PRESCRIPTION DRUG CONTROL UNDER THE FEDERAL CONTROLLED SUBSTANCES ACT: A WEB OF ADMINISTRATIVE, CIVIL, AND CRIMINAL LAW CONTROLS

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INTRODUCTION

The abuse of prescription medication by the famous and the unknown ranges from the bathroom to the street corner. It is a significant problem that garners little attention in American society. Abusers of prescription medication include generally law-abiding citizens hooked on medication overprescribed or misprescribed by their family physician as well as hardened drug addicts.[1] The following facts provide evidence of the scope of the problem:

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This Article does not address persons who conduct research with controlled substances, persons who manufacture controlled substances, or persons involved in narcotic treatment programs. This Article is dedicated to the memory of Stephen E. Stone, Esquire, former Associate General Counsel at the Drug Enforcement Administration, a friend. His wise counsel will be missed.

1. *See* Saralie Faivelson, *Hooked on Pain Relief*, NEW CHOICES FOR THE BEST YEARS, Feb. 1991, at 50-51.

- The 1990 National Household Survey on Drug Abuse revealed that approximately 24 million members of the household population of the United States had used psychotherapeutic drugs illicitly on at least one occasion, 8.6 million had used them in the year prior to the survey, and 2.9 million had used them in the past month;[2]
- Between 26-45% of visits to hospital emergency rooms between 1985 and 1989 which involved a controlled substance were attributable to the use of pharmaceuticals;[3]
- Pharmaceuticals resulted in an estimated 88,000 hospital emergency room visits in 1988 and 1989 — twice the number of hospital emergency room visits for heroin and more than 22 times those for LSD;[4]
- Anton Furst, the Oscar-winning Art Director of the 1989 film "Batman" committed suicide in 1992, reportedly after more than twenty years of dependence on Valium;[5] and
- The U.S. Drug Enforcement Administration and state agencies prosecute or revoke the license of hundreds of physicians each year for illegal drug activities.[6]

Prescription medication is a very attractive street drug. As Congressman Pete Stark, Chairman of the House Subcommittee on Health, noted, "Given an option between a white powder of unknown origin and quality and a pill with a manufacturer's logo, made under U.S. government quality control, the decision for the abuser is easy."[7] In part because of this attraction, the black market for such drugs is extremely lucrative.[8] The mark-up is substantial. For instance, the drug commercially named Dilaudid, a synthetic morphine made by Knoll Pharmaceutical, has a retail value in the

2. NATIONAL INSTITUTE ON DRUG ABUSE, U.S. DEP'T OF HEALTH & HUMAN SERVICES, NATIONAL HOUSEHOLD SURVEY ON DRUG ABUSE: HIGHLIGHTS 1990, at 35 (1991). "The summary measure 'non-medical use of any psychotherapeutic drugs' includes use of prescription-type psychotherapeutic drugs such as stimulants, sedatives, tranquilizers, and analgesics without a doctor's prescription or in amounts or for purposes other than prescribed." *Id.* at 3.

3. Pete Stark, *U.S. Taxpayers Are Funding Prescription Drug Abuse*, U.S.A. TODAY: MAG. OF THE AM. SCENE, July 1991, at 88.

4. *Id.* at 89.

5. Betsy Sharkey, *Anton Furst: Lost in the Dream Factory*, N.Y. TIMES, Feb. 16, 1992, § 2, at 1.

6. Stark, *supra* note 3, at 89.

7. *Id.* at 88.

8. *See infra* note 11 and accompanying text.

District of Columbia area of approximately one dollar per four milligram tablet. One tablet of Dilaudid is sold on the streets of the District of Columbia for approximately forty dollars.

Abuse of prescription drugs varies socio-economically and geographically. First, the so-called "suburban housewife" abuses a different drug than the street addict. The suburban housewife primarily abuses tranquilizers and sedatives obtained from a primary care physician. When physicians are asked to identify the most abused drug, they generally identify Valium or another tranquilizer. The street addict generally abuses narcotic pain-killers or amphetamine-type drugs. Second, street abuse of prescription drugs in one city may be different than abuse in another city. In the 1970s, heroin addicts in the District of Columbia would mix Preludin with relatively weak heroin to give the heroin a boost. A large quantity of the Preludin on the streets of the District of Columbia came from Philadelphia, where Preludin was not abused on the streets. Similarly, "T's and Blues," a combination of Talwin, an analgesic controlled substance, and pyribenzamine, an antihistamine, were combined to create a substitute for heroin. T's and Blues were popular in the St. Louis area but were virtually unknown in the District of Columbia.[9]

The federal government has grappled with prescription drug abuse for some time.[10] As part of the effort to control this problem, the federal government has investigated its nature and extent. In 1965, a Senate Report relating to stimulants and barbiturates noted that:

> [O]ver 9 billion barbiturates and amphetamine tablets are produced annually in the United States. It is estimated that over 50 percent, or 4 1/2 billion tablets, are distributed through illicit channels.

9. *See* United States v. Roth, 777 F.2d 1200, 1201 (7th Cir. 1985) (upholding conviction of pharmacist accused of unlawfully distributing 400,000 tablets of Talwin and 264,000 tablets of pyribenzamine from his drug store in the St. Louis area). Knowledge of the lack of abuse in the District of Columbia is based on the author's personal experience investigating drug abuse in the District and on conversations with police investigators.

10. See *infra* notes 21-55 and accompanying text for a discussion of federal anti-drug efforts. State governments have addressed this problem as well. Many states have passed legislation similar to the federal Controlled Substances Act of 1970, often modelled after the Uniform Controlled Substances Act. *See* UNIF. CONTROLLED SUBSTANCES ACT, 9 U.L.A. 1 (1990). These state statutes are beyond the scope of this Article.

> The human toll of drug abuse cannot be measured for it affects not only the abuser but his family and the community around him. Drug abuse is closely bound up with juvenile delinquency. It also contributes to the rising crime rate in the United States. Misuse of these drugs has contributed to the rising accidents on the highways.
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> The illegal traffic in drugs is enormously profitable. Barbiturates and amphetamines having a retail value of approximately $670 sell in illicit channels for in excess of $250,000.[11]

The House of Representatives noted that in 1969, the level of amphetamine and barbiturate diversion had not changed from the fifty percent level reported four years earlier.[12]

In 1984, the Senate, in discussing the need to amend the Controlled Substances Act,[13] reported that:

> Diversion of legally produced drugs into illicit channels is a major part of the drug abuse problem in the United States. It is estimated that between 60 and 70 percent of all drug-related deaths and injuries involve drugs that were originally part of the legitimate drug production and distribution chain. Also, diversion of legally produced drugs often evidences the same sort of large-scale trafficking more commonly associated with the trade in wholly illicit drugs. For example, the Justice Department informed the committee that 21 practicing practitioners registered to dispense controlled substances convicted as a result of an investigation named "Operation Script" were responsible for the diversion of approximately 21.6 million dosage units of controlled substances.
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> . . . .
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> . . . [I]t is estimated that 80 to 90 percent of all current diversion occurs at [the practitioner] level.[14]

Congressman Gilman commented that,

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11. S. REP. No. 337, 89th Cong., 1st Sess. (1965), *reprinted in* 1965 U.S.C.C.A.N. 1895, 1896.

12. H.R. REP. No. 1444, 91st Cong., 2d Sess. (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4572.

13. The Controlled Substances Act of 1970, Pub. L. No. 91-513, 84 Stat. 1242 (codified as amended at 21 U.S.C. §§ 801-978 (1988)).

14. S. REP. No. 225, 98th Cong., 2d Sess. 261-62 (1984), *reprinted in* 1984 U.S.C.C.A.N. 3182, 3443-44.

> Evidence suggests that prescription drugs diverted by legitimate medical distributors to the illicit drug market account for about three-fourths of the deaths and injuries due to drug abuse.[15]

In 1986, Congress observed that "at least 7 million individuals regularly use prescription drugs, mostly addictive ones, without medical supervision."[16] Congress established the current system of control in response to pervasive abuse of prescription drugs. The current system is:

> Designed to improve the administration and regulation of the manufacturing, distribution and dispensing of controlled substances by providing for a "closed" system of drug distribution for legitimate handlers of such drugs. Such a closed system should significantly reduce the widespread diversion of these drugs out of legitimate channels into the illicit market. . . .[17]

This system of control seeks to limit the abuse of prescription medication in three ways through administrative, civil, and criminal restraints. First, it limits the quantity of prescription drugs that are produced each year. Annual quotas are established for the manufacture of controlled substances in Schedules I and II.[18] Second, the system defines those situations in which such drugs can be legally prescribed or administered to persons in need.[19] Third, the system attempts to deter individuals from obtaining such drugs from legitimate sources for other than legitimate needs.[20]

I. HISTORICAL BACKGROUND

The federal government first established controls over medication at the turn of the century. The Pure Food and Drug Act of 1906[21] made it illegal to ship misbranded or adulterated food or drugs in

15. 130 CONG. REC. H9681 (daily ed. Sept. 18, 1984) (statement of Rep. Gilman).

16. Anti-Drug Abuse Act of 1986, Pub. L. No. 99-570, § 6006(a)(2), 100 Stat. 3207-160, *quoted in* Historical and Statutory Notes, 21 U.S.C.A. § 801 (Supp. 1993).

17. H.R. REP. NO. 1444, 91st Cong., 2d Sess. (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4571-72.

18. 21 C.F.R. §§ 1301.01-1303.27 (1993).

19. 21 U.S.C. § 829 (1988).

20. The Act makes it illegal to obtain controlled substances by "misrepresentation, fraud, forgery or subterfuge." 21 U.S.C. § 843(a)(3) (1988).

21. Pure Food and Drug Act of 1906, ch. 3915, 34 Stat. 768 (1906), *repealed by* Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, § 902, 52 Stat. 1040, 1059 (1938).

interstate commerce.[22] In 1914, Congress passed the Harrison Narcotic Act,[23] which solely regulated narcotic drugs. The federal Food, Drug, and Cosmetic Act, enacted in 1938, required prescriptions for all habit-forming drugs, particularly narcotics and barbiturates.[24] Regulation was substantially expanded with the 1965 Drug Abuse Control Amendments.[25] As discussed in more detail below, both the Harrison Narcotic Act and the Federal Food, Drug, and Cosmetic Act applied to the prescription and distribution of medicine by physicians and pharmacists.[26]

The Harrison Narcotic Act prohibited the dispensation or distribution of narcotic drugs without a written order on a form provided by the Commissioner of Internal Revenue.[27] This prohibition did not apply in certain situations, including:

> (a) To the dispensing or distribution of any of the aforesaid drugs to a patient by a physician . . . registered under this act in the course of his professional practice only. . . [or]
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> (b) To the sales, dispensing, or distribution of any of the aforesaid drugs by a dealer to a consumer under and in pursuance of a written prescription issued by a physician.[28]

Courts upheld the constitutionality of the Harrison Narcotic Act as applied to physicians and pharmacists, and thus provided the

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22. Pure Food and Drug Act of 1906, ch. 3915, § 2, 34 Stat. at 768.

23. Harrison Narcotic Act of 1914, ch. 1, 38 Stat. 785 (1914), *repealed by* Controlled Substances Act, Pub. L. No. 91-513, 84 Stat. 1291 (1970).

24. Food, Drug, and Cosmetic Act, ch. 675, § 502, 52 Stat. 1040, 1050, *amended by* Controlled Substances Act, § 701, 84 Stat. at 1281-82. *See infra* notes 32-36 and accompanying text.

25. Drug Abuse Control Amendments of 1965, Pub. L. No. 89-74, §§ 3-5, 79 Stat. 226, 227-33 (1965). *See infra* notes 37-40 and accompanying text.

26. *See, e.g.*, Webb v. United States, 249 U.S. 96, 99 (1919) (holding Harrison Narcotic Act applicable to physicians and pharmacists); White v. United States, 399 F.2d 813, 817 (8th Cir. 1968) (holding physicians liable for prescribing drugs outside the normal and ordinary course of business under Federal Food, Drug, and Cosmetic Act); United States v. DeFreese, 270 F.2d 730, 733-35 (5th Cir. 1959) (applying Federal Food, Drug, and Cosmetic Act to wholesale as well as retail pharmacist transactions); Brown v. United States, 250 F.2d 745, 746 (5th Cir.) (holding licensed physician liable for dispensing drugs covered by the Federal Food, Drug, and Cosmetic Act without a prescription), *cert. denied*, 356 U.S. 938 (1958).

27. Ch. 1, §§ 1-5, 38 Stat. 785, 785-88 (1914), *repealed by* Controlled Substances Act, Pub. L. No. 91-513, 84 Stat. 1291 (1970).

28. Harrison Narcotic Act § 2.

foundation for the future control of such professionals.[29] Under the Act, a physician's conduct was judged by a good faith standard.[30] The Supreme Court stated,

> Manifestly the phrases "to a patient" and "in the course of his professional practice only" are intended to confine the immunity of a registered physician, in dispensing the narcotic drugs mentioned in the act, strictly within the appropriate bounds of a physician's professional practice, and not to extend it to include a sale to a dealer or a distribution intended to cater to the appetite or satisfy the craving of one addicted to the use of the drug. A "prescription" issued for either of the latter purposes protects neither the physician who issues it nor the dealer who knowingly accepts and fills it.[31]

In 1938, Congress passed the Food, Drug, and Cosmetic Act.[32] This Act established a class of drugs that could only be dispensed by

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29. Linder v. United States, 268 U.S. 5 (1925) (holding that Harrison Narcotic Act is constitutional as applied to physicians and pharmacists who are registered but unconstitutional as applied to those who merely possess the drug); United States v. Behrman, 258 U.S. 280 (1922) (holding that physician who prescribed over 3,000 doses of heroin, morphine, and cocaine to an addict did not act in good faith, and therefore violated the Harrison Narcotic Act); Jin Fuey Moy v. United States, 254 U.S. 189, 192 (1920) ("[O]ne may take a principal part in a prohibited sale of a drug by unlawfully issuing a prescription to the would-be purchaser."); Webb v. United States, 249 U.S. 96 (1919) (holding the Harrison Narcotic Act constitutional as applied to pharmacists securing morphine to individuals without a physician's prescription); United States v. Doremus, 249 U.S. 86 (1919) (upholding the constitutionality of the Harrison Narcotic Act as a valid exercise of Congress's Article 1, § 8 taxing power); Dunford v. United States, 216 F.2d 184 (4th Cir. 1954) (stating that it is well settled that the Harrison Narcotic Act is constitutional).

30. *Dunford*, 216 F.2d at 184.

31. *Jin Fuey Moy*, 254 U.S. at 194. In Webb v. United States, 249 U.S. 96 (1919), the Supreme Court stated that to call an order for the use of morphine to sustain a person's habit a physician's prescription "would be so plain a perversion of meaning that no discussion of the subject was required." *Id.* at 99-100.

32. Food, Drug, and Cosmetic Act, ch. 65, 52 Stat. 1040 (1938), *amended by* Act of Oct. 26, 1951, Pub. L. No. 215, ch. 578, § 1, 65 Stat. 648 (1951) (codified at 21 U.S.C. § 353(b)(1) (1988)). The Act provides:

> A drug intended for use by man which —
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> (A) is a habit-forming drug to which section 352(d) of this title applies; or
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> (B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or
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> (C) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug, shall be dispensed only (i) upon a written prescription of a practi-

prescription. Narcotics and barbiturates, among other things, were included.[33] Dispensing a prescription drug without a valid prescription was "misbranding," a misdemeanor offense.[34] Since the Act controlled dispensation, prosecutions have been limited to cases in which there was an *exchange* of medication. Primarily, these prosecutions involved pharmacies and their employees.[35] However, a physician who sold pills to an undercover officer was also prosecuted under the Act.[36]

In 1965, Congress amended the Food, Drug, and Cosmetic Act.[37] These amendments explicitly set limits on the prescription of depressant and stimulant drugs, primarily amphetamines and barbitu-

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tioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist or, (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

21 U.S.C. § 503(b).

33. Drugs that contain "any quantity of narcotic or hypnotic substance" require prescriptions. 21 U.S.C. § 352(d) (1988).

34. 21 U.S.C. §§ 333, 353(b)(1)(c)(iii) (1988) (defining violation of § 353 or § 331 as a misdemeanor offense). Section 331(k) provides in pertinent part:

The following acts and the causing thereof hereby prohibited: (k) . . . The doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

Section 333 establishes a term of imprisonment of up to one year and/or a fine of up to $1000 for a first violation of § 331. 21 U.S.C. § 333(a)(1) (1988). Subsequent convictions carry a penalty of not more than three years imprisonment and/or a fine of not more than $10,000. § 333(a)(2).

35. *See, e.g.*, United States v. Siler Drug Store Co., 376 F.2d 89 (6th Cir. 1967) (holding that owner and company can be convicted for unlawful act of employee); Dugan Drug Stores, Inc. v. United States, 326 F.2d 835 (5th Cir. 1964) (upholding conviction of pharmacy despite acquittal of employees for violation of Food, Drug, and Cosmetic Act); United States v. Thomas Apothecary, Inc., 266 F. Supp. 890 (S.D.N.Y. 1967) (holding that when co-owners and employees of corporation are closely associated with each other and the offenses are so closely related as to show involvement by all defendants, joinder is proper); United States v. Gilbar Pharmacy, Inc., 221 F. Supp. 160 (S.D.N.Y. 1963) (determining that joinder of corporation, two of its principals, and an employee was in the interest of justice).

36. United States v. DeFreese, 270 F.2d 730 (5th Cir. 1959) (holding that the Food, Drug, and Cosmetic Act applies to both retail pharmacists and to physicians).

37. Drug Abuse Control Amendments of 1965, Pub. L. No. 89-74, § 4, 79 Stat. 226 (codified as amended in scattered sections of 21 U.S.C.).

rates.[38] The amendments, which applied to physicians while acting in the course of their professional practice,[39] limited the dispensation and distribution of such stimulants and depressants to the "ordinary and authorized course" of business, profession, occupation, or employment.[40]

The standard of "professional practice" in both the Harrison Narcotic Act and Drug Abuse Control Amendment remained in the Controlled Substances Act of 1970 (CSA)[41] which repealed portions of the two prior acts.[42] Under the CSA, professionals are exempt from criminal prosecution as long as their drug-related activity is within their "professional practice."[43]

The CSA established a framework for the control of the manufacture, distribution, and dispensation of controlled substances. The CSA requires individuals and companies who manufacture, handle, prescribe, or dispense controlled substances to register with the Drug Enforcement Administration (DEA).[44] The CSA sets forth

38. *Id.* § 3(a), (b), 79 Stat. 226, 227-31, *repealed by* Controlled Substances Act, Pub. L. No. 91-513, § 701(a), 84 Stat. 1236, 1281 (1970).

39. Drug Abuse Control Amendments of 1965, Pub. L. No. 89-74, § 3(b), 79 Stat. 226, 227-28. *E.g.*, White v. United States, 399 F.2d 813, 816-19 (8th Cir. 1968).

The Drug Abuse Control Amendments of 1965, § 5, amended 21 U.S.C. § 331(q)(2) as follows: "The following acts and the causing thereof are prohibited: . . . the sale, delivery, or other disposition of a drug in violation of section 511(b) of this title. . . ." This language was repealed by the Controlled Substances Act, Pub. L. No. 91-513, § 701(a), 84 Stat. 1236, 1281 (1970).

Section 3(b) of the Drug Abuse Control Amendments of 1965 amended the Food, Drug, and Cosmetic Act § 511(b) to read: "No person, other than — (1) a person described in subsection (a) while such person is acting in the ordinary and authorized course of his business, profession, occupation, or employment . . . shall sell, deliver, or otherwise dispose of any depressant or stimulant drug to any other person." Among those exempted from this section were "(4) Practitioners licensed by law to prescribe or administer depressant or stimulant drugs, while acting in the course of their professional practice." § 3(b), 79 Stat. at 228. Both amendments were repealed by the Controlled Substances Act, Pub. L. No. 91-513, § 701(a), 84 Stat. 1236, 1284 (1970).

40. Drug Abuse Control Amendments of 1965, Pub. L. No. 89-74, § 3(b), 79 Stat. 226, 229, *repealed by* Controlled Substances Act, Pub. L. No. 91-513, § 701(a), 84 Stat. 1236, 1281 (1970).

41. Controlled Substances Act of 1970, Pub. L. No. 91-513, §§ 100-709, 84 Stat, 1236, 1242-84 (1970) (codified in scattered sections of 21 U.S.C. §§ 801-904 (1988)).

42. *Id.* § 701(a), 84 Stat. 1236, 1281 (1970).

43. 21 U.S.C. § 844(a) (Supp. IV 1992).

44. 21 U.S.C. § 822(a) (1988).

laws and regulations restricting a registrant's activities.[45] There are both criminal and civil penalties for registrants who act in violation of these laws and regulations.[46]

The CSA also prohibits the illegal distribution or dispensation of controlled substances.[47] The "professional practice" exception appears in the definition section of the CSA.[48] A "practitioner" is defined as follows:

> [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 . . . a controlled substance in the course of professional practice.[49]

Courts have held that the phrase "professional practice" is not unconstitutionally vague[50] and that the regulation which sets it forth is valid.[51] In *United States v. Rosenberg*,[52] the Ninth Circuit noted,

> The statute does give fair notice. This language has been in the statute books since 1914 and no one has ever had problems with its interpretation. The language clearly means that a doctor is not exempt from the statute when he takes actions that he does not in good faith believe are for legitimate medical purposes.[53]

Further, the Ninth Circuit found,

> The ease and consistency with which the courts have interpreted this language convinces us that it is not vague. . . . Moreover, it is difficult to see how the language can be made more precise and at the same time ban the undesirable conduct on the part of physicians which Congress intended to make illegal and subject to sanctions.[54]

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45. *E.g.*, 21 U.S.C. §§ 823, 825-829, 841 (1988).

46. *Id.* §§ 841-843.

47. *Id.* § 841(a).

48. *Id.* § 802(21); 21 C.F.R. § 1306.05 (1991).

49. 21 U.S.C. § 802(21) (1988).

50. United States v. Rosenberg, 515 F.2d 190, 193 (9th Cir. 1975), *cert. denied*, 423 U.S. 1031 (1976); *accord* United States v. Collier, 478 F.2d 268 (5th Cir. 1973).

51. United States v. Green, 511 F.2d 1062, 1069 (7th Cir.), *cert. denied*, 423 U.S. 1031 (1975).

52. 515 F.2d 190, 193 (9th Cir. 1975), *cert. denied*, 423 U.S. 1031 (1976).

53. *Rosenberg*, 515 F.2d at 193.

54. *Id.* at 198 (citations omitted).

The corresponding language that relates to pharmacists similarly passes constitutional muster.[55]

II. The Regulatory Framework

The CSA established a comprehensive framework to control the abuse of prescription drugs by limiting the misuse of those drugs and their diversion into illegal channels. Thus, the CSA established controls over the manufacture of the drugs as well as their wholesale and retail distribution, including dispensation and prescription by health care professionals.[56]

The CSA specifies that the Attorney General is responsible for implementation.[57] The Attorney General has delegated her responsibilities to the Administrator of the Drug Enforcement Administration (DEA).[58]

Individuals who violate the CSA may be subject to criminal convictions.[59] The registration requirement, when combined with the Attorney General's authority to promulgate rules and regulations under the Act, means that registrants who act outside of those rules and regulations illegally distribute or dispense controlled substances.[60] The Supreme Court has upheld the constitutionality of the CSA and its regulations.[61]

A. *Scheduling of Controlled Substances*

The CSA established five schedules of controlled substances differentiated on the basis of potential for abuse, currently accepted

55. United States v. Hayes, 595 F.2d 258, 260 (5th Cir.), *cert. denied*, 444 U.S. 866 (1979).

56. 21 U.S.C. §§ 823, 825-829, 841-843 (1988).

