We intend this card to serve as a basic guide to prosecuting prescription drug diversion cases. Users should check recent cases and, where necessary, consult with their supervisors before making a final decision regarding charging strategies. For space purposes, we left the "U.S." out of all of our citations. If the cite involves a civil case, we noted the same.

Why Drug Diversion Prosecutions-Civil and Criminal?

■The Controlled Substances Act, 21/801 *et seq.*, states that "except as provided by this subchapter, it shall be unlawful for any person ***knowingly or intentionally . . . to distribute, or dispense a controlled substance***. 21/841(a)(1). Section 842(c)(1) authorizes civil penalties for a violation of the act. "In order to enable physicians and certain others (e.g., manufacturers, nurses, and pharmacists) lawfully to distribute or dispense drugs within the course of their professional practice, Congress provided that '[p]ersons registered . . . under this subchapter . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter.'" 21/822(b). "This exemption from the Act granted to medical practitioners engaged in distribution of controlled substances ***is a limited one since practitioners possess increased access to controlled substances and therefore greater opportunities for diversion***. *ALN Corp.*, 1993 WL 402803, *2 (D. Conn.) (Civil case), quoting *Vamos*, 797 F.2d 1146, 1152-53 (2d Cir. 1986); *see also Moore*, 423 U.S. 122, 135 (1975); Clinical Leasing Service, Inc., 759 F. Supp. 310, 316-17 (E.D. La. 1990) (civil case). ■ Congress provides an exemption to physicians and other medical practitioners who use their ability to issue controlled substances to heal patients, but allows prosecution of those unscrupulous medical professionals who use these privileges to deal and steal. See *Singh*, 54 F.3d 1182, 1188-89 (4th Cir. 1995) ("Congress gave doctors the power to authorize the distribution of dangerous addictive drugs, and with that power, Congress also places upon [the doctor] the responsibility to distribute them wisely within the course of [the doctor's] medical practice").

Relevant Definitions

■**Practitioner** means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.**21/802(21).** ■**Controlled Substance** means a drug or other substance, or immediate precursor, included in Schedule I, II, III, IV, or V of 21/812. **21/802(6).** ■**Deliver** means the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship.**21/802(8)**. ■**Dispense** means to deliver a controlled substance to an ultimate user or research subject, by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.**21/802(10).** ■**Distribute** means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term "distributor" means a person who so delivers a controlled substance or a listed chemical.**21/802(11)**. ■**Ultimate User** means a person who has lawfully obtained, and who possess[es], a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.**21/802(27).** See *Bartee*, 479 F.2d 484 (10th Cir. 1973) (various definitions).

Basic Element of § 841 Offense

■ The basic elements are: (1) the defendant knowingly or intentionally, (2) distributed or dispensed, (3) a controlled substance. The statutory language of 21/841 does not contain any other elements. However, to prove that the distribution or dispensation via prescription was illegal, the government must show that there was no legitimate medical purpose for the prescription and the same was not issued/filled in the usual course of professional practice or was beyond the bounds of medical practice. *Singh*.

When is a Prescription for a Controlled Substance Effective?

■A prescription for a controlled substance is effective if issued **(1) for a legitimate medical purpose (2) by an individual practitioner (3) acting in the usual course of his professional practice. 21 C.F.R. §1306.04(a).** ■The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. **See *Milicia*, 769 F. Supp. 877, 878-80 & n.8 (E.D. Pa. 1991), citing § 1306.04(a).** ■Any individual practitioner who issues or fills a prescription knowing that the prescription was not issued for a legitimate medical purpose in the usual course of professional treatment (or for legitimate and authorized research), shall be subject to penalties provided for violations of the controlled substances law. A conviction will be upheld even if the government does not present compelling evidence that the doctor prescribed with malicious motive or the desire to make a profit. *Singh,* at 1188.

What is a Legitimate Medical Purpose?

