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Project on Harm Reduction in the Health Care System  

Memorandum

Date: February 10, 2000; Revised June 3, 2005
Subject: Prescribing and Dispensing Injection Equipment in California

INTRODUCTION

Numerous medical organizations and even the federal government itself now recommend that injection drug users employ a new, sterile syringe each time they inject.\(^1\) Unfortunately, the number of sterile syringes required to follow this standard — approximately one billion\(^2\) —


exceeds the available supply by many millions. The continuing shortage of syringes contributes to the spread of HIV, and is thus a major health problem. Many commentators have suggested that the health care system can help increase access to safe injection equipment through prescription, pharmacy sales and other measures such as hospital or clinic-based needle exchange programs (NEPs).

This Memorandum assesses the legality, under California law, of physician prescription and pharmacy sale of injection equipment to patients who are known to be injecting illegal drugs. It assumes that ensuring a patient’s access to sterile injection equipment is clinically effective and conducive to public health, ethical, and constitutes only one facet of the care the patient is receiving from the physician. These assumptions are justified and discussed in three companion reports: Zita Lazzarini, *The Ethics of Providing Injection Equipment to IDU Patients*; Josiah Rich, *The Clinical and Public Health Benefits of Providing Sterile Injection Equipment to IDU Patients: A Review of the Science*, and Josiah Rich, *Clinical Guidelines for Syringe Prescription to IDU Patients*. The risk of malpractice liability is discussed in a fourth companion piece, *Professional Liability in the Prescription and Dispensing of Sterile Injection Equipment to IDU Patients*, by Maxwell Mehlman.

We conclude that physicians may legally prescribe and pharmacists may legally dispense syringes to injection drug users (IDUs) as a health care intervention to prevent a patient acquiring or transmitting HIV.

This Memorandum addresses the following specific questions:

1) May a physician legally prescribe sterile injection equipment to an IDU patient?  
2) May a pharmacist legally fill such a prescription?  
3) How might California law be changed or clarified to promote access to sterile injection equipment for IDUs through the health care system?

I. May a Physician Legally Prescribe Sterile Injection Equipment to an IDU Patient?

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Answering this question requires a two-step analysis. We determine first whether prescription of sterile injection equipment is consistent with the general law governing medical practice. If so, we then ask whether any other law, such as a drug paraphernalia provision, prohibits prescription of syringes to an IDU patient. We begin with an overview of the regulatory environment.

A. The Regulatory Scheme

Medical Practice Law

The practice of medicine in California is governed by the Medical Practice Act, Cal. Bus. & Prof. Code §2000 et seq., with the Medical Practice Regulations found in Cal. Code Regs. Tit. 16, §1300 et seq. The Medical Board of California consists of two divisions, a Division of Medical Quality, and a Division of Licensing. Cal. Bus.& Prof. Code §2003. The Act vests in the board the power to adopt such regulations as it deems necessary to carry out the purposes of

4 Osteopathic physicians are governed under a separate act, Cal. Bus. & Prof. Code §3600 et seq. As the rules for osteopaths are substantially similar to the rules governing allopaths, the osteopathic rules will not be further discussed.

5 The Division of Medical Quality is responsible for:
   (a) The enforcement of the disciplinary and criminal provisions of the Medical Practice Act.
   (b) The administration and hearing of disciplinary actions.
   (c) Carrying out disciplinary actions appropriate to findings made by a medical quality review committee, the division, or an administrative law judge.
   (d) Suspending, revoking, or otherwise limiting certificates after the conclusion of disciplinary actions.
   (e) Reviewing the quality of medical practice carried out by physician and surgeon certificate holders under the jurisdiction of the board.
Cal. Bus. & Prof. Code §2004. The Division of Licensing is responsible for:
   (a) Approving undergraduate and graduate medical education programs.
   (b) Approving clinical clerkship and special programs and hospitals for such programs.
   (c) Developing and administering the physician's and surgeon's licensure examination.
   (d) Issuing licenses and certificates under the board's jurisdiction.
   (e) Administering the board's continuing medical education program.
   (f) Administering the student loan program.
Cal. Bus. & Prof. Code §2005. Since the Division of Medical Quality is responsible for carrying out the provisions relevant to this memorandum, it will simply be referred to as “the board.”
that Act, including authority to promulgate regulations defining the accepted standard of care that all practitioners must meet. Cal. Bus.& Prof. Code §2018.⁶

California medical licensure law is silent on the physician’s general authority to write prescriptions for or dispense drugs and devices. Leaving aside any limitations imposed by other laws, a physician is free to prescribe any drug or device he believes will benefit the patient and the prescription of which is consistent with the accepted standard of care. According to the Medical Practice Act, the Board is required to take action against a physician who is guilty of unprofessional conduct, which includes:

(a) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provision of this chapter.
(b) Gross negligence.
(c) Repeated negligent acts.
(d) Incompetence.
(e) The commission of any act involving dishonesty or corruption which is substantially related to the qualifications, functions, or duties of a physician and surgeon.
(f) Any action or conduct which would have warranted the denial of a certificate.

Cal. Bus.& Prof. Code §2234.⁷ Another example of unprofessional conduct resulting in disciplinary action is:

Repeated acts of clearly excessive prescribing or administering of drugs or treatment . . . as determined by the standard of the community of licensees is unprofessional conduct for a physician and surgeon . . . However, pursuant to Section 2241.5, no physician and surgeon in compliance with the California Intractable Pain Treatment Act shall be subject to disciplinary action for lawfully prescribing or administering controlled substances in the course of treatment of a person for intractable pain.