57. 21 U.S.C. § 811(a) (1988). The delegation of authority to the Attorney General is constitutional. Touby v. United States, 500 U.S. 160 (1991); United States v. Dunar, 614 F.2d 39, 41 (5th Cir. 1980).

58. 28 C.F.R. § 0.100(b) (1993).

59. United States v. Seelig, 622 F.2d 207, 210-11 (6th Cir.), *cert. denied*, 449 U.S. 869 (1980).

60. *Id.*

61. United States v. Moore, 423 U.S. 122 (1975); United States v. Henry, 727 F.2d 1373, 1378-79 (5th Cir.), *rev'd on other grounds*, 749 F.2d 203 (5th Cir. 1984) (en banc); United States v. Hayes, 595 F.2d 258 (5th Cir.), *cert. denied*, 444 U.S. 866 (1979); United States v. Davis, 564 F.2d 840 (9th Cir. 1977), *cert. denied*, 434 U.S. 1015 (1978); United States v. Collier, 478 F.2d 268 (5th Cir. 1973).

medical usage, and effects of abuse.[62] The highest schedule, Schedule I, is for substances that have a high potential for abuse and no currently accepted medical use in the United States.[63] Substances in Schedule I include heroin, cocaine, and marijuana.[64] Substances in Schedules II through V have decreasing abuse potential and effects from abuse, and increasingly accepted medical usage.[65] Prescription drugs and controlled substances fall into schedules II through IV.[66] Examples of medications containing Schedule II controlled substances are Demerol,[67] Dilaudid,[68] and Ritalin.[69] Examples of medications containing Schedule III controlled substances are Tylenol with Codeine[70] and Didrex.[71] Examples of medications containing Schedule IV controlled substances are Darvon,[72] Miltown,[73] and Valium.[74] Schedule V consists of compounds, mixtures, or preparations containing limited amounts of certain narcotic drugs.[75] Some Schedule V controlled substances are contained in prescription medications while others are contained in over-the-counter drugs. An example of a Schedule V drug is cough syrup with Codeine, such as Robitussin.[76] The prescribing and dispensing of medication on all schedules is controlled by laws and regulations.[77]

62. 21 U.S.C. § 812 (1988 & Supp. IV 1992).

63. *Id.* § 812(b)(1).

64. There have been unsuccessful attempts to force the rescheduling of marijuana. *E.g.*, NORML v. DEA, 559 F.2d 735 (D.C. Cir. 1988) (refusing to reschedule marijuana).

65. The fact that a substance has no currently accepted medical use does not disqualify it from being on Schedule II. *Id.* at 748.

66. 21 U.S.C. § 812 (1988 & Supp. IV 1992).

67. PHYSICIANS' DESK REFERENCE 2142 (47th ed. 1993).

68. *Id.* at 1199.

69. *Id.* at 909.

70. *Id.* at 1430 (tablets).

71. *Id.* at 2450.

72. PHYSICIANS' DESK REFERENCE 1290 (47th ed. 1993).

73. *Id.* at 2500.

74. *Id.* at 2028.

75. 21 U.S.C. § 812 (1988 & Supp. IV 1992).

76. *E.g.*, *Seelig*, 622 F.2d at 210.

77. *See infra* notes 140-70 and accompanying text.

B. *Registration*

The CSA established a process for registering professionals who wish to handle controlled substances.[78] Registrants can lawfully handle controlled substances within the bounds of their professional practice.[79] Registration imposes responsibilities upon these individuals beyond those of professional practice. If any of these responsibilities are violated, registration can be revoked.[80]

1. Obtaining a Registration

Doctors and pharmacies that dispense controlled substances must be registered with the DEA,[81] but individual pharmacists need not register. Physicians who dispense and/or administer controlled substances must obtain separate registrations for each office at which they dispense or administer regulated drugs.[82] Registration is granted to anyone authorized under state law to prescribe, dispense, or conduct research with controlled substances, unless the DEA determines that such registration is not in the public interest.[83] The Act requires the DEA to consider the following factors in determining the public interest:

> 1. The recommendation of the appropriate State licensing board or professional disciplinary authority;
> 2. The applicant's experience in dispensing, or conducting research with respect to controlled substances;
> 3. The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances;
> 4. Compliance with applicable State, Federal, or local laws relating to controlled substances; and,

78. 21 U.S.C. § 823(b), (e), (f) (1988); 21 C.F.R. § 1301.21 (1993).

79. 21 U.S.C. § 823(b), (e), (f) (1988); 21 C.F.R. § 1301.21 (1993).

80. *See infra* notes 97-120 and accompanying text.

81. 21 U.S.C. § 822 (1988); 21 C.F.R. § 1301.21 (1993). As of the early 1980s, the DEA registered 600,000 registrants per year at a rate of approximately 50,000 a month. Kirk v. Mueller, 749 F.2d 297, 298 (6th Cir. 1984).

82. 21 C.F.R. § 1301.23(a)(3) (1993). *See also* United States v. Clinical Leasing Serv., Inc., 925 F.2d 120 (5th Cir.) (holding that the regulation requiring a separate registration of each principal place of business was not unconstitutionally vague), *cert. denied sub nom.* Varnishung v. United States, 112 S. Ct. 188 (1991).

83. 21 U.S.C. § 823(b), (e), (f) (1988).

5. Such other conduct which may threaten the public health and safety.[84]

Under the "public interest" provision, the DEA may deny or revoke a registration based upon any controlled substance-related misdemeanor conviction, even if the conviction is not directly related to the DEA registration.[85] An applicant or registrant's failure to fully admit any drug abuse problem may also result in a public interest denial.[86] In addition, falsifying statements in a registration application is a criminal offense.[87]

Practitioners may register for any or all schedules except Schedule I.[88] Registrants indicate for which schedules they seek to register as part of their applications. Each registrant is issued a certificate stating the registrant's authorized schedules and DEA registration number. The DEA number must be placed on all prescriptions for controlled substances.[89] It is illegal to use a fictitious, revoked, suspended, or expired registration number; or a number issued to someone else.[90] No allegation of diversion or criminal intent is necessary for indictment; all that need be alleged is that the act was knowing or intentional.[91]

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84. *Id.*

85. Trawick v. DEA, 861 F.2d 72 (4th Cir. 1988).

86. Shatz v. United States Dep't of Justice, 873 F.2d 1089 (8th Cir. 1989); *Trawick*, 861 F.2d at 77.

87. 21 U.S.C. § 843(a)(4)(A) (1988). *E.g.*, United States v. Ferguson, 776 F.2d 217 (8th Cir. 1985) (holding that a failure to disclose prior surrender of DEA registration is a criminal offense), *cert. denied*, 475 U.S. 1020 (1986).

88. 21 C.F.R. § 1301.22(c) (1993). Only individuals who are conducting research may be registered for use of Schedule I controlled substances. *Id.*

The filing fee for physicians who prescribe ("distribute") controlled substances is $60 for three years; for pharmacies that dispense controlled substances, $125 per year. The cost is the same regardless of the number of schedules involved. 21 C.F.R. § 1301.11 (1993).

Each pharmacy location must have a separate registration. A physician, however, does not need to register each office unless he administers or dispenses controlled substances as part of his professional practice at each office or unless he maintains controlled substances at each. 21 C.F.R. § 1301.24(a), (b)(3) (1993).

89. 21 C.F.R. 1306.05(a) (1993). The DEA number begins with a letter representing the state in which the practitioner is registered followed by the first initial of the physician's last name and a series of numbers that are created in such a way as to be self-checking.

90. 21 U.S.C. § 843(a)(2) (1988).

91. United States v. Carranza, 632 F. Supp. 1030, 1032-33 (S.D.N.Y. 1986).

"Registration circumscribes the authority to dispense controlled substances."[92] A physician who prescribes or dispenses a controlled substance that is on a schedule for which he is not registered can be convicted of illegal distribution of that drug.[93] Courts may also impose civil penalties.[94]

Pharmacies and practitioners stocking controlled substances must provide "effective controls and procedures to guard against theft and diversion."[95] The DEA has established standards for both physical security and operating procedures, including employee screening procedures.[96]

2. Suspension of a Registration

The DEA can suspend or revoke all schedules of a registration.[97] Suspension or revocation can occur for any of the following reasons:

1. Material falsification of any application;
2. Conviction of a felony involving a controlled substance;
3. Suspension, revocation, or denial of a State license and loss of authority to distribute or dispense controlled substances or where such suspension, revocation, or denial has been recommended;
4. Commission of such acts as would render registration inconsistent with the public interest; or
5. Exclusion from the Medicare/Medicaid program.[98]

92. United States v. Blanton, 730 F.2d 1425, 1430 (11th Cir. 1984).

93. *Id.* at 1429. In *Blanton*, the court rejected the defendant's argument that he could only be prosecuted under the less serious provisions in 21 U.S.C. §§ 842-843 because he had committed only a "technical" violation rather than the more serious violation of 21 U.S.C. § 841(a)(1) for which he was convicted. *Id.* at 1429-30.

94. 21 U.S.C. § 842(c)(1) (1988); United States v. Clinical Leasing Serv., Inc., 925 F.2d 120 (5th Cir.) (affirming fine imposed by lower court for dispensing controlled substances without proper registration), *cert. denied sub nom.* Varnishung v. United States, 112 S. Ct. 188 (1991).

95. 21 C.F.R. § 1301.71(a) (1993).

96. 21 C.F.R. §§ 1301.72-1301.76, 1301.90-1301.93 (1993). The employee screening procedures include a criminal record check and inquiry into prior use of controlled substances. *Id.* § 1301.90.

97. 21 U.S.C. § 824(a), (b) (1988); 21 C.F.R. § 1301.45(a)-(c) (1993).

98. 21 U.S.C. § 824(a) (1988). The provision relating to suspension, revocation, or denial based on the public interest was added to the CSA in 1984. As noted by Representative Gilman in the debate on the amendment:

> [T]he bill amends the Controlled Substances Act to make it easier for the Drug Enforcement Administration [DEA] to suspend or revoke the authority of phy-

The "DEA has consistently held that termination of a registrant's state authority to handle controlled substances requires that DEA revoke the registrant's DEA Certificate of Registration."[99]

No registration can be suspended or revoked without the DEA Administrator issuing an order to show cause and, if requested by the registrant, holding a hearing.[100] However, the Administrator can, without prior notice, suspend any registration simultaneously with the institution of proceedings to suspend or revoke it "where he finds that there is an imminent danger to the public health or safety."[101] If there is no "imminent danger," then an emergency suspension is inappropriate.[102]

An emergency suspension continues "until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction."[103] Judicial review of an emergency suspension is limited to a determination of whether the agency's action was "rational, based on relevant factors, and within the agency's statutory authority."[104]

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sicians . . . who write or dispense prescriptions in a way that is threatening to the public health or safety.

130 CONG. REC. H9681 (daily ed. Sept. 18, 1984) (statement of Rep. Gilman).

99. 57 Fed. Reg. 27,790 (1992) (statement of Mark L. Fincher, M.D.).

100. The order to show cause is governed by 21 C.F.R. § 1301.48 (1993). A hearing is held only upon the request of the registrant. *Id.* § 1301.48(d). The hearing is governed by 21 C.F.R. §§ 1301.51-1301.57 (1993).

101. 21 U.S.C. § 824(d) (1988). *See also* 21 C.F.R. §§ 1301.45(c), 1301.46(a) (1993). An order of immediate suspension shall contain a statement of the Administrator's findings. *Id.* § 1301.46(a).

102. Norman Bridge Drug Co. v. Banner, 529 F.2d 822, 828 (5th Cir. 1976). In *Norman Bridge*, the court found that a six month-old conviction of the pharmacy's owner for distributing 100 Didrex on one occasion, combined with recordkeeping violations that had been discovered seven months previously, did not amount to an "imminent danger." In contrast, failure to maintain required records, denial on the part of patients that they had received controlled substances indicated in their records, denial of dispensing of controlled substances at the office, and the ordering of additional controlled substances after the execution of an administrative search warrant provided a basis for the emergency suspension of a physician's registration. *In re* Burka, 684 F. Supp. 1300 (E.D. Pa. 1988).

103. 21 U.S.C. § 824(d) (1988). *See also Norman Bridge*, 529 F.2d at 828.

104. *Burka*, 684 F. Supp. at 1305 (quoting Shane Meat Co. v. United States Dep't of Defense, 800 F.2d 334, 336 (3d Cir. 1986) (quoting Frisby v. United States Dep't of Hous. and Urban Dev., 755 F.2d 1052, 1055 (3d Cir. 1985))).

The burden of persuasion and production in a license revocation or denial hearing rests, in the first instance, with the Administrator.[105] Once the Administrator produces evidence supporting his action, the registrant bears the burden of production to rebut that evidence.[106] Hearsay evidence is admissible and the Administrator's decision may be based on such evidence.[107]

Additionally, evidence obtained pursuant to a grant of immunity is admissible against the person from whom it came.[108] Expert testimony is not required in the revocation process.[109] "Because of his expertise in matters relating to the misuse of controlled substances, the Administrator of the Drug Enforcement Administration would have been free to reject expert opinion testimony and to use his own experience to draw reasonable conclusions from the facts in evidence."[110] When revocation or suspension is based upon a controlled substance-related felony conviction, the scope of the hearing is limited.[111] The question presented is whether the registrant was convicted "in fact or in effect" for violating a relevant law.[112]

The Administrator has consistently held that the controlled substance-related felony conviction upon which his action is based need not involve the individual's registration.[113] Action can also be taken in response to a street level controlled substance violation.[114] The action can also be based on a plea of *nolo contendere* to a felony

105. Shatz v. United States Dep't of Justice, 873 F.2d 1089, 1091 (8th Cir. 1989).

106. *Id.*

107. Klinestiver v. DEA, 606 F.2d 1128, 1129 (D.C. Cir. 1979) (rejecting a claim that 21 C.F.R. § 1316.59(a) requires a higher standard for admissibility of evidence in a DEA hearing). However, the registrant may request that the Administrative Law Judge subpoena an absent witness to attend the hearing. *See* 21 C.F.R. § 1316.52(d) (1993).

108. Burley v. DEA, 443 F. Supp. 619 (M.D. Tenn. 1977) (holding that information obtained from the pharmacist under federal grant of immunity may be provided to and used by the State Board of Pharmacy because the proceeding is civil, not penal).

109. Noell v. Bensinger, 586 F.2d 554, 557 (5th Cir. 1978).

110. *Id.*

111. *Id. See also* Pearce v. United States Dep't of Justice, 867 F.2d 253, 255-56 (6th Cir. 1988) (per curiam).

112. *Pearce*, 867 F.2d at 256.

113. Trawick v. DEA, 861 F.2d 72, 75 (4th Cir. 1988) (quoting 51 Fed. Reg. 17,556-57 (1986) (statement of Paul Stepak, M.D.)); Fourth Street Pharmacy v. United States Dep't of Justice, 836 F.2d 1137 (8th Cir. 1988) (per curiam).

114. *Trawick*, 861 F.2d at 73.

because such a plea represents a "conviction" within the meaning of the statute.[115] Because the Administrator has the option of revocation or suspension, information relating to the prescribing practices of the registrant is relevant even in light of a felony conviction.[116]

A misdemeanor drug conviction that is unrelated to the defendant's registration may form the basis of a revocation in the public interest.[117] Such action may be taken even though the state licensing board that reviewed the registrant's actions felt that only a probationary period was necessary.[118]

In denying or revoking a DEA registration, the Administrator must include in his Order the findings of fact and conclusions of law upon which the Order is based.[119] Decisions of the Administrator are reviewed by the federal courts of appeal using an abuse of discretion standard.[120]

C. *Recordkeeping*

The CSA established a system of recordkeeping to track controlled substances from manufacture to wholesale distribution to the ultimate user.[121] Failure to abide by these recordkeeping requirements could subject a registrant to criminal and/or civil sanctions.[122]

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115. *Pearce*, 867 F.2d at 255; *Noell*, 586 F.2d at 556; Sokoloff v. Saxbe, 501 F.2d 571 (2d Cir. 1974). The possibility of revocation does not have to be disclosed during a plea of guilty to distribution. United States v. Fitzhugh, 801 F.2d 1432, 1434-35 (D.C. Cir. 1986); *Noell*, 586 F.2d at 556.

116. *Pearce*, 867 F.2d at 256.

117. *Trawick*, 861 F.2d at 75. Dr. Trawick pled guilty to misdemeanor possession of cocaine as part of a plea agreement that included dropping all felony charges including aiding and abetting a distribution. The Administrator found that Dr. Trawick's registration was inconsistent with the public welfare because of the misdemeanor conviction and because his failure to fully admit his criminal involvement and drug abuse problems caused "grave reservations about [petitioner's] rehabilitation." *Id.* at 76 (alteration in original).

118. *Id.* at 74.

119. 21 C.F.R. § 1301.57 (1993).

120. *See, e.g.*, *Pearce*, 867 F.2d at 256.

121. *See generally* 21 U.S.C. §§ 821-863 (1988 & Supp. IV 1992); 21 C.F.R. §§ 1301-1306 (1993).

122. 21 U.S.C. § 842 (a)(5), (10) (1988) (civil); 21 U.S.C. § 843(a)(4)(A) (1988) (criminal). In United States v. Norton, 640 F. Supp. 1257 (D. Colo. 1986), the DEA also obtained an injunction requiring Dr. Norton to comply with the recordkeeping requirements including conducting an inventory and establishing a method by which he was to do so.

The recordkeeping requirements apply to pharmacy owners, even if they are not pharmacists, and to the pharmacists at a store even if they are not owners.[123] Registered individual practitioners such as doctors[124] are not generally required to keep records, unless they "regularly engage[ ] in the dispensing or administering of controlled substances *and charge[ ] patients*, either separately or together with charges for other professional services, for substances so dispensed or administered"[125] or they prescribe "in the course of maintenance or detoxification treatment of an individual."[126]

The records that registrants are required to maintain under the Act are a bi-annual inventory of controlled substances,[127] order forms,[128] theft/loss reports, and where appropriate, prescriptions and other evidence of dispensing.[129] The regulations require that these records be kept for at least two years.[130]

Records related to Schedule II controlled substances must be kept separate from those related to drugs in other schedules.[131] This generally means that pharmacies maintain files of prescriptions for Schedule II controlled substances separate from other prescriptions.

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123. *See* United States v. Robinson, 707 F.2d 811, 814 (4th Cir. 1983) (holding that non-pharmacist owner of pharmacy was properly charged); United States v. Goldfine, 538 F.2d 815, 820 (9th Cir. 1976) (holding that pharmacist who did not own pharmacy was properly charged).

124. An "individual practitioner" is "a physician, dentist, veterinarian, or other individual licensed, registered or otherwise permitted, by the United States or the jurisdiction in which he practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner." 21 C.F.R. § 1306.02(b) (1993).

125. 21 C.F.R. § 1304.03(d) (1993) (emphasis added).

126. *Id.* § 1304.03(c), (d).

127. *Id.* § 1304.04(a). *See also id.* §§ 1304.11-1304.17 (outlining inventory requirements).

128. Registrants are generally required to maintain records of controlled substances received or sold. *Id.* § 1304.21(a). In particular, all Form 222s must be maintained for two years. *Id.* § 1305.13(c).

129. *Id.* §§ 1304.04(h), 1306.15, 1306.25.

130. 21 C.F.R. § 1304.04(a) (1993).

131. *See id.* § 1304.04(h)(1), (2) (applying to pharmacists); *id.* § 1304.04(g) (applying to physicians). *But see* U.S. DEP'T OF JUSTICE DRUG ENFORCEMENT ADMIN., PHARMACIST'S MANUAL: AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT OF 1970, at 15 (1990) (stating that prescriptions for Schedule II controlled substances may be filed in a separate file with other prescriptions for controlled substances) [hereinafter PHARMACIST'S MANUAL]. The non-Schedule II prescriptions must be marked with a red "C." *Id.* at 17.

In turn, records related to controlled substances must be kept separate from other records the registrant may keep, or else stored in a readily retrievable fashion.[132] In most pharmacies, prescriptions for controlled substances in Schedules III and IV are marked or stamped with a large, red "C" and filed along with the other, non-Schedule II prescriptions filled at the pharmacy.[133]

It is a criminal offense under the Act "[t]o furnish false or fraudulent material information in, or omit any material information from, any . . . report, record or other document required to be made, kept, or filed."[134] In the prosecution of such an offense, the government is not required to prove that the defendant was aware of the statute's recordkeeping requirements.[135]

It is also a violation for registrants to:

> [R]efuse or fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required . . . .[136]

Violations of this provision are criminal if it is alleged and proven that they were done "knowingly."[137] Otherwise, violations constitute a civil offense carrying only a fine.[138] In the civil context, persons failing to maintain the required records are strictly liable.[139]

D. *Writing and Filing Prescriptions*

1. A Prescription Defined

A prescription is defined as follows:

> An order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is

132. The term "readily retrievable" includes records that can be separated out from all others in a reasonable time and/or records that are visually identifiable apart from the others. 21 C.F.R. § 1304.02(h) (1993).

133. § 21 C.F.R. 1304.04(h)(2); PHARMACIST'S MANUAL, *supra* note 131, at 15. The "C" must be "in red ink, not less than one inch high, in the lower right corner." *Id.* at 17.

134. 21 U.S.C. § 843(a)(4)(A) (1988).

135. United States v. Averi, 715 F. Supp. 1508, 1511 (M.D. Ala. 1989). However, the DEA generally sends each registrant, at the time of registration, a booklet that outlines the recordkeeping responsibilities under the Act. *Id.*

136. 21 U.S.C. § 842(a)(5) (1988).

137. 21 U.S.C. § 842(c)(2)(A) (1988).

138. 21 U.S.C. § 842(c)(1) (1988). The fine is "not more than $25,000" per violation. *Id.*

139. United States v. Green Drugs, 905 F.2d 694, 698 (3d Cir. 1990).

> dispensed for immediate administration to the ultimate user (*e.g.*, an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription.)[140]

Prescriptions for controlled substances can only be issued by individual practitioners who are authorized to prescribe controlled substances by their local jurisdiction and either registered or exempted from registration by the DEA.[141] In order for a prescription for a controlled substance to be valid, it "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."[142]

The only specific limitation on prescribing by a physician contained in the CSA or its regulations relates to the treatment of a narcotics addict. A prescription may not be issued by an individual practitioner for the dispensing of narcotic drugs for "detoxification treatment" or "maintenance treatment."[143] However, in an emergency, practitioners may write orders for the administration, but may not prescribe, narcotic drugs to individuals under the following conditions:

> [F]or the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three days and may not be renewed or extended.[144]

Additionally, narcotic drugs may be administered or dispensed, in a hospital setting, under the following conditions:

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140. 21 C.F.R. § 1306.02(f) (1993).

141. *Id.* § 1306.03(a)(1), (2).

142. *Id.* § 1306.04(a).

143. *Id.* § 1306.04(c). "Maintenance treatment" is "the dispensing, for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs." 21 U.S.C. § 802(29) (1988). "Detoxification treatment" is defined as follows:

> [T]he dispensing, for a period not in excess of one hundred and eighty days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period.

21 U.S.C. § 802(30) (1988). The operation of a maintenance treatment or detoxification treatment program constitutes the operation of a narcotics treatment program which requires a separate registration. 21 C.F.R. §§ 1301.02(i), 1301.11(f) (1993).

144. 21 C.F.R. § 1306.07(b) (1993).

