indictment) (screenshots on file with author).
319. *Order, supra* note 310.
320. *See* Volkman v. U.S. Drug Enforcement Admin., 567 F.3d 215, 225 (6th Cir. 2009) (“[Dr. Volkman] was, at times, the largest practitioner-purchaser of oxycodone in the nation, and the DEA’s 2005 audit revealed that Volkman could not account for thousands of dosage units.”).
321. In the Matter of Paul H. Volkman, M.D., Report and Recommendation, Oh. St. Med. Bd. (Dec. 10, 2008), <http://med.ohio.gov/formala/35070722.pdf> [perma.cc/2PA8-Z42N].
322. *See* U.S. v. Volkman, 736 F.3d 1013, 1017 (6th Cir. 2013).
323. *See* Br. and App. of Def.-Appellee at 12, 14, Frey v. City of Chicago, 288 Ill. App. 3d. 1094 (Ill. App. Ct. 1st Dist., 5th Div. 1994) (Nos. 94-1102, 94-1544), 1994 WL 16168801 (The nurse at CMH “asked him if he was sure about the intubation. Based on her own experience with epiglottitis, she told him that it would be a difficult intubation [and] ... advised that he immediately transfer Amanda to the nearest emergency room. *Volkman told her not worry about it — he had had two years of experience in anesthesia — and he hung up the telephone.*”) (emphasis added).
324. *Id.* at 14–23.

325. *Id.* at 12, 24.
326. *See Volkman*, 736 F.3d at 1017; Paul H Volkman, M.D., Report and Recommendation, Order to Show Cause and Immediate Suspension of Registration, at ¶3 (Feb. 10, 2006), <http://med.ohio.gov/formala/35070722.pdf> [perma.cc/2PA8-Z42N] [hereinafter Show Cause Order].
327. *See id.* at 1017–18.
328. *Id.* at 1018; *see also* Show Cause Order, *supra* note 328, at ¶9 (Feb. 10, 2006), <http://med.ohio.gov/formala/35070722.pdf> [perma.cc/2PA8-Z42N].
329. *Volkman*, 567 F.3d at 217–18, 225 (6th Cir. 2009).
330. *Id.* at 218.
331. *See id.*
332. *Order*, *supra* note 330, at ¶ 15. To put that in context, the maximum dose per day of either drug or in combination should be 8 to 12 pills per day because of the liver damage associated with acetaminophen. *See FDA Drug Safety Communication: Prescription Acetaminophen Products to be Limited to 325 mg Per Dosage Unit; Boxed Warning Will Highlight Potential for Severe Liver Failure*, FDA, <http://www.fda.gov/Drugs/DrugSafety/ucm239821.htm>, [perma.cc/A7DW-8282]. There is absolutely no justification for these prescriptions as they exceed even maximum doses significantly, even if they were for a 90-day supply.
333. *Id.* at ¶ 19.
334. *United States v. Volkman*, 736 F.3d 1013, 1018 (6th Cir. 2013).
335. *United States v. Volkman*, 797 F.3d 377, 384 (6th Cir. 2015).
336. *Volkman v. U.S. Drug Enforcement Agency*, 567 F.3d 215, 219 (6th Cir. 2009) (denying Volkman’s appeal of the DEA’s actions).
337. *See* Memorandum in Support of Jurisdiction at Appx. 6, 4, *Eastley v. Volkman*, 972 N.E.2d 512 (Ohio 2012) (No. 11-0605); *Eastley v. Volkman*, 972 N.E.2d 517, 521 (Ohio 2012).
338. Paul Volkman, *Why DEA Goes After Pain Docs*, War on Docs/Pain Crisis Blog (Apr. 1, 2007), <http://doctordeluca.com/wordpress/archive/volkman-dea-targets-pain-docs/> [perma.cc/2QKR-M4SN].
339. *Id.* (emphasis added).
340. Andrew Colegrove, *Many Speak Out as Pill Mill Doctor Sentenced to Four Life Terms*, Associated Press, Feb. 14, 2012, http://www.wsaz.com/news/headlines/Federal_Trial_Underway_For_Ohio_Pain_Cinic_Operator__Charged_in_12_Deaths.html [perma.cc/AZ3D-U774].
341. *See Volkman v. Ohio St. Med. Bd.*, Decision and Final Judgment Entry Affirming the State Medical Board of Ohio’s Permanent Revocation of Appellants Certificate to Practice Medicine and Surgery, (Court of Common Pleas, Franking County, Ohio 2011) (on remand from the Court of Appeals of Ohio Tenth Appellat District (Jan. 2010) (granting motion for remand of decision in *Volkman v. State Medical Board of Ohio*, Case No. 08 CVF 18288, Decision and Final Entry Dismissing Administrative Appeal, Court of Common Pleas, Franklin County, Ohio (2009)).
342. Press Release, Fed. Bureau of Investigation Cincinnati Division, Chicago Physician Receives Four Life Sentences for Illegally Distributing Pills that Led to Deaths of Four People, (Feb. 14, 2012), <https://www.fbi.gov/cincinnati/press-releases/2012/chicago-physician-receives-four-life-sentences-for-illegally-distributing-pills-that-led-to-deaths-of-four-people> [perma.cc/6JLX-PKHN] [hereinafter DEA Press Release].
343. Andrew Colegrove, *Many Speak Out as Pill Mill Doctor Sentenced to Four Life Terms*, Associated Press, Feb. 14, 2012, http://www.wsaz.com/news/headlines/Federal_Trial_Underway_For_Ohio_Pain_Cinic_Operator__Charged_in_12_Deaths.html [perma.cc/AZ3D-U774].
344. *United States v. Volkman*, 736 F.3d 1013 (6th Cir. 2013) (affirming the decision in that sentencing was warranted; evidence was sufficient to support convictions for firearm possession in furthering drug trafficking, unlawful distribution, and conspiracy; expert testimony was proper; and defendant’s conduct was sufficient to support findings that he acted outside the scope of medical practice and not in usual course of business).
345. *Volkman v. United States*, 135 S. Ct. 13, 13 (2014) (Alito, J., concurring) (granting cert and remanding but carefully stating that there is no basis for acquittal and remand is limited only to

