

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

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3	UNITED STATES OF AMERICA,) Case No.: 07-10234-WEB
4)
5	Plaintiff,) DEFENDANTS’ JOINT MEMORANDUM
6) AND AUTHORITES IN SUPPORT OF
7	vs.) THEIR MOTION TO DISMISS THE
8) INDICTMENT AS
9	STEPHEN J. SCHNEIDER) UNCONSTITUTIONAL
10	and)
11	LINDA K. SCHNEIDER, a/k/a)
12	LINDA ATTERBURY,)
13	d/b/a/ SCHNEIDER MEDICAL CLINIC,)
14)
15	Defendants.	

**DEFENDANTS’ JOINT MEMORANDUM AND AUTHORITES IN SUPPORT OF
THEIR MOTION TO DISMISS THE INDICTMENT AS UNCONSTITUTIONAL**

Statement of the Case

This case is an effort by the federal government to define and regulate the practice of medicine masquarading as a criminal prosecution. This case should not be about whether Dr. Schneider fell short of the standard of care for certain patients, but whether he engaged in the legitimate practice of medicine.

All of the accusations against Dr. Schneider and Ms. Atterbury revolve around matters of medical science, professional judgment, and evolving standards of practice. However, by seizing on widespread ignorance and hysteria surrounding the use of opioid analgesics in the treatment of chronic pain, the government has endeavored to shoehorn these matters, which bear no relevance to criminal culpability, into the rubric of drug dealing and health care fraud. With regard to the charges related to the Controlled Substance Act (“CSA”), the sole question should be whether Dr. Schneider was a drug dealer “as conventionally understood.” Instead, the government confounds this question with irrelevant facts and improper standards.

1 The Indictment may stem from an irrational fear or suspicion of the medical science
2 of pain treatment. It may also stem from federal authorities' misguided belief that only they,
3 and not the states and their regulatory bodies, can properly regulate the practice of medicine.
4 In any event, the Indictment is an abuse of the federal criminal process, and an affront to the
5 constitutional rights of the sick and those who attempt to care for them.

6 **1. Background and Development of the Case**

7
8 The Indictment in the case at hand is sixty-five pages long. Its first paragraph consists
9 of two sentences that provide a remarkably full reflection of the nature, tone, and emptiness
10 of the instant prosecution. (Indictment ¶ 1.) That paragraph contains two facts. (1)
11 "Defendant Stephen J. Schneider is a doctor of osteopathic medicine, licensed in Kansas, and
12 board certified in family medicine," and (2) "Prior to becoming a doctor, he was a butcher."
13 (Indictment ¶ 1.) This paragraph contains no allegation of criminal conduct, instead, it is an
14 effort to paint its subject as sinister and dangerous, and a transparent attempt to justify
15 making Dr. Schneider the defendant in a federal criminal prosecution.

16 Dr. Stephen Schneider began his medical career as an Intern at the Riverside Hospital
17 in Wichita, Kansas. He was board certified in family practice in 1988, and began working in
18 family practice for Riverside Hospital in a clinic in Haysville, Kansas shortly thereafter. He
19 worked there for more than thirteen years.

20 After Riverside Hospital was sold to Via Christi, Dr. Schneider briefly became a
21 partner in Family Medical Centers in Haysville. In 2002, he founded the Schneider Medical
22 Clinic with his wife, Linda Atterbury. Dr. Schneider and Ms. Atterbury invested over
23 \$2,000,000 to construct a brand new, state-of-the-art facility in Haysville, which provided
24 general family practice, as well as ambulatory care and pain treatment.

25 Needless to say, it came as shock to the community when, on December 21, 2007, a
26 front-page story in the Wichita Eagle announced that Dr. Schneider and Ms. Atterbury were
operators of a "pill mill", "linked" to 56 deaths. The article plastered the defendants' mug

1 shots amidst these grim and shocking words. (Exhibit 1, *Feds: 56 of doctor's patients OD'd*,
2 The Wichita Eagle, Dec. 21, 2007, at 1A.) The government's press release, employing the
3 same loaded language, including the phrase "pill mill," in describing the Schneider Medical
4 Clinic was intended to create a sense of relief among the populace that these dangerous
5 individuals were finally behind bars. (Exhibit 2, Department of Justice Press Release, Dec.
6 20, 2007.)

7 However, it is clear that despite its dramatic presentation, masterfully orchestrated
8 and carried out, the government itself knew that Dr. Schneider and Ms. Atterbury were not
9 dangerous. We know this, because the government acted on numerous occasions to prevent
10 the Kansas State Board of Healing Arts (the "KSBHA") from holding hearings to determine
11 whether Dr. Schneider had failed to provide adequate care to his patients, and if he did,
12 whether his license to practice medicine should therefore be suspended or revoked. (Exhibit
13 3, Stevens Aff., Jan. 25, 2008; Exhibit 4, Jay Aff., Jan. 25, 2008; Exhibit 5, Bellquist Aff.,
14 Jan. 25, 2008.) According to a sworn statement by an attorney working with KSHBA, the
15 government did this on at least four occasions. (Exhibit 3, Stevens Aff., Jan. 25, 2008.) Thus,
16 the same government claiming that the defendants were operating a "Pill Mill" and
17 "narcotics delivery system" delayed any review or action against Dr. Schneider's license for
18 at least nine months. (*Id.*; Indictment ¶ 4.)

19 The government's interest in preventing the hearings is obvious: on every prior
20 occasion in which Dr. Schneider was reviewed by the KSBHA, the Board found that he was
21 practicing good medicine and had done nothing wrong. Of course, such findings would
22 obliterate the legitimacy of the ongoing "investigation," as well as any subsequent
23 prosecution. For these reasons, the likelihood of absolution by a medical board empowered
24 to, and experienced in conducting the reviews of such cases according to accepted standards
25 of medical practice, and the law of the State of Kansas, had to be eliminated.

26 While the government was convincing the KSBHA not to act, it was at the same time
enlisting the services of Mr. Larry Wall. Mr. Wall is a malpractice attorney in Wichita who

1 has made a cottage industry out of suing Dr. Schneider. Mr. Wall has gained substantial
2 financial benefits from these endeavors.

3 Mr. Wall became an important ally to the government because he had the ability to
4 conduct depositions and discovery under a civil standard far less restrictive than that which
5 applies in the criminal context. Serving as the government's apparatchik, Mr. Wall set out to
6 do its bidding by collecting evidence and conducting depositions, and promptly reporting
7 their contents to the government. (Exhibit 6, Letter from Larry Wall to David Schippers,
8 May 29, 2007; Exhibit 7, Schippers Aff., June 14, 2007; Exhibit 8, Letter from Tanya
9 Treadway to David Schippers, June 26, 2007.)

10 The full extent of Mr. Wall's involvement with the government is not known, but
11 there are several facts that indicate that the ties run deep. We know that much of the content
12 of Mr. Wall's pleadings, for example, written in the civil malpractice context before the
13 Kansas courts, made its way into the Indictment in the instant case. (Exhibit 9, Roxana
14 Hegemon, *Doctor seeks to quash subpoenas on malpractice settlements*, The Associated
15 Press, Apr. 18, 2008.) We know that Mr. Wall communicated and "cooperated" with the
16 government extensively. (Exhibit 6, Letter from Larry Wall to David Schippers, May 29,
17 2007; Exhibit 7, Schippers Aff., June 14, 2007; Exhibit 8, Letter from Tanya Treadway to
18 David Schippers, June 26, 2007.)

19 Furthermore, we know that Mr. Wall continues to cooperate with the government:
20 When the government issued subpoenas regarding confidential settlements that have no
21 proper use in this criminal case, Mr. Wall promptly sent a letter to the other attorneys
22 involved stating that he would unquestioningly provide the confidential information. (Exhibit
23 10, email correspondence from Larry Wall to Chris Cole, Apr. 8, 2008.) He did this at the
24 same time that other attorneys moved to quash the subpoenas. (*Id.*)

25 When the government sought to gag the speech of a private citizen, Siobhan
26 Reynolds, who asked difficult questions about the government's case, Mr. Wall moved in
lockstep with the government and subpoenaed her for a deposition in a case to which she had

1 no conceivable connection. Mr. Wall had apparently followed Ms. Reynolds' activities
2 closely, for he knew with whom she met, where, for what purposes, and even what beverages
3 were consumed at the meeting. (Exhibit 11, Estivo Aff., Mar. 3, 2008, 97-101.) This
4 information was undoubtedly relayed to the government. The reason for Mr. Wall's ready
5 and unquestioning cooperation with the government is not known, but the government's
6 affiliation with and reliance on an individual who clearly has extensive financial interests in
7 these matters is unsettling.

8 But Mr. Wall is not the only actor with significant financial incentives involved in the
9 case, on the side of the government. The Health Care Benefit Programs ("HCBPs") claim
10 that Dr. Schneider and Ms. Atterbury were not forthright in their claims for reimbursement
11 for the care and treatment of patients. Of course, all things being equal, the HCBPs would
12 prefer to pay as little as possible for patient care, and if Dr. Schneider's care was viewed as
13 costing too much, there was a clear incentive to put an end to it. The full extent of the
14 HCBPs' involvement is not known at this early stage, but the Indictment has clearly and
15 unquestioningly taken their "findings" and published them as substantive allegations in its
16 Indictment.