> [T]o maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or . . . to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.[145]

2. Prescription Procedures

Each prescription for a controlled substance must be dated and signed on the date of issue.[146] It must include the full name and address of the patient and the name, address, and registration number of the prescribing practitioner.[147] A prescription may be prepared for the physician's signature but the practitioner is responsible to see that the prescription conforms with the requirements.[148] A "prescription" that does not fulfill these requirements is arguably not a prescription and therefore its writing and filling are illegal acts. At a minimum, however, evidence of a physician's failure to follow these requirements has been used to show that he was involved in the illegal distribution of controlled substances.[149]

While controlled substances on Schedules III, IV and V may be prescribed orally or in writing, Schedule II controlled substances may be dispensed only pursuant to a written prescription.[150] However, in the case of an emergency, a Schedule II controlled substance may be dispensed pursuant to an oral authorization by a prescribing practitioner as long as the quantity involved is limited to that required during the emergency period, the pharmacist immediately reduces the oral authorization to writing, the pharmacist knows the practitioner or makes a reasonable effort to determine his legitimacy, and within 72 hours a written prescription is delivered to the pharmacy.[151] Prescriptions for Schedule II drugs may

145. *Id.* § 1306.07(c).

146. *Id.* § 1306.05(a).

147. *Id.*

148. *Id.*

149. See *supra* note 102 for a discussion of *Norman Bridge*.

150. 21 C.F.R. §§ 1306.11(a) (Schedule II), 1306.21(a) (Schedules III and IV), 1306.31(a) (Schedule V) (1993).

151. 21 C.F.R. § 1306.11(d)(1)-(4) (1993). An emergency situation exists when (a) immediate administration of the controlled substance is necessary for proper treatment, (b) no appropriate alternative treatment is available, and (c) it is not reasonably possible for the prescribing practitioner to provide a written prescription. 21 C.F.R. § 290.10 (1993). The words "Authorization for Emergency Dispensing"

not be refilled; prescriptions for controlled substances in the other schedules may be refilled up to five times in six months if the prescription so provides.[152] After five refills or six months, a new prescription, either oral or written, is required.[153] The refilling of an expired prescription — one that is older than six months — or one for which no further refills exist is unlawful.[154]

Certain Schedule V controlled substances do not require a prescription.[155] The amount and frequency of dispensing such Schedule V substances is controlled by regulation.[156] Dispensing Schedule V controlled substances in violation of that regulation is an unlawful act.[157]

An individual practitioner may not write, nor a pharmacist fill, a prescription for a Schedule II controlled substance written for "office use."[158] An individual practitioner who wishes to obtain controlled substances on Schedule II to dispense as part of his practice must order them using a DEA Form 222.[159] This form authorizes a

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and the date of the oral order must be written on the prescription. *Id.* § 1306.11(d)(4).

152. 21 C.F.R. §§ 1306.12 (Schedule II), 1306.22 (Schedules III and IV) (1993).

153. 21 C.F.R. § 1306.22(a) (1993).

154. *See* United States v. Seelig, 622 F.2d 207, 209 (6th Cir.) (indicting pharmacists for unauthorized refilling of prescriptions), *cert. denied*, 449 U.S. 869 (1980). Unauthorized refilling of prescriptions also violates the Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(k) (Supp. IV 1992). *E.g.*, Kadis v. United States, 373 F.2d 370, 371 (1st Cir. 1967); Rush v. United States, 370 F.2d 520, 521 (8th Cir.), *cert. denied*, 387 U.S. 943 (1967); United States v. Gilbar Pharmacy, Inc., 221 F. Supp. 160, 160 (S.D.N.Y. 1963).

155. PHARMACIST'S MANUAL, *supra* note 131, at 8-9.

156. 21 C.F.R. § 1306.32 (1993). Dispensing of such a substance may be done only by the pharmacist himself, the purchaser must be 18, the purchaser must be known to the pharmacist or present identification, a bound book recording information relating to the dispensing must be kept, and a limited amount may be dispensed within any 48-hour period. *Id.*

157. *Seelig*, 622 F.2d at 209.

158. 21 C.F.R. § 1306.04(b) (1993) (providing that "[a] prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients"). *See also id.* § 1307.11 (outlining distribution by dispenser to another practitioner); PHARMACIST'S MANUAL, *supra* note 131, at 15 (providing that Schedule II prescriptions may not be refilled and that such prescription orders must be kept in a separate file).

159. 21 C.F.R. § 1305.03 (1993). The forms are obtained from the DEA and are available to persons who are properly registered to handle Schedules I and II controlled substances. *Id.* § 1305.04. The name and address of the registrant are pre-

supplier to give the practitioner the drugs requested. A Form 222, although generally filled by a wholesale distributor, can be filled by a retail pharmacist.[160] An individual practitioner may obtain controlled substances on schedules other than Schedule II by using a prescription form marked for "Office Use" and having it filled.[161] It must be clear that the physician is not issuing a prescription for personal use.[162]

3. Responsibilities in Writing and Filling Prescriptions

Both the individual practitioner writing a prescription for a controlled substance and the pharmacist filling it have independent responsibility for ensuring that the prescription is lawful.[163]

> The responsibility for the proper prescribing and dispensing of controlled substances lies upon the prescribing physician, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. § 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.[164]

The regulation does not require a pharmacist to practice medicine although some effort must be made to establish the validity of a prescription.[165]

A booklet for pharmacists published by the DEA lists the following indicia that may show that a prescription was issued illegally:

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printed on the form and the drugs can only be shipped to that person. UNITED STATES DEP'T OF JUSTICE DRUG ENFORCEMENT ADMIN., DRUGS OF ABUSE 7 (1988). The form consists of three copies, two of which go to the supplier and one remains with the purchaser. 21 C.F.R. § 1305.09(a) (1993). The supplier then sends one copy to the DEA. *Id.* § 1305.09(d).

160. A practitioner may obtain controlled substances from another practitioner, using Form 222, under limited circumstances. *Id.* § 1307.11.

161. 21 C.F.R. § 1307.11 (1993).

162. *Id.* § 1306.04(b).

163. *Id.* § 1306.04(a).

164. *Id.*

165. *Id.* § 1306.05(a).

> (1) whether the purported prescription order contains an indication [for which it has been prescribed] other than one found in the package insert; (2) whether the prescriber writes for antagonistic drugs, such as depressants and stimulants at the same time; and (3) whether patients appear to be returning too frequently.[166]

Two commentators interpreted these recommendations as establishing three steps for a pharmacist: "(1) examine the prescription for facial validity, (2) call the prescriber, and (3) talk to the patient."[167] However, mere "verification" of the "prescription" by the issuing physician is not enough. As the Fifth Circuit noted:

> Verification by the issuing practitioner on request of the pharmacist is evidence that the pharmacist lacks knowledge that the prescription was issued outside the scope of professional practice. But it is not an insurance policy against a fact finder's concluding that the pharmacist had the requisite knowledge despite a purported but false verification. The pharmacist is not required to have a "corresponding responsibility" to practice medicine. What is required of him is the responsibility not to fill an order that purports to be a prescription but is not a prescription within the meaning of this statute because he knows that the issuing practitioner issued it outside the scope of medical practice.
>
> . . . .
>
> The challenged regulation makes clear that this is the responsibility imposed on pharmacists. Standing alone, the phrase "corresponding responsibility" is not crystal clear, but when read in context the regulation gives adequate notice of proscribed conduct to pass muster. It is also evident that a pharmacist can fulfill his responsibility under [21 C.F.R.] § 1306.04 without practicing medicine. . . . [A] pharmacist can know that prescriptions are issued for no legitimate medical purpose without his needing to know anything about medical science.[168]

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166. David B. Brushwood & Jeffrey J. Carlson, *The Pharmacist's Responsibility to Evaluate Suspicious Prescriptions*, 46 FOOD DRUG COSM. L.J. 467, 481 (1991) (citing PHARMACIST'S MANUAL, *supra* note 131, at 31-32).

167. *Id.*

168. United States v. Hayes, 595 F.2d 258, 261 n.6 (5th Cir.), *cert. denied*, 444 U.S. 866 (1979).

The responsibility imposed on pharmacists has been held constitutional.[169] A pharmacist always has the option not to fill a prescription.[170]

III. The Criminal Framework

In keeping with the objective of the CSA to stem the diversion of controlled substances from legitimate channels, the CSA makes it illegal to knowingly or intentionally "distribute" or "dispense" a controlled substance except as authorized by law.[171] In the context of health care professionals, this applies "within the usual course of professional practice."[172] While at one time it was argued that all registrants were "authorized by law," this argument was rejected by the Supreme Court in *United States v. Moore*.[173]

In *Moore*, a medical doctor was convicted at trial of felony violations charging illegal distribution of methadone, a Schedule II controlled substance, in violation of 21 U.S.C. § 841(a)(1).[174] Dr. Moore asserted that he could not be prosecuted for illegal distribution under the provisions of the Act that make such distribution a felony because he was a registrant.[175] He argued, and the Court of Appeals for the District of Columbia Circuit agreed, that he could only be prosecuted for relatively minor violations contained in 21 U.S.C. §§ 842 and 843 relating to misdeeds by registrants.[176]

The Supreme Court disagreed. In a unanimous opinion, the Court held that registrants could be prosecuted for the serious felony violations set out in section 841(a) when their actions are outside "the usual course of professional practice."[177] The Supreme Court found that "only the lawful acts of registrants are exempted. By its terms § 841 reaches 'any person.' It does not exempt (as it could have) 'all registrants' or 'all persons registered under this

169. United States v. Henry, 727 F.2d 1373, 1378-79 (5th Cir.), *rev'd on other grounds*, 749 F.2d 203 (5th Cir. 1984) (en banc); *Hayes*, 595 F.2d at 260.

170. For a discussion of situations in which a pharmacist's actions have been determined to be illegal, see *infra* notes 184-96.

171. 21 U.S.C. § 841(a)(1) (1988).

172. 21 C.F.R. § 1306.04(A) (1993).

173. 423 U.S. 122 (1975).

174. *Id.* at 124-25.

175. *Id.* at 131.

176. *Id.* at 128-31.

177. *Id.* at 124.

Act.'"[178] Any distribution or dispensing by a registrant that is not within his "professional practice" is not authorized and is therefore illegal.[179]

A. *The Crime*

The majority of the prosecutions of registrants involve allegations of illegal writing or filling of prescriptions.[180] Prosecutions also arise from the outright sale of controlled substances by registrants, which is often discovered when they are unable, during an audit, to account for controlled substances that have come into their possession.[181] A less common type of prosecution involves physicians obtaining controlled substances by fraudulently writing prescriptions in others' names.[182]

Under the CSA, the issuance of a prescription for a controlled substance is tantamount to the dispensing or distribution of that substance.

> [A] prescription for a controlled substance cannot be regarded as less than the constructive or attempted transfer of the substance itself, since a prescription is the written representation of the drug and enables its possessor to claim physical custody and control over the drug prescribed.[183]

Therefore, when a prescription for a controlled substance is not issued in the usual course of professional practice, the person writing it as well as the person who knowingly fills it commits an illegal act.

Courts have identified the following situations as indicative that the defendant practitioner is illegally issuing prescriptions for controlled substances:

- Physician sells prescriptions;[184]

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178. *Moore*, 423 U.S. at 131.

179. *Id.* at 138-43.

180. *See infra* notes 183-213 and accompanying text.

181. *See infra* notes 214-16 and accompanying text.

182. *See infra* notes 217-18 and accompanying text.

183. United States v. Tighe, 551 F.2d 18, 20 (3d Cir.), *cert denied*, 434 U.S. 823 (1977).

184. *See* United States v. Johnson, 831 F.2d 124, 126 (6th Cir. 1987), *cert. denied sub nom.* Taylor v. United States, 485 U.S. 968 (1988); United States v. Jamieson, 806 F.2d 949, 951 (10th Cir. 1986) (exchanging prescriptions for sex); United States v. Vamos, 797 F.2d 1154, 1155 (2d Cir. 1986), *cert. denied*, 479 U.S. 1036 (1987); United States v. Larson, 722 F.2d 139, 141 (5th Cir. 1983), *cert. denied*, 466 U.S. 907 (1984) (exchanging prescriptions for camera equipment); United States v. Andrew,

- Physician charges for an office visit based on the amount of controlled substances prescribed or charges an exorbitant amount;[185]
- Prescriptions are issued without any prior physical examination of the alleged patient,[186] or issued after an inadequate examination;[187]

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666 F.2d 915, 917 (5th Cir. 1982) (exchanging prescriptions for cash); United States v. Thompson, 624 F.2d 740, 741 (5th Cir. 1980) (exchanging prescriptions for cash to doctor and receptionist); United States v. Kirk, 598 F.2d 773, 779 (6th Cir.) (charging patient only if prescription written), *cert. denied*, 459 U.S. 1048 (1978); United States v. Rosen, 582 F.2d 1032, 1034 n.7 (5th Cir. 1978) (exchanging prescriptions for cash); United States v. Green, 511 F.2d 1062, 1064-66 (7th Cir.) (same), *cert. denied*, 423 U.S. 1031 (1975); United States v. Stewart, 443 F.2d 1129, 1130 (10th Cir. 1971) (same).

185. *See* Jin Fuey Moy v. United States, 254 U.S. 189, 192 (1920) (selling or giving away drugs); United States v. Word, 806 F.2d 658, 660, 664 (6th Cir. 1986) (charging $200 to $1,000 per prescription), *cert. denied*, 480 U.S. 922 (1987); United States v. Hoffner, 777 F.2d 1423, 1425 (10th Cir. 1985) (billing $30 for regular office visit, $100 for controlled substances visit); United States v. Stump, 735 F.2d 273, 276 (7th Cir.) (exchanging prescriptions for excessive money or for goods or services), *cert. denied*, 469 U.S. 864 (1984); United States v. Andrew, 666 F.2d 915, 917 (5th Cir. 1982) (charging $250 per prescription); United States v. Larson, 507 F.2d 385, 387 (9th Cir. 1974) (charging flat cash rate per prescription); United States v. Moore, 505 F.2d 426, 446 (D.C. Cir. 1974) (charging $15 for 50 pills, $25 for 75 pills, $35 for 100 pills, $50 for 150 pills), *rev'd on other grounds*, 423 U.S. 122 (1975).

186. *Jin Fuey Moy*, 254 U.S. at 193 (citing failure of physician to give physical examination); United States v. Kaplan, 895 F.2d 618, 620 (9th Cir. 1990) (same). *Accord Word*, 806 F.2d at 663-64; United States v. Schuster, 777 F.2d 264, 271 (5th Cir.), *vacated on other grounds*, 778 F.2d 1132 (5th Cir. 1985); *Larson*, 722 F.2d at 142; *Andrew*, 666 F.2d at 917; United States v. Outler, 659 F.2d 1306, 1308 (5th Cir. Unit B Oct. 1981), *cert. denied*, 455 U.S. 950 (1982); United States v. Potter, 616 F.2d 384, 386 (9th Cir.), *cert. denied*, 449 U.S. 832 (1980); United States v. Dunbar, 614 F.2d 39, 42 (5th Cir. 1980); United States v. Rogers, 609 F.2d 834, 838 (5th Cir. 1980); United States v. Smurthwaite, 590 F.2d 889, 890 (10th Cir. 1979); United States v. Roya, 574 F.2d 386, 389 (7th Cir.), *cert. denied*, 439 U.S. 857 (1978); United States v. Fellman, 549 F.2d 181, 182 (10th Cir. 1977); United States v. Rosenberg, 515 F.2d 190, 192 (9th Cir.), *cert. denied*, 423 U.S. 1031 (1975); United States v. Green, 511 F.2d 1062, 1066 (7th Cir.), *cert. denied*, 423 U.S. 1031 (1975); United States v. Badia, 490 F.2d 296, 297 (1st Cir. 1973); United States v. Jobe, 487 F.2d 268, 269 (10th Cir. 1973), *cert. denied*, 416 U.S. 955 (1974); United States v. Bartee, 479 F.2d 484, 485 (10th Cir. 1973); United States v. Warren, 453 F.2d 738, 741 (2d Cir.), *cert. denied*, 406 U.S. 944 (1972); White v. United States, 399 F.2d 813, 816 (8th Cir. 1968); Brown v. United States, 250 F.2d 745, 745 (5th Cir.), *cert. denied*, 356 U.S. 938, *reh'g denied*, 357 U.S. 933 (1958); Dunford v. United States, 216 F.2d 184, 184 (4th Cir. 1954); United States v. Brandenburg, 155 F.2d 110, 112-13 (3d Cir. 1946), *cert. denied*, 332 U.S. 769 (1947); United States v. Krasnoff, 480 F. Supp. 723, 728 (S.D.N.Y. 1979); United States v. Dallman, 32 M.J. 624, 627 (A.C.M.R. 1991).

187. *Jin Fuey Moy*, 254 U.S. at 193 (citing failure of physician to perform adequate physical examination); *accord Johnson*, 831 F.2d at 126; United States v. Chin,

- Physician prescribes a particular controlled substance that the patient either named or described;[188]
- Physician writes a prescription in a fictitious name or in a name other than that of the patient who was present at the time;[189]

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795 F.2d 495, 500 (5th Cir. 1986); United States v. Norris, 780 F.2d 1207, 1208 (5th Cir. 1986); *Stump*, 735 F.2d at 276; United States v. Betancourt, 734 F.2d 750, 751 (11th Cir. 1984). *See also* United States v. Albert, 675 F.2d 712, 715 (5th Cir. 1982) (examining only blood pressure and weight); United States v. Varma, 691 F.2d 460, 462-63 (10th Cir. 1982) (citing failure of physician to perform adequate physical examination); *Outler*, 659 F.2d at 1308 (same); United States v. Guerrero, 650 F.2d 728, 739 (5th Cir. Unit A July 1981) (examining only weight and pulse); United States v. Kirk, 584 F.2d 773, 783 (6th Cir. 1978) (examining only weight and blood pressure); United States v. Boettjer, 569 F.2d 1078, 1079 (9th Cir.) (citing failure of physician to perform adequate physical examination), *cert. denied*, 435 U.S. 976 (1978); *Rosen*, 582 F.2d at 1035 (examining only blood pressure and weight); United States v. Hooker, 541 F.2d 300, 305 (1st Cir. 1976) (citing failure of physician to perform adequate physical examination); *Green*, 511 F.2d at 1065 (same); United States v. Hipsch, 34 F. Supp. 270, 272 (W.D. Mo. 1940). *See also* United States v. Zwick, 413 F. Supp. 113, 115-16 (N.D. Ohio 1976) (setting standards of treatment for patients suffering from obesity).

As one court observed when discussing this point:

> [N]o medical history of the patient was taken. Specifically, the patient was not asked whether he was allergic to any type of drugs, whether he had a heart condition or any other ailments which might affect him, anything in particular about his general health or previous illnesses or illnesses from which he might be suffering at the time of the visit, his employment, etc. . . . On a patient's subsequent visit no history was taken, no questions were asked as to whether there were any ill effects from taking pills, and the only conversation between the patient and the doctor was a comment as to whether weight was gained or lost, and what type of drug would be prescribed.

Rosen, 582 F.2d at 1034 n.7.

188. *Johnson*, 831 F.2d at 126 (prescribing drugs that a patient wanted); *accord Chin*, 795 F.2d at 501; *Norris*, 780 F.2d at 1208; *Varma*, 691 F.2d at 462; United States v. Voorhies, 663 F.2d 30, 34 (6th Cir. 1981); *Guerrero*, 650 F.2d at 739-40 app.; United States v. Thompson, 624 F.2d 740, 741 (5th Cir. 1980); *Potter*, 616 F.2d at 386; *Rogers*, 609 F.2d at 835; *Smurthwaite*, 590 F.2d at 890; *Roya*, 574 F.2d at 389; *Boettjer*, 569 F.2d at 1079; *Rosenberg*, 515 F.2d at 192; *Green*, 511 F.2d at 1066; *Bartee*, 479 F.2d at 485-86; *White*, 399 F.2d at 815-16; *Hipsch*, 34 F. Supp. at 272. *See also Kirk*, 584 F.2d at 783 (giving the patient a choice of drugs); *Moore*, 505 F.2d at 428 (allowing patient to also choose drug quantity).

189. *Jin Fuey Moy*, 254 U.S. at 193 (prescribing drugs for a person not present); *Word*, 806 F.2d at 662 (prescribing drugs knowingly for persons under false names); *Chin*, 795 F.2d at 501 (prescribing drugs for a spouse not present); *Stump*, 735 F.2d at 276 (prescribing drugs knowingly to fictitious persons); *Larson*, 722 F.2d at 141-42 (prescribing drugs knowingly to persons under false names); *Andrew*, 666 F.2d at 917 (prescribing drugs for a person not present); United States v. Harrison, 651 F.2d 353, 355 (5th Cir. July 1981) (en banc) (prescribing drugs knowingly for persons under false names); *Guerrero*, 650 F.2d at 732 (same); United States v. Thompson,

- Physician was aware that the drugs were not to be used for therapeutic or medical purposes at the time the prescription was written;[190]
- Physician writes an inordinate number of prescriptions for controlled substances overall or to individual patients or both;[191]
- Physician is writing prescriptions too frequently; that is, the medication as prescribed should not have run out at the time a second prescription was written;[192]

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624 F.2d 740, 741 (5th Cir. 1980) (same); *Potter*, 616 F.2d at 386 (same); *Smurthwaite*, 590 F.2d at 890 (prescribing drugs for a spouse not present); *Kirk*, 584 F.2d at 778 (prescribing drugs knowingly for persons under false names); *Roya*, 574 F.2d at 389 (prescribing drugs for a boyfriend not present); United States v. Greenfield, 574 F.2d 305, 308 (5th Cir.) (prescribing drugs knowingly to persons under false names), *cert. denied*, 439 U.S. 860 (1978); *Green*, 511 F.2d at 1065, 1066 (prescribing drugs to same patients under different names); *White*, 399 F.2d at 816 (prescribing drugs for persons not present); *Jamieson*, 605 F. Supp. at 119, 124 (prescribing drugs for same patients under different names).

190. *Word*, 806 F.2d at 663-64 (prescribing drugs for resale); *Chin*, 795 F.2d at 501 (prescribing drugs for partying and staying up while driving); *Voorhies*, 663 F.2d at 34 (prescribing drugs for partying); *Outler*, 659 F.2d at 1308 (prescribing drugs for partying and resale); *Guerrero*, 650 F.2d at 732 (prescribing drugs for resale); *Dunbar*, 614 F.2d at 42 (same); United States v. Millen, 594 F.2d 1085, 1086 (6th Cir.) (prescribing drugs for patient's addiction), *cert. denied*, 444 U.S. 829 (1979); *Smurthwaite*, 590 F.2d at 890 (prescribing drugs for partying); *Rosen*, 582 F.2d at 1036 (prescribing drugs to a patient known to be delivering the drugs to others); *Roya*, 574 F.2d at 389 (same); *Hooker*, 541 F.2d at 302, 304-05 (prescribing drugs for recreational use); *Rosenberg*, 515 F.2d at 192 (same); *Green*, 511 F.2d at 1066 (same); *Badia*, 490 F.2d at 297-98 (prescribing drugs for resale); *Bartee*, 479 F.2d at 489 (same); United States v. Warren, 453 F.2d 738, 741 (2d Cir.) (prescribing drugs for recreational use), *cert. denied*, 406 U.S. 944 (1972).