the issue of causation using the standard announced in *Burrage*); see Appellant's Supplemental Brief, 797 F.3d 377 (No. 12-3212) (filed after the Supreme Court remanded *Volkman v. United States* in light of *Burrage*).

346. *United States v. MacKay*, 715 F.3d 807, 813 (10th Cir. 2013).
347. See generally *id.* (It is notable that here, like in many of the other cases of misprescribing, the physician failed to attend to basic procedural requirements of care such as taking histories, documenting responses, etc.).
348. *Id.* at 817–819.
349. *Id.*
350. *Id.* at 813.
351. *Id.* at 823–824 (quoting *United States v. Feingold*, 454 F.3d 1001, 1004 (9th Cir. 2006)) (internal quotation marks omitted).
352. *United States v. MacKay*, 20 F. Supp. 3d 1287, 1291 (D. Utah 2014).
353. *Id.* at 1299 (defendant's sentence reduced in light of *Burrage*).
354. *Id.* at 1297.
355. *Id.* (“To the extent the government attempts to depict MacKay as a despicable type of criminal, the Court disagrees. He has no prior criminal history of any kind and his good works are many and cannot be overlooked.”)
356. See DuBois et al., *supra* note 51, at 2.
357. *Id.*
358. See Joseph Heath, *Business Ethics and Moral Motivation: A Criminological Perspective*, 83 J. Bus. Ethics 595, 599 (2008) (“There is no doubt that the majority of white collar crime is motivated by what might broadly be referred to a pecuniary incentives”); see also DuBois et al., *supra* note 46, at 12.
359. Timothy Brezina & Volkam Topalli, *Criminal Self-Efficacy: Exploring the Correlates and Consequences of a “Successful Criminal” Identity*, 39 Crim. Just. & Behav. 1042, 1042 (2012).
360. *Id.* at 1046–1058.
361. Banja, John. The Normalization of Deviance in Healthcare Delivery. 2010; 139:143.53 Bus. Horizons
362. Joseph Heath, *supra* note 359, at 602–610 (They often acknowledge that their acts are technically criminal but serve a higher purpose and may use one of several neutralizing techniques identified by Sykes & Matza and expanded upon by Heath: 1) “[d]enial of responsibility” (forced to break overly restrictive laws) 2) “[d]enial of injury” (claims of helping rather than harming patients); 3) “[d]enial of the victim” (sometimes in the form of “taking what [is] ... owed”); 4) “[c]ondemnation of the condemners” (lashing out at law enforcement); 5) “[a]ppeal to higher loyalties” (did it for the benefit of family or for the benefit of the patients in pain); 6) “[e]veryone else is doing it”; and 7) claim to “[e]ntitlement” (denial of the legitimacy of the broken laws).
363. Heumann, et al., *supra* note 137, at 174.
364. *Id.*
365. Fed’n of St. Med. Bds., Report of the Ad Hoc Committee on Physician Impairment 2 (Apr. 1995), http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/1995_grpol_Physician_Impairment.pdf [perma.cc/7PKH-SD87]; see also AMA Council of Mental Health, *The Sick Physician: Impairment by Psychiatric Disorders, Including Alcoholism and Drug Dependence*, 223 J. Am. Med. Ass’n 684, 686 (1973) (including “deterioration through the aging process, or the loss of motor skill[s]” as impairment).
366. See Holtman, Matthew C. Disciplinary Careers of Drug-Impaired Physicians. 2007; 543:543.64 Soc. Sci. & Med
367. *Id.* at 545.
368. *Id.* at 551.
369. See McLellan et al., *supra* note 25, at 2.
370. Merlo, Lisa J., Gold, Mark S. Prescription Opioid Abuse and Dependence Among Physicians: Hypotheses and Treatment. 2008; 181:181.16 Harv. Rev. Psychiatry
371. *Id.* at 183.