17 The Indictment is the creation of our government, and it is the choice of our
18 government to bring it. The Indictment is full of shocking and inflammatory rhetoric. It is all
19 the more disturbing when the rhetoric is stripped away from and juxtaposed with the
20 substantive allegations in its counts, which are wholly deficient. The most disturbing aspect
21 of this case is the Indictment itself and the allegations it contains, which are the subject of the
22 instant Motion to Dismiss.

23 While the statement regarding Dr. Schneider's previous occupation as a butcher is
24 transparent and insulting to the defendant, the Court, and the process as a whole, other
25 aspects of the pleading are worse than merely insulting. They are also abusive. What use, we
26 ask, can the inclusion of deaths that were neither "contributed to" nor "caused by" the
defendant possibly serve? (Indictment, Attachment I.) Unless the government is relying on

1 some theory of strict liability, that Dr. Schneider is responsible for the death of anyone he
2 treated or who was treated at his clinic, these claims have no legal basis or purpose.

3 The most likely answer for their inclusion is a troubling one: to distract from the lack
4 of substance that permeates the Indictment. We know that despite the government's zeal to
5 lock up the defendants, the government's heart is not in the allegations of the Indictment. It
6 characterizes the Schneider Medical Clinic as a "Pill Mill" and a "narcotics delivery system,"
7 yet it is the government itself that took steps that allowed the clinic to remain open for
8 months, repeatedly asking the KSBHA not to take action.

9 Before turning to the specific allegations of the Indictment, we note that in over two
10 years of investigating this case, the government does not allege so much as one instance of
11 true, objective criminal conduct. This explains why so much ink was spilled on matters that
12 have no legal relevance or import, but that greatly prejudice the defendants.

13 **2. The Indictment**

14
15 The Indictment can be divided into four groups of counts. Count 1 purports to allege
16 a "conspiracy" between the defendants to commit the acts set forth in Counts 2-34. Counts 2-
17 6 purport to allege violations of 21 U.S.C. § 841 (The Controlled Substances Act, "CSA").
18 Counts 7-17 purport to allege violations of 18 U.S.C. § 1347, on a variety of theories.
19 Finally, counts 18-34 are wholly derivative, and allege unlawful monetary transactions and
20 money laundering based on the foregoing counts. We discuss the groups of counts with
21 some specificity to attempt to determine what, if anything, is actually being alleged.

22 **Counts 2-6 – The CSA**

23
24 Counts 2-6 purport to allege violations of the CSA, either on the basis of an apparent
25 disagreement with Dr. Schneider's treatment decisions, or on no basis at all. Counts 2-4 and
26 count 6 fall into the former category, while count 5 falls into the latter.

1 Counts 2-4 allege that Dr. Schneider prescribed controlled substances “not for a
2 legitimate medical purpose” and/or “beyond the bounds of professional medical practice.”
3 The basis for the government’s belief and allegations that Dr. Schneider’s prescribing was
4 somehow criminal is not readily apparent, but seems to be based on one or more of the
5 following: (1) escalating dosages of controlled substances; (2) varying amounts of controlled
6 substances; (3) prescribing despite “signs” of addiction (including early refills); (4)
7 prescribing despite increasing pain; (4) failure to perform “sufficient” examinations; (5)
8 failure to obtain “sufficient” medical history; (6) failure to alter treatment despite “notice”
9 that other patients died of alleged overdoses. Thus, the theory of criminality appears to be
10 based either on a disagreement with the treatment plan, or a “failure to take notice,” or some
11 combination thereof.

12 Conspicuously absent from the Indictment are any allegations of what would
13 traditionally be considered drug dealing, as covered by the CSA, and not merely negligence
14 or even recklessness in medical practice (which is not covered by the statute). For example,
15 the Indictment lacks any allegation that Dr. Schneider knew that any of the drugs he
16 prescribed were diverted by patients, that he made any statements to federal agents that
17 would indicate knowledge of criminal activity, that Dr. Schneider traded sex for drugs, or
18 that he completely failed to conduct any physical examinations or to obtain medical histories
19 prior to prescribing controlled substances. Rather, the Indictment’s claims are based on what
20 appears to be *perceived* deficiencies in care, or faulty medical judgment (which, we submit,
21 are also not present).

22 It must be kept in mind that this is not a negligence case, and that allegations in a
23 criminal case cannot properly be based on the government’s disagreement with Dr.
24 Schneider’s medical decisions. Ironically, many of the Indictment’s allegations in these
25 counts are based on what the government itself has previously acknowledged to be legitimate
26 medical practice. (see generally Exhibit 12, Prescription Pain Medications: Frequently
Asked Questions and Answers for Health Care Professionals, and Law Enforcement

1 Personnel, “Frequently Asked Questions”.) Other allegations in counts 2-4, which the
2 Indictment attempts to portray as criminal, are based on theories that are inaccurate or
3 improbable as a matter of medical science.

4 Count 6 of the Indictment is both novel and extraordinary. In it, the government
5 takes issue with Dr. Schneider’s off-label prescribing of Actiq to patients with non-cancer
6 pain. The Indictment provides a list of patients, the cause of the pain, the age of the patient,
7 and the quantity of the medication prescribed. This count is not only a concession that the
8 government is fully aware that Dr. Schneider was practicing medicine but it also reveals
9 disagreement with Dr. Schneider’s decision as to the best means to treat his patients’ pain
10 with the long-established, entirely legal, practice of prescribing “off-label.” Off-label
11 prescribing simply means that once a medication has been approved by the FDA as safe and
12 effective for one or more medical conditions, it may be prescribed by licensed M.D.'s and
13 D.O.'s for any other medical condition, as long as the physician can defend the scientific
14 rationality of such a prescription, usually by citing peer-reviewed medical literature. In the
15 particular example of Actiq, (fentanyl citrate), there is a robust literature on its safe and
16 effective use in a variety of painful conditions, and not only in patients with malignancy
17 suffering breakthrough pain. This aspect of the Indictment improperly reads the FDA’s
18 regulations into substantive criminal law.

19 Finally, count 5 does not even so much as attempt to allege any basis of criminality
20 whatsoever, but merely parrots the language of the statute and the interpretive regulations
21 and case law. It then provides a list of 12 individuals to whom Dr. Schneider allegedly issued
22 “unlawful” prescriptions, supposedly leading to serious bodily injury or death.

23 **Counts 7-17 – 18 U.S.C. § 1347 (Healthcare Fraud)**

24
25 Counts 7-17 purport to allege violations of 18 U.S.C. § 1347. These counts
26 incorporate by reference all of the foregoing paragraphs of the Indictment, including
paragraphs 89-99, which provide what appears to be a hodge-podge of policies, rules,

1 definitions and principles. In this section, the government relies on several sources,
2 including the policies of HCBPs, certain “well-established principles,” Kansas law, and the
3 Current Procedural Terminology (“CPT”) code book. These various references appear to be
4 intended to provide a basis for the government’s theories as to why the conduct alleged in
5 Counts 7-17 constitutes criminal fraud. However, it is important to note at the outset that,
6 with the exception of the law of the State of Kansas (which the Indictment briefly mentions
7 without specific citation and which the federal authorities do not have the power to enforce),
8 nothing else discussed by the government is law.

9 For example, as discussed more fully below with specific reference to the relevant
10 counts, the Indictment appears to treat the policies of HCBPs as law, stating that they require
11 “written medical records which accurately and truthfully describe patient histories, pertinent
12 findings, examinations results, test result, and bona fide recommendations for services
13 rendered to the patient.” (Indictment ¶ 94.) The Indictment also presents as controlling
14 what it purports to be a “well-established principle in the health care industry” that if a
15 service is not documented, it did not happen, and that if the health care provider happens to
16 have bad hand writing, reimbursement can also be denied. (Indictment ¶ 96.) While these
17 “rules” and policies may have some import in the bureaucratic world of billing and
18 reimbursement for medical services, they are not legal rules or criminal laws, and do not
19 have the force of such. The same is true of the CPT code book.

20 The CPT code book is a privately written, trademarked and copyrighted publication
21 of a commercial affiliate of the American Medical Association. The CPT code book is itself
22 a complex and dense document that requires supplementation in the form of journals and
23 newsletters, which are privately published and commercially marketed. In *Practice*
24 *Management Information Corp. v. American Medical Association*, 121 F.3d 516, 520 (9th
25 Cir. 1997), the Ninth Circuit held that the CPT copyright was not rendered invalid as public
26 law, and analogized the CPT code book to required public-school textbooks (the court also
held that the AMA engaged in copyright misuse where the Health Care Financing

1 Administration was granted a license to incorporate the CPT code into its system for
2 Medicare and Medicaid billing in exchange for the HCFA's agreement not to use a
3 competing billing system). *See also American Society of Dermatology v. Shalala*, 962 F.
4 Supp. 141 (D.D.C. 1996), *aff'd without published opinion*, 116 F.3d 941 (D.C. Cir. 1997)
5 (holding that judicial review under the Administrative Procedures Act of the use of the CPT
6 code in Medicaid and Medicare was precluded, and apparently accepting the government's
7 argument that the administrative action was not a "rule" under the APA).

8 Thus, the CPT code is neither a public law nor a rule even in the context of Medicare
9 and Medicaid. It has even less standing in the context of private HCBPs. Yet, along with
10 bureaucratic rules and "industry principles," the government attempts to treat the CPT code
11 as law, and together they form a major part of the government's fraud allegations.