191. Webb v. United States, 249 U.S. 96, 98 (1919) (dispensing 4000 prescriptions); United States v. Kaplan, 895 F.2d 618, 621 (9th Cir. 1990) (issuing 19 prescriptions to one patient and 21 prescriptions to another patient in 1 month); Shatz v. United States Dep't of Justice, 873 F.2d 1089, 1090 (8th Cir. 1989) (ordering 20 ounces of cocaine for "office use"); *Betancourt*, 734 F.2d at 754 (prescribing 45 tablets of methaqualone during 99.64% of his 6,745 patient visits); United States v. Blanton, 730 F.2d 1425, 1431 (11th Cir. 1984) (dispensing 300,000 methaqualone tablets in 18 months); *Potter*, 616 F.2d at 386 (prescribing excessive amounts to one individual); *Kirk*, 584 F.2d at 778 (issuing an unusually large quantity of prescriptions); *Larson*, 507 F.2d at 387 (prescribing excessive amounts to one individual); United States v. Abdallah, 149 F.2d 219, 221 (2d Cir.) (issuing 12 morphine prescriptions in 20 days), *cert. denied*, 326 U.S. 724 (1945); Melanson v. United States, 256 F. 783, 785 (5th Cir. 1919) (prescribing excessive amounts of drugs).

192. *See Stump*, 735 F.2d at 276 (writing multiple prescriptions to the same persons during a short period of time); *Smurthwaite*, 590 F.2d at 890 (prescribing a different controlled substance before prior prescription of another substance ran out); Noell v. Bensinger, 586 F.2d 554, 558 (5th Cir. 1978) (concluding it is permissi-

- The prescriptions written show a failure to individualize treatment or are not appropriate for the claimed illnesses;[193]
- Physician lacks records related to the prescriptions in question[194] or those records are false;[195]
- Physician sends the patients to one particular pharmacy, recommends a particular pharmacy, or directs them to different pharmacies in an effort to spread the prescriptions around.[196]

When a physician and a pharmacist have been charged together with illegal distribution, courts have identified the following evidence to support those charges:

- Physician gave discount coupons for the pharmacy;[197]

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ble to infer that drugs are misused if frequently prescribed in large volumes to same individuals); *Kirk*, 584 F.2d at 778 (prescribing drugs three or four times a week to the same patient); *Roya*, 574 F.2d at 389 (issuing a second prescription within three days of a previous prescription for a month's supply); United States v. Greenfield, 554 F.2d 179 (5th Cir. 1977) (prescribing drugs before prior prescription ran out); United States v. Ellzey, 527 F.2d 1306, 1307 (6th Cir. 1976) (writing each person a monthly prescription at each office); *Green*, 511 F.2d at 1065 (prescribing multiple prescriptions); *Moore*, 505 F.2d at 447 (MacKinnon, J., dissenting) (prescribing the same drug on the same day during two different visits); *Bartee*, 479 F.2d at 485 (issuing post-dated prescriptions); Brown v. United States, 250 F.2d 745 (5th Cir.) (selling 3000 tablets to 2 persons), *cert. denied*, 356 U.S. 938 (1958). *See also* United States v. Brandenburg, 155 F.2d 110, 113 (3d Cir. 1946) (prescribing drugs twice a day or two days in a row); *Abdallah*, 149 F.2d at 221 (prescribing 12 prescriptions within 20 days to the same person).

193. *Dunbar*, 614 F.2d at 42. *See Zwick*, 413 F. Supp. at 115-16.

194. United States v. Larson, 722 F.2d 139, 142 (5th Cir. 1983) (failing to produce records indicates lack of compliance with customary medical practice), *cert. denied*, 466 U.S. 907 (1984); United States v. Bridwell, 583 F.2d 1135, 1137 (10th Cir. 1978) (same); *see Blanton*, 730 F.2d at 1431 (holding that though physician was not required to keep records, the jury was free to infer that no legitimate researcher would fail to record the results of his experiments).

195. *Shatz*, 873 F.2d at 1091 (upholding suspension of license for egregious conduct including keeping false records); *Chin*, 795 F.2d at 501 (establishing evidence of false recordkeeping); *Guerrero*, 650 F.2d at 732 (same); *Smurthwaite*, 590 F.2d at 891 (same); *Abdallah*, 149 F.2d at 222 (upholding inference of bad faith because of discrepancies in prescription records).

196. *Jin Fuey Moy*, 254 U.S. at 193 (sending patients to one particular drugstore); *Hoffner*, 777 F.2d at 1425 (instructing patients to go to different pharmacies when filling their prescriptions to avoid suspicion); *Stump*, 735 F.2d at 276 (same); *Andrew*, 666 F.2d at 917 (recommending a pharmacy to fill prescriptions); *Potter*, 616 F.2d at 386 n.5 (instructing patients to go to different pharmacies when filling their prescriptions to avoid suspicion); *accord Rosen*, 582 F.2d at 1036; *Larson*, 507 F.2d at 387-88; *Bartee*, 479 F.2d at 486, 489; *Abdallah*, 149 F.2d at 221.

197. United States v. Coward, 669 F.2d 180, 182 (4th Cir.), *cert. denied*, 456 U.S. 946 (1982).

- Direct telephone lines linked the doctor's office and the pharmacy;[198]
- Physician and pharmacy were located on the same premises;[199]
- Physician provided pharmacy with pre-signed prescription pads to facilitate prescription-by-telephone services;[200]
- Physician's patients were not from the local area;[201]
- The volume of prescriptions issued by the physician for controlled substances was exceptional.[202]

In cases in which pharmacists have been prosecuted, courts have cited the following evidence as proving the knowing filling of illegal prescriptions:

- Pharmacy handled an exorbitant amount of a particular controlled substance;[203]
- Controlled substances in question were dispensed pursuant to the prescriptions of one physician;[204]

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198. *Id.*; United States v. Ellison, 557 F.2d 128, 134-35 (7th Cir.), *cert. denied*, 434 U.S. 965 (1977); *Green*, 511 F.2d at 1065.

199. *See* United States v. Hammond, 781 F.2d 1536, 1538 (11th Cir. 1986) (doctor's office next door to pharmacy); *Green*, 511 F.2d at 1065 (doctor's office across the hall from pharmacy); *Melanson*, 256 F.2d at 787 (doctor in room behind pharmacy).

200. *Coward*, 669 F.2d at 182.

201. *Hammond*, 781 F.2d at 1537 (serving clientele of which 90% resided outside the county).

202. Webb v. United States, 249 U.S. 96, 96 (1919) (filling 4000 prescriptions for morphine in 11 months); *Hammond*, 781 F.2d at 1538 (purchasing 82.3% of a drug in the sales territory for distribution in a town of 1200 people).

203. *Webb*, 249 U.S. at 99 (ordering 30 times as much morphine as the average pharmacy in the area); United States v. Hughes, 895 F.2d 1135, 1143 (6th Cir. 1990) (distributing Tylenol 3 to 90% of the patients from the clinic); *Roth*, 777 F.2d at 1201 (selling 20% of the Talwin in the State of Illinois); *Hammond*, 781 F.2d at 1538 (purchasing 82.3% of drug in a sales territory for distribution in a town of 1200 people); United States v. Lartey, 716 F.2d 955, 958 (2d Cir. 1983) (finding over 1 million tablets missing from defendant's pharmacies); United States v. Irwin, 661 F.2d 1063 (5th Cir. Nov. 1981) (finding pharmacy's sale of drug decreased from 1400 tablets to 180 tablets during period of investigation), *cert. denied*, 456 U.S. 907 (1982); *Green*, 511 F.2d at 1071 (buying 1 million Ritalin tablets for resale in 11 months). *See also* United States v. August, 984 F.2d 705, 713 (6th Cir. 1992) (involving a podiatrist whose drug orders were double that of an average U.S. pharmacy, were 55 times larger than an average physician's purchase, were 4 times as great as the orders of an average U.S. hospital, and constituted 99% of all the drug sold to podiatrists in Michigan over 3 years).

204. *Hughes*, 895 F.2d at 1143 (citing high volume and percentage of prescriptions for Tylenol with Codeine from one clinic); United States v. Mahar, 801 F.2d 1477, 1488 (6th Cir. 1986) (citing amounts of pain medications and weight loss medi-

- Prescriptions for multiple people were brought in by one person;[205]
- Customers were not from the local area;[206]
- Pharmacists had prior notice of possible illegality on the part of the prescribing physician and/or patient;[207]
- Pharmacist charged more than the market rate for the controlled substance prescribed;[208]
- Prescriptions were not written in the proper form;[209]
- Lack of other medication appropriate to the alleged condition in conjunction with the controlled substance prescription or antagonistic medications written;[210]
- Frequency of prescriptions for individual patients, *i.e.*, the patient received more medication than would have been neces-

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cations disproportionately prescribed by one clinic); *Hammond*, 781 F.2d at 1538 (citing pharmacy as a pipeline for one doctor's prescriptions); *Lartey*, 716 F.2d at 955, 958 (noting that 95% of the prescriptions were written by one doctor); *Lawson*, 682 F.2d at 482 (citing large number of prescriptions all written by one doctor and all presented by one person); *Hayes*, 595 F.2d at 261 (citing tremendous number of prescriptions filled for one doctor); *Melanson*, 256 F. at 787 (same). *See also* PHARMACIST'S MANUAL, *supra* note 131, at 36 (instructing pharmacists that a doctor who writes significantly more prescription orders than other doctors may be writing illegal or fraudulent prescription orders).

205. United States v. Cooper, 868 F.2d 1505, 1512 (6th Cir.), *cert. denied*, 490 U.S. 1094 (1989); United States v. Henry, 727 F.2d 1373, 1374 n.1 (5th Cir.), *rev'd on other grounds*, 749 F.2d 203 (5th Cir. 1984) (en banc); *Lawson*, 682 F.2d at 482. *See also* PHARMACIST'S MANUAL, *supra* note 131, at 36 (instructing pharmacists to be suspicious of patients presenting prescriptions written for other people).

206. *Hammond*, 781 F.2d at 1537 (finding 90% of Didrex prescriptions written by one doctor were for residents outside the county); *Lawson*, 682 F.2d at 481-82 (involving a doctor in Philadelphia and a pharmacy in Ocean City, Maryland). *See also* PHARMACIST'S MANUAL, *supra* note 131, at 36 (instructing pharmacists to be suspicious of prescriptions written from outside the community).

207. *Henry*, 727 F.2d at 1374. *See Lawson*, 682 F.2d at 481, 483; United States v. Barbacoff, 416 F. Supp. 606, 609 (D.D.C. 1976); United States v. Williams, 416 F. Supp. 611, 614 (D.D.C. 1976).

208. *Cooper*, 868 F.2d at 1512 (charging $13 to $15 for each pill); United States v. Irwin, 661 F.2d at 1063, 1066 (5th Cir. Nov. 1981) (increasing price from $18 to $30-$40 per prescription), *cert. denied*, 456 U.S. 907 (1982); *Hayes*, 595 F.2d at 261 (charging unusually high prices).

209. *Irwin*, 661 F.2d at 1066.

210. United States v. Mahar, 801 F.2d 1477, 1487 (6th Cir. 1986); PHARMACIST'S MANUAL, *supra* note 131, at 35 (warning pharmacists about prescriptions for antagonistic drugs).

sary if the pills were taken according to instructions or accepted dosage levels;[211]

- High percentage of the controlled substances purchased by the pharmacy were unaccounted for.[212]

The government must also show that the drug involved is a controlled substance.[213]

Registrants who obtain controlled substances to dispense, such as pharmacists and some physicians, have been prosecuted when an audit of those controlled substances shows a substantial shortage.[214] In such a case, the total amount of controlled substances ordered, as evidenced by DEA Form 222, prescriptions, or other order forms, is compared to the amount of controlled substances dispensed as evidenced by filled prescriptions, office records of administration, and the stock on hand. If the discrepancy is large enough, the government can bring a prosecution and assert an inference that since the pharmacist or physician had been in possession of a large quantity of controlled substances that cannot be accounted for, the controlled substances must have been distributed.[215] However, such an inference is only permissible if there is a showing of exclusive possession on the part of the pharmacist or physician, or credible evidence that others with access did not take the drugs.[216]

Finally, physicians who write prescriptions in others' names and fill them in order to obtain drugs for themselves commit the crime of obtaining a controlled substance by fraud.[217] A charge of illegal distribution against a pharmacist in these circumstances, under the

211. *Irwin,* 661 F.2d at 1069 (filling more than double the medically acceptable amount of Preludin in a three-month period); *Hayes,* 595 F.2d at 261 (filling 34 prescriptions for Dilaudid and 75 prescriptions for Percodan in 1 month for a single patient).

212. United States v. Roth, 777 F.2d 1200, 1201-02 (7th Cir. 1985) (accounting for a few hundred out of 664,000); *Lartey,* 716 F.2d at 958 (accounting for 20% of tablets received); United States v. Schiffman, 572 F.2d 1137, 1139 (5th Cir. 1978) (accounting for 10% of tablets received); *Barbacoff,* 416 F. Supp. at 608 (failing to inventory drugs).

213. United States v. Carroll, 518 F.2d 187, 188 (6th Cir. 1975).

214. United States v. Bycer, 593 F.2d 549, 550-51 (3d Cir. 1979) (failing to account for 100,000 tablets and 400 grams of cocaine).

215. *Id.*

216. *Id.*

217. 21 U.S.C. § 843(a)(3). *See Shatz,* 873 F.2d at 1090 (charging doctor whose records indicated patients received cocaine but where patients disclaimed receipt of cocaine).

theory that the physician caused the pharmacist to illegally distribute the drugs, has been rejected by one district court.[218]

B. *Obtaining Documentary Evidence*

Documentary evidence in the prosecution of a registrant generally consists of prescriptions, patient files, and related office files such as appointment books and receipt books. This evidence is usually obtained in one of three ways: administrative search,[219] criminal search warrant,[220] or grand jury subpoena.[221]

1. Administrative Search

The CSA provides for administrative inspections of "controlled premises."[222] A "controlled premise" is one where required records are kept or where a registrant holds, manufactures, distributes, or dispenses controlled substances. A pharmacy is a controlled premise, as is the office of a physician who dispenses controlled substances.[223] The office of a doctor who merely prescribes controlled substances is not a controlled premise.[224]

The DEA has the authority to conduct administrative searches of a controlled premise either by consent of the owner or through the use of a warrant.[225] Such a search can be the source of evidence later used in a criminal prosecution as long as the administrative search occurred prior to the formal decision by the DEA to institute criminal proceedings.[226]

Upon a statement of purpose, presentation of credentials and written notice, and consent of the owner, a DEA Compliance Investigator has the right to enter a controlled premise and conduct an inspection that includes copying and verifying required documents, inspecting equipment, and taking inventory of controlled sub-

218. United States v. Kast, No. 92-0043, slip op. at 7-12 (D.D.C. Dec. 23, 1992).

219. *See infra* notes 222-46 and accompanying text.

220. *See infra* notes 247-73.

221. *See infra* notes 274-94 and accompanying text.

222. 21 U.S.C. § 880 (1988 & Supp. IV 1992); 21 C.F.R. §§ 1316.01-1316.13 (1993).

223. 21 C.F.R. § 1316.02(b), (d) (1993).

224. 21 U.S.C. § 880(a) (1984); 21 C.F.R. § 1316.02(c) (1993).

225. *See infra* notes 227-35 and accompanying text.

226. *See infra* notes 241-44 and accompanying text.

stances.[227] If a request for entry to conduct an inspection is denied, an inspection warrant is required before an inspection may be conducted unless there is an imminent danger to the public health or some other emergency.[228]

An administrative inspection warrant may be issued by a federal judge or magistrate judge upon an affidavit establishing grounds.[229] The applicant for an inspection warrant must establish "probable cause" under the statute.[230] This statutory probable cause is defined as:

> [A] valid public interest in the effective enforcement of this subchapter or regulations thereunder sufficient to justify administrative inspections of the area, premises, building, or con-

227. 21 U.S.C. § 880(b) (1984 & Supp. 1992); 21 C.F.R. § 1316.08 (1993). *See generally* United States v. Enserro, 401 F. Supp. 460, 462 (W.D.N.Y. 1975) (holding that a consent-based search is illegal if in response to a threat of criminal prosecution); United States v. Anile, 352 F. Supp. 14 (N.D. W. Va. 1973) (holding that consent without meaningful choice was not valid consent).

The regulations state that whenever possible such consent should be in writing and shall acknowledge that the person consenting was informed (1) of his constitutional right not to have an inspection without an administrative warrant, (2) of his right to refuse consent, (3) that anything incriminating that is found may be seized and used against him in a criminal prosecution, (4) that he has been presented with a notice of inspection, and (5) that the consent is voluntary. 21 C.F.R. § 1316.08(b) (1993).

228. 21 U.S.C. § 880(c) (1984). This section provides that no inspection warrant is required under the following circumstances:

(1) consent;
(2) imminent danger to health or safety;
(3) inspection of conveyances where mobility makes it impracticable to obtain a warrant;
(4) in any other exceptions or emergency circumstance where time or opportunity to apply for a warrant is lacking; or
(5) in any other situation where a warrant is not constitutionally required.

Subsection (5) does not generally eliminate the need for an administrative inspection warrant even though the pharmaceutical industry is closely regulated. *Enserro*, 401 F. Supp. at 463; United States v. Montrom, 345 F. Supp. 1337, 1340 n.1 (E.D. Pa. 1972), *aff'd*, 480 F.2d 919 (3d Cir. 1973).

229. 21 U.S.C. § 880(d)(1), (2) (1984); 21 C.F.R. § 1316.09 (1993). According to the regulation, the application for an administrative inspection warrant shall contain: (1) the name and address of the controlled premises to be inspected; (2) a statement of statutory authority and the fact that the inspection is designed to insure compliance with the Act; (3) a statement relating to the nature and extent of the administrative inspection; and (4) a statement that the premises were never inspected or when last inspected. 21 C.F.R. § 1316.09 (1993).

230. 21 U.S.C. § 880 (1984); 21 C.F.R. § 1316.10 (1993).

> veyance, or contents thereof, in the circumstances specified in the application for the warrant.[231]

Statutory probable cause[232] is established upon an averment that a premises has never been inspected,[233] a substantial period of time has elapsed since the last inspection,[234] or that the registrant has recently received an inordinately large supply of a controlled substance.[235]

The DEA can identify registrants who are ordering large supplies of controlled substances through a system for monitoring controlled substance traffic called ARCOS (Automation of Reports and Consolidated Orders System).[236] ARCOS computerizes Schedule II controlled substance orders at the retail level. It is based on, among other things, the Form 222 order forms submitted by registrants to obtain controlled substances for distribution to the public.[237] The ARCOS unit "identifies those physicians and other medical practitioners [and pharmacies] who have purchased large quantities of controlled substances through the issuance of Excessive Purchase

231. 21 U.S.C. § 880(d)(1) (1984).

232. This probable cause standard is constitutional. United States v. Schiffman, 572 F.2d 1137, 1141-43 (5th Cir. 1978); *Montrom*, 345 F. Supp. at 1342.

233. United States v. Nechy, 827 F.2d 1161, 1165 (7th Cir. 1987); United States v. Voorhies, 663 F.2d 30, 33 (6th Cir. 1981), *cert. denied*, 456 U.S. 929 (1982); United States v. Prendergast, 585 F.2d 69, 70 (3d Cir. 1978); United States v. Goldfine, 538 F.2d 815, 819 (9th Cir. 1976); *Burka*, 684 F. Supp. at 1304; United States v. Greenberg, 334 F. Supp. 364, 367 (W.D. Pa. 1971). *See also* United States v. Acklen, 690 F.2d 70, 71 (6th Cir. 1982) (approving a warrant that averred the absence of a prior inspection); 21 C.F.R. § 1316.09(4)(i) (1993).

234. United States v. Osborne, 512 F. Supp. 413, 414-15 (E.D. Tenn. 1980) (holding that "inspected previously . . . approximately three years ago" is sufficient to establish probable cause), *cert. denied*, 454 U.S. 831 (1981); United States v. Prendergast, 436 F. Supp. 931, 932 (W.D. Pa. 1977), *aff'd*, 585 F.2d 69 (3d Cir. 1978); *Greenberg*, 334 F. Supp. at 367. 21 C.F.R. § 1316.09(b)(4)(ii) (1993) requires that the date when the premises was last inspected be included in the affidavit.

235. *Nechy*, 827 F.2d at 1165 (holding that purchase of "suspicious quantities" provided probable cause); *Schiffman*, 572 F.2d at 1140-41 (noting that large purchases of controlled drugs by a registered retail pharmacy alone create a valid public interest supporting inspection); *Burka*, 684 F. Supp. at 1303-04 (holding that "excessive purchases" of Dilaudid provided probable cause); *Montrom*, 345 F. Supp. at 1342 ("mammoth purchases"); *Greenberg*, 334 F. Supp. at 367 ("extraordinary quantities").

236. 21 C.F.R. § 1304.04 (1993).

237. United States v. Blanton, 730 F.2d 1425, 1427 n.1 (11th Cir. 1984).

Reports."[238] Instances of apparent excessive ordering are generally referred for further investigation.

The administrative inspection warrant can authorize the inspection, copying, and/or seizure of records.[239] The warrant must be executed and returned within ten days of the date of its issuance unless additional time is granted by the judge or magistrate judge who issued the warrant upon a showing of need by the government.[240]

An administrative inspection may be conducted even though there is suspicion that criminal activity has occurred.[241] The pharmaceutical industry is a pervasively regulated one. Consequently, pharmacists and distributors subject to the CSA have a reduced expectation of privacy in the records they keep in compliance with the Act, and the "administrative search" exception to the Fourth Amendment applies.[242] Therefore, the motive of the searcher is generally irrelevant. As long as the administrative inspection warrant is issued on statutory probable cause and the scope and manner of the search conform with the statute, the administrative search is appropriate.[243] However, once it has been decided to proceed with

238. *Burka*, 684 F. Supp. at 1302. *See also* United States v. August, 984 F.2d 705, 708 (6th Cir. 1992). ARCOS reports are limited to drug purchases and do not provide information on prescribing other than through its impact on the purchases made by pharmacies at which the prescriptions are filled. 21 C.F.R. § 1304.04 (1993).

ARCOS develops its excess purchaser reports by comparing a registrant's purchases of a particular drug against the average purchases of that drug within the registrant's state. *Id.* ARCOS reports those registrants who purchase amounts greater than one or two standard deviations above the state's average. *Id.*

239. 21 U.S.C. § 880(d)(1) (1988). *See* United States v. Nechy, 827 F.2d 1161, 1165-66 (7th Cir. 1987).

240. 21 U.S.C. § 880(d)(3) (1988). The inspection shall begin as soon as practicable after the issuance of the warrant and shall be completed promptly. 21 C.F.R. § 1316.11 (1993).

241. *Nechy*, 827 F.2d at 1161 (validating administrative search although an ulterior motive was to obtain evidence of criminal activity); United States v. Acklen, 690 F.2d 70, 71 (6th Cir. 1982) (holding evidence seized during administrative search admissible); United States v. Goldfine, 538 F.2d 815, 819 (9th Cir. 1976) (refusing to exempt a pharmacy from search because a possible violation is expected).

242. *Acklen*, 690 F.2d at 75.