372. *Id.*
373. *Id.*
374. *Id.* at 184.
375. *Id.*
376. Morrow, Carol Klaperman. Sick Doctors: The Social Construction of Professional Deviance. 1982; 92:104.30 Soc. Probs
377. *Id.* at 93.
378. See *id.*
379. Brian Goldman, Helping the Impaired Physician: A Program for Colleagues. 1998. p. 8<http://www.fanlight.com/downloads/Helping%20the%20Impaired%20Physician.pdf> [perma.cc/Y6V6-YDRD]
380. Simone Marie Cummings et al., *Mechanisms of Prescription Drug Diversion Among Impaired Physicians*, 30 J. Addictive Diseases (2011) (original pagination unavailable).
381. Parran, Theodore V., Jr, Grey, Scott F. The Role of Disabled Physicians in the Diversion of Controlled Drugs. 2000; 35:39–40.19 J. Addictive Diseases
382. McLellan, A Thomas, et al. Five Year Outcomes in a Cohort Study of Physicians Treated for Substance Use Disorders in the United States. 2008; 1154:1155.337 Brit. Med. J
383. Merlo & Gold, *supra* note 371, at 185 (many states allow physicians to enter treatment anonymously and avoid being reported to the board of medicine if they do so voluntarily).
384. *Id.* at 185.
385. *Id.* at 190.

Table 1

The 3C Model of Physician Misprescribers with Description and Proposed Sanctions.

Category	Description	Relationship to 4D model	Primary appropriate government action and sanction	
Careless (including recklessness)	This category describes <i>behavior</i> that extends beyond an isolated deviation from the standard of care. Prescribers in this category must demonstrate a pattern of conduct or an egregious deviation from the standard of care. This category implicates the “bad doctor” standard from <i>Feingold</i> . ¹ It does not describe the reasons for the behavior so much as the behavior itself and attendant culpability.	Includes “dated” and “duped” prescribing only when it rises to the level of carelessness or recklessness. This requires behavior that displays a careless disregard for professional obligations to the well-being of the patient. Eliminates “duped” as category of misprescribing when evaluation of patient was careful.	1	Professional discipline through SMB: remediation, education measures, and possible monitoring.
			2	Regulatory action through DEA: Revocation or suspension of COR, depending upon circumstances.
Corrupt	Physician who has abandoned professional obligations and identity and acts for his or her interests in face of palpable harm to others. Motivations are typically financial gain or other personal advantages such as sexual favors.	Replaces “dishonest” category, because dishonesty fails to capture adequately the criminal nature of the prescribing.	1	Criminal prosecution (federal or state): knowing violation of criminal laws such as the CSA. Actions must meet standard for knowledge, including the willful blindness standard.
			2	Professional discipline through BOM: license revocation or sustained suspension with probation and remediation if mitigating factors exist.
			3	Regulatory action through DEA: revocation of COR.
Compromised by Impairment	Physicians who misprescribe because of SUD or other serious illness that substantially impairs judgment and decision making in prescribing. This category describes the major underlying reason for behavior. This is separated because of existing research and success with this population.	Replaces disabled category. Compromised is more accurate because it describes what happens to the physician’s behavior because of an underlying disability or impairment.	1	Professional discipline through SMB: license probation conditioned on mandatory Impaired Physician Program, ongoing treatment and regular monitoring by SMB.
			2	Regulatory Action through DEA-Suspension of COR.

Abbreviations: SMB=State Medical Board, COR=Certificate of Registration to prescribe controlled substances, CSA=Controlled Substances Act, DEA=Drug Enforcement Agency.

¹United States v. Feingold, 454 F.3d 1001, 1007 (9th Cir. 2006)