12 In counts 7-9, the government's theory of fraud seems to rest on several diffuse
13 allegations. First, the Indictment bootstraps the theory of prescribing not for a legitimate
14 medical purpose, now recasting this conduct as fraud. Second, the Indictment alleges "up-
15 coding," or using what the government views as the wrong (and higher-paying) CPT code, to
16 bill for a higher level of service. Finally, apparently relying on the "well-established
17 principle" that if something is not written clearly it didn't happen at all, the government takes
18 issue with the provider's handwriting and alleges fraud on this basis. These counts also
19 contain a variety of numbers, such as the number of patients seen that day, for which no
20 context or comparison to other providers is given, and the purpose of which is unclear.

21 Counts 13-17 are also based on "up-coding" allegations. This time each count with
22 specific reference to a HCPB that was allegedly defrauded. Here, the Indictment relies on a
23 "statistically valid" sample of claims that were allegedly false or fraudulent some percentage
24 of the time, but fails to provide any basis for comparing these rates to those of other
25 providers. The Indictment treats the HCBP's alleged findings that claims were "false and
26 fraudulent" as the equivalent of findings of criminal fraud.

1 Counts 10-12 are based on billing to HCBPs for the off-label prescriptions of Actiq to
2 patients with non-cancer pain. These counts seem to rest on the principle that if a service is
3 not covered by the HCBP, then submitting a bill for that service, even if it fully discloses the
4 medication prescribed as well as the purpose, is an act of criminal fraud. Notably, the
5 Indictment clearly states that once the defendants were informed by a particular HCBP (First
6 Guard) that the off-label prescribing of Actiq was not a covered service, the defendants
7 stopped billing that HCBP for such prescriptions. Thus, there is no allegation of defendant's
8 submitting misrepresentation of any fact with respect to these counts, or attempting in any
9 way to mislead any HCBP.

10 **Counts 18-34 – Money Laundering/Unlawful Monetary Transactions**

11
12 Counts 18-34 are derivative, and cast the defendants' monetary transactions as
13 unlawful because they are "connected" to the other offenses alleged in the Indictment.

14 **ARGUMENT**

15 **The charging statutes are unconstitutional on their face, and as applied**

16 "[A] statute may be challenged on its face when it threatens to chill constitutionally
17 protected conduct, especially conduct protected by the First Amendment." *United States v.*
18 *Gaudreau*, 860 F.2d 357, 360 (citing *Colautti v. Franklin*, 439 U.S. 379, 390-91, 394, 396
19 (1979)). On the other hand, as-applied challenges consider whether the statute is
20 unconstitutional "in light of the conduct with which the [defendants] are charged." *Id.* at 361
21 (internal citations omitted).

22 We address the constitutionally impermissible vagueness of the CSA in this case in
23 light of the conduct with which Dr. Schneider and Ms. Atterbury stand charged. However,
24 we note that this conduct – the medical care of patients with chronic pain - is constitutionally
25 protected by the First Amendment as well as the due process clause of the Fourteenth
26 Amendment. *See, e.g., Rust v. Sullivan*, 500 U.S. 173, 200 (1991) (recognizing a physician's
First Amendment Right to advise his patient); *Planned Parenthood v. Wichita*, 729 F. Supp.

1 1282, 1288 (D. Kan. 1990) (“The physician counseling a pregnant woman enjoys a
2 constitutional [First Amendment] right to dispense medical information on the basis of her
3 individual circumstances”); *Washington v. Glucksberg*, 521 U.S. 702 (1997). Dr.
4 Schneider’s patients also have a constitutionally protected right to relief from unnecessary
5 suffering, which this prosecution violates. See, e.g., *Glucksburg*, 521 U.S. 702.¹ Therefore,
6 the instant challenge to the application of the CSA to the defendants constitutes a facial
7 challenge to the statute.

8 **I. The Controlled Substances Act is Unconstitutional On Its Face, and As** 9 **Applied In This Case**

10 **A. The CSA Fails to Provide Adequate Notice**

11
12 As applied in the Indictment, the CSA fails to adequately and meaningfully inform
13 physicians of what conduct is proscribed, largely because such conduct is arbitrarily and
14 unilaterally determined by enforcement authorities lacking knowledge and expertise with
15 respect to issues of medical science and ethics.

16 “No one may be required at peril of life, liberty or property to speculate as to the
17 meaning of penal statutes. All are entitled to be informed as to what the State commands or
18 forbids.” *Lanzetta v. New Jersey*, 306 U.S. 451, 453 (1939). “As generally stated, the void-
19 for-vagueness doctrine requires that a penal statute define the criminal offense with sufficient
20 definiteness that ordinary people can understand what conduct is prohibited . . .” *Gaudreau*,
21 860 F.2d at 361; See, e.g., *Colautti v. Franklin*, 439 U.S. 379 (1979); *Interstate Circuit, Inc.*
22 *v. City of Dallas*, 390 U.S. 676 (1968). See also *United States v. Evans*, 318 F.3d 1011, 1016
23 (10th Cir. 2003) (“[B]ecause we assume that man is free to steer between lawful and

24
25 ¹ See Robert A. Burt, *The Supreme Court Speaks: Not Assisted Suicide but a Constitutional Right to*
26 *Palliative Care*, 337 New Eng. J. Med. 1234, 1234 (1997) (stating that a majority of the Court in *Washington v.*
Glucksberg 521 U.S. 702 (1997) "effectively required all states to ensure that their laws do not obstruct the
provision of adequate palliative care. . ."); Kathryn L. Tucker, *The Death with Dignity Movement: Protecting*
Rights and Expanding Options after Glucksberg and Quill, 82 Minn L. Rev. 923, 935 (1998).

1 unlawful conduct, we insist that laws give the person of ordinary intelligence a reasonable
2 opportunity to know what is prohibited, so that he may act accordingly." (quoting *United*
3 *States v. Reed*, 114 F.3d 1067, 1069-70 (10th Cir. 1997) (citing *Grayned v. City of Rockford*,
4 408 U.S. 104, 108 (1972))). While the words of a statute might be vague, their well-settled
5 meaning in court decisions may clarify their meaning. *See, e.g., United States v. Lanier*, 520
6 U.S. 259 (1997).

7 The Supreme Court case of *Colautti v. Franklin* addressed the issue of
8 unconstitutional vagueness in the medical context, and its analysis is illuminating in the
9 instant case. 439 U.S. 379 (1979). The case involved a challenge to a Pennsylvania statute
10 that required, *inter alia*, physicians performing or inducing an abortion to make a
11 determination that the fetus is not viable "based on his experience, judgment, or professional
12 competence." *Id.* at 391. If such a person determines that the fetus is viable, he must adhere
13 to the prescribed standard of care. *Id.* He must also adhere to the prescribed standard of
14 care if "there is sufficient reason to believe that the fetus may be viable." *Id.* With respect to
15 the first part of the statute, the Court explained that it set out a standard of subjective good
16 faith. *Id.* However, with respect to the second part of the statute, the Court held that its
17 meaning was impermissibly vague with respect to when a fetus "may be viable." In
18 particular, it was unclear whether this determination should turn on the subjective opinion of
19 the physician, or be based on some other perspective, such as a panel of experts or a cross
20 section of the medical community. *Id.* at 391-394.

21 The Court held this viability-determination requirement impermissibly vague on two
22 grounds. First, as discussed above, the Court found the "may be viable" standard
23 unconstitutionally vague. *Id.* The Court further held that the ambiguity in the statute was
24 particularly troublesome because the statute applied to a physician, who must by definition
25 exercise medical judgment in his practice. *Id.* By contrast, the statute as written did not
26 permit the physician to make a decision in light of "all attendant circumstances –
psychological and emotional as well as physical – that might be relevant to the well-being of

1 the patient . . . afford[ing] broad discretion to the physician.” *Id.* at 394. Rather, the statute
2 “condition[ed] potential criminal liability on confusing and ambiguous criteria.” *Id.* Second,
3 the Court found that the provision’s lack of a subjective scienter requirement presented the
4 potential of criminal liability without fault. *Id.* The CSA similarly subjects physicians to an
5 ambiguous and therefore arbitrary standard. The statute also fails to account for the many
6 factors a physician must consider and also fails to provide sufficient breathing space for the
7 exercise of discretion. We discuss this defect of the CSA below, and address the lack of a
8 scienter requirement in part I(C).

9 The CSA provides that prescribing must be for a “legitimate medical purpose” or in
10 the “course of professional practice.” This language is troublesome, because it does not
11 further define the word “legitimate.” While the subsequent interpretation and application of
12 statutes by courts may sufficiently narrow and define a statute so as to mitigate its lack of
13 notice, *Gaudreau*, 860 F.2d at 362, courts interpreting the CSA have expressly refused to set
14 out a definitive list of acts or practices that are considered unlawful. Rather, they have made
15 their determinations on a case-by-case basis.² *Gonzales v. Raich*, 545 U.S. 1, 73 (2005). The
16 acts considered to violate the CSA are many and diverse, and can exist in an infinite variety
17 of combinations. A subset of these consists of conduct with no medical purpose at all, and
18 does not present any serious problem of notice. *See, e.g., United States v. Nelson*, 383 F.3d
19 1227 (10th Cir. 2004); *United States v. Celio*, 230 Fed. Appx. 818 (10th Cir. 2007).
20 However, there are also instances of conduct that are consistent with the practice of medicine
21 and the products of the exercise of medical judgment. All of the allegations relating to
22 unlawful prescribing in the instant case fall in the latter category.