Any person who engages in repeated acts of clearly excessive prescribing or administering of drugs or treatment is guilty of a misdemeanor and shall be punished by a fine of not less than one hundred dollars ($100) nor more than six hundred dollars ($600), or by imprisonment for a term of not less than 60 days nor more than 180 days, or by both

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⁶ Also under Cal. Bus.& Prof. Code §2018, the Division of Medical Licensing is authorized to adopt regulations to carry out the purposes of the Act that fall within its jurisdiction.
⁷ The Division of Licensing may also deny, revoke, or restrict a license, but the Division of Medical Quality is solely responsible for enforcing those sanctions. Cal. Bus.& Prof. Code §2221.
the fine and imprisonment.

Cal. Bus. & Prof. Code §725. Unprofessional conduct also includes:

(a) The conviction of a charge of violating any federal statutes or regulations or any statute or regulation of this state, regulating dangerous drugs or controlled substances, constitutes unprofessional conduct. The record of the conviction is conclusive evidence of such unprofessional conduct. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this section.

Cal. Bus.& Prof. Code §2237. In fact, not only a conviction, but any

[V]iolation of any federal statute or federal regulation or any of the statutes or regulations of this state regulating dangerous drugs or controlled substances constitutes unprofessional conduct.

Cal. Bus.& Prof. Code §2238. Further,

Unless otherwise provided by this section, the prescribing, selling, furnishing, giving away, or administering or offering to prescribe, sell, furnish, give away, or administer any of the drugs or compounds mentioned in Section 2239 [controlled substances, dangerous drugs or alcohol] to an addict or habitue constitutes unprofessional conduct.

If the drugs or compounds are administered or applied by a licensed physician and surgeon or by a registered nurse acting under his or her instruction and supervision, this section shall not apply to any of the following cases:

(a) Emergency treatment of a patient whose addiction is complicated by the presence of incurable disease, serious accident or injury, or the infirmities attendant upon age.

(c) Treatment of addicts [for drug addiction] as provided for by Section 11217.5 of the Health and Safety Code.

Cal. Bus.& Prof. Code §2241. The Act also states:

(a) Notwithstanding any other provision of law, a physician and surgeon may prescribe or administer controlled substances to a person in the course of the physician and surgeon's treatment of that person for a diagnosed condition causing intractable pain. 

(b) "Intractable pain," as used in this section, means a pain state in which the cause of the pain cannot be removed or otherwise treated . . .
(c) No physician and surgeon shall be subject to disciplinary action by the board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain.
(d) This section shall not apply to those persons being treated by the physician and surgeon for chemical dependency because of their use of drugs or controlled substances.
(e) This section shall not authorize a physician and surgeon to prescribe or administer controlled substances to a person the physician and surgeon knows to be using drugs or substances for nontherapeutic purposes.
(f) This section shall not affect the power of the board to deny, revoke, or suspend the license of any physician and surgeon who does any of the following:
   (1) Prescribes or administers a controlled substance or treatment that is nontherapeutic in nature or nontherapeutic in the manner the controlled substance or treatment is administered or prescribed or is for a nontherapeutic purpose in a nontherapeutic manner.
   
   (4) Prescribes, administers, or dispenses in a manner not consistent with public health and welfare controlled substances listed in the California Controlled Substance Act or scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.
   (5) Prescribes, administers, or dispenses in violation of either Chapter 4 (commencing with Section 11150) or Chapter 5 (commencing with Section 11210) of Division 10 of the Health and Safety Code or this chapter.

Cal. Bus.& Prof. Code §2241.5. The Medical Practice Regulations offer no further definitions or examples of unprofessional conduct.

Unless otherwise expressly provided, violations of this Act are misdemeanors. Cal. Bus.& Prof. Code §2314(a). These misdemeanors are punishable by fines of not less than two hundred dollars nor more than one thousand two hundred dollars or by imprisonment of not less than 60 days nor more than 180 days, or by both. Cal. Bus.& Prof. Code §2315(a).

(Controlled Substances Law Generally)

Prescribing powers with respect to certain drugs are defined in the California Uniform Controlled Substances Act (the Controlled Substances Act). Cal. Health & Safety Code §11000
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et seq.\textsuperscript{8} These provisions are not strictly applicable to syringes,\textsuperscript{9} but are relevant in assessing the nature of the physician’s authority to prescribe. The Act’s “Prescriptions” chapter states:

(a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice . . . Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.

(b) Any person who knowingly violates this section shall be punished by imprisonment in the state prison or in the county jail not exceeding one year, or by a fine not exceeding twenty thousand dollars ($20,000), or by both a fine and imprisonment.

Cal. Health & Safety Code §11153. Also,

A physician . . . may prescribe for, furnish to, or administer controlled substances to his or her patient when the patient is suffering from a disease, ailment, injury, or infirmities attendant upon old age, other than addiction to a controlled substance.

The physician . . . shall prescribe, furnish, or administer controlled substances only when in good faith he or she believes the disease, ailment, injury, or infirmity requires the treatment.

The physician . . . shall prescribe, furnish, or administer controlled substances only in the quantity and for the length of time as are reasonably necessary.

Cal. Health & Safety Code §11210. In sum, a controlled substances prescription is valid if it is issued in good faith, for a legitimate medical purpose, and in the usual course of the physician’s professional practice. The provision reinforces these guidelines by stating:

(a) Except in the regular practice of his or her profession, no person shall knowingly

\textsuperscript{8} Cal. Health & Safety Code §11150 explicitly states that “[n]o person other than a physician . . . shall write or issue a prescription.”

