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# FEDERAL LAW AND SYRINGE PRESCRIPTION AND DISPENSING

*Daniel Abrahamson*<sup>†</sup>

## INTRODUCTION

**THIS PAPER ADDRESSES** the following two questions:

- (1) To what extent do federal controlled substances, food and drug, or paraphernalia laws regulate the individual physician's or pharmacist's discretion to provide sterile injection equipment for injection drug users (IDUs)?; and
- (2) How could federal officials use their legal and political authority to discourage physicians or pharmacists from acting?

It concludes that, at present, federal law does not regulate physician prescription or pharmacist dispensing of syringes (pursuant to a valid prescription) to IDUs. Before federal officials could lawfully intervene in this area of medicine, new legislation expressly conferring power on federal authorities to regulate the physician prescription (and pharmacist dispensing) of syringes would need to be enacted. Nonetheless, as physicians in California and Oregon learned in recent years, federal officials might try to intimidate physicians if syringe prescription and dispensing were considered to be at odds with national drug war orthodoxy. The California and Oregon examples, however, also illustrate that when federal officials overstep their

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authority to control the practice of medicine at the state level, this overreaching can be rebuffed.

## DISCUSSION

### 1. The Limits of Federal Law in Proscribing Syringe Prescription

Three bodies of federal statutory law conceivably cover syringe prescribing and dispensing: the Food, Drug and Cosmetic Act (FDCA), the Controlled Substances Act (CSA), and the Federal Mail Order Drug Paraphernalia Control Act ("Paraphernalia Act"). As explained below, none of these reach the physicians who prescribe or pharmacists who dispense syringes. Accordingly, federal law need not pose an obstacle to physician prescribing and pharmacy dispensing of syringes to IDUs.

#### a. The FDCA

The Federal Food, Drug and Cosmetic Act<sup>1</sup> empowers the Department of Health and Human Services to approve drugs, devices, and cosmetics as safe and effective for medical use, public consumption, and marketing in interstate commerce. Syringes, like most medical devices, are deemed Class II devices by the FDCA—devices that pose some, but not a great risk of harm and which are subject to modest controls "necessary to provide adequate assurance of safety and effectiveness."<sup>2</sup>

The FDCA's classification scheme, however, aims to regulate the design, manufacturing, labeling, and marketing in interstate commerce of medical devices and products—it does not attempt to regulate medical practice, which is left to the states. Thus, while the FDCA authorizes federal officials to regulate syringe manufacturers to insure that they produce a sound medical device, and that syringe distributors insure proper labeling of their medical products, the FDCA does not authorize federal officials to dictate how syringes that are lawfully produced, packaged, marketed, and distributed are to be used by health professionals in the course of their professional practice.

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<sup>1</sup> 21 U.S.C.A. §§ 301-397 (West 1999 & Supp. 2000).

<sup>2</sup> 21 U.S.C.A. § 360c(a)(1)(B) (West 1999).

### b. The CSA

The Controlled Substances Act is an anti-drug abuse law enforcement statute administered by the Attorney General and enforced by the Drug Enforcement Administration (DEA), which is part of the Department of Justice.<sup>3</sup> As its name suggests, the CSA controls the authorized distribution of scheduled drugs, not the distribution of devices. Accordingly, by its terms, the CSA does not purport to regulate access to syringes.

Even if one were to ignore the plain language of the CSA and construe the definition of controlled substances to encompass syringes (and there are several reasons why a court would not permit this to occur), the CSA, like the FDCA, does not regulate the practice of medicine, which is left to the states.<sup>4</sup> Thus, even this implausible reading of the CSA would not authorize DEA officials to second-guess the propriety of a physician's prescription of a syringe to an IDU, or the pharmacist's filling of that prescription. Put differently, while the DEA can sanction physicians who act contrary to the "public interest," outside "the usual course of medical practice," or in the absence of a "legitimate medical purpose,"<sup>5</sup> historically these standards have been established at the state level as opposed the federal level. Thus, the propriety of a physician's prescription practice is an inquiry left traditionally, and almost without exception, to the states and their medical licensing boards. It is not clear that the DEA has ever sanctioned a physician for prescribing a controlled substance or medical device absent a prior finding at the state level that the physician acted improperly or in bad faith.

### c. The Paraphernalia Act

The Federal Mail Order Drug Paraphernalia Control Act ("Paraphernalia Act") governs interstate or foreign commerce in equipment intended for drug consumption.<sup>6</sup> The Paraphernalia

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<sup>3</sup> 21 U.S.C.A. §§ 801-971 (West 1999 & Supp. 2000).