24 ² The Supreme Court has recently clarified the meaning and scope of the CSA in *Gonzales v.*
25 *Oregon*, 56 U.S. 243 (2006). The Court held that the what constitutes “legitimate” medical practice is not
26 subject to interpretation by the Attorney General. *Id.* at 260. The Court also held that the CSA carves out for
criminalization only conduct that constitutes “drug dealing as conventionally understood.” *Id.* at 269-270.
While the meaning of the CSA itself has not actually changed, we submit that the Supreme Court’s decision
clarifying its meaning and scope impacts significantly on how courts may apply it and how the government may
enforce it, and that enforcement can no longer proceed on a case-by-case basis.

1 Like the statute at issue in *Colautti*, the CSA as applied in this case fails to provide
2 reasonable notice of the conduct proscribed by the CSA, and therefore criminalizes medical
3 decisions. The Indictment presents the context of these decisions as a set of simple
4 propositions, and characterizes some of Dr. Schneider's specific decisions as simple
5 instances of criminal conduct. However, in reality the field of pain management presents a
6 complex landscape of scientific and ethical issues where the answers are seldom clear. In
7 considering the issues below, three important points should be kept in mind. First, in making
8 medical decisions, physicians must consider scientific and ethical questions, and must use
9 their knowledge and practical experience to arrive at an answer. They must have discretion
10 in exercising their professional judgment in this way. Second, all of the relevant allegations
11 of the Indictment are inextricably tied to substantive medical questions, and the Supreme
12 Court has recently held that the federal enforcement authorities are not authorized to make
13 substantive medical decisions, because they are not qualified to do so. *Gonzales*, 546 U.S.
14 243, 260. Finally, as also held by the Supreme Court in *Gonzales*, the power to define
15 medical practice is given to the states, and the federal authorities must defer to the states'
16 determinations on issues of medical practice. With respect to pain management, Kansas has
17 adopted a set of guidelines as expressed in the Joint Policy Statement of the Kansas Boards
18 of Helaing Arts, Nursing and Pharmacy on the Use of Controlled Substances for the
19 Treatment of Pain ("Guidelines"). (Exhibit 13, Guidelines.) Where applicable, we refer to
20 the articulated view of the State of Kansas, as expressed in those Guidelines.

21 *Pain is a disease of its own.* During the past two decades, there has been a revolution in
22 the scientific and medical understanding of pain and its proper treatment. Physicians have
23 come to appreciate that more than merely an unpleasant side effect of injury or disease,
24 which can or should be endured, pain is a significant cause of other morbidity, including
25 progressive brain damage.³ Persistent pain can destroy quality of life and erode the will to
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³ A. Vania Apkarian et al., *Chronic Back Pain Is Associated with Decreased Prefrontal and Thalamic Gray Matter Density*, 24 J. Neuroscience 46:10410-15 (2004). These researchers at Northwestern University

1 live.⁴ Pain can be debilitating.⁵ The disease is a malignancy in the sense that when it goes
 2 untreated it tends to increase in intensity, and to spread to areas of the body that weren't
 3 previously affected. In doing so, it inflicts progressive damage upon the sufferer's health and
 4 functioning.

5 This spread occurs through physiological processes recognized as central sensitization
 6 and neuroplasticity. These processes adversely alter the chemical and anatomical makeup of
 7 the areas of the spinal cord and brain that modulate the transmission of pain signals.⁶

8 Ongoing pain is the single condition prerequisite to the development of the disease state of
 9 chronic pain. As a result, the term "pain" is used to identify both the disease vector, and the
 10 illness.

11 *Escalation of doses, prescribing of multiple opioids.* Dr. Schneider is accused of
 12 violating the CSA in part because of the dosages he prescribed, and the fact that in some
 13 cases he escalated dosages or prescribed multiple controlled substances at the same time to
 14 the same patient. The prescribing of escalating amounts of controlled substances is known in

16
 17 found that, "Patients with [chronic back pain] CBP showed 5-11% less neocortical gray matter volume than
 18 control subjects. The magnitude of this decrease is equivalent to the gray matter volume lost in 10-20 years of
 normal aging. The decreased volume was related to pain duration, indicating a 1.3 cm³ loss of gray matter for
 every year of chronic pain."

19 ⁴ See: Bernard Lo, et al., *Physician-assisted suicide in context: constitutional, regulatory, and*
 20 *professional challenges*. 24 J. L. Med. & Ethics 3:181-182 (1996) ("Adequate palliation of pain may be likely
 21 to reduce requests for physician-assisted suicide."); Robin Bernhoft, *How We Can Win the Compassion*
 22 *Debate*, Citizen Magazine, June 24, 1996. (noting that "patients often want to die because of under treated
 23 pain" and arguing that the response is better palliative care rather than legalization of suicide); Kathleen. M.
 Foley, *The Relationship of Pain and Symptom Management to Patient Requests for Physician-Assisted*
Suicide, 6 J. Pain & Symptom Mgmt. 289 (1991). See also, *Washington v. Glucksberg*, 521 U.S. 702 (1997)
 (noting that "many people who request physician assisted suicide withdraw that request if their depression and
 pain are treated").

24 ⁵ Roper Starch Worldwide, *Chronic Pain in America: Roadblocks to Relief*, Report to the American Pain
 25 Society (1999) http://www.ampainsoc.org/links/roadblocks/conclude_road.htm. "Untreated pain or pain not
 under control has a significant unfavorable impact on the sufferer's quality of life. It affects their ability to
 concentrate, [work], exercise, socialize, [sleep]... perform chores [and] have sex."

26 ⁶ D. Brookoff, *Chronic Pain: A New Disease?* 35 Hospital Practice. 7:45 (2000). "As pain signals are
 repeatedly generated, neural pathways undergo physiochemical changes that make them hypersensitive to the
 pain signals and resistant to antinociceptive input. In a very real sense, the signals can become embedded in the
 spinal cord, like a painful memory."

1 medical practice as “titration to analgesic effect,” and actually represents the standard of care
2 in the practice of pain management. It is described as follows:

3 *Once an opioid and route of administration are selected, the dose should be*
4 *increased until adequate analgesia occurs or intolerable and unmanageable side*
5 *effects supervene. Titration of the opioid dose may be necessary at the start of*
6 *therapy and repeatedly during the patient’s course. Inadequate pain relief usually*
7 *should be addressed through gradual escalation of the dose until adequate analgesia*
8 *is reported or intolerable and unmanageable side effects limit further dose escalation.*
9 *Adherence to this guideline requires repeated assessment and the ongoing*
10 *management of side effects.*⁷

11 Furthermore, it is recognized that given the body’s metabolization of opioids,
12 effective titration often requires the fairly rapid escalation of dosages.⁸ Therefore, what the
13 government presents as a ground for its theory that Dr. Schneider engaged in crime actually
14 reflects the standard of care in the field of pain treatment.

15 The government’s allegations that certain dosages were “excessive” and “out of
16 proportion” to the pain being treated are also dubious. It is well recognized in the field of
17 pain treatment that pain is subjective and treatment must be uniquely tailored to each
18 patient.⁹ It is also recognized that some patients may require large doses to effectively treat
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21 ⁷ Perry G. Fine & Russel K. Portenoy, *A clinical guide to OPIOID ANALGESIA*, (2004) available at
22 <http://www.stoppain.org/pcd/content/forpros/opiodbook.asp>; See also, Russel K. Portenoy, *Substance Abuse: A*
23 *Comprehensive Textbook*, (Joyce H. Lowinson, ed., 3d ed. 1997). The Joint Commission on Accreditation of
24 Healthcare Organizations (JCAHO) has adopted this standard. See Joint Commission on Accreditation of
25 Healthcare Organizations, *Pain Assessment and Management, An Organizational Approach* (2000).

26 ⁸ Adequate titration may require as much as a 25-50% escalation in dosage for mild to moderate pain
per dosage interval, and as much as a 50-100% escalation for moderate to severe pain. Joint Commission on
Accreditation of Healthcare Organizations, *Pain Assessment and Management, An Organizational Approach*
(2000).

⁹ “A person’s report of pain is the optimal standard upon which all pain management interventions are
based.” (Exhibit 13, Guidelines 2.); “After treatment begins, the drug therapy plan should be adjusted to the
individual medical needs of each patient.” (*Id.* at 3); see, also, Oxford Textbook of Palliative Medicine 169
(Derek Doyle, et al. eds, 1993).

1 pain, and there is nothing wrong with providing such doses (if properly titrated) because
2 opioids are not toxic even at high levels.¹⁰

3 The prescribing of multiple controlled substances is also a recognized practice in the
4 treatment of pain, although such prescribing requires an added measure of caution.¹¹ The
5 government itself acknowledged in a consensus statement that treating physicians may
6 choose to do so in their discretion.¹² Although the government subsequently withdrew the
7 document in which it approved of this practice, it continues to be accepted in the medical
8 community.

9 *Patient involvement in prescribing decisions.* The Indictment blames Dr. Schneider
10 for “prescribing controlled drugs in the type and amount a patient requested.” (Indictment ¶
11 37(b).) The concept of patient involvement in pain treatment is well-recognized, and has a
12 medical name: “patient-controlled analgesia.”¹³ There is no objective medical test of pain; it
13 is a subjective phenomenon. Patient-controlled analgesia (PCA) has become a widely
14 adopted medicine. In the early postoperative setting most studies have demonstrated better
15 pain control, fewer postoperative complications, greater patient satisfaction, and lower total
16 opioid dose required, and PCA can lead to quality of life improvements in ambulatory
17 outpatients with severe chronic pain.¹⁴ Only the patient can tell a trusted physician what
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19 ¹⁰ Perry G. Fine & Russel K. Portenoy, *A clinical guide to OPIOID ANALGESIA*, (2004) available at
20 <http://www.stoppain.org/pcd/content/forpros/opiodbook.asp>; Joint Commission on Accreditation of Healthcare
21 Organizations, *Pain Assessment and Management, An Organizational Approach* (2000) (“There is no maximum
22 dose or analgesic ceiling with most opioids”).