■A physician is acting with a legitimate medical purpose when he or she prescribes medical treatments that are in **strict compliance with well-established and generally accepted medical guidelines, and administers medical treatments that appropriately and correctly address and relieve the present medical condition**. *Tran Trong Coung*, 18 F.3d 1132 (4th Cir. 1994) (reversed and remanded). ■To decide whether a physician acted without a legitimate medical purpose, you must examine all of the defendant's actions and the circumstances surrounding them. ■Abbreviated or no medical history or physical examination is probative on the question of whether a legitimate medical purpose exists. *Chin*, 795 F.2d 496, 500 (5th Cir. 1986). ■Evidence that a doctor tells patients where to get their prescriptions filled, prescribes drugs even after learning of a patient's addiction to them, or asks patients about the amount or type or type of drugs they want, is probative of whether a legitimate medical purpose exists for the dispensed controlled substances. *Singh*, 54 F.3d 1182; *Coung*, 18 F.3d 1132.

What is the Usual Course of Professional Practice?

■"There are no specific guidelines concerning what is required to support a conclusion that an accused acted outside the usual course of professional practice. Rather, the courts must engage in a case-by-case analysis of evidence to determine whether a reasonable inference of guilt may be drawn from specific facts." *Singh*, at 1187, quoting *August*, 984 F.2d 705, 713 (6th Cir. 1992), and *Cuong*, at 1137-38. ■A physician must act in a good faith manner that is in direct accordance with the reasonableness standard set forth in the medical community. *Boettjer*, 569 F.2d 1078, 1080-82 (9th Cir. 1978). ■A physician must use reasonableness and sound medical discretion in following generally accepted medical guidelines in the administration of correct medical treatment throughout the physician/ patient relationship. *Moore*, 423 U.S. at 139. ■Licensed physicians who prescribe controlled substances outside bounds of their professional medical practice are subject to prosecution and are no different from large scale drug dealers. **Comprehensive Drug Abuse Prevention Act of 1974, § 401(a), 21 U.S.C.A. § 841(a).** ■The indictment need not charge that the dispensation was done outside the course of professional practice, *Steele*, 147 F.3d 1316 (11th Cir. 1998) (en banc), citing 21/885(a)(1), because the government does not have to negate any exemption or exception set forth in Title 21 in the indictment). ■The better practice, however, is to include this language to familiarize the jury with the concept and make clear your basis for the illegal dispensation and distribution charges. *Roya*, 574 F.2d 386 (7th Cir. 1978).

Deliberate Ignorance/Willful Blindness

■The government may show knowledge by proof that the physician or pharmacist deliberately closed his or her eyes to the true nature of a prescription. *Lawson*, 682 F.2d 480 (4th Cir. 1982) (pharmacist charged with illegal distribution of controlled substances); *Neville*, 82 F.3d 750, 759-60 (7th Cir. 1996). ■"When a pharmacist is faced with a large number of prescriptions all written by one doctor and all presented by one person, this constitutes evidence that the prescriptions are not legitimate." *Lawson*, at 482, citing *Hayes*, 595 F.2d 258, 260 (5th Cir. 1979); *see also Milicia*, 769 F. Supp. at 884. ■"[U]niform dosages and quantities belied any conclusion that the prescriptions . . . were ordered *for individual patients*." 682 F.2d at 482-83 & n6 (discussing expert testimony that uniformity of prescriptions should signal to a pharmacist that the prescriptions were not legitimate). ■The nature of the physician's practice does not match the nature of the prescriptions (proving outside the course of professional practice and lack of