\textsuperscript{9} These provisions only apply to controlled substances which are defined as drugs, substances, or immediate precursors which are listed in any schedule in Section 11054, 11055, 11056, 11057, or 11058. Cal. Health & Safety Code §11007.
prescribe, administer, dispense, or furnish a controlled substance to or for any person or animal which is not under his or her treatment for a pathology or condition other than addiction to a controlled substance, except as provided in this division.

Cal. Health & Safety Code §11154. Further,

(a) Except as provided in Section 11159 . . . no controlled substance classified in Schedule II shall be dispensed without a prescription meeting the requirements of this chapter. Except as provided in Section 11159 or when dispensed directly to an ultimate user by a practitioner, other than a pharmacist or pharmacy, no controlled substance classified in Schedule III, IV, or V may be dispensed without a prescription meeting the requirements of this chapter.

(c) Except as otherwise prohibited or limited by law, a practitioner specified in Section 11150, may administer controlled substances in the regular practice of his or her profession.


On the subject of drug dependent persons, the chapter states:

No person shall prescribe for or administer, or dispense a controlled substance to an addict or habitual user, or to any person representing himself as such, except as permitted by this division.


Drug Paraphernalia Law


10 The language of this section – “No person shall write, issue, fill, compound, or dispense a prescription that does not conform to this division” – suggests that the standards for prescribing controlled substances are applicable to all prescriptions. We identified no case law that addressed this question of interpretation.

The definitions section of the Controlled Substances Act provides a tri-partite definition of "drug paraphernalia." First, it defines drug paraphernalia generally as "all equipment, products and materials of any kind which are designed for use” with controlled substances in violation of this division. Cal. Health & Safety Code §11014.5. Second, it lists eight types of items as examples of drug paraphernalia. Id. Finally, it offers seven factors to be considered when determining whether an item is drug paraphernalia. Id.

The statute refers to injection in the roster of drug-use practices that contribute to defining paraphernalia under the first part of the definition, and includes “[h]ypodermic syringes, needles, and other objects designed for use or marketed for use in parenterally injecting controlled substances into the human body,” in its list of items that can qualify as drug paraphernalia under some circumstances. Cal. Health & Safety Code §11014.5(a)(7). The seven factors to be considered are:

(1) Statements by an owner or by anyone in control of the object concerning its use.
(2) Instructions, oral or written, provided with the object concerning its use for ingesting, inhaling, or otherwise introducing a controlled substance into the human body.
(3) Descriptive materials accompanying the object which explain or depict its use.
(4) National and local advertising concerning its use.
(5) The manner in which the object is displayed for sale.
(6) Whether the owner, or anyone in control of the object, is a legitimate supplier of like or related items to the community, such as a licensed distributor or dealer of tobacco products.
(7) Expert testimony concerning its use.


The law has two main regulatory sections. One, which we will refer to as the “retail paraphernalia law,” prohibits the operation of “any place of business in which drug paraphernalia is kept, displayed or offered in any manner, sold, furnished, transferred or given away unless such drug paraphernalia is completely and wholly kept, displayed or offered within a separate room or enclosure to which persons under the age of 18 years not accompanied by a parent or legal guardian are excluded.” Cal. Health & Safety Code §11364.5(a). This section
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includes its own tri-partite definition of drug paraphernalia that includes twelve examples of paraphernalia and ten factors to be considered. Cal. Health & Safety Code § 11364.5(d) and (e). Due to the four additional examples of paraphernalia, hypodermic syringes and needles are listed as item ‘11.’ Cal. Health & Safety Code § 11364.5(d). The three additional factors to consider are:

... 
(2) Prior convictions, if any, of an owner, or of anyone in control of the object, under any state or federal law relating to any controlled substance.
(3) Direct or circumstantial evidence of the intent of an owner, or of anyone in control of the object, to deliver it to persons whom he or she knows, or should reasonably know, intend to use the object to facilitate a violation of this section. The innocence of an owner, or of anyone in control of the object, as to a direct violation of this section shall not prevent a finding that the object is intended for use, or designed for use, as drug paraphernalia.
...
(9) The existence and scope of legitimate uses for the object in the community.

Cal. Health & Safety Code § 11364.5(e). This section exempts from its restrictions

(1) Any pharmacist or other authorized person who sells or furnishes drug paraphernalia described in paragraph (11) of subdivision (d) [hypodermic syringes and needles] upon the prescription of a physician, dentist, podiatrist or veterinarian.
(2) Any physician, dentist, podiatrist or veterinarian who furnishes or prescribes drug paraphernalia described in paragraph (11) of subdivision (d) to his or her patients.
(3) Any manufacturer, wholesaler or retailer licensed by the California State Board of Pharmacy to sell or transfer drug paraphernalia described in paragraph (11) of subdivision (d).


There is also an exemption for personal possession of 10 or few syringes if the local government permits it.

(a) It is unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphernalia used for unlawfully injecting or smoking (1) a controlled substance . . . .
(c) Pursuant to authorization by a county, with respect to all of the territory within the
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county, or a city, with respect to the territory within the city . . . subdivision (a) shall not apply to the possession solely for personal use of 10 or fewer hypodermic needles or syringes if acquired from an authorized source.

Cal. Health & Safety Code § 11364. The drug paraphernalia act also has a broader prohibition of paraphernalia distribution, which we will refer to as the “general paraphernalia law,” and which states:

(a) Except as authorized by law, any person who delivers, furnishes, or transfers [or] possesses with intent to deliver, furnish, or transfer . . . drug paraphernalia, knowing, or under circumstances where one reasonably should know, that it will be used to . . . inject, ingest, inhale, or otherwise introduce into the human body a controlled substance . . . in violation of this division, is guilty of a misdemeanor.