23 ¹¹ Perry G. Fine & Russel K. Portenoy, *A clinical guide to OPIOID ANALGESIA*, (2004) available at
24 <http://www.stoppain.org/pcd/content/forpros/opiodbook.asp>

25 ¹² “The physician may determine that it is beneficial for the patient to use more than one opioid at a
26 time.” (Exhibit 12, Frequently Asked Questions 25.) (“*Can more than one opioid at a time be prescribed to a
patient?*”)

27 ¹³ “A person's report of pain is the optimal standard upon which all pain management interventions are
28 based. The goal of pain management is to reduce the individual's pain to the lowest, while simultaneously
increasing the individual's level of functioning to the greatest extent possible. The exact nature of these goals is
determined jointly by the patient and the health care provider.” (Exhibit 13, Guidelines 2.)

¹⁴ M. Smythe, *Patient Controlled Analgesia: a Review*. 12 *Pharmcotherapy* 132 (1992); Rights and
Responsibilities of Physicians in the use of Opioids for the Treatment of Pain.
<http://www.ampainsoc.org/advocacy/rights.htm>

1 hurts, and what helps. Dr. Scott Fishman, a former president of the American Academy of
2 Pain Medicine, and head of pain medicine at the University of California at Davis has
3 articulated the basis for the concept as follows:

4 One of the ironies of my specialty is that I am most effective when a patient is a
5 full-fledged, active partner in the business of controlling pain. The notion that
6 you can control your pain, or at least have a major influence on it, is a powerful
7 analgesic. The therapeutic value of giving patients some control over their pain
8 was the inspiration for a revolutionary approach to dispensing analgesia.¹⁵

9
10 It should be noted that the Indictment only appears to make this allegation with
11 respect to one patient, and does not claim that the patient did not have a medical need for the
12 medication.

13 *Treatment of addicts.* Dr. Schneider is blamed in the Indictment for his “failure” to
14 change the course of treatment of patients who were addicted. This presents two issues.
15 First, it assumes that addiction is obvious, and that Dr. Schneider or any other physician
16 could diagnose or recognize addiction in his patients with any degree of accuracy. This is
17 simply not so. In order to fully understand the concept of addiction, it must be distinguished
18 from the phenomena of tolerance and dependence.¹⁶

19 Tolerance refers to the body's tendency to become accustomed to a substance such that,
20 over time, more of the substance is needed to produce the same physical effect.¹⁷ Physical

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23 ¹⁵ Scott Fishman, War On Pain 47 (2000); *see also*, The American Pain Society, *The Use of ‘As-Needed’*
24 *Range Orders for Opioid Analgesics in the Management of Acute Pain: A Consensus Statement of the American*
25 *Society for Pain Management Nursing and the American Pain Society*, 23 Home Healthcare Nurse 388 (2005),
26 available at <http://www.ampainsoc.org/pub/bulletin/jul04/consensus1.htm>

¹⁶ “Healthcare providers authorized to prescribe, administer, or dispense drugs, including controlled substances, should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.” (Exhibit 13, Guidelines 2.)

¹⁷ Russell K. Portenoy and Richard Payne, *Substance Abuse, A Comprehensive Textbook* 564 (Joyce H. Lowinson et al. eds., 1997) (“Tolerance is a pharmacological property of opioid drugs defined by the need for increasing doses to maintain effects.”) (footnotes omitted).

1 dependence, by contrast, is defined solely in relationship to withdrawal: a person who suffers
2 from withdrawal symptoms when she stops taking a drug is said to be physically
3 dependent.¹⁸ Addiction is a separate phenomenon, and refers to the negative or harmful
4 behavioral attributes of the drug user.¹⁹

5 As the Indictment itself acknowledges, addiction is not common in treatment with
6 opioids.²⁰ (Indictment ¶ 23.) Often, a physician cannot reliably distinguish between an
7 untreated or undertreated pain patient, and an "addict" not otherwise in pain seeking drugs.
8 It is therefore unreasonable to expect that an informed physician would conclude that a
9 patient is addicted, before considering and ruling-out the more likely cause of drug seeking in
10 a population of chronic pain patients, which is persistent pain. This issue overlaps to a large
11 degree with the issue of "red flags," discussed more fully below.

12 Second, even if Dr. Schneider were able to determine conclusively that a patient was
13 addicted or had instances of abuse, it does not follow that he should stop treating the patient
14 with opioids. This issue presents difficult medical and ethical considerations, and the
15 government has previously acknowledged instances of abuse do not require physicians to

17 ¹⁸ Portenoy & Payne, *supra* note 10, at 564 (Physical dependence "is defined solely by the occurrence of
18 an abstinence syndrome (withdrawal) following abrupt dose reduction or administration of an antagonist [which
strips the drug from the body].").

19 ¹⁹ See Portenoy & Payne, *supra* note 10, at 564 (characterizing addiction as "a psychological and
20 behavioral syndrome in which there is drug craving, compulsive use, and a strong tendency to relapse after
withdrawal, [combined with] rumination about the drug and an intense desire to secure its supply"); *id.*
21 ("[A]ddiction is a chronic disorder characterized by 'the compulsive use of a substance resulting in physical,
psychological or social harm to the user and continued use despite that harm.'). See also, 21 U.S.C. § 802(1)
22 ("The term 'addict' means any individual who habitually uses any narcotic drug so as to endanger the public
morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power
of self-control with reference to his addiction.").

23 ²⁰ Overwhelmingly, research has failed to show that chronic opioid therapy is associated with any
24 significant level of addiction outcomes. This has been a consistent finding over decades. Jose L. Medina &
Seymour Diamond, *Drug Dependency in Patients with Chronic Headaches*, 17 *Headache* 1:12 (1977); Jose L.
25 Medina & Seymour Diamond, *A headache clinic's experience: Diamond Headache Clinic, Ltd.*, 36 *NIDA Res*
Monogr 130 (1981); Dwight E. Moulin et al., *Randomized trial of oral morphine for chronic non-cancer pain*,
26 347 *The Lancet* 8995:143 (1996); J.C. Ballantyne & J. Mao, *Medical Progress: Opioid Therapy for Chronic*
Pain, *New Eng. J. Med.* (2003); Portenoy & Payne, *supra* note 10, at 581; See Samuel Perry & George
Heidrich, *Management of Pain During Debridement: A survey of U.S. Burn Units*, 13 *Pain* 267, 274 (1982);
Jane Porter and Hershel Hick, *Correspondence, Addiction Rare in Patients Treated with Narcotics*, 302 *New*
Eng. J. Med. 123 (1980).

1 report the patient to authorities, or to cut the patient off from treatment.²¹ While some
2 alteration in the course of treatment might be necessary, the broad clinical consensus among
3 experts in the field is that even patients currently suffering from the disease of addiction, as
4 well as those who carry a past but not current history of substance abuse are entitled to, and
5 ethically must be provided relief from severe chronic pain, including opioid analgesic
6 medications. Studies conducted at Harvard Medical School and the University of
7 Washington indicate that a past history of substance abuse has little or no predictive value
8 concerning the success or failure of opioid treatment.²²

9 “Red flags.” Aberrant Drug-Related Behaviors (“ADRBs”) are commonly referred to
10 in slang vernacular as “red flags.” When complex human behaviors are categorized in this
11 way and seen primarily as indicators of “addiction,” or as triggers for investigation of a
12 physician, there is a high likelihood that they will be misunderstood. While some ADRBs
13 are highly suggestive of a substance use disorder (for example, injection of oral preparations
14 or the selling of prescribed medications), other behaviors strongly suggest undertreatment of
15 chronic pain (for example, complaining about need for higher doses, obtaining additional
16 pain medication from family or friends, and unsanctioned dose increases).

17 Indeed, a pain patient may exhibit identical behaviors for entirely different (and
18 understandable) reasons: for example, the patient may quite reasonably have learned through
19 experience that one medication works better and has fewer side effects than another; or, the
20 patient may be so apprehensive at the thought of being without pain medication in the event
21 of an acute or prolonged bout that he or she sets aside medication for a future emergency.
22 Thus, it is difficult and often impossible for physicians to determine whether a “red flag”
23
24

25 ²¹ (Exhibit 12, Frequently Asked Questions 35-38)

26 ²² S.A. Dunbar & N.P. Katz, *Chronic opioid therapy for non-malignant pain in patients with a history of substance abuse: report of 20 cases*. 11 J. Pain & Symptom Mgmt. 163 (1996); C. Chabal et al., *Prescription opiate abuse in chronic pain patients: clinical criteria, incidence, and predictors*, 13 Clin. J. Pain 150 (1997).

1 indicates that a patient is abusing drugs, or is legitimately seeking medication for
2 undertreated pain.