243. *Id.* at 74; *Nechy*, 827 F.2d at 1165; United States v. Prendergast, 585 F.2d 69, 70-71 (3d Cir. 1978); *Goldfine*, 538 F.2d 815, 818-19 (9th Cir. 1976). The use of uniformed police officers to accompany and assist DEA Compliance Investigators in the execution of an administrative inspection warrant may violate 21 U.S.C. § 880(b)(2), but is not a justification for suppressing the results of a search. *Nechy*, 827 F.2d at 1165.

a criminal prosecution, administrative warrants may no longer be available.[244]

Refusal of entry to inspectors armed with an inspection warrant is a criminal violation.[245] The regulations provide that individuals who refuse entry to an inspector upon a warrant shall be advised of this provision; if they persist in their refusal, they may be arrested, after which the search will commence.[246]

2. Criminal Search Warrant

Records may also be obtained from a registrant through a criminal search warrant.[247] Search warrants are generally used to obtain records from a physician's office since most such offices are not "controlled premises" that can be administratively inspected.[248] From a law enforcement perspective, search warrants have an advantage over administrative inspection warrants because they allow the search and seizure of all criminally-related evidence, not just records required under the CSA. Thus, while financial records can-

244. United States v. Lawson, 502 F. Supp. 158, 165 (D. Md. 1980). *See also* United States v. Acklen, 690 F.2d 70, 72-75 (6th Cir. 1982). In *Acklen*, there were three administrative searches. The second search occurred after the DEA Compliance Investigator recommended to his superiors that a criminal prosecution be instituted. The third search occurred after the DEA referred the case to the United States Attorney's Office for prosecution. The trial court suppressed all evidence seized during the second and third searches. The government appealed only the suppression of the fruits of the second search. The Sixth Circuit reversed the decision of the trial court to suppress the second administrative search but indicated that its decision might be different had the third search been appealed. *But see* United States v. Gel Spice Co., 773 F.2d 427 (2d Cir. 1985) (allowing the FDA to continue to conduct civil inspections even after decision to proceed criminally has been made).

245. 21 U.S.C. § 842(a)(6) (1984); United States v. Enserro, 401 F. Supp. 460 (W.D.N.Y. 1975).

246. 21 C.F.R. § 1316.12 (1993).

247. *E.g.*, United States v. August, 984 F.2d 705, 709 (6th Cir. 1992) (pharmacy); United States v. Borromeo, 954 F.2d 245 (4th Cir.) (doctor's office), *cert. denied*, 112 S. Ct. 3012 (1992); United States v. Kaplan, 895 F.2d 618, 623 (9th Cir. 1990) (mail fraud investigation); United States v. Word, 806 F.2d 658 (6th Cir. 1986) (doctor's office), *cert. denied*, 480 U.S. 922 (1987); United States v. Hayes, 794 F.2d 1348 (9th Cir. 1986) (doctor's office), *cert. denied*, 479 U.S. 1086 (1987); United States v. Outler, 659 F.2d 1306 (5th Cir. Unit B Oct. 1981) (medical records), *cert. denied*, 455 U.S. 950 (1982); United States v. Kershman, 555 F.2d 198, 201 (8th Cir.) (pharmacy), *cert. denied*, 434 U.S. 892 (1977); United States v. Krasnoff, 480 F. Supp. 723 (S.D.N.Y. 1979) (health facility).

248. See *supra* notes 222-24 and accompanying text for a discussion of "controlled premises."

not be reviewed during an administrative inspection,[249] they can be reviewed during the execution of a criminal search warrant.[250]

As in the case of administrative search warrants, probable cause must be demonstrated.[251] However, traditional probable cause under the Fourth Amendment is required for a criminal search warrant. The search warrant affidavit has to establish the probability that a crime is being or has been committed and that specific, identified evidence of that crime is probably located at the premises to be searched.[252]

In the case of a search of a physician's office, probable cause must be shown that illegal distribution of controlled substances is or has been occurring and that records which are evidence of the illegal distribution exist and are currently present in the doctor's office. Generally, in seeking to establish probable cause that illegal distribution has occurred, the affidavit in support of the search warrant sets forth the facts of the investigation showing that the targeted physician is not issuing prescriptions or dispensing controlled substances in the usual course of medical practice for a legitimate medical need. This investigation often consists of having undercover police officers visit the target physician as patients or interviewing selected patients who have received suspicious prescriptions.[253] Often, the affidavit then cites some source of expertise to demonstrate that the target registrant's practices, as evidenced by the experiences of the undercover officers and other patients, are inappropriate. Statements of expertise may be quotations from recognized texts, such as the *Physician's Desk Reference*,[254] setting forth the proper circumstances under which the controlled substances at issue should be prescribed.[255] Statements from a practic-

249. 21 U.S.C. § 880(b)(4) (1984); 21 C.F.R. § 1316.04 (1993).

250. *E.g.*, *Borromeo*, 954 F.2d at 246 (patient billing records).

251. *E.g.*, *Nechy*, 827 F.2d at 1165.

252. United States v. Harris, 403 U.S. 573, 584 (1971).

253. See Jeffrey D. Lane, *The Respectable Pusher*, *in* FBI LAW ENFORCEMENT BULLETIN 11-14 (Oct. 1991) for a discussion of various investigative techniques used in these types of cases.

254. The PHYSICIANS' DESK REFERENCE (47th ed. 1993) [hereinafter PDR] is a commonly used guide that provides information about the approved uses and possible side effects of medication.

255. In United States v. Johnson, 831 F.2d 124, 130 (6th Cir. 1987), *cert. denied sub nom.* Taylor v. United States, 485 U.S. 968 (1988), two experts called by the government "testified that the PDR was recognized as a reference but was not con-

ing physician or other medical practitioner who has reviewed the case are also acceptable.[256] Such expert evidence is not required where the illegality is so clear that no special medical judgment is necessary to determine that probable cause exists.[257]

The fact that the records in question are probably in the doctor's office is generally established through the statements of undercover officers, patients, and evidence of the general practice of physicians to create and maintain patient records. While this level of proof provides an unimpeachable basis for the belief that evidence is in the target physician's office, the Sixth Circuit found probable cause to believe that patients' medical records were at the doctor's office based merely on the fact that the patients' names appeared on prescriptions written by the doctor.[258]

Finally, the records themselves need to be described. First, a specific request is made for the records of those patients reasonably suspected of receiving controlled substances that were illegally dispensed or prescribed.[259] Second, in the author's experience, there generally is a request for all other records that evidence a similar pattern of misprescribing.[260]

Criminal search warrants of this type have been challenged for being "general."[261] The Fourth Amendment requires that a search

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sidered authoritative, although the defendant's expert claimed that the PDR was an authority." *See also* United States v. Larson, 722 F.2d 139, 140 n.1 (5th Cir. 1983), *cert. denied*, 466 U.S. 907 (1984) (noting government introduced evidence from the PDR); United States v. Irwin, 661 F.2d 1063, 1069 n.11 (5th Cir. Nov. 1981), *cert. denied*, 456 U.S. 856 (1982) (noting the PDR was read to the jury).

256. *E.g.*, United States v. Hayes, 794 F.2d 1348, 1355 (9th Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987). After reviewing Dr. Hayes's prescriptions, a medical consultant "concluded that there was a high probability that Hayes 'caused, abetted, or prolonged addi[c]tion or habituation to controlled substances.'" *Id.*

257. United States v. Krasnoff, 480 F. Supp. 723, 728 (S.D.N.Y. 1979) (noting that facts surrounding the prescribing clearly showed illegal conduct).

258. United States v. Word, 806 F.2d 658, 662 (6th Cir. 1986), *cert. denied*, 480 U.S. 922 (1987).

259. *E.g.*, United States v. Borromeo, 954 F.2d 245, 246 (4th Cir. 1992) (granting request for access to suspect patient's records).

260. *E.g.*, United States v. Betancourt, 734 F.2d 750, 755 (11th Cir.), *cert. denied sub nom.* Gerwitz v. United States, 469 U.S. 1021, *and cert. denied sub nom.* Sando v. United States, 469 U.S. 1076 (1984) (regarding the specific description of requested records).

261. *E.g.*, United States v. Hayes, 794 F.2d 1348, 1354-56 (9th Cir. 1986) (holding that warrants for search and seizure of physicians' offices were not "general" be-

warrant describe with particularity the things to be seized.[262] Warrants that do not satisfy the particularity requirement are considered "general" and evidence seized pursuant to such a warrant is inadmissible.[263] However, as long as the description of the items to be seized is sufficiently detailed so that total discretion is not vested in the seizing officers and the description is "as specific as the circumstances and nature of the activity permit[s]," the warrant will be upheld.[264]

The Ninth Circuit, in *United States v. Hayes,*[265] upheld a warrant that authorized the seizure from three separate medical offices of "all records which document the purchasing, dispensing, and prescribing of controlled substances, including, but not limited to, records contained in patient charts and all relevant records required to be maintained by . . . [Federal and State law]; patient logs, appointment books and other records and ledgers reflecting distribution of controlled substances."[266] This search warrant was based on an affidavit showing that fifty-eight patients had been illegally prescribed Schedule II controlled substances.[267] However, since the defendant did not attack the magistrate's finding that there was probable cause to seize all records relating to all controlled substances, the search was sustained.[268]

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cause the officers could only seize documents regarding controlled substances), *cert. denied*, 479 U.S. 1086 (1987).

262. U.S. CONST. amend. IV.

263. *E.g.*, Marron v. United States, 275 U.S. 192, 195-96 (1927) (requiring particular descriptions for search warrants).

264. *E.g., Betancourt*, 734 F.2d at 755. In *Betancourt*, the warrants were for medical clinics that were described as "prescription-mills." In each case the warrant sought, and the court upheld, requests for "patient records, limited to those records showing the dates of patient visits, all diagnostic tests performed and results obtained, diagnoses made, medications prescribed and the name of the diagnosing physician, from on or about June 15, 1981 [January 1, 1982], to the present which are evidence of violations of Title 21, United States Codes, Section 841(a)(1)." *Id.* This warrant is as broad as possible. It was upheld because the evidence showed that over 99% of the prescriptions issued by these clinics were probably illegal. *Cf.* United States v. Abrams, 615 F.2d 541 (1st Cir. 1980) (invalidating warrant for patient records in a Medicaid fraud investigation for being too general).

265. 794 F.2d 1348 (9th Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987).

266. *Id.* at 1355.

267. *Id.* at 1356 (Pregerson, J., dissenting).

268. *Id.* at 1355.

As the dissent in *Hayes* points out, the warrant would have been better drawn if it had been limited in the first instance to the records of the fifty-eight identified patients, and then allowed the seizure of all other records related to the prescribing of Schedule II controlled substances.[269] Such a warrant could not be challenged as it related to the fifty-eight named individuals because there was a specific finding of probable cause that was firmly based on the affidavit. Thus, if a reviewing court ultimately found that this was the limit of probable cause, the seizure of these records could be severed and upheld.[270]

Second, based on a finding of probable cause relating to the fifty-eight patients, there is inferential support for a finding that the doctor is probably engaged in a pattern and practice of illegally prescribing Schedule II controlled substances. This finding in turn would support the issuance of a warrant for records relating to all instances of the prescribing of those drugs. It is more difficult to discern how these recitals would support any finding that all of the doctor's controlled substance prescriptions, regardless of schedule, were illegal without additional evidence that the doctor was not engaged in a legitimate medical business.

The seizure of medical records pursuant to a criminal search warrant intrudes on the privacy rights of patients. Although patients do have a privacy right in this context, it is subject to a balancing against the legitimate interests of the State in securing the information.[271] In one case where the balancing test was applied, production was required where disclosure was to a grand jury and the district court specifically directed the government attorneys to maintain confidentiality.[272]

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269. *Id.* at 1358 (Pregerson, J., dissenting). *See also* United States v. Borromeo, 954 F.2d 245, 246 (4th Cir.), *cert. denied*, 112 S. Ct. 3012 (1992) (allowing the admission of 35 named patients' records).

270. *Borromeo*, 954 F.2d at 246-47.

271. *In re* Search Warrant (Sealed), 810 F.2d 67, 71-73 (3d Cir.), *cert. denied,* 483 U.S. 1007 (1987). *See also* United States v. Burzynski Cancer Research Inst., 819 F.2d 1301, 1311 & n.33 (5th Cir. 1987) ("The patients had no legitimate expectation of privacy in the records maintained by Dr. Burzynski that could be asserted against the search warrant."), *cert. denied*, 484 U.S. 1065 (1988); United States v. Colletta, 602 F. Supp. 1322, 1327 (E.D. Pa.) (holding that records seized pursuant to search warrant were admissible at trial), *aff'd,* 770 F.2d 1076 (3d Cir. 1985).

272. *In re Search Warrant*, 810 F.2d at 69-73.

Special problems arise if the records relate to treatment for drug abuse or alcohol abuse in a program "directly or indirectly assisted by any department or agency of the United States" because of the statutory protection given to these records.[273]

3. Grand Jury Subpoena

Records can also be obtained through the use of a grand jury subpoena.[274] However, subpoenas create problems for the government that do not exist in the case of a criminal search warrant. First, there are Fifth Amendment implications in the use of a subpoena. Subpoenaed individuals can resist the production of their personal records if the act of turning them over would tend to incriminate them.[275] Second, there may be privacy implications as well. A physician may resist turning over medical records based on the physician-patient privilege.[276] Third, the subpoenaed individual may object to the scope of the subpoena as being burdensome or oppressive, requiring litigation of the subpoena's validity before any records can be obtained. Fourth, subpoenaed records are subject to grand jury secrecy, a problem that does not arise when records are taken during a search. Fifth, the recipient of a subpoena can object to it in court, thereby delaying the investigation and possibly resulting in a reduction in the information obtained. Finally, records can be tampered with prior to being produced in response to a sub-

273. 42 U.S.C. §§ 290dd-3, 290ee-3 (1988); 42 C.F.R. § 2.1 (1992). The statutes provide for the disclosure of records from treatment programs upon the following:

> [A]n appropriate order of a court . . . after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any records is necessary, shall impose appropriate safeguards against unauthorized disclosure.

42 U.S.C. §§ 290dd-3(b)(2)(C), 290ee-3(b)(2)(C) (1988).

274. *See, e.g.*, United States v. Lartey, 716 F.2d 955 (2d Cir. 1983) (holding that grand jury subpoenas may lawfully obtain pharmacy records); United States v. Plesons, 560 F.2d 890 (5th Cir.) (acknowledging the lawful use of grand jury subpoenas to obtain pharmacy records), *cert. denied*, 434 U.S. 966 (1977); United States v. Rosenberg, 515 F.2d 190, 199 n.15 (9th Cir.) (describing the acquisition of patient records through a grand jury subpoena), *cert. denied*, 423 U.S. 1031 (1975).

275. *E.g.*, United States v. Doe, 465 U.S. 605, 612-17 (1984).

276. *See infra* notes 284-94 and accompanying text.

poena. These problems generally lead law enforcement to favor administrative inspection or criminal search warrants.[277]

The application of the Fifth Amendment privilege in this context may be limited. First, the privilege does not apply to the records of a corporation, including a physician's professional corporation or an incorporated pharmacy.[278] Furthermore, the contents of voluntarily prepared business records do not fall within the scope of the privilege because their creation was not compelled.[279] Second, the privilege does not apply to records required to be kept by law.[280] The "required records" exception applies to documents that satisfy a three-part test:

> (1) the requirement that they be kept must be essentially regulatory, (2) the records must be of a kind that the regulated party has customarily kept, and (3) the records themselves must have assumed "public aspects" that render them analogous to public documents.[281]

This exception has been applied to require the production of both prescription records and patient files.[282] Because judicial interpretation of state law regulating the practice of medicine requires the creation and maintenance of medical records, these records satisfy the test set out above.[283]

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277. *See* United States v. Hayes, 794 F.2d 1348, 1358 n.5 (9th Cir. 1986) (describing the government's method of obtaining criminal search warrants after the target physician resisted its efforts to subpoena records).

278. United States v. White, 322 U.S. 694 (1944); Wilson v. United States, 221 U.S. 361 (1911); *Lartey*, 716 F.2d at 961 n.3; *In re* Zuniga, 714 F.2d 632, 642 (6th Cir.), *cert. denied*, 464 U.S. 983 (1983); United States v. Radetsky, 535 F.2d 556, 568-69 (10th Cir.), *cert. denied*, 429 U.S. 820 (1976); Reamer v. Beall, 506 F.2d 1345 (4th Cir. 1974), *cert. denied*, 420 U.S. 955 (1975); *In re* Grand Jury Subpoenas Duces Tecum Dated January 30, 1986, 638 F. Supp. 794, 799 (D. Me. 1986); *In re* Jellen, 521 F. Supp. 251, 252-53 (N.D. W. Va. 1981); *In re* Grand Jury Subpoena, 460 F. Supp. 150, 151 (W.D. Mo. 1978).

279. United States v. Doe, 465 U.S. 605 (1984). However, the act of production may be privileged. *Id.* at 612-14.

280. *E.g.*, Shapiro v. United States, 335 U.S. 1 (1948).

281. *In re* Doe, 711 F.2d 1187, 1189-91 (2d Cir. 1983).

282. *In re* Grand Jury Proceedings, John Doe, M.D., 801 F.2d 1164 (9th Cir. 1986) (per curiam) (holding that records relating to purchase, sale, and prescription of anabolic steroids are not privileged under California law); *In re* Kenny, 715 F.2d 51 (2d Cir. 1983) (holding that medical records and X-rays are not privileged under New Jersey law); *In re* Doe, 711 F.2d 1187 (2d Cir. 1983) (holding that prescriptions and medical records are not privileged under New York law).

283. *Kenney*, 715 F.2d at 52-53; *Doe*, 711 F.2d at 1187.

A practitioner may object to complying with a subpoena on the basis of the physician-patient privilege, arguing that the privilege prevents the production of the individual patient's records.[284] Because there was no such privilege under federal common law, and none was adopted as part of Rule 501 of the Federal Rules of Evidence, most federal courts have concluded that none exists under federal law and have rejected the privilege as a basis of refusing to produce patient records.[285]

The physician-patient privilege objection has also been rejected because it was found not to apply to the facts of prescription drug cases. First, "the purpose of such a privilege is the protection of the patient and it cannot be asserted by the physician."[286] Second, the records sought are not privileged because they are not those of "patients."[287]

Professor Wigmore has articulated four conditions necessary to the establishment of a privilege against the disclosure of communications. They are:

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284. The privilege generally shields the physician from disclosing information received from patients in the course of treatment. *See, e.g.*, D.C. CODE ANN. § 14-307(a) (1981). The physician-patient privilege has been enacted in about three-fourths of the states. 2 WEINSTEIN & BERGER, WEINSTEIN'S EVIDENCE UNITED STATES RULES § 504[01] (1991).

285. Whalen v. Roe, 429 U.S. 40 (1977) (holding that there is no physician-patient privilege at common law); *Doe*, 711 F.2d at 1193 (same); United States v. Meagher, 531 F.2d 752, 753 (5th Cir.) (holding that no psychiatrist-patient privilege is recognized in federal criminal trials), *cert. denied*, 429 U.S. 853 (1976); United States v. Witt, 542 F. Supp. 696, 697-98 (S.D.N.Y.) (declining to recognize a physician-patient privilege), *aff'd without op.*, 697 F.2d 301 (2d Cir. 1982); Hardy v. Riser, 309 F. Supp. 1234, 1236-37 (N.D. Miss. 1970) (holding that physician testimony is not subject to physician-patient privilege). *See* United States v. Colletta, 602 F. Supp. 1322, 1327 (E.D. Pa.) (noting absence of federal common law physician-patient privilege), *aff'd without op.*, 770 F.2d 1076 (3d Cir. 1985); *In re* Verplank, 329 F. Supp. 433, 438 (C.D. Cal. 1971) (noting that the court was unable to find a case granting clear recognition of the physician-patient privilege).

The existence in the federal courts of a psychotherapist-patient privilege, different from the physician-patient privilege, is a matter of dispute. The Second and Sixth Circuits recognize the privilege. *See, e.g.*, *In re* John Doe, 964 F.2d 1325 (2d Cir. 1992) (recognizing psychotherapist-patient privilege); *In re* Zuniga, 714 F.2d 632, 639 (6th Cir.) (recognizing the existence of psychotherapist-patient privilege but ruling it inapplicable), *cert. denied*, 464 U.S. 983 (1983).

286. *In re* Jellen, 521 F. Supp. 251, 253 (N.D. W. Va. 1981) (quoting City & County of San Francisco v. Superior Court, 231 P.2d 26, 26 (Cal. 1951) (holding that the psychoanalyst-patient privilege may only be used to protect the patient)).

287. *E.g.*, *In re Doe*, 711 F.2d at 1194.

> (1) the communications must be made in the belief that it will not be disclosed; (2) confidentiality must be essential to the maintenance of the relationship between the parties; (3) the relationship should be one that society considers worthy of being fostered; and, (4) the injury to the relationship incurred by disclosure must be greater than the benefit gained in the correct disposal of litigation.[288]

In the situation where the patient's primary purpose in visiting the doctor is to illegally secure drugs rather than seek treatment, there is no physician-patient relationship and the privilege does not apply.[289] Furthermore, in the situation of a criminal investigation of drug abuse under these circumstances, the required balancing process generally favors the government.[290]

Even if the privilege were found to apply, it would not shield information regarding an office visit and the writing of a prescription.[291] The privilege is designed to protect communications from patients to their physicians that are necessary for the patients' treatment.

> The privilege is intended to protect only those communications that are necessary for obtaining the benefits of the professional relationship — in other words, for enabling the physician to prescribe remedies or relief.
>
> . . . .
>
> The mere fact of making a communication, as well as the date of the consultation and the number of the consultations are therefore not privileged from disclosure so long as the subject communicated is not stated.[292]

Claims that the production of such records invade the patient's privacy interests are also unsuccessful if it is found that "a person possesses no reasonable expectation that his medical history will remain completely confidential."[293] However, if the records relate to

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288. *Id.* at 1193 (citing 8 J. WIGMORE, EVIDENCE § 2285 (1961)).

289. *Id.*

290. *Id.; Witt*, 542 F. Supp. at 698. *See also Grand Jury Subpoena*, 710 F. Supp. at 1014 (holding that the psychotherapist-patient relationship does not apply when it is potentially criminal in nature).

291. *In re* Zuniga, 714 F.2d 632, 640-41 (6th Cir.) (finding the identity of the patient and the fact and time of his treatment not privileged), *cert. denied*, 464 U.S. 983 (1983).

292. 8 J. WIGMORE, EVIDENCE §§ 2383-2384 (1961).

293. *In re* Grand Jury Proceedings, John Doe, M.D., 801 F.2d 1164, 1169 (9th Cir. 1986) (per curiam).

treatment for drug or alcohol abuse in a federally funded program, a court order is required to obtain any patient records.[294]

C. *Indictment*

As outlined below, there has been significant debate over the appropriate form of a registrant's indictment under the CSA. Courts have taken differing positions on whether the crime was "distribution" or "dispensation," and whether there need be an allegation that the prescribing was outside of the usual course of medical practice. Based on the author's experience, the following wording appears sufficient to resolve all challenges that have been raised:

> On or about [date], within the [judicial district], [defendant][295] did knowingly, intentionally, and unlawfully distribute and dispense [and attempt to distribute and dispense] __ tablets of [drug — trade name and active ingredient], a Schedule ____ [narcotic drug] controlled substance pursuant to a prescription which was issued not in the usual course of professional practice for a legitimate medical reason, in violation of Title 21, United States Code, Section 841(a) and Title 21, Code of Federal Regulations, Section 1306.04.

1. Distribute or Dispense

The CSA defines distribution as "to deliver (other than administering or dispensing) a controlled substance or a listed chemical."[296] It further defines "deliver" as "the actual, constructive or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship."[297] The writing of a prescription constitutes the constructive or attempted transfer of a controlled substance because it is the necessary predicate to obtaining the drug. Therefore, physicians who write prescriptions that are not in the usual course of medical practice for a legitimate medical rea-

294. *See supra* note 285 and accompanying text.

295. Either in introductory language, or as part of the identification of the defendant, it should be alleged that the defendant was a person registered with the Drug Enforcement Administration to prescribe, distribute, and/or dispense controlled substances only in the usual course of medical practice for a legitimate medical reason. In the case of a pharmacist, it should be alleged that the prescription was issued by a physician in the usual course of his medical practice for a legitimate medical reason.

296. 21 U.S.C. § 802(11) (Supp. IV 1992).