No public entity, its agents, or employees shall be subject to criminal prosecution for distribution of hypodermic needles or syringes to participants in clean needle and syringe exchange projects authorized by the public entity pursuant to a declaration of a local emergency due to the existence of a critical local public health crisis.

. . .

(c) Except as authorized by law, any person, 18 years of age or over, who violates subdivision (a) by delivering, furnishing, or transferring drug paraphernalia to a person under 18 years of age who is at least three years his or her junior . . . knowing, or under circumstances where one reasonably should know, that it will be used by a person under 18 years of age to inject into the human body a controlled substance, is guilty of a misdemeanor and shall be punished by imprisonment in a county jail for not more than one year, by a fine of not more than one thousand dollars ($1,000), or by both that imprisonment and fine.

(d) The violation, or the causing or the permitting of a violation, of subdivision (a), (b), or (c) by a holder of a business or liquor license issued by a city, county, or city and county, or by the State of California, and in the course of the licensee's business shall be grounds for the revocation of that license.

Cal. Health & Safety Code §11364.7. Violations of the drug paraphernalia act, for which no penalty is specifically provided, are misdemeanors punishable by a fine of not less than thirty dollars nor more than five hundred dollars, or by imprisonment for not less than 15 nor more than 180 days, or by both. Cal. Health & Safety Code §11374.
Syringe Prescriptions

Article 9 of chapter 9 of the Pharmacy Act sets out comprehensive rules for the possession and distribution of syringes. Cal. Bus. & Prof. Code § 4140 ("No person shall possess or have under his or her control any hypodermic needle or syringe except when acquired in accordance with this article."). Only licensed persons are authorized to sell or furnish syringes. Id. § 4141. “Except as otherwise provided by this article, no hypodermic needle or syringe shall be sold at retail except upon the prescription of a physician, dentist, veterinarian, or podiatrist.” Cal. Bus. & Prof. Code § 4142.11

However, local governments may authorize the sale of syringes without a prescription, in the amount of 10 or fewer per sale.

(a) Notwithstanding any other provision of law, a pharmacist or physician may, without a prescription or a permit, furnish hypodermic needles and syringes for human use, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist or physician for human use, if one of the following requirements is met:

(1) The person is known to the furnisher and the furnisher has previously been provided a prescription or other proof of a legitimate medical need requiring a hypodermic needle or syringe to administer a medicine or treatment.

(2) Pursuant to authorization by a county, with respect to all of the territory within the county, or a city, with respect to the territory within the city, for the period commencing January 1, 2005, and ending December 31, 2010, a pharmacist may furnish or sell 10 or fewer hypodermic needles or syringes at any one time to a person 18 years of age or older if the pharmacist works for a pharmacy that is registered for the Disease Prevention Demonstration Project pursuant to Chapter 13.5 (commencing with Section 121285) of Part 4 of Division 105 of the Health and Safety Code and the pharmacy complies with the provisions of that chapter.

11 Non-prescription sales are allowed to licensed wholesale and retail distributors, Cal. Bus. & Prof. Code § 4143, or industrial users, id. § 4144. No prescription is required for “human use in the administration of insulin or adrenaline . . . .” Cal. Bus. & Prof. Code § 4145. Section 4146 requires the seller of a nonprescription syringe to maintain a record of the sale.

Other sections address disposal and confiscation of improperly possessed syringes. Id. §§ 4147 - 4148. Apart from requiring a prescription for the sale of syringes, there are no substantive guidelines provided to determine the validity of a prescription.

B. Analysis

The Pharmacy Act requires a prescription for the dispensing of a syringe under most circumstances (unless the local government explicitly authorized sale without prescription), but provides no substantive standard for determining the validity of a syringe prescription. We must therefore look to the general authority of physicians to prescribe. California law nowhere sets out in positive terms the extent or basis of the physician’s general authority to write prescriptions for syringes or other devices. But cf. note 10, supra, and accompanying text. This authority is assumed, as an aspect of the professional practice of medicine. The law and regulations governing the prescription of controlled substances and drugs, however, set out the standard that would almost certainly be borrowed by courts in a syringe prescription case. Indeed, the Medical Practice Act and the Controlled Substances Act judge the validity of a prescription by essentially the same standard: it is valid if it is written (1) in good faith, (2) in the usual course of professional practice, and (3) for a legitimate medical purpose. A prescription for sterile injection equipment, issued to a patient who cannot or will not enter drug treatment, for the purpose of preventing the transmission of a serious communicable disease during injection, would seem to be well within the parameters of allowable discretion set by this standard.

California courts have asserted that these three requirements are clear and readily understandable to practitioners. See generally Davis v. Board of Medical Examiners, 108 Cal.App.2d 346, 239 P.2d 78(1951); People v. Gandotra, 11 Cal.App.4th 1355(1992). The cases, none of which involve situations comparable to those at issue here, offer scant further insight. In normal usage, “[g]ood faith is that state of mind denoting honesty of purpose, freedom from intention to defraud, and, generally speaking, means being faithful to one's duty or obligation.” The People v. Lonergan, 219 Cal.App.3d 82, 90, 267 Cal.Rptr. 887, 892(1990)(citation and quotations omitted). It entails a genuine concern for the well-being of the patient (and, presumably, others who might be infected through sharing injection equipment with the patient), and conduct devoid of malice or deception. See, e.g., Davis, 108 Cal.App.2d 346, 239 P.2d 78.