3 In evaluating any given patient's behaviors, the clinical literature must serve as
4 medical context. ADRB is very common in clinical pain practice, being noted in about 45%
5 of opioid-treated patients in two recent, independent and mutually-replicating, studies.²³ Pain
6 specialists do not have a uniform view of how ADRBs should be interpreted.²⁴

7 As previously noted, it is well-documented that pain is undertreated. Also as
8 previously noted, opioid treatment does not result in a significant level of addiction. In
9 summary, in opioid-treated chronic pain populations, ADRBs are very common, addiction as
10 a consequence of treatment is very uncommon, undertreatment of chronic pain is very
11 common, and pain experts lack uniformity in interpreting the relative importance and
12 significance of various ADRBs. Given this context, leaping to a conclusion that any
13 particular behavior is caused by substance abuse or diversion of prescribed medication is
14 unwarranted and represents a failure to employ a proper medical evaluation process.

15 Applying common medical differential diagnosis analysis (medical thinking) to
16 ADRBs that arise in clinical practice is the medical standard of care. Undertreatment of pain
17 is overwhelmingly more common than substance abuse in the chronic pain population, and is
18 therefore the most likely diagnosis in the differential for the majority of ADRBs arising in
19 the clinical practice of pain management. Thus, it is unreasonable to expect informed
20 physicians to adhere slavishly to the law enforcement view of red flags.

21 *Off-label Prescribing of Actiq.* The government's treatment of the off-label
22 prescribing of Actiq for non-cancer pain is yet another theory with respect to which Dr.

23
24 ²³ S. D. Passik et al., *Monitoring outcomes during long-term opioid therapy for noncancer pain: Results*
25 *with the pain assessment and documentation tool.* 1 J Opioid Mgmt 527 (2005); L. R. Webster, *Predicting*
26 *aberrant behaviors in opioid-treated patients. Preliminary validation of the opioid risk tool.*, 6 Pain Med 432
(2005).

²⁴ In fact, a recent study of 100 pain specialists attending a meeting found that "an experienced group of
pain clinicians does not view ADRBs uniformly." S. D. Passik et al., *Pain clinicians' rankings of aberrant*
drug-taking behavior, 16 J. Pain & Palliative Care Pharmacotherapy 39 (2002).

1 Schneider did not have fair notice. With respect to this issue, we incorporate the relevant
2 discussion of the off-label prescribing of Actiq in the Defendants' Joint Memorandum of
3 Points and Authorities in Support of their Motion to Dismiss the Indictment Under Rule 7(c).
4 Briefly, the salient points from that discussion are that (1) off-label prescribing of controlled
5 substances is ethical and well-accepted in the medical community; (2) there is scientific
6 literature discussing the off-label prescribing of Actiq, so at the very least it is the subject of
7 academic dispute among specialists, and (3) the government has not asserted that the patients
8 receiving Actiq did not have pain, but merely that they had non-cancer pain. The
9 undersigned counsel could find no reported or unreported case in which off-label prescribing
10 served as the basis for a case brought pursuant to 21 U.S.C. § 841(a)(1). Under these
11 circumstances, the Indictment's position that the off-label prescribing of Actiq for non-cancer
12 pain is an application of the CSA that fails to give provide notice.

13 *Patient Deaths.* Finally, with respect to the Indictment's allegations that Dr.
14 Schneider somehow failed to act in response to patient deaths from purported overdoses, or
15 that he reasonably should have accepted the conclusion that such deaths were the result of his
16 treatment, is yet another example of the government's distorted view of the medical reality.
17 First, the Indictment does not even allege that Dr. Schneider "caused" or even "contributed
18 to" the vast majority of the deaths listed in the Indictment. It is therefore clear from the face
19 of the Indictment that such deaths could not provide Dr. Schneider with notice of anything.
20 Count 5 fails to provide any details as to the deaths listed therein, so we cannot meaningfully
21 address the issue as to those deaths. However, in counts 2, 3 and 4, we know that the patients
22 were treated with opioids over a significant period of time, with the patient receiving the
23 shortest period of treatment being treated for over a year and a half.

24 While death from respiratory depression caused by opioids is commonly feared, it is
25 accepted knowledge among pain specialists that this is a most unlikely outcome in patients
26

1 who have become tolerant to opioids through long-term use.²⁵ Therefore, the suggestion that
2 Dr. Schneider would conclude that the patient deaths occurred as a result of pain treatment,
3 much less that he received “fair notice” that he must alter his conduct in response to this
4 exceedingly unlikely contingency or face criminal prosecution, is doubtful. Therefore, in
5 reality, each ground that the government presents as a simple instance of “illegitimate”
6 prescribing is actually part of a complex scientific and ethical context, which requires a
7 physician to engage in a complicated decision-making process, often with few “correct”
8 answers.

9 The application of the CSA in the instant case is therefore similar to statute struck
10 down in *Colautti* in several ways. First, like the statute in *Colautti*, neither the CSA nor the
11 interpretive cases provide any definitive statement of what conduct is forbidden. The
12 Supreme Court’s recent clarification of the CSA’s scope would seem to exclude the type of
13 conduct alleged in this case. Nevertheless, the Indictment itself reveals that the government
14 considers itself empowered to allege any collection of disagreements with medical decisions
15 as an offense.

16 Second, like the statute in *Colautti*, the CSA as applied in this case fails to provide the
17 physician with sufficient breathing space to exercise the discretion and professional judgment
18 necessary to make complex scientific and ethical decisions. Rather, as applied, the statute
19 seeks to subject the physician’s decisions to an after-the-fact evaluation by a third party. A
20

21 ²⁵ The American Pain Society, *The Use of ‘As-Needed’ Range Orders for Opioid*
22 *Analgesics in the Management of Acute Pain: A Consensus Statement of the American*
23 *Society for Pain Management Nursing and the American Pain Society*, 23 Home Healthcare
24 Nurse 388 (2005), available at <http://www.ampainsoc.org/pub/bulletin/jul04/consensus1.htm>
25 (“It is now accepted by practitioners of the specialty of pain medicine that respiratory
26 depression induced by opioids tends to be a short-lived phenomenon, generally occurs only
in the opioid-naive patient, and is antagonized by pain.”); see also, Perry G. Fine & Russel K.
Portenoy, *A clinical guide to OPIOID ANALGESIA*, (2004) available at
<http://www.stoppain.org/pcd/content/forpros/opioidbook.asp>; F. Tennant, *Overcoming*
Opiophobia and Doing Opioids Right, Pain Treatment Topics (2007),
<http://pain-topics.org/pdf/OvercomingOpiophobia.pdf>.

1 fact that makes this problem somewhat worse in this case, and that was not present in
2 *Colautti*, is that the third party second-guessing medical judgments here is an arm of the
3 government that is neither authorized nor qualified to make substantive medical judgments.
4 Furthermore, this instant case seems a particularly extreme example of an exercise in ex post
5 carping: the clinic treated over 10,000 patients over the course of some six years, and yet the
6 ambiguous acts stated in the Indictment are the sum total of everything the government could
7 collect after a multi-year investigation.

8 As the Supreme Court recognized, the harm of a vague statute is not only that it may
9 unfairly impose punishment without fault, but that its unpredictability can also chill
10 constitutionally protected conduct. In this case, we know that the CSA does both, harming
11 not only physicians, but also their patients.

12

13 **B. The CSA Lacks Meaningful Enforcement Standards**

14

15 “Due process requires that legislation state reasonably clear guidelines for law
16 enforcement officials, juries and courts to follow in discharging their responsibility of
17 identifying and evaluating allegedly illegal conduct.” *Gaudreau*, 860 F.2d at 363 (citing
18 *Kolender v. Lawson*, 461 U.S. 352, 357-58 (1983); *Grayned*, 408 U.S. at 108; *Smith v.*
19 *Goguen*, 415 U.S. 566, 574-75 (1974); *United States v. Cohen Grocery Co.*, 255 U.S. 81, 89,
20 (1921); *United States v. Reese*, 92 U.S. 214, 221, (1876)). “Criminal statutes that fail to
21 provide minimal guidelines may permit ‘a standardless sweep [that] allows policemen,
22 prosecutors and juries to pursue their personal predilections.’ *Id.* (citing *Kolender*, 461 U.S.
23 at 358 (other citations omitted)). “A vague law impermissibly delegates basic policy matters
24 to policemen, judges, and juries for resolution on an ad hoc and subjective basis, with the
25 attendant dangers of arbitrary and discriminatory application.” *Evans*, 318 F.3d at 1016
26 (citing *Grayned*, 408 U.S. at 108-109).

1 The “notice” prong of void-for-vagueness analysis overlaps to a large degree with the
2 “lack of enforcement standards” prong, and the two may be viewed as different sides of the
3 same coin. It is clear, however, that a statute that is considered to provide notice may
4 nevertheless fail to provide law enforcement authorities with meaningful guidance and
5 therefore opens the door to arbitrary enforcement.²⁶ Therefore, even if the CSA is considered
6 to provide fair notice to physicians of the conduct proscribed in light of their understanding
7 of what constitutes the legitimate practice of medicine or of the decided cases, the statutory
8 text fails to provide enforcement authorities with any guidance as to what constitutes
9 legitimate medical practice.

10 This lack of guidance has resulted in an unabashed overreaching by federal
11 authorities, claiming to possess the power to regulate medicine through the criminal process.
12 What is perhaps most remarkable in this context is the clarity and transparency with which
13 the government has previously expressed its misplaced and dangerous belief that federal
14 prosecutors hold the power to determine what constitutes the practice of medicine, and their
15 consequent refusal to be bound by any guidelines or standards.