<sup>4</sup> The sole exception to this general rule is the CSA's prohibition of the prescription of opioids to maintain an opiate addiction. *See* 21 U.S.C. § 823(g) (1994) (requiring practitioners to annually obtain registration if they are dispensing narcotic drugs for maintenance or detoxification treatments).

<sup>5</sup> *See, e.g.*, 21 U.S.C. § 823(f) (1994) (stating that the Attorney General may deny practitioner registration applications if issuance would be inconsistent with the public interest).

<sup>6</sup> 21 U.S.C. § 863 (1994). Technically speaking, the Paraphernalia Act is part of the Controlled Substances Act, having been repealed as a free-standing law and

Act ostensibly defines syringes as drug paraphernalia and purports to regulate their distribution.<sup>7</sup> However, there is a persuasive argument that the Act, by its terms, does not apply to physician-prescribed or pharmacy-dispensed syringes. The Act sets forth various criteria for determining whether an object is drug paraphernalia, and contrasts paraphernalia with objects used by "legitimate suppliers" that have "legitimate uses . . . in the community."<sup>8</sup>

The Act further contemplates reliance on expert testimony about whether the object is drug paraphernalia or something else, such as a medical device.<sup>9</sup> When applied to the prescribing or dispensing of sterile syringes to IDUs by health professionals, there is a strong argument that these syringes fall outside the Act's definition of paraphernalia and squarely within the category of medical devices, much like the syringes prescribed and/or dispensed to diabetics.

Even if one were to reject this definitional argument, the Paraphernalia Act only regulates equipment that is sold or offered for sale, or transported by the mails, or any other facility of interstate commerce.<sup>10</sup> Thus, to the extent that a physician issues a prescription for a syringe without use of the mails or other facilities of interstate commerce (e.g., the phone lines), the Act would not reach the physician's conduct. A valid prescription for syringes, in turn, would serve to transform the syringes from drug paraphernalia into a medical device that the pharmacist would be permitted to dispense or sell.

Finally, and perhaps most decisively, subsection (f) of section 863, entitled "Exemptions," states that "[t]his section shall not apply to . . . any person authorized by local, State, or Federal law to manufacture, possess, or distribute such items."<sup>11</sup> The exemption reflects Congress' focus on the commercial head-shop industry, and its intention not to sweep within the paraphernalia law persons who have traditionally used covered items for legitimate purposes. Physicians and pharmacists are explicitly authorized to possess, use, and distribute syringes in

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inserted virtually unaltered into the CSA in 1990. For purposes of this paper, however, the CSA and Paraphernalia Act are discussed as distinct statutory schemes.

<sup>7</sup> See 21 U.S.C. § 863(d) (1994).

<sup>8</sup> 21 U.S.C. § 863(e)(5), (7) (1994).

<sup>9</sup> See 21 U.S.C. § 863(e)(8) (1994).

<sup>10</sup> See 21 U.S.C. § 863(a) (1994).

<sup>11</sup> 21 U.S.C. § 863(f)(1) (1994).

about half the states, and in the remainder have the implicit authorization of their professional status and long-standing practice. The exemption, moreover, applies to the person, not the specific transaction, so that even if it were claimed that the specific provision of the syringe was prohibited by state law, the fact that the provider is generally authorized to possess or distribute the item would be sufficient to trigger the immunity.

In sum, federal law should not pose a bar to syringe prescription.

## 2. The Limits of Federal Muscle Flexing in Proscribing Syringe Prescription

In light of the politicization of our national drug control policy, it is conceivable that, notwithstanding the above legal analysis, federal authorities might try to discourage physicians from prescribing or pharmacists from dispensing sterile injection equipment to IDUs. Indeed, as this paper goes to press, such a scenario gains plausibility with President-elect George W. Bush's nomination of Senator John Ashcroft of Missouri to be the next Attorney General. Senator Ashcroft has publicly claimed that "[a] government which takes the resources that we would devote toward the interdiction of drugs and converts them to treatment resources . . . and also implements a clean needle program is a government that accommodates us at our lowest and least instead of calls us to our highest and best."<sup>12</sup> It is not difficult to imagine parents or religious groups, for example, attempting to mobilize the Justice Department to quash syringe prescription and dispensing to IDUs, claiming that these practices somehow weaken the "Just Say No to Drugs" philosophy which has dominated the federal response to the problem of substance abuse for over twenty years.