In determining whether a prescription arises within the usual course of professional practice, courts may consider such matters as whether a bona fide physician-patient relationship existed, whether other care was provided, whether proper records were kept of the encounter, whether the prescription was based on a proper history or individualized assessment of the
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patient's risk factors, efforts to provide other harm reducing services, follow up and so on. See generally United States v. Moore, 423 U.S. 122, 142-43, 96 S.Ct. 335, 345 ("The evidence presented at trial was sufficient for the jury to find that respondent's conduct exceeded the bounds of "professional practice." ...[H]e gave inadequate physical examinations or none at all. He ignored the results of the tests he did make. ... He did not regulate the dosage at all, prescribing as much and as frequently as the patient demanded. He did not charge for medical services rendered, but graduated his fee according to the physician." ) A physician who is providing syringes to a patient who cannot or will not enter drug treatment, and whose injection drug use places him at high risk of contracting or spreading a communicable disease, should have no difficulty satisfying these two prongs of the prescription standard.

On the third prong, it is the burden of the prosecution to prove not simply that some physicians disagree with the practice at issue, but that no responsible segment of the medical profession exists which accepts appellant's methods. See Glover v. Board of Medical Quality Assurance, 231 Cal. App.3d 203, 208(1991)("As long as the differences of opinion are legitimate, we have no dispute with the notion that different methods of treatment can all be considered acceptable medical practice."); accord Lonergan, 219 Cal.App.3d 82, 91, 267 Cal.Rptr. 887, 893("[The fact that a Physician might have . . . acted in a fashion different from that of other practitioners is immaterial if the Physician acted in good faith.") There is ample support for the position that prescribing sterile injection equipment comports with treatment principles accepted by a responsible segment of the medical profession. See Zita Lazzarini, The Ethics of Providing Injection Equipment to IDU Patients; Josiah Rich, The Clinical and Public Health Benefits of Providing Sterile Injection Equipment to IDU Patients: A Review of the Science, and Josiah Rich, Clinical Guidelines for Syringe Prescription to IDU Patients.

Conclusion: A prescription for sterile injection equipment to an IDU patient is consistent with the standard for a valid prescription under the Medical Practice Act and the prescription provision of the Controlled Substances Act.

We turn now to the second question: Do any other laws prohibit physicians from prescribing sterile injection equipment to IDU patients? There are two main possibilities.

Cal. Health & Safety Code §11156, the provision prohibiting a physician from prescribing controlled substances to a known addict or habitual user, could be the basis of an argument that providing sterile injection equipment must also be illegal. Per this argument, providing syringes enables drug users to violate the law, and is therefore inconsistent with the basic purposes of the act.

This argument has a common-sense appeal, but should fail on at least three grounds.
First, the plain language of the prohibition does not embrace syringes, and it is a cardinal rule of California statutory construction that criminal laws are to be construed “as favorably to the defendant as its language and the circumstances of its application may reasonably permit . . . [T]he defendant is entitled to the benefit of every reasonable doubt as to the true interpretation of words or the construction of language used in a statute.” Keeler v. Superior Court of Amador County, 2 Cal.3d 619, 631, 470 P.2d 617, 624(1970). Under this rule, a court should not read a criminal statute as prohibiting conduct it does not explicitly prohibit, unless the results would be absurd. Second, even if we accept the analogy between providing controlled substances and providing sterile equipment for injecting them, the provision itself makes an exception for prescriptions authorized by other provisions of the Controlled Substances Act. As seen above, the Act authorizes physician's to prescribe controlled substances to addicts for therapeutic purposes, not for the purpose of maintaining the patient's addiction. Preventing the spread of infectious disease, while not literally curing or treating a disease, is a plainly acceptable medical intervention, and so would seem to fall well within a broad interpretation of the provision. Finally, the legislature’s recent approval of locally-operated needle exchange programs precludes any argument that providing sterile injection equipment is contrary to public policy.12

A more serious possibility is the drug paraphernalia law. As we will discuss further in the pharmacy analysis below, syringes can be drug paraphernalia under some circumstances. Although it may be argued that prescription of syringes is governed by the specific prescription provision of Cal. Bus. & Prof. Code § 4142, and not by the more general drug paraphernalia law, for purposes of this analysis, we will assume that syringes are drug paraphernalia.

The law prohibits delivering, furnishing or transferring “drug paraphernalia, knowing, or under circumstances where one reasonably should know, that it will be used to . . . inject, ingest, inhale, or otherwise introduce into the human body a controlled substance . . . in violation of this division.” Cal. Health & Safety Code §11364.7(a). Writing a prescription does not fall within the definition of any of these terms.

Delivery is defined as “the actual, constructive, or attempted transfer from one person to another of a controlled substance, whether or not there is an agency relationship.” Cal. Health & Safety Code §11009. Furnish is defined as “to supply by any means, by sale or otherwise.” Cal.Bus. & Prof.Code § 4026. Transfer is not specially defined, so is interpreted according to common usage. All these acts would require the syringe to pass from the possession of the physician into the possession of the patient, and so each entails the physician’ actually, or at the very least constructively, possessing the syringe.

12 There are currently 25 syringe exchange programs operating in California. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5427a1.htm
A physician who writes a prescription for an item is not actually transferring possession of that item to the patient, but merely providing the patient with instructions and authorization for the pharmacist who will transfer possession by dispensing the prescription. Nor does the concept of a constructive delivery or transfer embrace the writing of a prescription. Constructive delivery requires at least constructive possession. “Constructive possession exists where a defendant maintains some control or right to control contraband that is in the actual possession of another.” People v. Morante, 20 Cal.4th 403, 417, 975 P.2d 1071, 1080, 84 Cal.Rptr.2d 665, 674(1999).

The authority to write a prescription for a syringe does not give the physician the ability to exercise control or dominion over it; like the patient, he would have to go to the pharmacy and purchase the syringe in order to possess it, and so cannot be said to constructively possess it.16

**Conclusion:** Writing a prescription for a syringe does not violate any California law. A physician may therefore legally prescribe injection equipment to an IDU patient.