legitimate medical purpose). 682 F.2d at 482-83 (giving the example of Dilaudid being used only for those people with excruciating pain, such as with a doctor operating a clinic that treats terminally ill cancer patients). ■The *Lawson* court held that the evidence proved the defendant pharmacist "willingly ignored every signal that he should question the volume of controlled substances being dispensed from his pharmacies." Id. & n.17, citing *Seelig*, 622 F.2d 207, 213 (6th Cir. 1980) (jury instructions). ■**Others:** Prescriptions written on a large-scale basis (i.e., over 90% of the prescriptions written by the physician were for controlled substances, a figure expert testimony will show is outrageously high and dramatically out of line with professional medical practices of other similarly-situated physicians). *Hammond*, 781 F.2d 1536 (11th Cir. 1986). ■**Consider a pharmacist** expert witness, and have them testify that "pharmacists are not allowed to fill every prescription issued by a licensed physician and they must screen their patients for 'drug-seeking' behaviors." *Sims-Robertson*, 16 F.3d 1223, 1994 WL 12212 (6th Cir. (Mich.) (Unpublished). ■**See the DEA Pharmacist's Manual** (on their web-site). See also *Leal*, 75 F.3d 219 (6th Cir. 1996) (pill mill case, defendant pharmacist, and "ostrich" instruction approved); *Veal*, 23 F.3d 985 (6th Cir. 1994).

Dispense or Distribute or Both?

■**The case law is not always clear about whether the act of prescribing or filling controlled substances without a legitimate medical purpose and outside the course of professional practice is Illegal Dispensing or Distribution or Both.** ■Here are a few cases illustrating different charging theories. ■**PRESCRIBING:** "Improperly issuing a prescription for a controlled substance is sufficient to warrant a conviction under the [CSA] ***even though the doctor does not himself actually distribute the drugs and even though the prescription is not subsequently filled.*** The sheer number of prescriptions written to any individual is proof that the defendant knew he was ***prescribing drugs improperly***. *Cuong*, 18 F.3d at 1139, quoting *Stump*, 735 F.2d 273, 275-76 (7th Cir. 1984). ■**DISPENSING:** "A doctor's authority to prescribe controlled substances is violated when he uses that authority to assist another in maintaining a drug habit ***or when he dispenses controlled substances for other than a legitimate medical purpose***. *Singh*. ■**DISTRIBUTION:** The indictment was not defective because the government charged the defendant with illegal distribution instead of illegal dispensation. *Ellzey*, 527 F.2d 1306 (6th Cir. 1976). ■**BOTH:** In *Green*, 511 F.2d 1062 (7th Cir. 1975), a physician was charged and convicted of illegal dispensation and a pharmacist was charged and convicted of illegal distribution. In *Hoffman*, 129 F.3d 1196 (11th Cir. 1997), the plea agreement charged both illegal dispensing and distribution. In *Sutherland*, 2001 WL 1502913 (W.D. Va.), the jury convicted the defendant of 427 counts of ***unlawfully dispensing and distributing controlled substances***. In *Dunbar*, 614 F.2d 39, 41 (5th Cir. 1980), the court said "a licensed medical doctor can be prosecuted for the distribution or dispensation of Schedule II controlled substances outside the usual course of professional practice, citing *Moore*, 423 U.S.122. ■**The "Go-Figure" Winners are:** "[t]o convict a physician of distributing a controlled substance . . ., the government must prove . . . that the defendant 'distributed or dispensed a controlled substance.'" *Singh*, 54 F.3d at 1186-87, quoting *Cuong*, 18 F.3d at 1141; *see also Chin*, 795 F.2d at 499 (diet pill doc). ■**REAL DISTINCTION?:** Read *Harrison*, 651, F.2d 353 (5th Cir. 1981); *Thompson*, 624 F.2d 740 (5th Cir. 1980); and *Leigh*, 487 F.2d 206 (5th Cir. 1976). ■**SOLUTION?:** Read ***Moore*, 423 U.S. 122.** You cannot create a hyper-technical distinction between dispense and distribute as both involve delivery. *Fellman*, 549 F.2d 181, 182 (10th Cir. 1977); *see also Badia*, 490 F.2d 296 (1st Cir. 1973); *Rosenburg*, 515 F.2d 190 (9th Cir. 1975).