297. 21 U.S.C. § 802(8) (Supp. IV 1992).

son "distribute" controlled substances — even though others need to take action by filling the prescription before the controlled substance actually comes into the possession of the "patient."

> [B]y creating the means by which controlled substances can be transferred, a doctor "distributes" within the meaning of 21 U.S.C. § 841(a) by the act of writing a prescription outside the usual course of professional practice and not for a legitimate medical purpose.[298]

In contrast, "dispense" means to deliver "pursuant to the lawful order of a practitioner, including the prescribing and administering . . ."[299] Reasoning from these "definitions," some courts have held that a registrant could only be charged with "dispensing" because that definition is restricted to the act of prescribing.[300] Others have concluded that the proper charge was "distributing" because "dispensing" included the lawful prescription of the drugs.[301]

The First, Sixth, and Ninth Circuits have agreed that the physician who delivers a controlled substance outside of the course of professional practice is guilty of "distribution" and not dispensing.[302] As the Ninth Circuit said in *United States v. Black*,[303]

> By definition "dispense" expressly contemplates a "lawful order;" if the order is not such, the prescription is not lawful under 21 U.S.C. § 829. If the prescription is not lawful, the "practitioner" does not dispense; rather, under § 802(11), he "distributes" — that is, he effects delivery "other than by dis-

298. United States v. Davis, 564 F.2d 840, 845 (9th Cir. 1977), *cert. denied*, 434 U.S. 1015 (1978); *see also* United States v. Ellzey, 527 F.2d 1306, 1308 (6th Cir. 1976) (holding that a physician who prescribed amphetamines without examining the patients was guilty of conspiring to distribute a controlled substance).

However, possession of a prescription is not equivalent to constructive possession of the drug described therein because there is no legal duty of a pharmacist to fill every prescription presented. United States v. Walker, 972 F.2d 679, 681 (6th Cir. 1992).

299. 21 U.S.C. § 802(10) (1988).

300. See *infra* note 309 and accompanying text for a discussion of circuits holding that a registrant can only be charged with dispensing.

301. *See infra* notes 302-08 and accompanying text.

302. United States v. Ellzey, 527 F.2d 1306, 1308 (6th Cir. 1976); United States v. Black, 512 F.2d 864, 866 (9th Cir. 1975); United States v. Badia, 490 F.2d 296, 298 (1st Cir. 1973) (per curiam).

303. 512 F.2d 864 (9th Cir. 1975).

pensing." In short, a "practitioner" who dispenses does not violate the Act.[304]

Other circuits disagree. In *United States v. Leigh*,[305] the Fifth Circuit determined that "dispensing" was the appropriate charge, sustaining the dismissal of an indictment which alleged that a physician "did knowingly and intentionally distribute and cause to be distributed . . . a controlled substance by means of a prescription . . . ."[306] The court, citing the definitions of "dispense" and "distribute," found that the indictment did not charge an offense within the applicable statute.[307] The court did not address the failure of the indictment to allege that the distribution was "unlawful" nor that the prescriptions were outside the scope of acceptable medical practice.[308]

The Third and Seventh Circuits both sustained convictions alleging "dispensing."[309] The Tenth Circuit sustained convictions for both "dispensing" and "distributing;"[310] it also concluded that

304. *Id.* at 866. *Accord Davis*, 564 F.2d at 844-45 (holding that a doctor who issues a prescription for a non-medical reason is guilty of distributing); United States v. Rosenberg, 515 F.2d 190, 200 (9th Cir.) (holding that a doctor who prescribed a controlled substance outside of the scope of his practice was guilty of distributing), *cert. denied*, 423 U.S. 1031 (1975).

305. 487 F.2d 206 (5th Cir. 1973).

306. *Id.* at 207.

307. *Id.* at 208.

308. In a subsequent case, the Fifth Circuit stated that the reason the physician in *Leigh* could not be indicted for distribution was because the indictment failed to allege that he unlawfully administered or prescribed the drug. United States v. Harrison, 651 F.2d 353, 354 n.1 (5th Cir. July 1981) (en banc), *reh'g denied*, 657 F.2d 1251 (5th Cir. Sept. 1981), *and cert. denied*, 454 U.S. 1126 (1981). The Fifth Circuit affirmed a conviction for illegal dispensing in United States v. Rogers, 609 F.2d 834, 840 (5th Cir. 1980).

309. United States v. Roya, 574 F.2d 386, 394 (7th Cir.) (sustaining the conviction for dispensing on the ground that the defendant physician prescribed the drugs outside of the course of his professional practice), *cert. denied*, 439 U.S. 857 (1978); United States v. Tighe, 551 F.2d 18, 21 (3d Cir.) (affirming the conviction of a physician for dispensing), *cert. denied*, 434 U.S. 823 (1977).

310. United States v. Smurthwaite, 590 F.2d 889, 892 (10th Cir. 1979) (sustaining convictions for dispensing and distributing); United States v. Fellman, 549 F.2d 181, 183 (10th Cir. 1977) (sustaining conviction for distributing); United States v. Jobe, 487 F.2d 268, 270 (10th Cir. 1973) (sustaining conviction for distributing), *cert. denied*, 416 U.S. 955 (1974); United States v. Bartee, 479 F.2d 484, 489 (10th Cir. 1973) (sustaining conviction for dispensing).

there was no difference between the two for double jeopardy purposes.[311]

After the Supreme Court decision in *United States v. Moore*,[312] the Fifth Circuit sustained the conviction of a physician for illegal "distribution."[313] Although the case contains no reference to the court's previous decision in *Leigh*, the Fifth Circuit cited *Moore* for the proposition that a physician could be prosecuted for dispensing or distributing.[314] In a later case, *United States v. Thompson*,[315] the Fifth Circuit considered and rejected the argument that a physician was improperly charged with dispensing instead of distributing.[316] The court noted, however, that even if the indictment was incorrect, Thompson suffered no prejudice from the mistake.[317] Finally, the Fifth Circuit explained the rationale of its *Leigh* decision in *United States v. Harrison*.[318] In *Harrison*, the court stated:

> Here the indictment charged distribution that was "unlawful" and "for other than a legitimate medical purpose and not in the usual course of medical practice." This states an offense. The allegations present in this case protect the doctor from exposure to criminal prosecution for errors of judgment as to the amount prescribed and as to the necessity for the prescription.[319]

More recently, the Fifth Circuit affirmed a conviction that charged unlawful distribution and dispensation.[320]

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311. United States v. Genser, 710 F.2d 1426 (10th Cir. 1983). Genser, a non-practitioner, was indicted for "dispensing." The charge was dismissed during his trial because he was not a practitioner and therefore could not be convicted for "dispensing." His subsequent indictment for "distributing" was ordered dismissed by the court of appeals on double jeopardy grounds.

312. 423 U.S. 131 (1975).

313. United States v. Dunbar, 614 F.2d 39 (5th Cir.) (per curiam), *cert. denied*, 447 U.S. 926 (1980).

314. *Id.* at 41.

315. 624 F.2d 740 (5th Cir. 1980).

316. *Id.* at 741-42.

317. *Id.* at 742 n.2.

318. 651 F.2d 353 (5th Cir. July 1981), *cert. denied*, 454 U.S. 1126 (1981). The indictment charged a doctor with "unlawfully and knowingly distribut[ing] and caus[ing] to be distributed a controlled substance for other than a legitimate medical purpose and not in the usual course of professional practice." *Id.* at 353.

319. *Id.* at 354-55.

320. United States v. Schuster, 777 F.2d 264, 266 (5th Cir.), *vacated*, 778 F.2d 1132 (5th Cir. 1985).

While most pharmacists appear to have been charged with illegal distribution,[321] some have been charged with illegal dispensing.[322] The only court to address this distinction held that a pharmacist had been incorrectly charged with distributing instead of dispensing, but held that such error was harmless. In *United States v. Nechy*,[323] the Seventh Circuit held that Nechy, a pharmacist, was a "dispenser."[324] The court, after citing the definition of "dispensing" as meaning "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 . . . of a controlled substance," stated:

> Since "practitioner" includes a pharmacist licensed to dispense a controlled substance, see § 802(20), the fact that Nechy was not acting under the lawful order (valid prescription) of a doctor does not prevent him from being deemed an illegal dispenser, just as a doctor would be a dispenser if he gave a drug to a patient even though the doctor would not be doing so "pursuant to the lawful order of" anyone. . . . Since Nechy was a dispenser, and since under the statute a dispenser cannot also be a distributor — "The term 'distribute' means to deliver (*other than by* administering or *dispensing*) a controlled substance," § 802(11) — [defendant] was indicted and convicted for a different offense from the one he committed.[325]

The court held, however, that the variance between the indictment that charged distribution and the proof was harmless.[326] The court did not state that an indictment so worded should be dismissed.

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321. United States v. Hammond, 781 F.2d 1536, 1537 (11th Cir. 1986); United States v. Lartey, 716 F.2d 955, 957 (2d Cir. 1983); United States v. Lawson, 682 F.2d 480, 481 (4th Cir.), *cert. denied*, 459 U.S. 991 (1982); United States v. Seelig, 622 F.2d 207, 209 (6th Cir.), *cert. denied*, 449 U.S. 869 (1980); United States v. Schiffman, 572 F.2d 1137, 1138 (5th Cir. 1978); United States v. Kershman, 555 F.2d 198, 199 (8th Cir.), *cert. denied*, 434 U.S. 892 (1977); United States v. Goldfine, 538 F.2d 815, 817 (9th Cir. 1976); United States v. Green, 511 F.2d 1062, 1064 (7th Cir.), *cert. denied*, 423 U.S. 1031 (1975).

322. United States v. Henry, 749 F.2d 203, 206 (5th Cir. 1984) (en banc); United States v. Irwin, 661 F.2d 1063, 1066 (5th Cir. Nov. 1981), *cert. denied*, 456 U.S. 907 (1982).

323. 827 F.2d 1161 (7th Cir. 1987).

324. *Id.* at 1169.

325. *Id.* at 1168-69 (citations omitted; emphasis original). Nechy was indicted and convicted for a different offense than the one that he committed. *Id.*

326. *Id.* at 1169.

2. Outside the Usual Course of Accepted Medical Practice

There is a split in authority as to the necessity of an allegation in the indictment that the defendant acted outside the usual course of professional practice. As noted above, the distribution or dispensing by a practitioner of a controlled substance is only illegal if done outside of the usual course of medical practice or pursuant to a prescription that was so issued.[327] However, the statute provides:

> It shall not be necessary for the United States to negative any exemption or exception set forth in this subchapter in any complaint, information, indictment, or other pleading or in any trial, hearing, or other proceeding under this subchapter, and the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit.[328]

In *United States v. Black*,[329] the Ninth Circuit held that this provision, at most, requires the practitioner to present evidence that he is a "practitioner" — evidence that is generally brought out in the government's case-in-chief.[330] Once such evidence has been produced, the burden shifts to the government to prove that the prescriptions were not issued in the usual course of medical practice.[331] The practitioner is not required to show that the prescriptions were issued in the usual course of medical practice.[332] The court stated that "[section] 885(a)(1) effectively creates a presumption dictating that any transfer of a controlled substance is non-authorized and consequently criminal unless the accused introduces some evidence that the transfer is lawful under the statute."[333]

In *United States v. King*,[334] the Ninth Circuit cited *Black* for the proposition that lack of authorization to distribute or dispense is an element of the crime.[335] In *Black*, the Ninth Circuit held that the indictment of a registrant must allege that the distribution was with-

327. *See supra* notes 28-52 and accompanying text.

328. 21 U.S.C. § 885(a)(1) (1988).

329. 512 F.2d 864 (9th Cir. 1975).

330. *Id.* at 869.

331. See *infra* notes 361-66 and accompanying text for a discussion of the burden of proof.

332. *Black*, 512 F.2d at 870.

333. *Id.* at 868.

334. 587 F.2d 956 (9th Cir. 1978).

335. *Id.* at 963.

out authorization even if the case does not involve allegations relating to the individual's professional practice.[336] The indictment charged a conspiracy to possess with intent to distribute cocaine in a "street" sale.[337] The physician defendant was identified as a doctor in the indictment when it named him as "Stanley E. Deal, M.D."[338] The doctor allegedly distributed an unknown quantity of cocaine.[339] The Ninth Circuit held that lack of authorization is an essential element of the offense and the failure to charge it required a reversal of the doctor's conviction.[340]

The next court to consider this question, the Seventh Circuit, came to a different result. In *United States v. Roya*,[341] the indictment included language that the defendant dispensed "pursuant to a prescription not written in the course of professional practice."[342] After ruling that the inclusion of this language without citation to the regulation from which it came does not make the indictment impermissibly vague, the Seventh Circuit went on to hold that the language was unnecessary.[343] The court held that when an indictment is founded on a general provision of a statute, it need not negative an exception made by a proviso or other distinct clause, whether in the same section or elsewhere.[344]

The Fifth Circuit, after considering both *King* and *Roya*, adopted the Ninth Circuit's position, holding that the language is required. In *United States v. Outler*,[345] the Fifth Circuit held that the absence of an allegation that the prescription lacked a legitimate medical reason was fatal to the indictment, and required dismissal because there was no assurance that the grand jury had found probable cause as to this element.[346] The court reasoned that lack of a legiti-

336. *Id.* at 963-64.

337. *Id.* at 963. The indictment did not allege in either the general conspiracy language or in the overt act that Dr. Deal "illegally" distributed controlled substances or that he intended to "illegally" possess with intent to distribute.

338. *Id.*

339. *Id.*

340. *Id.* at 963-64.

341. 574 F.2d 386 (7th Cir.), *cert. denied*, 439 U.S. 857 (1978).

342. *Id.* at 390.

343. *Id.*

344. *Id.* at 391.

345. 659 F.2d 1306 (5th Cir. Unit B Oct. 1981), *cert. denied*, 455 U.S. 950 (1982).

346. *Id.* at 1311.

mate medical purpose was an "essential element" of the offense because it "embodies the culpability of the offense. Without behavior beyond professional practice, there is no crime."[347]

The Sixth Circuit took a different approach. In *United States v. Seelig*,[348] a group of pharmacists was charged with distribution of certain drugs in violation of 21 U.S.C. § 841(a) through the illegal refilling of prescriptions.[349] Noting that "the allegation of distribution in violation of § 841(a)(1) includes the legal definition that the drugs were not dispensed, i.e., distributed in the usual course of professional practice,"[350] the court held that the specific language "not in the usual course of professional practice" did not need to be included in the indictment.[351]

In the most recent decision on this point, the Third Circuit in *United States v. Polan*[352] held that an indictment need not expressly allege that the drug distribution was not authorized under the Act or was not in the usual course of professional practice.[353] The court's opinion was based on the statutory language set out at the beginning of this section[354] and the Supreme Court's decision in *McKelvey v. United States*.[355] The Third Circuit rejected the contrary decisions of the Ninth and Fifth Circuits primarily because of their failure to cite the statutory language set forth above, adopting instead the rea-

347. *Id.* at 1309.

348. 622 F.2d 207 (6th Cir.), *cert. denied*, 449 U.S. 869 (1980).

349. *Id.* at 211.

350. *Id.*

351. *Id.* at 212.

352. 970 F.2d 1280 (3d Cir. 1992), *cert. denied*, 113 S. Ct. 1367 (1993).

353. *Id.* at 1282.

354. *See supra* note 344 and accompanying text.

355. 260 U.S. 353 (1922). The Third Circuit quoted the following language from *McKelvey*:

> By repeated decisions it has come to be a settled rule in this jurisdiction that an indictment or other pleading founded on a general provision defining the elements of an offense, or of a right conferred, need not negative the matter of an exception made by a proviso or other distinct clause, whether in the same section or elsewhere, and that it is incumbent on one who relies on such an exception to set it up and establish it.

970 F.2d at 1282 (quoting *McKelvey*, 260 U.S. at 357 (1922)).

soning of the Seventh Circuit in *Roya* as well as the cases decided under the predecessor statute.[356]

A requirement that the indictment expressly negative the exemption seems to be the stronger position. Indictments of practitioners raise the fact of the defendant's practitioner status on the face of the indictment either through identifying the defendant as a doctor in the caption or through descriptive language elsewhere. Even in *King,* which alleged a street level conspiracy, the physician was identified in the indictment as an "M.D."[357] Once the defendant's status as a practitioner has been raised, the case falls outside of the situation addressed by the statutory language and it becomes incumbent upon the government to allege that the defendant's activities were outside of his practitioner status. So charging, however, does not require use of language "outside of the usual course of professional practice," although certainly it appears to be preferred. The Third Circuit in *Polan* noted that the indictment's allegations that the defendant acted "unlawfully" and that he "distributed" both show that the act of prescribing was "not 'authorized' under the federal drug laws and did not occur in the course of the defendant's professional practice."[358]

3. Counts

Each separate illegal prescription represents a different criminal act even when they are issued to the same person on the same day.[359] Thus, each may be charged as a separate count in the indictment.[360]

D. *Trial*

The government bears the burden of proving beyond a reasonable doubt that prescriptions issued by a physician were not issued in the

356. *Polan*, 970 F.2d at 1283. The Third Circuit cited United States v. Collier, 478 F.2d 268, 273 (5th Cir. 1973), and United States v. Rowlette, 397 F.2d 475, 479 (7th Cir. 1968), as cases decided under the predecessor statute.

357. *King*, 587 F.2d at 963.

358. *Polan*, 970 F.2d at 1283.

359. *E.g.,* United States v. Thompson, 624 F.2d 740, 743 (5th Cir. 1980); United States v. Davis, 564 F.2d 840, 847 (9th Cir. 1977), *cert. denied*, 434 U.S. 1015 (1978); United States v. Krasnoff, 480 F. Supp. 723, 730 (S.D.N.Y. 1979).

360. *See supra* note 359.

usual course of medical practice for a legitimate medical reason.[361] The elements that must be proven are:

> (1) that [the defendant] distributed or dispensed a controlled substance, (2) that he acted knowingly and intentionally, and (3) that he did so other than for a legitimate medical purpose and in the usual course of his professional practice.[362]

Generally, only the third element is truly at issue.

The government need not prove that the illegally issued prescription was actually filled; the placing of such a prescription in the hands of an ultimate user completes the offense.[363] Generally, to avoid any confusion by the jury on this point, the prescriptions obtained from a physician during an undercover operation are either in fact filled, or the indictment charges both distribution and an attempt to distribute the controlled substance called for on the prescription.[364]

For a pharmacist, the government must show that the defendant, charged with filling prescriptions not issued in the usual course of medical practice, knew that they were so issued.[365] This element of knowledge may be inferred by the jury from proof that the pharmacist deliberately closed his eyes to the true nature of the prescription.[366]

1. Testimonial Issues

a. Admissibility of Prescriptions Not Charged In the Indictment

The prosecution often seeks to admit into evidence prescriptions in addition to those specifically related to charges in the indictment.

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361. United States v. Black, 512 F.2d 864 (9th Cir. 1975).

362. United States v. Rosen, 582 F.2d 1032, 1033 (5th Cir. 1978).

363. United States v. Tighe, 551 F.2d 18, 21 (3d Cir.), *cert. denied*, 434 U.S. 823 (1977).

364. United States v. Green, 511 F.2d 1062 (7th Cir.), *cert. denied*, 423 U.S. 1031 (1975) (holding that writing a prescription is all that is required for an attempt). Attempt carries the same potential penalty as the completed act. 21 U.S.C. § 846 (1984).

365. United States v. Hughes, 895 F.2d 1135, 1143 n.11 (6th Cir. 1990); United States v. Lawson, 682 F.2d 480, 482 (4th Cir.), *cert. denied*, 459 U.S. 991 (1982); United States v. Hayes, 595 F.2d 258, 260 (5th Cir.), *cert. denied*, 444 U.S. 856 (1979).

366. *Lawson*, 682 F.2d at 482; United States v. Seelig, 622 F.2d 207, 213 (6th Cir.), *cert. denied*, 449 U.S. 869 (1980); United States v. Kershman, 555 F.2d 198, 200 (8th Cir.), *cert. denied*, 434 U.S. 892 (1977).

Generally, these prescriptions are either additional prescriptions written for individuals named in the indictment as recipients of illegal prescriptions or prescriptions written for the same or similar controlled substances as those mentioned in the indictment.[367]

Prescriptions offered to prove that they were used to obtain the drug indicated are not hearsay. Since uncharged prescriptions are considered "other crimes evidence," Rule 404(b) of the Federal Rules of Evidence controls their admissibility. Rule 404(b) states:

> Evidence of other crimes, wrongs, or acts is not admissible to prove the character of a person in order to show that he acted in conformity therewith. It may, however, be admissible for other purposes, such as proof of motive, opportunity, intent, preparation, plan, identity or absence of mistake or accident.[368]

Rule 404(b) requires a balancing test. The trial court must determine "whether the danger of undue prejudice outweighs the probative value of the evidence" in ruling on its admissibility.[369]

For example, additional prescriptions are generally offered to show motive, intent, and absence of mistake or accident.[370] Given the government's burden of showing that the charged prescriptions were not issued in the usual course of professional treatment for a legitimate medical reason, the additional prescriptions become relevant and are generally admitted.[371]

Additional prescriptions issued to "patients" named in the indictment have been held admissible. In both *United States v. Bartee*[372] and *United States v. Greenfield,*[373] the courts approved testimony

367. *E.g.*, United States v. Seelig, 622 F.2d 207 (6th Cir.), *cert. denied*, 449 U.S. 869 (1980).

368. FED. R. EVID. 404(b).

369. *Id. See generally* 2 WEINSTEIN & BERGER, WEINSTEIN'S EVIDENCE UNITED STATES RULES § 404[18] (1991).

370. United States v. Stump, 735 F.2d 273, 275 (7th Cir.) (admitting evidence of additional prescriptions to show intent, opportunity, plan, preparation, and lack of mistake), *cert. denied*, 469 U.S. 864 (1984); United States v. Harrison, 651 F.2d 353, 355 (5th Cir. July 1981), *cert. denied*, 454 U.S. 1126 (1981) (plan, design, or scheme); United States v. Rogers, 609 F.2d 834, 839 (5th Cir. 1980) (intent, knowledge, motive, willfulness, plan, and scheme); United States v. Ellzey, 527 F.2d 1306, 1307-08 (6th Cir. 1976) (intent and willfulness); United States v. Abdallah, 149 F.2d 219, 223 (2d Cir.) (bad faith), *cert. denied*, 326 U.S. 724 (1945); Melanson v. United States, 256 F. 783, 786 (5th Cir. 1919) (bad faith).

371. *See, e.g., Harrison*, 651 F.2d at 355.

372. 479 F.2d 484 (10th Cir. 1973).

373. 574 F.2d 305 (5th Cir.), *cert. denied*, 439 U.S. 860 (1978).

about visits to the defendant physician before and/or after the indicted instances. The *Greenfield* court noted that such testimony was "clearly material to the question whether [Greenfield's] continuing prescriptions for the same patient . . . were for a legitimate medical purpose. The evidence was not inflammatory, the judge issued a proper limiting instruction. . . ."[374]

However, where a patient was unsure which of the prescriptions written to him were legitimate and which were not, the trial court refused to allow admission of those additional prescriptions about which the patient had no clear recollection.[375] When the government could not establish a prima facie case that these prescriptions had been issued illegally,[376] the court, upon a motion for reconsideration, allowed admission of the prescriptions knowingly written under fictitious names because the illegality, and recollection thereof, was clear.[377]

Prescriptions written for persons other than those mentioned in the indictment are also offered to show that the charged registrant is operating outside the usual course of medical practice.[378] Thus, prescriptions may be offered to show that the doctor was freely prescribing controlled substances not commonly prescribed within the medical community;[379] that the defendant was involved in a continuing scheme of unlawful practice outside the scope of a legitimate medical practice spanning a single period of time;[380] that the physician was prescribing controlled substances over inappropriate lengths of time or for inappropriate diseases;[381] that the physician was prescribing a "grab-bag" of controlled substances to particular patients;[382] and that a substantial part of the physician's practice was devoted to writing prescriptions for controlled substances which ex-

374. *Id.* at 308.