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16 It should be noted that courts interpreting controlled substances laws have sometimes interpreted terms like "sell," "dispense," "furnish" or "distribute" to embrace the writing of a prescription for a controlled substance. See, e.g., Jin Fuey Moy v. United States, 254 U.S. 189, 41 S.Ct. 98, 65 L.Ed. 214 (1920); United States v. Thompson, 624 F.2d 740 (C.A.5, 1980); Commonwealth v. Comins, 371 Mass. 222, 356 N.E.2d 241 (1976), certiorari denied (1977), 430 U.S. 946, 97 S.Ct. 1582, 51 L.Ed.2d 793; State v. Moody, 393 So.2d 1212 (La.1981). See generally Christopher Vaeth, State Law Criminal Liability of Licensed Physician for Prescribing or Dispensing Drug or Similar Controlled Substance, 13 A.L.R.5th 1, 73-84 (1993). This interpretation, however, is not supported by California law. See Baker v. Superior Court of Los Angeles County, 24 Cal App 3d 124, 100 Cal Rptr 771(1972).

Although a physician who prescribes a syringe does not physically provide a needle to the patient, and therefore could not be said to engage in conduct potentially covered by the paraphernalia statute, there is a risk that prescribing a syringe could be prosecuted as aiding and abetting a violation of the paraphernalia statute that would occur when the pharmacist dispensed the syringe, or for conspiracy to violate the paraphernalia statute.

These charges are available to a motivated prosecutor. The risk to the physician is slight, however, for several reasons. Such a prosecution would be unusual: there is no reported case in California of a charge of aiding and abetting a paraphernalia violation, nor are either conspiracy or accomplice charges commonly deployed where the core offense is a misdemeanor. More importantly, both crimes depend upon the underlying illegality of providing sterile injection equipment by prescription. Our analysis suggests that this behavior is not a crime. With a valid prescription, a patient is not violating the paraphernalia law when he purchases the needle, and the physician, or pharmacist, cannot be his accomplice or co-conspirator.
II. May a Pharmacist Legally Fill a Such a Prescription?

A. The Regulatory Environment

**Pharmacy Licensure Law**

The practice of pharmacy in California is governed by the Pharmacy Law, Cal. Bus.& Prof. Code §4000 et seq., with regulations found in Cal. Code Regs. Tit. 16, §1700 et seq. The Act vests in the State Board of Pharmacy power to adopt such regulations as may be necessary to carry out the purposes of that Act. Cal. Bus.& Prof. Code §4005.

The Pharmacy Act regulates the sale of “dangerous devices,” defined to include “[a]ny other ... device that by federal or state law can be lawfully dispensed only on prescription.” Id. § 4022(2). The act states: “(a) No person shall furnish any ... dangerous device, except upon the prescription of a physician . . .” Cal.Bus. & Prof.Code § 4059. Regardless of whether syringes were intended to fall within the definition of dangerous devices, the Pharmacy Law also speaks directly sale of syringes: “No person shall furnish hypodermic needles or syringes, by sale or otherwise, without a license issued by the board, except as otherwise provided by this article.” Cal. Bus. & Prof. Code §4141. Additionally, “Except as otherwise provided by this article, no hypodermic needle or syringe shall be sold at retail except upon the prescription of a physician, dentist, veterinarian, or podiatrist.” Cal. Bus.& Prof. Code §4142. The pharmacist may dispense syringes without prescription with authorization from the local government and if the pharmacy is registered with the Disease Prevention Demonstration Project pursuant to Cal. Health & Safety Code § 121285. Cal. Bus. & Prof. Code § 4145.

The disciplinary provisions of the Pharmacy Act and the code authorize action against the license of a pharmacist who is found to have been guilty of unprofessional conduct:

Unprofessional conduct for a pharmacist may include acts or omissions that involve, in whole or in part, the exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

Cal. Bus.& Prof. Code §4306.5. The Pharmacy Law also states:

(a) Any person who knowingly violates any of the provisions of this chapter, when no other penalty is provided, is guilty of a misdemeanor, and upon conviction thereof shall be punished by a fine of not less than two hundred dollars ($200), and not more than two
thousand dollars ($2,000), or by imprisonment of not less than 30 days nor exceeding six months, or by both that fine and imprisonment.

(b) In all other instances, any person who violates any of the provisions of this chapter, when no other penalty is provided, is guilty of an infraction, and upon conviction thereof may be punished by a fine not to exceed one thousand dollars ($1,000).


A pharmacist is authorized to dispense medications ordered by a valid prescription, and is ordinarily expected to do so in the absence of a good reason to refuse. Strauss S. The Pharmacist and the Law. Baltimore MD: Williams & Wilkins, 1980:29-31; Steven W. Huang, The Omnibus Reconciliation Act of 1990: Redefining Pharmacists’ Legal Responsibilities, XXIV Am. J. L & Med. 417 (1998). The pharmacy regulations state that:

Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4047.6 of the Business and Professions Code.

Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-accepted pharmaceutical practice in the compounding or dispensing of a prescription.

Cal. Code Regs. Tit. 16, §1716. Further,

Prior to consultation . . . a pharmacist shall review a patient's drug therapy and medication record before each prescription drug is delivered. The review shall include screening for severe potential drug therapy problems.

Cal. Code Regs. Tit. 16, §1707.3. Finally,

(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

Controlled Substance and Drug Paraphernalia Laws

The controlled substances and paraphernalia discussed in I.A. above are also applicable to pharmacists. The Controlled Substances Act makes it clear that a pharmacist has an independent responsibility to ensure that controlled substances are properly prescribed: “The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.” Cal. Health & Safety Code §11153(a).