Recent precedent is instructive both as to the willingness of federal authorities to exceed their legal authority, as well as the ability of citizens to have federal law enforced. Specifically, in December 1996, the DEA and other federal officials threatened to sanction California physicians who recommended the medical use of marijuana to their patients and other physicians pur-

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<sup>12</sup> *Ashcroft Hailed Confederates as 'Patriots'* (posted Dec. 28, 2000) <<http://www.msnbc.com/news/508290.asp#BODY>>.

suant to that State's Compassionate Use Act.<sup>13</sup> In 1997, the DEA threatened to sanction Oregon physicians who prescribed narcotics to hasten their patients' deaths pursuant to Oregon's Death with Dignity Act.<sup>14</sup> Physicians aware of these precedents may be concerned that prescribing syringes could make them a target of similar pressure. Nevertheless, a brief analysis of these events suggests that the ability of the government to actually sanction physicians is remote.

In California, shortly after being threatened with sanctions for recommending medical marijuana to patients, physicians filed a class action suit in federal court against the Administrator of the DEA, the Director of the Office of National Drug Control Policy (the "drug czar"), the Attorney General of the United States, and the Secretary for Health and Human Services. The physicians claimed that the federal threats abridged their First Amendment rights of free speech and unlawfully exceeded the federal government's authority by attempting to regulate medical practice absent express authority to do so by the CSA. Shortly after the suit was filed, a federal trial court issued a preliminary injunction preventing the government from acting upon its threats.<sup>15</sup> In September 2000, the court issued a permanent injunction, finding that the government exceeded its statutory authority under the CSA to threaten doctors with sanctions for having certain discussions with, or making particular medical recommendations to their patients.<sup>16</sup> As part of its analysis, the court emphasized that Congress was silent as to whether it intended the CSA to reach the specific conduct (physicians recommending medical marijuana) that gave rise to the federal threats.<sup>17</sup> As discussed above, the CSA is similarly silent about physicians prescribing or pharmacists dispensing sterile syringes to IDUs.

In Oregon, when the DEA threatened physicians who prescribed narcotics in compliance with that State's Death with Dignity Act, it was pointed out to lawyers for the Department of Justice that, as with the DEA's threats against California doc-

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<sup>13</sup> CAL. HEALTH & SAFETY CODE § 11362.5 (West Supp. 2000) (giving Californians the right to obtain and use medically prescribed marijuana without fear of criminal prosecution).

<sup>14</sup> OR. REV. STAT. §§ 127.800-127.995 (1999).

<sup>15</sup> See *Conant v. McCaffrey*, 172 F.R.D. 681 (N.D. Cal. 1997).

<sup>16</sup> See *Conant v. McCaffrey*, 2000 U.S. Dist. LEXIS 13024, at \*\*33-34

<sup>17</sup> See *id.*

tors, the DEA's threats against Oregon physicians were made without statutory basis. Attorney General Janet Reno, upon reviewing the Controlled Substances Act and other federal laws agreed. In publicly retracting the DEA's threats, Attorney General Reno explained:<sup>18</sup>

There is no evidence that Congress, in the CSA, intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice. Indeed, the CSA is essentially silent with regard to regulating the practice of medicine that involves legally available drugs . . . .<sup>19</sup>

The Attorney General's analysis is equally applicable to the practice of medicine that involves the prescription of legally available medical devices such as syringes. As a result, even if politics prompted federal officials to voice opposition to physician prescription and pharmacy dispensing of syringes to IDUs, federal law, as it currently stands, does not authorize the officials to sanction these health care professionals.

## CONCLUSION

For the foregoing reasons, it appears that federal law does not regulate physician prescription or pharmacist dispensing of syringes to IDUs. Such regulation would take place at the state level, if at all.

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<sup>18</sup> Statement of Attorney General Reno on Oregon's Death with Dignity Act, Dep't of Justice Press Release (June 5, 1998), at 3. Available at <<http://www.usdoj.gov/opa/pr/1998/June/259ag.htm.html>> (visited Sept. 22, 2000).

<sup>19</sup> In recognition of the CSA's general silence when it comes to regulating medical practice, the U.S. House of Representatives passed H.R. 2260, the "Pain Relief Promotion Act of 1999," which, if signed into law, would give the DEA authority to regulate medical practice in the field of pain management by permitting DEA agents to assess physician intent in prescribing narcotic analgesia to pain patients to determine whether the narcotics were prescribed in order to relieve pain or hasten death. See H.R. 2260, 106th Cong. (2000).