375. United States v. Jamieson, 605 F. Supp. 119, 123-25 (D. Kan. 1985).

376. *Id.* at 121.

377. *Id.* at 124-25.

378. *E.g.*, United States v. Rogers, 609 F.2d 834 (5th Cir. 1980). *See also* United States v. Seelig, 622 F.2d 207 (6th Cir.) (applying rule to pharmacists), *cert. denied*, 449 U.S. 869 (1980).

379. Use of such prescriptions as evidence has been observed by the author in his personal experience.

380. United States v. Stump, 735 F.2d 273, 275 (7th Cir.), *cert. denied*, 469 U.S. 864 (1984).

381. *See supra* note 379.

382. *See supra* note 379.

pert testimony shows is contrary to the usual course of medical practice.[383]

The mass of evidence offered under these circumstances has been substantial.[384] For instance, in *United States v. Ellzey*,[385] the prosecution offered into evidence three suitcases containing 29,000 prescriptions.[386] The government also introduced a survey of amphetamine prescriptions that had been filled in six local drug stores.[387] The survey showed that a total of 39,000 prescriptions for Schedule II controlled substances had been written by 152 physicians and dentists over 22 months.[388] Of those 39,000 prescriptions, Dr. Ellzey had written 29,000, and all but 200 of his Schedule II prescriptions were for amphetamines or amphetamine-like drugs.[389] The trial court admitted these additional prescriptions as relevant to issues of intent and willfulness and gave a limiting instruction.[390] The Sixth Circuit found no error.[391]

In *United States v. Jackson*,[392] the prosecution offered 5,000 prescriptions written over a 15-month period that were unrelated to the

383. Experts have expressed the opinion that, on average, general practitioners do not write more than 50% of their prescriptions for controlled substances and that the percentage reaches that level only because of the common prescribing of Darvon and Valium. *See* United States v. Hammond, 781 F.2d 1536, 1537 (11th Cir. 1986) (noting expert testimony that prescription practice consisting of 90% controlled substances was "outrageously high and dramatically out of line with the practice of other physicians").

384. United States v. Coward, 669 F.2d 180 (4th Cir.), *cert. denied*, 456 U.S. 946 (1982) (concerning 800 prescriptions written by the defendant doctor and filled by the defendant pharmacist); United States v. Jackson, 576 F.2d 46, 49 (5th Cir. 1978); United States v. Ellzey, 527 F.2d 1306, 1307 (6th Cir. 1976). *See also* United States v. Henry, 727 F.2d 1373, 1377-78 (5th Cir.) (allowing introduction of additional prescriptions filled by defendant pharmacist for testifying "patient" to show knowledge of absence of legitimate medical need for the controlled substances charged in the indictment), *rev'd on other grounds*, 749 F.2d 203 (5th Cir. 1984) (en banc).

385. 527 F.2d 1306 (6th Cir. 1976).

386. *Id.* at 1307.

387. *Id.*

388. *Id.*

389. *Id.*

390. *Ellzey*, 527 F.2d at 1307. The limiting instruction given is not set forth in the appellate opinion.

391. *Id. See also* United States v. Devous, 764 F.2d 1349, 1351 (10th Cir. 1985) (noting testimony that the Demoral ordered by the defendant physician for "office use" in his office in a small town was more than that used at the hospital in a nearby bigger town).

392. 576 F.2d 46 (5th Cir. 1978).

charges in the indictment.[393] The Fifth Circuit ruled that the prescriptions were relevant to prove motive because they helped to establish that Dr. Jackson was "in the business of writing prescriptions for drugs commonly used 'on the street.' Moreover, each prescription was for twenty-four tablets [of Quaaludes] and each was filled at the same pharmacy."[394]

Prescriptions other than those charged in the indictment have been offered against pharmacists as well. In *United States v. Henry*,[395] the prosecution offered prescriptions that were written by a physician other than the one whose prescriptions formed the basis of the indictment.[396] The trial court approved the additional prescriptions as showing:

> [T]he relationship between the defendant and the doctor, to impeach defendant's testimony that he had no knowledge of the confidential informant's intention to misuse the drugs, and generally to show acts substantially identical to the charged offenses.[397]

The Fifth Circuit affirmed the trial court's acceptance of the prescriptions.[398]

The admission of other prescriptions, however, cannot be allowed to overwhelm the charges in the indictment and to bootstrap an otherwise weak case. In *United States v. Jones*,[399] Dr. Jones was charged with two counts of illegally distributing Quaaludes to an undercover police officer.[400] The government offered 478 prescriptions written over a 20-month period for Schedule II drugs other than Quaaludes.[401] The government also offered testimony that many of the people for whom these prescriptions had been written had "recognizable track marks."[402] The Eighth Circuit noted, how-

393. *Id.* at 49.

394. *Id.*

395. 727 F.2d 1373 (5th Cir.), *rev'd on other grounds*, 749 F.2d 203 (5th Cir. 1984) (en banc).

396. *Id.* at 1377.

397. *Id.*

398. *Id.* at 1378. *See also* United States v. Seelig, 622 F.2d 207, 214 (6th Cir.) (noting 32 sales charged, while evidence of 1,409 sales offered), *cert. denied*, 449 U.S. 869 (1980).

399. 570 F.2d 765 (8th Cir. 1978).

400. *Id.* at 766.

401. *Id.* at 767.

402. *Id.*

ever, that "the prosecution did not introduce any evidence concerning the doctor-patient relationship existing with respect to these prescriptions, nor did it present other proof that the prescriptions had not been issued for a proper medical purpose."[403] The court ruled that "[a]bsent any evidence bearing upon Dr. Jones' treatment of the patients in question, issuance of the prescriptions without more does not show that Dr. Jones acted unprofessionally in using these prescriptions," and their admission was error.[404]

Summaries are sometimes offered in the form of charts or testimony because of the large volume of prescriptions at issue.[405] This evidence can summarize transactions involving named individuals, or demonstrate that other physicians are not writing or other pharmacists are not filling such prescriptions in the quantities in which they are written or filled by the defendant. For instance, in *United States v. Hammond*,[406] the government offered evidence showing that the defendant's pharmacy purchased 82.3% of the Diderex sold in a wholesale sales territory comprised of 66 pharmacies, 35.2% of that sold in north Georgia, and 19.5% of that sold in the entire state.[407] Furthermore, the volume sold at the defendant pharmacy was compared to two other pharmacies in the same town.[408] In one year, Hammond's pharmacy sold 512,500 tablets, compared to 2,700 and 5,200 for the other pharmacies.[409] In another case, the government used summaries to prove that over a two-year period the pharmacy had received over 40,000 tablets of Talwin, approximately 20% of the amount prescribed in the State of Illinois during that period.[410]

Under Rule 1006 of the Federal Rules of Evidence, evidentiary summaries are permissible where a case involves "voluminous writings . . . which cannot be conveniently examined in court."[411] However, Rule 1006 requires that the underlying material be made

403. *Id.* at 768.

404. *Jones*, 570 F.2d at 768.

405. *E.g.*, United States v. Hammond, 781 F.2d 1536, 1538 (11th Cir. 1986).

406. 781 F.2d 1536 (11th Cir. 1986).

407. *Id.* at 1538.

408. *Id.*

409. *Id.*

410. United States v. Roth, 777 F.2d 1200, 1201 (7th Cir. 1985).

411. FED. R. EVID. 1006.

available to all parties for inspection and copying.[412] In order to introduce evidence of such a summary, a proper foundation must be laid through the testimony of the witness who supervised its preparation.[413] To meet the foundation requirement, the government generally offers testimony about the seizure of the prescriptions being summarized, the determination of which prescriptions were to be summarized, and the preparation of the information on the chart so that it accurately reflects the information contained on the prescriptions.[414] Although such evidence is admissible if properly prepared and fairly presented,[415] the trial court should generally give a limiting instruction indicating that the summaries are merely aids in evaluating evidence, and not evidence in and of themselves.[416]

When the summary evidence offered is comparative, the comparisons must be valid.[417] In two cases involving doctors, courts approved comparisons of the volume of their Schedule II prescriptions filled at particular pharmacies to that of other doctors whose prescriptions were filled at those same pharmacies.[418] In a case involving a podiatrist, testimony was elicited comparing the amount of the drug hydrocodone ordered by the defendant to the amount ordered by other podiatrists in his state as well as by the average pharmacy, hospital, and physician in the United States.[419] In contrast, in a case concerning a summary comparison of the amount of drugs dis-

412. *Id.*

413. United States v. Scales, 594 F.2d 558, 563 (6th Cir.), *cert. denied*, 441 U.S. 946 (1979).

414. *See, e.g.*, United States v. Behrens, 689 F.2d 154, 161 (10th Cir.), *cert. denied sub nom.* Wilkett v. United States, 459 U.S. 1088 (1982).

415. United States v. Schuster, 777 F.2d 264, 269 (5th Cir.) (admitting chart that recompiled prescriptions to correspond with counts of the indictment together with explanations of the drug usages, potencies, and side effects), *vacated*, 778 F.2d 1132 (5th Cir. 1985); *Behrens*, 689 F.2d at 154, 161; *Seelig*, 622 F.2d at 214; United States v. Kirk, 584 F.2d 773 (6th Cir.), *cert. denied*, 459 U.S. 1048 (1978); *Ellzey*, 527 F.2d at 1308. *See also Scales*, 594 F.2d at 563-64.

416. *E.g.*, *Seelig*, 622 F.2d at 214.

417. *Compare Kirk*, 584 F.2d at 773, *and Ellzey*, 527 F.2d at 1306, *with Seelig*, 622 F.2d at 215-16 (holding that inappropriate comparisons constitute prejudicial error).

418. *Kirk*, 584 F.2d at 773; *Ellzey*, 527 F.2d at 1306.

419. United States v. August, 984 F.2d 705, 713 (6th Cir. 1992), *cert. denied*, 1993 U.S. LEXIS 5521 (U.S. Oct. 4, 1993). Dr. August did not challenge this testimony on appeal. The testimony was clearly relevant given the size of the disparity: August ordered 99% of the drug ordered by all podiatrists in the state. 984 F.2d at 708.

pensed by the target pharmacy with that of others, the comparison was disallowed because the prosecution failed to prove that all of the pharmacies were truly comparable in terms of hours, clientele, and total sales.[420]

b. Judicial Notice

The government sometimes seeks to streamline its presentation by requesting that the court take judicial notice of certain uncontrovertible facts.[421] In particular, the government may ask the court to take judicial notice of the appropriate DEA regulations or the fact that certain brand name drugs contain controlled substances that appear on particular schedules.[422]

Rule 201 of the Federal Rules of Evidence governs judicial notice of "adjudicative facts," the facts of a particular case. Rule 201(b) provides that a judicially noticed fact "must be one not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned."[423] A court *may* take judicial notice, whether requested or not, but *shall* take judicial notice if requested by a party and supplied with the necessary information.[424] However, a party is entitled to be heard as to the propriety of taking judicial notice.[425] In a criminal case, the jury is instructed that "it

420. *Seelig*, 622 F.2d at 215-16.

421. Judicial notice is that process by which a court may declare certain propositions to be proven, on the basis of general policy considerations, without requiring evidence of the same. It relieves a part of the burden of offering evidence of a particular fact since judicial notice of that fact is the same as proof of it and has equal force. Ricaud v. American Metal Co., 246 U.S. 304 (1918).

422. United States v. Wisniewski, 741 F.2d 138, 142 (7th Cir. 1984) (concerning certain drug on Schedule I); United States v. Harrison, 651 F.2d 353, 355 (5th Cir. July 1981) (noticing that the generic names of the four drugs charged were listed in the C.F.R. schedules for controlled substances).

These facts have also been proven by expert testimony, United States v. Dunbar, 614 F.2d 39, 41 (5th Cir.), *cert. denied*, 447 U.S. 926 (1980), and through stipulation, United States v. Boettjer, 569 F.2d 1078, 1079 (9th Cir.), *cert. denied*, 435 U.S. 976 (1978).

423. FED. R. EVID. 201(b).

424. FED. R. EVID. 201(c), (d).

425. FED. R. EVID. 201(e).

may, but is not required, to accept as conclusive any fact judicially noticed."[426]

Courts are required to take judicial notice of the DEA regulations as well as the presence within the various schedules of certain drugs because they are published as part of the Federal Register.[427] The fact that those drugs are contained in the brand name controlled substances for which prescriptions were written is a matter that is easily proven and beyond dispute, and is therefore appropriate for judicial notice.[428]

c. Proof of the Identity of the Drug

Where possible, the prosecution of a registrant is based, in part, on prescriptions that were filled in an undercover operation so that the drug obtained can be chemically analyzed and produced in court.[429] At other times, it may become necessary to prove that the drug called for in a prescription was actually dispensed. This is necessary to prove that it was not actually some other drug that was dispensed, even though the act of dispensing is long past and the drugs long gone.[430] In these circumstances, the proof offered consists of testimony relating to how such drugs are obtained, safeguarded, and dispensed in the ordinary course of business. For example, in *State v. Espinosa*,[431] the court summarized the pharmacist's testimony in a case where the government sought to prove that

426. FED. R. EVID. 201(g). In civil cases, the jury is instructed that it shall accept as conclusive any fact judicially noticed. *Id.*

427. 44 U.S.C. § 1505(a) (1992); *see generally* 2 WEINSTEIN & BERGER, WEINSTEIN'S EVIDENCE UNITED STATES RULES § 200[02] (1991).

428. United States v. Harrison, 651 F.2d 353, 355 (5th Cir. July 1981) (noticing that the generic names of the four drugs charged were listed in the C.F.R. schedules for controlled substances).

429. *See* Lane, *supra* note 253 (discussing methods of organizing and using evidence obtained during undercover operations).

430. *E.g.*, Smith v. State, 249 S.E.2d 353, 355 (Ga. App. Ct. 1978) (accepting as sufficient evidence testimony that appellant took drugs from labelled bottle); People v. Nelson, 225 N.E.2d 820, 823-24 (Ill. App. Ct. 1967) (finding that drug containers obtained by the defendant were labelled by manufacturer), *aff'd*, 238 N.E.2d 378 (Ill. 1968); State v. Wagner, 85 So.2d 272, 273 (La. 1956) (finding that the State satisfied its obligation by showing the narcotic passed from the hands of a physician to the defendant); State v. Espinosa, 66 So.2d 323, 326 (La. 1953) (finding that the State satisfied its obligation by tracing the narcotic from its source into the hands of the defendant).

431. 66 So.2d 323 (La. 1953).

the defendant had in fact obtained Dilaudid pursuant to a prescription found in a pharmacy. The pharmacist who filled the prescription testified that the Dilaudid:

> [h]ad been obtained by her from the wholesale drug firm of McKesson and Robbins upon her filling out and tendering to them an official narcotic form; . . . that upon receiving same . . . she placed the Dilaudid tablets in a narcotic drawer; that she was the sole custodian of the narcotic drawer which she kept under lock and key, and that the Dilaudid tablets . . . handed over by her to the defendant were taken from the original receptacle which she had personally received from McKesson and Robbins.[432]

The use of such circumstantial evidence is sufficient to prove the nature and quantity of the drug in question.[433]

d. Expert Testimony

The jury's determination of whether a registrant's professional practice is *bona fide* is based on the evidence relating to the particular transactions charged and surrounding circumstances.[434] The failure to act within the usual course of medical practice for a legitimate medical purpose is usually proven, in part, through expert testimony.[435] The use of expert testimony to establish the standard of medical practice is widely accepted in cases involving physicians[436] and pharmacists.[437] As one court noted, "[T]o reach its decision the jury needed medical testimony as to what the drug is, how it is prop-

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432. *Id.* at 326.

433. *E.g.*, United States v. Iacoppelli, 483 F.2d 159, 161 (2d Cir. 1973).

434. United States v. Collier, 478 F.2d 268, 272 (5th Cir. 1973) (quoting Linder v. United States, 268 U.S. 5, 18 (1925)).

435. *E.g.*, United States v. Davis, 564 F.2d 840, 845 (9th Cir. 1977), *cert. denied*, 434 U.S. 1015 (1978); United States v. Bartee, 479 F.2d 484, 488 (10th Cir. 1973).

436. *E.g.*, United States v. Hughes, 895 F.2d 1135, 1145 (6th Cir. 1990); United States v. Kaplan, 895 F.2d 618, 620 (9th Cir. 1990) (including expert testimony by both prosecution and defense); United States v. Betancourt, 734 F.2d 750, 757 (11th Cir. 1984); United States v. Varma, 691 F.2d 460, 462 (10th Cir. 1982); United States v. Smurthwaite, 590 F.2d 889, 891 (10th Cir. 1979) (involving a physician specializing in naturopathy). *See also* United States v. Vamos, 797 F.2d 1146, 1153 (2d Cir. 1986), *cert. denied*, 479 U.S. 1036 (1987); United States v. Guerrero, 650 F.2d 728, 732 (5th Cir. Unit A July 1981); White v. United States, 399 F.2d 813, 819-20 (8th Cir. 1968); Reeves v. United States, 263 F. 690, 691-92 (5th Cir. 1920); Melanson v. United States, 256 F. 783, 786 (5th Cir. 1919).

437. *Hughes*, 895 F.2d at 1142; United States v. Lawson, 682 F.2d 480, 482 (4th Cir.), *cert. denied*, 459 U.S. 991 (1982).

erly used, how it can be abused and the medical profession's view of the drug."[438] Additionally, given the professional status of the defendant the government almost universally offers expert testimony to overcome any appearance of legitimacy that status alone may confer on the defendant, and to reinforce its case with the jury.[439] However, expert testimony is not required for a successful prosecution;[440] and when offered, the jury is not bound to accept that testimony.[441]

Rules 702 and 704 of the Federal Rules of Evidence control the admissibility of expert opinion. Opinion testimony by an expert is permitted to assist the trier of fact in understanding the evidence or in determining a fact in issue.[442] Such testimony may even embrace an "ultimate issue."[443] In the prosecution of a physician, another physician is generally called as an expert witness to explain the proper procedures for prescribing a controlled substance and to opine on whether the prescription of drugs in the instances charged was justified.[444]

In the author's experience, the prosecution's expert witness will generally testify that proper procedures consist of the following actions. Prior to the prescription of any medication, a physician will usually obtain a medical history of the patient including childhood diseases, family diseases, and allergies, followed by a history of the

438. *Betancourt*, 734 F.2d at 757.

439. *See infra* note 444.

440. *E.g.*, United States v. Jamieson, 806 F.2d 949, 951 (10th Cir. 1986) (stating that "the very facts and circumstances surrounding the issuance of a drug prescription can support a finding that the prescription was *not* issued for a legitimate medical purpose"); United States v. Word, 806 F.2d 658, 662-64 (6th Cir. 1986) (concluding that there was sufficient evidence, without expert testimony, to show that defendant's conduct was not in the usual course of professional practice), *cert. denied*, 480 U.S. 922 (1987); United States v. Rogers, 609 F.2d 834, 839 (5th Cir. 1980) (holding that expert testimony is not absolutely necessary); *Smurthwaite*, 590 F.2d 892 (10th Cir. 1979) (concluding that expert testimony is not necessary where the issue is clear); United States v. Larson, 507 F.2d 385, 387 (9th Cir. 1974); United States v. Bartee, 479 F.2d 484, 488 (10th Cir. 1973) (stating that a jury is not bound by expert testimony and may consider other testimony).

441. *Bartee*, 479 F.2d at 488.

442. FED. R. EVID. 702.

443. FED. R. EVID. 704(a).

444. *See* United States v. Rosen, 448 F. Supp. 926, 932 (E.D. La. 1977). A pharmacologist has been qualified to give this type of testimony. *See* Henry R. Richmond & Daryle A. Jordan, *Doctors and the Distribution of Drugs*, ARMY LAW., Sept. 1991, at 8.

particular complaint for which that patient is seeking treatment.[445] The physician then conducts a general physical examination including a check of the eyes, ears, nose, throat, chest, heart, lungs, blood pressure, and extremities followed by an examination focused on the particular problem. As an adjunct to the examination, all appropriate tests are conducted.[446] The physician then forms a tentative diagnosis and treatment plan. The important information gathered during this process is recorded in the patient's record. Follow-up visits consist of a history of the complaint and an appropriate examination. The physician will also review the treatment history and effectiveness. Further testing will be conducted as warranted. The expert may also testify to the prescribing practices of the medical community relating to the drugs at issue, including whether they are the drugs of choice within the prescribing community.

Finally, the expert will review the transactions presented during the course of the trial and offer an opinion as to their legitimacy.[447] This testimony may take the form of a hypothetical question.[448] Expert testimony in the form of handwriting analysis may also be offered to prove that the defendant physician wrote the prescriptions with which he has been charged.[449]

In summary, expert testimony on the following topics relating to physicians is acceptable:

1. The customary procedures followed by licensed medical practitioners in treating a patient prior to prescribing a con-

445. *E.g.*, United States v. Chin, 795 F.2d 496, 500 (5th Cir. 1986); United States v. Thompson, 624 F.2d 740, 741 (5th Cir. 1980); *Smurthwaite*, 590 F.2d at 892; United States v. Moore, 505 F.2d 426, 448 (D.C. Cir. 1974), *rev'd*, 423 U.S. 122 (1975); *Rosen*, 444 F. Supp. at 932.

446. *E.g.*, United States v. Kirk, 584 F.2d 773, 785 (6th Cir.), *cert. denied*, 439 U.S. 1048 (1978); United States v. Dallman, 32 M.J. 624, 627 (A.C.M.R. 1991).

447. *See* Richmond & Jordan, *supra* note 444, at 8.

448. *E.g.*, United States v. Hughes, 895 F.2d 1135, 1145 (6th Cir. 1990).

449. United States v. Millen, 594 F.2d 1085, 1086 (6th Cir.), *cert. denied*, 444 U.S. 829 (1979). This element of proof is often resolved through a stipulation that the defendant wrote the prescriptions charged in the indictment. United States v. Johnson, 831 F.2d 124 (6th Cir. 1987). Authorship can also be proven by the testimony of an eyewitness to the prescription writing, usually the patient or undercover officer who obtained it. United States v. Brown, 763 F.2d 984 (8th Cir. 1985).

trolled substance,[450] including the importance of taking a thorough medical history;[451]

2. The importance of adequate warnings to the patient about the medication such as information about possible side effects;[452]

3. The adequacy of the examinations conducted by the defendant physician;[453]

4. The adequacy of the records kept by the defendant physician;[454]

5. The medical appropriateness of the prescriptions written by the defendant physician;[455]

6. The quantity of controlled substance prescriptions written by the physician;[456]

7. The usual medical procedures to be followed in prescribing the controlled substances in question;[457] and,

8. Whether the defendant physician was prescribing drugs in the usual course of professional practice and for a legitimate medical purpose.[458]

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450. United States v. Kaplan, 895 F.2d 618, 620 (9th Cir. 1990); *Hughes*, 895 F.2d at 1145; United States v. Varma, 691 F.2d 460, 463 (10th Cir. 1982); *Kirk*, 584 F.2d at 785; United States v. Rosenberg, 515 F.2d 190, 199 (9th Cir. 1975), *cert. denied*, 423 U.S. 1031 (1976); United States v. Green, 511 F.2d 1062, 1072-73 (7th Cir.), *cert. denied*, 423 U.S. 1031 (1975).