B. Analysis

We have concluded above that a physician’s prescription for sterile injection equipment, written under the factual conditions assumed for purposes of this Memorandum, is valid under California law. The syringe prescription regulation in the pharmacy code does not set any additional substantive standards for a syringe prescription, but rather simply requires a prescription as a condition of sale. Ordinarily, the pharmacist is required to fill a valid prescription. The next question is whether filling the prescription would be prohibited under any other provision of law.

Here the issue is, again, the paraphernalia law. The pharmacist is undoubtedly transferring the syringe, so if a syringe is drug paraphernalia in this situation, then the transfer is illegal. We thus come to the fundamental question of whether a syringe dispensed by a valid prescription, for legitimate medical reasons, falls within the definition of “drug paraphernalia” under California law. Whether something is drug paraphernalia depends, in narrowest terms, upon whether the seller knows or has reason to know that it will be used for illegal drug use. Cal. Health & Safety Code §11364.7(a). In all cases in which the pharmacist does not in fact know or have reason to know that the patient intends to use the syringe to inject illegal drugs, the pharmacist does not violate the paraphernalia law even if in fact the item will be used for drug abuse.

**Conclusion: Dispensing sterile injection equipment to an IDU does not violate California law where the pharmacist does not and reasonably should not know that the patient intends to use the equipment to illegally inject drugs.**

Many pharmacists will have occasion to learn or reasonably suspect that a patient presenting a valid syringe prescription is an IDU likely to use the syringes for illegal drug injection. In this case, there is a potential conflict between the general paraphernalia law, which would prohibit the sale, and the web of laws regulating the sale of syringes and other prescription medical devices, which would allow it. This presents a classic problem of statutory
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construction.

In California,

The fundamental goal of statutory construction is to ascertain the intent of the Legislature so as to effectuate the purpose of the law. In determining such intent, we first look to the words of the statute, giving the language its usual, ordinary import. The words of the statute must be construed in context, keeping in mind the statutory purpose. Statutes or statutory sections relating to the same subject must be harmonized to the extent possible. Where uncertainty exists, consideration should be given to the consequences that will flow from a particular interpretation. Both the legislative history and the wider historical circumstances of its enactment may be considered in ascertaining the legislative intent.

People v. Lamb, 76 Cal.App.4th 664, 678, 90 Cal.Rptr.2d 565, 574(1999). There are two possible readings that give effect to both provisions.

On one view, the Pharmacy Act and related sections of the Controlled Substances Act govern the legality of any drug or device prescribed or dispensed by a health care provider acting in his professional capacity. The paraphernalia law applies to people who are not legally authorized to prescribe or dispense drugs or devices, as well as to health care providers who are clearly acting outside their professional capacity (e.g., selling syringes on the street) or providing them without a prescription. Under this interpretation, the prescription and dispensing of needles to IDUs to prevent disease is not prohibited by the paraphernalia law.14

The paraphernalia statute may also be read as a limitation on the pharmacist’s authority to dispense. The prescription statute, on this reading, allows a professional to prescribe in good faith, in the usual course or practice, for a legitimate medical purpose, and authorizes the pharmacist to fill the prescription except when the pharmacist knows the patient intends to use the item for drug use, when the drug paraphernalia provision interposes its prohibition.

This Memorandum reviews the strengths and weaknesses of both positions in turn.

The Paraphernalia Law Does Not Apply to Syringes Validly Prescribed under the Pharmacy Act’s Syringe Provisions

14 This interpretation does not address distribution of injection equipment through needle exchange programs operated by non-practitioners, who are not “prescribing or dispensing” under California law.
The Pharmacy Act sets out a comprehensive and complete set of rules governing the legal sale and possession of syringes. Although it sets no substantive limits on the physician’s discretion to prescribe a syringe, it is reasonable to assume that the legislature intended to allow only prescriptions that would meet the generally applicable standards of professional conduct. As we have demonstrated, the plain text of the Pharmacy Act thus authorizes the prescription and dispensing of syringes to IDUs as a medical intervention to prevent the transmission of disease. Local governments can even authorize the sale of syringes without a prescription in the amount of 10 or fewer. Cal. Bus. & Prof. Code § 4145 (italics added). The general paraphernalia law forbids the delivery of syringes for purposes of illegal drug use, “except as authorized by law.” Cal. Health & Safety Code §11364.7 (italics added). The prescription provision of the Pharmacy Act, embedded in a system of professional licensure and regulation for both physicians and pharmacists, constitutes the authorization referenced in the paraphernalia law’s exception clause. This reading harmonizes the plain language of the two statutes.

If the clear and unambiguous language can resolve a question of statutory interpretation, California law requires the court look no further to search for legislative intent. See Delaney v. Superior Court, 50 Cal.3d 785, 798, 268 Cal.Rptr. 753, 789 P.2d 934 (1990); Brown v. Kelly Broadcasting Co., 48 Cal.3d 711, 724, 257 Cal.Rptr. 708, 771 P.2d 406 (1989). In any event, this reading is also consistent with legislative intent. The entire system of medical and pharmacy regulation is plainly designed to protect the discretion of practitioners in the usual and legitimate course of their professional work, while preventing abuse of the privileges of licensure. A physician or pharmacist who provides syringes or other paraphernalia not in good faith, for a legitimate medical reason, in the usual course of practice, is not shielded by the pharmacy act. Cf. Davis v. Board of Medical Examiners, 108 Cal.App.2d 346, 239 P.2d 78 (1951). The general paraphernalia act, for its part, was passed to deal with “head shops” involved in the large-scale commercial sale of items promoting drug use, for personal gain. See generally Lawrence O. Gostin, Zita Lazzarini. Prevention of HIV/AIDS Among Injection Drug Users: The Theory and Science of Public Health and Criminal Justice Approaches to Disease Prevention, 46 EMORY L J 587 (1997) (describing origins of drug paraphernalia statutes). It would apply to precisely the pharmacist who had abandoned his or her professional role and begun distributing syringes or other paraphernalia without medical justification. It would not, and never was intended, to regulate the practice of medicine or pharmacy.