16 In defending its decision to prosecute under the CSA conduct rendered legitimate
17 medical practice and enacted into law by the state of Oregon, the government wrote as
18 follows:

19 **Although the [House] Committee [enacting the CSA] is concerned about the**
20 **appropriateness of federal prosecutors determining the appropriate method of the**
21 **practice of medicine, it is necessary to recognize that for the last 50 years this is**
22 **precisely what has happened, through criminal prosecution of physicians whose**
23 **methods of prescribing narcotic drugs have not conformed to the opinions of**
24

25 ²⁶ This is supported by the fact that courts consider the two prongs separately in
26 assessing whether a statute is void for vagueness. *See, e.g., Gaudreau*. In *City of Chicago v. Morales*, 527 U.S. 41 (1999), for example, three justices found that the statutes at issue did not provide fair notice, while five justices concluded that the ordinance was void in that it allowed arbitrary enforcement.

1 **federal prosecutors of what constitutes appropriate methods of professional**
2 **practice.**

3
4 *Oregon v. Ashcroft*, 192 F.Supp.2d 1077 (2002) (quoting Defendant's Memorandum, 16-17).
5 The district court rejected the government's argument that it possessed this power with a
6 stinging rebuke, and both the Ninth Circuit, and the Supreme Court affirmed. *Gonzales v.*
7 *Oregon*, 546 U.S. 243 (2006), *aff'g Oregon v. Aschcroft*, 368 F.3d 1118 (2004).

8 Additionally, the government has unequivocally refused to be bound by any
9 guidelines in the enforcement of the CSA. In 2004, the Drug Enforcement Agency published
10 the Frequently Asked Questions. (Exhibit 12, Frequently Asked Questions.) The Frequently
11 Asked Questions were a collaborative effort between the DEA and academic pain specialists
12 that provided a consensus statement to guide health care providers and law enforcement
13 authorities alike. (*Id.*)

14 However, on the eve of the trial of a prominent pain physician, approximately two
15 months after their publication, the government suddenly withdrew the guidelines stating that
16 they contained "misstatements." (Exhibit 14, Marc Kaufman, *New DEA Statement Has Pain*
17 *Doctors More Fearful*, Washington Post, Nov. 30, 2004 at A17.) The DEA vowed to re-
18 publish a revised set, but never did. Thus, in the prosecution of physicians under the CSA
19 the government refuses to be bound even by its own document, produced in consultation over
20 a period of years with the country's leading pain specialists. Such refusal to be guided by
21 any standards at all has enabled the instant prosecution, all the while the state of Kansas has
22 provided guidelines on these matters.²⁷

23 The lack of enforcement standards has been a very real problem in the courtroom. In
24 one case, the government presented the testimony of Dr. Michael Ashburn, a former
25 president of the American Pain Society. Dr. Ashburn's colleagues considered his testimony
26

²⁷ (See generally Exhibit 13, Guidelines.)

1 so inaccurate that they took the extraordinary step of writing the court to express their
2 disagreement and shock. (Exhibit 15, Letter from Past Presidents of the American Pain
3 Society, Dec. 10, 2004.) Six former presidents of the American Pain Society wrote that Dr.
4 Ashburn's testimony was not accurate on the following points:²⁸

- 5
- 6 • "Dr. Ashburn repeatedly stated that the use of "high dose" opioid therapy is an
7 indication of drug abuse in populations with chronic non-cancer pain. It is factually
8 untrue that this is a consensus opinion of pain experts. We strongly hold the view that
9 patients with non-cancer pain may benefit from opioid therapy and that the dose
10 necessary to control pain may be high. Use of "high dose" opioid therapy for chronic
11 pain is clearly in the scope of medicine."
- 12 • "Dr. Ashburn asserts (page 23 of the transcript) that morphine at a dose of 195
13 mg/day constitutes a high dose. This statement is without foundation in the medical
14 literature and we believe that it is, on its face, absurd."
- 15 • "Dr. Ashburn implies that opioid treatment of a patient with a known addiction is
16 medically wrong and worsens the addiction. This is not the view of experienced
17 clinicians in the field. It is unacceptable to promulgate the view that the disease of
18 addiction automatically denies patients with severe pain the possibility of relief
19 through careful opioid therapy."
- 20 • "He states (page 37) that high dose opioids produce hyperalgesia (increased pain) and
21 therefore may worsen the clinical pain problem. Although this has been raised in the
22 literature as a theoretical concern affecting some patients, neither the prevalence nor
23 the clinical significance has been established and its putative risks have not led to any
24 change in clinical guidelines."
- 25 • "Dr. Ashburn speculates (page 37) that high dose opioids may compromise the
26 immune system. Again, this is considered to be a theoretical risk, one balanced by the
potential dysimmune effects of unrelieved pain itself; it has not found its way into any
accepted guideline for opioid use in any population."

The authors asserted that they were "stunned" by Dr. Ashburn's testimony. (Exhibit 15,
Letter from Past Presidents of the American Pain Society, Dec. 10, 2004.) Yet, the court did
not provide the jury with this letter. Although this is a different case, involving different
experts, the incident illustrates the fact that the government is so unrestrained as to present

²⁸ Six Past-Presidents of the American Pain Society Express Concern Regarding "Serious Misrepresentations" in the Testimony of the Government's Expert Witness in the Trial of Dr. Hurwitz - Portenoy, Campbell, Foley, Cleeland, Miaskowski, & Payne. Submitted to Judge Wexler, Dec. 10, 2004. (Exhibit 8, Letter from Past Presidents of the American Pain Society, Dec. 10, 2004.)

1 evidence that “stuns” leaders in the field of pain treatment. Juries, as a general matter, do not
2 have the scientific knowledge and medical training to debunk such inaccurate testimony.²⁹

3 The above-described instances reveal (1) the government’s belief that federal
4 prosecutors are qualified and empowered to regulate the practice of medicine; (2) that the
5 government refuses to be bound by any guidelines whatsoever in the enforcement of the
6 CSA; and (3) that the government does not consider itself bound by medical science even in
7 the courtroom. It is clear that the government intends to proceed along these lines in the
8 instant case, for it has placed its imprimatur on broad and general notions of pain treatment
9 that frame the allegations of the Indictment and the whole case with respect to the unlawful
10 prescribing allegations. While much of the Indictment reads like a discourse intended to
11 guide doctors in their practice, the following statements provide the bases for the
12 government’s theories:

13
14 *(1) “In Pain Management, to ‘do no harm,’ the treatment should not result in greater*
15 *risks to the patient than the condition being treated, especially if the risks of*
16 *treatment are life-threatening, and the underlying condition is not.” (Indictment ¶*
17 *21.)*

18
19 *(2) “If a provider practicing Pain Management makes a patient worse, and the*
20 *provider does not change the course of treatment, the provider is not practicing*
21 *legitimate medicine.” (Indictment ¶ 22.)*

22
23 *(3) “Continuing to prescribe controlled drugs to a patient who is demonstrating*
24 *aberrant behavior is doing harm to the patient. If this situation continues, it indicates*

25
26 ²⁹ The government’s early opposition to the rigorous application of *Daubert* and Rule 702 signals that similar problems are on the horizon in the instant case. (See Government’s Motion for Clarification and Modification of Scheduling Order)

1 *that the prescribing is for other than a legitimate medical purpose and is outside the*
2 *usual practice of medicine.”* (Indictment ¶ 24.)
3

4 Each specific allegation of the Indictment appears to relate to one or more of these
5 “nuggets of wisdom.” The Indictment sets out the above propositions as if they were
6 fundamental principles of pain practice and substantive standards of criminal law. They are
7 neither.

8 The first statement is the government’s adaptation of the Hippocratic Oath to the
9 practice of pain management. It purports to summarize the philosophy of pain treatment, but
10 constitutes a gross overgeneralization and oversimplification of a complex field of medical
11 science. This general philosophical statement is then directly applied to medical practice, but
12 this makes no sense.³⁰ It is not clear what place such a statement has in a federal criminal
13 indictment.

14 The second statement is offensive in two ways. First, it uses the word “worse,” to
15 build in an ambiguous, subjective and ultimately meaningless standard. It then grafts it on to
16 the standard of the CSA, which is only intended to cover drug dealing as conventionally
17 understood. Thus, the Indictment equates the unsuccessful efforts of a treating physician to
18 drug dealing, and pries open a door through which to inject its subjective and unqualified
19 judgments on substantive medical issues. In light of the Supreme Court’s holding in
20 *Gonzales*, such verbal sleight-of-hand achieves what can no longer be accomplished in the
21

22 ³⁰ Let us consider a hypothetical case: A patient has a good history and physical exam supporting the
23 diagnosis of fibromyalgia, and the patient is otherwise well, except for the disabling pain. The patient does an
24 exercise program, which helps, but has not been helped by non-controlled substances. Opioids help. Given this
25 case, the government’s normative statement requires that

- 26 1. since there is a risk of respiratory depression and death from opioids (although the risk to a
chronic user taking the medication for pain as directed is literally almost zero there is still a potential
"risk"), and,
2. since fibromyalgia is not a fatal disease - there is no risk of death from fibromyalgia per se,
therefore
3. fibromyalgia patients should never receive opioids.

Therefore, the patient’s pain would not be treated. This would fall below the standard of care. While
the enforcement authorities are free to ignore a patient's quality of life and their expressed informed consent and
choices regarding available therapies, physicians are not.