451. *Chin*, 795 F.2d at 500; *Thompson*, 624 F.2d at 741; *Rogers*, 609 F.2d at 838; *Smurthwaite*, 590 F.2d at 889-91; *Kirk*, 584 F.2d at 785; United States v. Roya, 574 F.2d 386, 394 (7th Cir.), *cert. denied*, 439 U.S. 857 (1978); United States v. Davis, 564 F.2d 840 (9th Cir. 1977), *cert. denied*, 434 U.S. 1015 (1978); United States v. Greenfield, 554 F.2d 179, 181 (5th Cir. 1977), *cert. denied,* 439 U.S. 860 (1978); *Green*, 511 F.2d at 1073; *Moore*, 505 F.2d at 448; White v. United States, 399 F.2d 813, 818 (8th Cir. 1968); *Rosen*, 448 F. Supp. at 932.

452. *Kirk*, 584 F.2d at 785; United States v. Jackson, 576 F.2d 46, 50 (5th Cir. 1978).

453. *Chin*, 795 F.2d at 500; *Jackson*, 576 F.2d at 50; *Moore*, 505 F.2d at 447-48.

454. *Jackson*, 576 F.2d at 50.

455. United States v. Varma, 691 F.2d 460, 464 (10th Cir. 1982); United States v. Rogers, 609 F.2d 834, 839 (5th Cir. 1980); United States v. Plesons, 560 F.2d 890, 891 (8th Cir.), *cert. denied*, 434 U.S. 966 (1977).

456. United States v. Mahar, 801 F.2d 1477, 1486 (6th Cir. 1986); United States v. Hammond, 781 F.2d 1536, 1537 (11th Cir. 1986); United States v. Rogers, 609 F.2d 834, 838-39 (5th Cir. 1980).

457. *E.g.*, United States v. Hooker, 541 F.2d 300, 305 (5th Cir. 1976); United States v. Rosen, 448 F. Supp. 926, 932 (E.D. La. 1977).

458. *See* United States v. Hughes, 895 F.2d 1135, 1144-45 (6th Cir. 1990); United States v. Kaplan, 895 F.2d 618, 621 (9th Cir. 1990); United States v. Chin, 795 F.2d 496, 504 (5th Cir. 1986); United States v. Hoffner, 777 F.2d 1423, 1426 (10th Cir.

Expert testimony is also offered in the prosecution of pharmacists. Such testimony has been offered to support the contention that the pharmacist knew or should have known that the prescriptions being filled were not issued in the usual course of medical treatment for a legitimate medical need.[459] In the author's experience, the expert witness will generally testify that a pharmacist first checks a prescription for a controlled substance to make sure that it is in the correct form and contains all of the required information. If the pharmacist is unfamiliar with the prescribing physician, a telephone call may be made to the physician's office in an attempt to determine whether the doctor issued the prescription. Verification by the physician's office does not necessarily mean the prescription is legitimate because either the doctor may be involved in the illegality, or the prescription may be bogus and the telephone is being answered by a co-conspirator whose job is to verify prescriptions. The pharmacist will then determine whether there is a relationship between the customer and the pharmacy; customers generally patronize a pharmacy that is located near home, work, or the doctor's office. If the controlled substance is a popular "street drug," or one not usually prescribed, the pharmacist may observe the customer to determine if he appears to need the drug and may inquire as to the reasons for it. A pharmacist can always avoid filling a prescription by claiming to be out of stock of the prescribed drug.

The expert may also testify as to the rules and regulations affecting the dispensing of controlled substances and how they are properly implemented.[460] Finally, experts will give their opinions of

1985); United States v. Rogers, 609 F.2d 834, 838-39 (5th Cir. 1980); United States v. Potter, 616 F.2d 384, 387 (9th Cir. 1979), *cert. denied*, 449 U.S. 832 (1980); United States v. Kirk, 584 F.2d 773, 784 (6th Cir.), *cert. denied*, 459 U.S. 1048 (1978); United States v. Roya, 574 F.2d 386, 394 (7th Cir.), *cert. denied*, 439 U.S. 857 (1978); United States v. Davis, 564 F.2d 840, 845 (9th Cir. 1977), *cert. denied*, 434 U.S. 1015 (1978); United States v. Greenfield, 554 F.2d 179, 181 (5th Cir. 1977); United States v. Viglia, 549 F.2d 335, 337 (5th Cir.), *cert. denied*, 434 U.S. 834 (1977); United States v. Moore, 505 F.2d 426, 447-48 (D.C. Cir. 1974), *rev'd*, 423 U.S. 122 (1975).

459. *E.g., Hammond*, 781 F.2d at 1538.

460. United States v. Seelig, 622 F.2d 207, 213-14 (6th Cir.), *cert. denied*, 449 U.S. 869 (1980). In *Seelig*, a DEA Compliance Officer was allowed to testify about the regulations relating to the filling of certain prescriptions and "what the routine practices of pharmacists should be according to the regulations" based on his expertise as a compliance officer. *Id.*

whether the defendant pharmacist's actions were illegal.[461] Expert testimony indicates that the following factors are evidence of illegal prescribing that a pharmacist should recognize:

1. The volume of prescriptions for controlled substances by a single physician;[462]
2. The lack of individual dosing indicated by a lack of variation of the quantity of pills dispensed among patients;[463] and
3. The custom or routine of local pharmacists, such as their practices in dispensing Schedule V drugs.[464]

2. Jury Instructions

Jury instructions generally begin with an instruction on the elements of the offense. This instruction must include all relevant statutory definitions.[465] When a physician is on trial for illegal distribution through the issuance of prescriptions, the jury charge needs to indicate that the government must prove the following elements beyond a reasonable doubt:

> 1) [The] defendant was a registrant authorized to dispense controlled substances for legitimate medical purposes; 2) that the defendant knowingly and intentionally issued a prescription; 3) that the prescription was for a Schedule ____ controlled substance as alleged; and 4) that the prescription was issued by him other than in good faith, without a legitimate medical purpose and outside of the usual course of his professional practice.[466]

461. *Hammond*, 781 F.2d at 1538. *See* United States v. Barbacoff, 416 F. Supp. 606, 609 (D.D.C. 1976); United States v. Williams, 416 F. Supp. 611, 613 (D.D.C. 1976).

462. United States v. Mahar, 801 F.2d 1477, 1487 (6th Cir. 1986); *Hammond*, 781 F.2d at 1538.

463. *Hammond*, 781 F.2d at 1538; United States v. Lawson, 682 F.2d 480, 482-83 (4th Cir.), *cert. denied*, 459 U.S. 991 (1982).

464. *Seelig*, 622 F.2d at 216 (holding that the defense should have been allowed to offer testimony about the customary practice in handling Schedule V drugs, particularly when the government had offered expert testimony as to what the regulations required).

465. *Seelig*, 622 F.2d at 213 (holding that defendants are entitled to have all relevant statutory definitions read to the jury).

466. United States v. Hayes, 794 F.2d 1348, 1351 (9th Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987). *See also* United States v. Norris, 780 F.2d 1207, 1209 (5th Cir. 1986); United States v. Jamieson, 605 F. Supp. 119, 122 (D. Kan. 1985), *aff'd*, 806 F.2d 949 (10th Cir. 1986).

In the trial of a physician, the court must instruct the jury that the defendant is exempt from the Act unless the physician was acting outside the usual course of professional practice.[467] This is true even if the distribution is not alleged to have been pursuant to the defendant's registration.[468] The courts prefer an affirmative instruction clarifying that "a registrant who *does* prescribe in the usual course of professional practice is *not* subject to the penalties" of the CSA.[469] The instruction should state clearly that a conviction is only proper where the doctor issued a prescription other than in good faith, without a legitimate medical purpose, and outside of medical standards generally recognized and accepted.[470]

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467. *Seelig*, 622 F.2d at 213; United States v. Rogers, 609 F.2d 834, 839 (5th Cir. 1980); *Hayes*, 595 F.2d at 259 n.2.

468. United States v. King, 587 F.2d 956, 965 (9th Cir. 1978).

469. United States v. Plesons, 560 F.2d 890, 896 (8th Cir.), *cert. denied*, 434 U.S. 966 (1977).

> The following instruction correctly states the rights of a physician under the CSA:
> [The] defendant, a doctor of medicine, is exempt from the provision . . . [of the Act], if you find that he wrote prescriptions for the persons referred to in the evidence in the course of his professional practice; that the law permits the defendant, being a doctor of medicine, to write prescriptions for the drugs referred to in the evidence, and unless you find and believe that he did not prescribe the drugs in the course of his professional practice, then you must acquit him.
>
> You are further instructed that under the statute, a physician is exempted from the prohibitions against the sale and delivery, or causing the sale or delivery of . . . [a controlled substance] only when he acts in the ordinary and authorized course of his practice.

White v. United States, 399 F.2d 813, 816-17 (8th Cir. 1968). *See also Carroll*, 518 F.2d at 190 (approving the instruction in *White*).

470. United States v. Boettjer, 569 F.2d 1078, 1081 (9th Cir.), *cert. denied*, 435 U.S. 976 (1978). The Ninth Circuit in *Boettjer* emphasized the need for clarity and expressed concern with regard to potentially ambiguous instructions. *Id.* Note, however, that the Fifth Circuit in *Norris* approved the following instruction, which is not entirely clear on this point:

> A controlled substance is prescribed by a physician in the usual course of a professional practice, and, therefore, lawfully, if the substance is prescribed by him in good faith, medically treating a patient in accordance with a standard of medical practice generally recognized and accepted in the United States.

Norris, 780 F.2d at 1209. *See also* United States v. Green, 511 F.2d 1062, 1071 n.22 (7th Cir.), *cert. denied*, 423 U.S. 1031 (1975). This instruction is problematic because of inherent ambiguities. For example, a jury may incorrectly interpret this instruction to permit a finding of guilt merely on the basis of malpractice. The Ninth Circuit preferred a modified version of this instruction in United States v. Davis, 564 F.2d 840, 845-46 (9th Cir. 1977), *cert. denied*, 434 U.S. 1015 (1978). That instruction read:

A "good faith medical treatment instruction" informs the jury that:

> In order to determine whether or not a prescription or prescriptions were issued in the course of a defendant physician's professional practice, you may consider all of the evidence of circumstances surrounding the prescribing of the substance in question, the statements of the parties to the prescription transaction, any expert testimony as to what is the usual course of medical practice, and any other competent evidence bearing on the purpose for which the substances in question were prescribed.
>
> Unless you find beyond a reasonable doubt that an act of prescribing charged in the indictment against a defendant physician was not done by the physician in the course of his professional practice, then you should find him not guilty.[471]

The "usual course of professional practice" is an objective standard.[472] A physician cannot argue that he alone can determine what constitutes proper medical practice.[473] The jury should consider whether a defendant *subjectively* considered that his actions were pursuant to a legitimate medical reason,[474] as well as whether the drugs were *objectively* dispensed in the usual course of a professional practice.[475]

In the case of a pharmacist, the jury is instructed that it first must find that the prescriptions in question were not issued in the usual course of professional practice for a legitimate medical reason and that the defendant pharmacist knew that fact.[476] The elements of

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> [Y]ou must also find beyond a reasonable doubt that a physician, who knowingly and intentionally, did dispense or distribute by prescription certain controlled substances and did so other than in good faith and not in the usual course of a professional practice, and not in accordance with a standard of medical practice generally recognized and accepted in the United States.

Id. at 845-46.

471. *Green*, 511 F.2d at 1071 n.22; *see also* United States v. Kaplan, 895 F.2d 618, 623-24 (9th Cir. 1990).

472. *Norris*, 780 F.2d at 1209.

473. *Id. Accord* United States v. Vamos, 797 F.2d 1146, 1153 (2d Cir. 1986), *cert. denied*, 479 U.S. 1036 (1987).

474. *See, e.g., Norris*, 780 F.2d at 1209 n.2 (approving an instruction with both objective and subjective considerations).

475. *Id.* at 1209.

476. United States v. Kershman, 555 F.2d 198, 200 (8th Cir.), *cert. denied*, 434 U.S. 892 (1977).

the offense for a pharmacist are: "[T]he defendant distributed a controlled substance as charged; he did so other than in the usual course of his profession; and he acted knowingly and intentionally."[477]

The key question of knowledge may be shown "by proof that the defendant deliberately closed his eyes to the true nature of the prescription" under appropriate circumstances.[478] The instruction must require the jury to find that the pharmacist "deliberately and consciously closed his eyes;" a reasonable man standard does not apply.[479] As with the case of a physician, the jury should be instructed that if the pharmacist believed in good faith that the prescription was properly issued, he is excepted from criminal responsibility.[480]

An instruction indicating that the state supervisory authorities' failure to act does not constitute a defense is only appropriate with regard to the issue of the defendant's intent.[481]

E. *Sentencing*

The Sentencing Reform Act of 1984 provides for the development of guidelines for the sentencing of persons convicted in the federal courts.[482] The Act established the United States Sentencing Commission to promulgate the required guidelines.[483] The guidelines, which went into effect on November 1, 1987, set forth the methodology to determine the length of sentences in federal court.[484]

Under the guidelines, the weight of the controlled substance is a factor in determining the appropriate sentence for illegal distribution.[485] The greater the weight, the higher the sentence.[486] No pre-

477. United States v. Irwin, 661 F.2d 1063, 1070 (5th Cir. Nov. 1981), *cert. denied*, 456 U.S. 907 (1982). *Accord* United States v. Rosenberg, 515 F.2d 190, 197 (9th Cir. 1975), *cert. denied*, 423 U.S. 1031 (1976); United States v. Plesons, 560 F.2d 890, 896-97 (8th Cir.), *cert. denied*, 434 U.S. 966 (1977).

478. United States v. Lawson, 682 F.2d 480, 482 (4th Cir.), *cert. denied*, 459 U.S. 991 (1982); United States v. Seelig, 622 F.2d 207, 213 (6th Cir.), *cert. denied*, 449 U.S. 869 (1980); *Kershman*, 555 F.2d at 200-01.

479. *Kershman*, 555 F.2d at 201.

480. *Id.*

481. United States v. Hammond, 781 F.2d 1536, 1540-41 (11th Cir. 1986).

482. 28 U.S.C. §§ 991-998 (Supp. 1992).

483. *Id.*

484. UNITED STATES SENTENCING COMMISSION, GUIDELINES MANUAL 1, 2-4 (1993) [hereinafter U.S.S.G.].

485. U.S.S.G. § 2D1.1(c) (1993).

scription controlled substance is pure, as each contains additives necessary to form the tablet or solution containing the controlled substance. Under the guidelines, however, prescription controlled substances are treated as a "mixture" containing the controlled substance.[487] Therefore, the appropriate "weight" is the actual weight of the tablets involved. If the actual pills are unavailable, an estimated weight is acceptable.[488]

A court cannot impose probation with the condition that the defendant surrender his state license to practice his profession if an established state procedure regarding revocation exists. In *United States v. Sterber*,[489] the Second Circuit held that since the State of New York had an elaborate scheme for resolving allegations of professional misconduct against pharmacists, the trial court acted improperly when it required Sterber to surrender his license as a special condition of probation.[490]

F. *Forfeiture*

The CSA provides for the forfeiture of conveyances, real property, and assets connected with or derived from violations of the Act.[491] Conveyances used or intended to be used to "transport, or in any manner to facilitate the transportation, sale, receipt" of controlled substances are forfeited.[492] Also forfeited is:

> All real property, including any right, title, and interest (including any leasehold interest) in the whole of any lot or tract of

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486. *Id.* The guidelines define "weight" as "the entire weight of any mixture or substance containing a detectable amount of the controlled substance." *Id.* at 86.

487. *See* United States v. Young, 992 F.2d 207, 209 (8th Cir. 1993) (Dilaudid tablets); United States v. Blythe, 944 F.2d 356, 362-63 (7th Cir. 1991) (Dilaudid tablets); United States v. Shabazz, 933 F.2d 1029, 1032 (D.C. Cir.) (Dilaudid pills), *cert. denied*, 112 S. Ct. 431 (1991). *See also* Chapman v. United States, 111 S. Ct. 1919 (1991) (holding that the weight of the blotter paper containing LSD, not the weight of the pure LSD, controls).

488. *Shabazz*, 933 F.2d at 1034. The weight of a Dilaudid tablet was estimated to be 90 milligrams based on information from the DEA, the *Physicians' Desk Reference*, and the manufacturer of the pill. *Id.* at 1031-34.

489. 846 F.2d 842 (2d Cir. 1988). This case was decided under the Federal Probation Act which has since been repealed. However, the logic of the case is applicable to any situation where probation would be available under the sentencing guidelines.

490. *Id.* at 844.

491. 21 U.S.C. § 881(a)(4)-(7) (Supp. 1992).

492. *Id.* § 881(a)(4).

> land and any appurtenances or improvements, which is used or intended to be used, in any manner or part, to commit, or to facilitate the commission of, a violation of this subchapter. . . .[493]

Finally, for "all moneys . . . or other things of value furnished by any person in exchange for a controlled substance in violation of this subchapter, all proceeds traceable to such an exchange" are forfeited.[494] Forfeiture under these provisions does not require a federal criminal prosecution and has been applied to defendants in state criminal proceedings.[495]

These provisions have been applied to the assets of practitioners. For example, on two separate occasions, the Fourth Circuit has affirmed decisions granting forfeiture of buildings housing physicians' offices based on the physicians' convictions for illegal distribution of controlled substances.[496] In the earlier opinion, the Fourth Circuit noted that it was not holding that "any writing of an illegal prescription on a given property automatically renders the property forfeitable."[497] Rather, the court held that forfeiture was mandated where the office had been used over forty times to write illegal prescriptions during a four-month period because a direct and continuing relationship existed between the property and the crimes.[498] In a later case, the Fourth Circuit affirmed the trial court's finding that the offending physician wrote illegal prescriptions in his office for a particular patient[499] and that the building was "substantially connected to the illegal distribution of controlled substances."[500]

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493. *Id.* § 881(a)(7).

494. *Id.* § 881(a)(6).

495. *E.g.*, Brantz v. United States, 724 F. Supp. 767 (S.D. Cal. 1989).

496. United States v. Cullen, 979 F.2d 992 (4th Cir. 1992); United States v. Schifferli, 895 F.2d 987 (4th Cir. 1990).

497. *Schifferli*, 895 F.2d at 991.

498. *Id.* The district court, in upholding the forfeiture, noted that there was a substantial connection between the property and the illegal activity because (1) the practice had to have a situs to give it legitimacy and (2) the doctor received money for the illegal prescriptions on the premises. United States v. 117 Trafalgar Street S.W., 700 F. Supp. 857, 862 (D.S.C. 1988), *aff'd sub nom.* United States v. Schifferli, 895 F.2d 987 (4th Cir. 1990).

499. *Cullen*, 979 F.2d at 994.

500. *Id.* at 995.

The forfeiture of assets allegedly traced to illegal proceeds has also been applied in the registrant context.[501] Additionally, forfeiture may be based on the Racketeer Influenced and Corrupt Organizations Act (RICO).[502] The Fourth Circuit used that statute to prosecute a physician for "conducting the affairs of his medical practice through a pattern of racketeering activity."[503]

IV. Civil Enforcement Actions

Not only are there criminal penalties such as incarceration and criminal fines for violations of the Controlled Substances Act, there are civil penalties as well. These penalties can be used as an alternative to or in addition to criminal prosecution.[504]

The Act establishes original federal court civil jurisdiction to enforce civil penalties of up to $25,000.[505] The civil penalty may be imposed for any of the following violations: (1) wrongful distribution or dispensing of a controlled substance; (2) failure to keep or furnish required records; (3) refusal of entry for an administrative inspection; and (4) distribution without adequate registration.[506] The charges in civil cases brought under the Act against pharmacists have been for filling prescriptions with mechanically reproduced signatures,[507] filling incomplete prescriptions,[508] filling forged prescriptions,[509] failing to maintain proper records,[510] and filling

501. Brantz v. United States, 724 F. Supp. 767, 768 (S.D. Cal. 1989) (upholding seizure of physician's automobile for violating this provision).

502. Pub. L. No. 91-452, §§ 901-902, 84 Stat. 941 (1970) (codified as amended at 18 U.S.C. §§ 1961-1968 (1992)).

503. United States v. Borromeo, 954 F.2d 245, 246 (4th Cir.), *cert. denied*, 113 S. Ct. 25 (1992).

504. Excessive civil fines after the imposition of criminal sanctions for the same offense may violate the double jeopardy clause if the fines are characterized as deterrent or retributive. United States v. Halper, 490 U.S. 435 (1989).

505. 21 U.S.C. § 842(c)(1) (Supp. 1992).

506. *Id.* § 842. An unregistered physician who distributes controlled substances is properly penalized under § 842(a)(1) and not under § 842(a)(2), which applies to registrants. United States v. Clinical Leasing Serv., Inc., 930 F.2d 394, 395 n.1 (5th Cir.), *cert. denied*, 112 S. Ct. 188 (1991).

507. United States v. Barbacoff, 416 F. Supp. 606, 610 (D.D.C. 1976); United States v. Williams, 416 F. Supp. 611, 614 (D.D.C. 1976).

508. *Williams*, 416 F. Supp. at 614.

509. *Barbacoff*, 416 F. Supp. at 607-09; *Williams*, 416 F. Supp. at 613.

510. United States v. Green Drugs, 905 F.2d 694 (3d Cir.), *cert. denied*, 498 U.S. 985 (1990); *Barbacoff*, 416 F. Supp. at 607-08; *Williams*, 416 F. Supp. at 614.

prescriptions that were not issued in the course of legitimate medical treatment.[511] Charges have also been brought against a clinic and its physicians for distributing controlled substances without the required registration.[512] Each separate act in violation of any one of these provisions can result in the maximum fine.[513]

The United States Attorney's Office seeks to impose civil penalties by filing a civil complaint.[514] In determining the amount of the fine, the court should consider: "(1) [T]he willfulness of the violations; (2) how much the defendant earned as the result of his unlawful activities; (3) the harm to the public; and (4) the financial capacity of the defendant to pay."[515]

The Act imposes strict liability for civil violations, and inadvertent mistake is not a defense to liability.[516] In *United States v. Green Drugs*,[517] the government sought the imposition of civil penalties on a drugstore for shortages of Schedule II controlled substances.[518] Even though the drugstore claimed inadvertent recordkeeping failures and lack of pecuniary gain, liability was found.[519] However, the apparent "innocence" of the store was reflected in the imposition of only a $2,000 penalty per count.[520]

With the strict liability requirement, civil penalties constitute a strong weapon in the hands of prosecutors. It is surprising that prosecutors do not invoke these provisions more frequently.

V. CONCLUSION

The Controlled Substances Act creates a complex web of administrative, civil, and criminal regulations designed to regulate the distribution of controlled substances and to prevent their diversion to illegitimate uses. Within that web, the activities of individual practi-

511. *Barbacoff*, 416 F. Supp. at 610; *Williams*, 416 F. Supp. at 614.

512. *Clinical Leasing Serv.*, 925 F.2d at 120.

513. *Green Drugs*, 905 F.2d at 695. One count was brought for each controlled substance for which it was alleged that the store had failed to maintain accurate records. *Id.*

514. *E.g.*, *Green Drugs*, 905 F.2d at 695.

515. *Williams*, 416 F. Supp. at 614. *See also Barbacoff*, 416 F. Supp. at 610.

516. 21 U.S.C. § 842(c) (Supp. 1992).

517. 905 F.2d 694 (3d Cir.), *cert. denied*, 498 U.S. 985 (1990).

518. *Id.* at 695.

519. *Id.* at 698.

520. *Id.* at 695.

tioners are circumscribed and their professional judgments are subject to examination. When confronted with allegations of diversion, legal practitioners must familiarize themselves fully with both the medical and legal aspects of the case.