Unit of Prosecution

■The unit of prosecution is each act of dispensation or distribution (each prescription written or filled). *Sugar*, 606 F. Supp. 1134 (S.D.N.Y. 1985); *Elliott*, 849 F.2d 886 (4th Cir. 1988).

Death or Serious Bodily Injury

■If you have evidence of patient overdoses resulting from the physician's prescribing pattern, consider charging the enhanced penalty provisions under 21/841(b). There are *Apprendi* issues here.

Expert Witness Issues

■"Neither the government nor the defendant is required to provide expert testimony on the issue of whether the actions taken by the defendant were or were not for a legitimate medical purpose or in the usual course of professional practice." *Polito*, 111 F.3d 132, 1997 WL 178879, *5 (6th Cir. (Ohio)), quoting *Word*, 806 F.2d 658, 663 (6th Cir. 1993). ■"There are cases in which the lay testimony is so clear that no expert testimony is required to determine that the defendant's actions were not for a legitimate medical purpose nor in the usual course of professional practice." *Polito* quoting *Word*. ■Many cases are not that clear cut because the target physician or pharmacist may also have legitimate patients or fill legitimate prescriptions. ■**Potential Areas of Expert Testimony:** Signs of addiction and how a physician discovers them. The effects of all of the drugs prescribed, and their proper uses overall, the legal requirements for issuing a prescription, and the inappropriateness of the prescriptions in each § 841 count. The danger of long-term use of narcotic analgesics, which contain acetaminophen, and their toxic nature to the human body. The process of titrating narcotic dosages upward as the body adjusts and develops tolerance to them, and why you do not prescribe high dosages to a patient that is not opioid-tolerant. The distinctions in treating acute, malignant, and chronic, non-malignant pain patients, and the distinctions between abuse, addiction, dependance, and tolerance. Poly-pharmacy or prescribing specific drug combinations – when to and when not to. This is important because many pill docs prescribe in cocktail fashion, i.e., hydrocodone, soma, oxycodone, and Xanax. Note: pain is subjective and requires a specific treatment plan for each patient. This is important because the bad doctors prescribe the same drugs in the same amounts to all or most of their patients, including patients within the same family. Use a pain specialist to review medical files and provide opinion testimony concerning legitimate medical use of opioid therapy without other non-invasive or invasive therapies. Make sure your expert has reviewed pharmaceutical literature re: drugs at issue and prescribes these drugs in his/her practice. Determine whether your expert has served on the drug manufacturer's speakers' bureau.

Sample Count Table

■Consider using the following table to set out each substantive dispensation or distribution count in your indictment:

Count	Date	Controlled Substance, Schedule & Form	Number of Pills	Strength
1	7/8/01	Amphetamine (S-II) Adderall®	90	30mg
2	7/10/01	Oxycodone (S-II) OxyContin®	90	40mg
3	7/11/01	Hydrocodone (S-III) Norco®	180	10mg

Sentencing Issues for Pill Cases

■**Equivalency ratios are used in determining drug weight for sentencing purposes in pill cases.** Thus, "to determine the base offense level, the probation officer [will use] the drug equivalency tables to convert oxycodone, [amphetamine, and hydrocodone] into an equivalent marihuana weight." *Sutherland*, 2001 WL 1502913, *3, discussing sentencing on Schedule II oxycodone and amphetamine. **See OxyContin Sentencing Table**. ■The "guidelines do not differentiate between oxycodone and its salts," so the whole weight of the pill counts. *Sutherland*, citing the guidelines and *Soto*, 1 F.3d 920, 922-23 (9th Cir. 1993). ■**A defendant's special training as a doctor constitutes a special skill used in the commission of [drug diversion] offenses. Same with a pharmacist.** *Sutherland.*

Further Guidance

■For further guidance on these issues contact the authors:

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