1 open. In this case, it is also clear that the absolute standard that the government attempts to
2 impose is inconsistent with Kansas's view on the matter which imposes a discretionary
3 standard.³¹

4 Finally, as amply demonstrated in our discussion of ADRBs in the previous section,
5 the third statement is inaccurate. It represents the kind of uninformed, one-size-fits-all
6 approach to the practice of medicine that pervades the instant case, and is both medically and
7 morally offensive, as it implies that patients with active substance abuse problems, or with a
8 history of such problems, are not entitled to the same standard of care in pain management as
9 anybody else. According to the American Society of Addiction Medicine, the American
10 Academy of Pain Management, and the American Pain Society:

11 *“A decision whether to prescribe opioids may be particularly difficult in patients with*
12 *concurrent addictive disorders, or with risk factors for addiction, such as a personal*
13 *or family history of addictive disorder... It is, nonetheless, **a medical judgment that***
14 ***must be made** by a HCP (health care provider) in the context of the provider-patient*
15 *relationship based on knowledge of the patient, awareness of the patient's medical*
16 *and psychiatric conditions and on observation of the patient's response to treatment.”*
17 *(emphasis added)*³²

18 The kinds of absolute statements asserted in the Indictment, unfiltered by any
19 guidelines and subject to no limitations, coupled with the power to prosecute and punish,
20 allow the government to assert a stranglehold over the practice of pain management to the
21 detriment of both doctors and patients.

22 Thus, even at this early stage, it is clear that the very foundations of the Indictment
23 and of the instant prosecution are the products of a completely unrestrained process. This
24 presents the unacceptable risk that two individuals will be confined in prison for decades
25 based on “crimes” that were never established as such by Congress. Rather, they were dreamt

26 ³¹ “If treatment goals are not being achieved despite medication adjustment, the healthcare provider's
[sic] should reevaluate the appropriateness of continued treatment”

³² ASAM, AAPM, and APS. Consensus Statement: Public Policy Statement on Rights and
Responsibilities of Healthcare Professionals in the use of Opioids for the Treatment of Pain (2006)
<http://161.58.165.114/ppol/Opioids%20for%20Treatment%20of%20Pain.htm>

1 up by the government, musing on the philosophy and normative aspects of medical practice,
2 promulgated as “law” in a criminal indictment.

3 **C. The Scierter Requirement Fails to Mitigate the CSA’s Vagueness**

4
5 The Indictment charges a violation of the CSA in the instant case with no *mens rea*
6 requirement as to the “legitimate medical practice” or “course of professional practice”
7 component of the offense. The Indictment seeks to convict Dr. Schneider not for knowingly
8 or intentionally abandoning his role as a physician to become a “pusher,” but rather on the
9 basis of acts it presents as deviations from the standard of care. The Indictment alleges no
10 act that is consistent only with a non-medical purpose, such as would allow a fact finder to
11 infer a subjective intent to engage in illicit drug dealing as conventionally understood, rather
12 than to attempt to treat a patient’s pain. The Tenth Circuit’s decision in *United States v.*
13 *Celio*, 230 Fed. Appx. 818 (10th Cir. 2007), which holds that the CSA does not require a
14 showing of subjective intent with respect to the “legitimate medical purpose” or “course of
15 professional practice” element, arguably supports this view.³³

16 Again, *Colautti v. Franklin* provides a close analogy to the instant case. In *Colautti*,
17 in addition to finding that the challenged provision of the statute failed to provide adequate
18 notice of the proscribed conduct, see discussion *supra*, the Court addressed the *mens rea*
19 requirement of the statute. The Court found that that the uncertainty of the statute was
20 “aggravated by the absence of a scierter requirement with respect to the finding of viability.”
21 *Colautti*, at 390. The Court explained that the many factors a physician must consider in
22 making a determination of viability, as well as the fact that different physicians do not view
23 these factors uniformly, made a determination of viability “uncertain.” *Id.* at 395-396. The
24 Court the addressed the practical implications of the criminalization of medical decisions that
25 are based on complex decision-making but do not require an element of subjective scierter:

26

³³ In the contemporaneously-filed Motion to Dismiss Under Rule 7(c), we explain why this holding is distinguishable from the instant case, and should not apply given the facts alleged in the Indictment.

1 In the face of these uncertainties, it is not unlikely that experts will disagree over
2 whether a particular fetus in the second trimester has advanced to the stage of
3 viability. The prospect of such disagreement, in conjunction with a statute imposing
4 strict civil and criminal liability for an erroneous determination of viability, could
5 have a profound chilling effect on the willingness of physicians to perform abortions
6 near the point of viability in the manner indicated by their best medical judgment.

7
8 *Id.* at 396. The Court held that “the absence of a scienter requirement in the provision
9 directing the physician to determine whether the fetus is or may be viable [renders] the
10 statute [] little more than ‘a trap for those who act in good faith.’” *Id.* at 395 (citing *United*
11 *States v. Ragen*, 314 U.S. 513, 524 (1942)).

12 The problem presented in *Colautti* with respect to the lack of a scienter requirement is
13 also present in the instant case. First, it should be noted that the application of the scienter
14 requirement in the statute at issue in *Colautti* is remarkably similar to the Indictment and the
15 Tenth Circuit’s application under the CSA. In *Colautti*, the statute required a showing of
16 intent with respect to the causing of a death, but not with respect to the finding that a fetus
17 may be viable. *Id.* at 394-395. Similarly, in the instant case, the Indictment and the Tenth
18 Circuit require that the act of prescribing was done knowingly or intentionally (it is difficult
19 to imagine how the act could be done otherwise in this context), but that there is no
20 requirement to show subjective intent with respect to the legitimacy of the prescription,
21 *Celio*, 230 Fed. Appx. At 825-26, but rather only objective disagreement by the fact-finder.
22 The *Colautti* court described this as a “strict liability” offense with respect to the viability
23 determination, and that characterization is equally apt in this context with respect to the
24 determination of legitimacy.

25 Like the determination of viability, decisions made in the course of treating pain
26 involve the consideration of numerous factors, including scientific as well as ethical issues.
Furthermore, similar to the factors applied in determining viability, there is a lack of

1 uniformity in the way pain physicians view medical issues, patient behaviors, and ethical
2 duties in the practice of pain treatment. With respect to the scienter requirement, the
3 application of the CSA in the instant case operates in a similar manner to the statute in
4 *Colautti*: the government seeks to impose an objective knowledge standard in the context of
5 complex decision-making, which can later be second-guessed and disagreed with by others
6 (as in the case of the government and its experts). Perhaps most importantly, the Supreme
7 Court's incisive analysis of almost thirty years ago rings true in the context of the CSA's
8 application to pain treatment today: the lack of a meaningful, subjective scienter requirement
9 chills the willingness of physicians to adequately treat pain. For all of these reasons, the
10 CSA's scienter requirement fails to mitigate its vagueness in this context.

13 **II. 18 U.S.C. § 1347 is Unconstitutionally Applied by the Indictment**

14
15 For the reasons discussed in Part I above, 18 U.S.C. § 1347 is unconstitutionally
16 vague as applied to the medical prescribing decisions of Dr. Schneider, and is therefore void.
17 The Indictment's reliance on the CPT codes and the policies of health care benefit providers
18 or of the practices of the industry as substantive law is also unconstitutional.

19 The CPT coding system, the policies or reviews of the HCBPs, and the practices of
20 the industry are not law, and do not have the force of law. It is unconstitutional for
21 prosecutors to treat them as if they have such force. It would be unconstitutional for
22 Congress to create a statute stating that it was a crime to engage in conduct forbidden by the
23 AMA, or by particular HCBPs, or by the health care industry as a whole. This is because
24 neither the AMA, nor the HCBPs, nor the health care industry more generally are
25 governmental entities, and Congress does not have the power to delegate law-making
26 authority outside of the government.

1 “The definition of the elements of a criminal offense is entrusted to the legislature,
2 particularly in the case of federal crimes, which are solely creatures of statute.” *Liparota v.*
3 *United States*, 471 U.S. 419, 424 (1985). Courts and agencies sometimes have a role in
4 defining, particularizing or interpreting the meaning of statutes. Private entities do not, and
5 cannot, have such a role under our Constitution. The Constitution forbids the allocation of
6 governmental powers to non-governmental entities. Additionally, due process requires that
7 any standard having legislative effect must be enacted through the constitutionally-qualified
8 legislative process. *See INS v. Chadha*, 462 U.S. 919 (1983). To the extent that counts 7-9
9 and 13-17 are based on CPT codes, on the rules of HCBPs, or on “industry practice,” they
10 fail to adhere to these constitutional requirements.

11 Additionally, as with the CSA, the application of section 1347 is also unconstitutional
12 in this case in that it fails to give adequate breathing space for the constitutionally protected
13 interests of physicians and their patients. *Griswold v. Connecticut*, 381 U.S. 479 (1965).

14
15 **III. Counts 1, and 18-34 are Derivative and Defective**

16
17 The constitutional deficiencies of the Indictment affect these counts, and they should
18 be dismissed. There counts are entirely derivative of the preceding CSA and fraud counts. If
19 those counts are dismissed, these counts must also be dismissed.

20 **CONCLUSION**

21 For the foregoing reasons, the Indictment should be dismissed.

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24
25 Respectfully Submitted,

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Kevin P. Byers Co., L.P.A.

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CERTIFICATE OF SERVICE

I certify that on May 16, 2008, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system which will send notice of electronic filing to:

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