Interpreting the general paraphernalia law to exempt sales authorized under the syringe prescription provision of the Pharmacy Act is also supported, if not required, by the rule of ejusdem generis. This canon of statutory construction requires that, where general and specific terms are employed, all relating to the same things, the special terms limit the general ones. This traditional common law rule is codified in California in Cal.Code Civ. Pro. § 1859: “In the construction of a statute the intention of the Legislature ... is to be pursued, if possible; and when
a general and particular provision are inconsistent, the latter is paramount to the former. So a particular intent will control a general one that is inconsistent with it.” See English Manor Corp. v. Vallejo Sanitation and Flood Control Dist., 117 Cal.Rptr. 315, 42 Cal.App.3d 996 (1974); People v. Superior Court In and For Los Angeles County, 18 Cal.Rptr. 557, 199 Cal.App.2d 303 (1962); People v. Perez, 18 Cal.Rptr. 164, 198 Cal.App.2d 460 (1962); Rose v. State, 123 P.2d 505, 19 Cal.2d 713 (1942).

The syringe law is plainly the more specific provision. It applies to only one type of item, a syringe, while the paraphernalia law covers everything from paper clips to water pipes intended to be used for illegal drug consumption. The syringe law is also more specific in the body of distributors it governs. With narrow exceptions, it limits legal possession of syringes to licensed persons and those who have obtained syringes by prescription. In areas where the government permits it, individuals may carry 10 or fewer syringes for personal use if obtained from an authorized source. Cal. Health & Safety Code § 11364(c). The paraphernalia statute apparently applies to any person in any setting. The syringe law creates a narrow and highly regulated method of obtaining syringes, which requires individuals acquiring a syringe for most medical purpose to have a prescription.15 The paraphernalia law was deliberately drafted to cover a vast array of potential sellers, buyers and modes of distribution. See Lawrence O. Gostin, Zita Lazzarini. Prevention of HIV/AIDS Among Injection Drug Users: The Theory and Science of Public Health and Criminal Justice Approaches to Disease Prevention, 46 Emory LJ 587 (1997). To the extent that there is any irreconcilable conflict between the paraphernalia law and the pharmacy act’s syringe provisions, the latter should clearly control.16

The rule of lenity supports this interpretation. “The rule has been stated as follows: ‘If the statutory language is ambiguous and susceptible to two plausible interpretations, we must, because this is a criminal statute, adopt the one more favorable to the defendant.’ ... This rule is applicable in situations of true ambiguity, where there is no indication of legislative intent.” People v. Lamb, 76 Cal.App.4th 664, *682, 90 Cal.Rptr.2d 565, **577 (Ct. App. 1999) (citations omitted). "The rule of lenity provides guidance when the language of a penal statute is

15 “[A] ‘prescription’ [is] an oral order or electronic transmission prescription for a controlled substance given individually for the person(s) for whom prescribed, directly from the prescriber to the furnisher or indirectly by means of a written order of the prescriber.” Cal. Health & Safety Code§ 11027(a).
16 The fact that we are construing a criminal act only supports this conclusion. See People v. Superior Court (Perez), 45 Cal.Rptr.2d 107, 38 Cal.App.4th 347 (Ct. App. 1995) (particular or specific provisions of statute will generally take precedence over conflicting general provisions; however, if ambiguity exists in penal statute, construction more favorable to defendant will generally be adopted. )
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"susceptible" of two or more interpretations.” People v. Garcia, 21 Cal.4th 511A (1999). The rationale for the rule is the injustice of convicting a person without clear notice to him that his contemplated conduct is unlawful, as well as notice of the penalties. Given the obvious ambiguity in the proper interpretation of the paraphernalia and prescription provisions, lenity requires a court to hold that a practitioner acting legally under the former provision cannot be charged with violating the latter.17

The Paraphernalia Law Does Apply to Prescription Syringes Valid under the Pharmacy Act’s Syringe Provisions

The statutes may also be harmonized by interpreting the paraphernalia provision as a general limitation on the prescription provision, so that read together the two create a regime in which a practitioner may prescribe or dispense a syringe in good faith, in the usual course of practice, and for a legitimate medical purpose, unless the practitioner knows or should know that the individual intends to use it for illegal drug use. The legislature has often manifested its intent to reduce illegal drug use, and both the prescription and the paraphernalia laws were passed to prevent drug users from obtaining the tools necessary to use illegal drugs. The exemption provision of the retail paraphernalia law is proof that the legislature knew how to write such an exemption when it wanted to; its absence from the general paraphernalia law should therefore be seen as deliberate. This reading gives effect to both statutes, and has the advantage of effectuating a “zero tolerance” legislative intent.18

17 The exemption for physicians and pharmacists in the retail paraphernalia law is helpful to this argument, exhibiting a legislative intent to exclude pharmacists and physicians from coverage of the paraphernalia regulatory scheme. As we note below, however, the exemption in one paraphernalia law also raises the question of why the legislature also did not exempt physicians and pharmacists from the general law. There is, however, at least one straightforward reason why the legislature might have placed an exemption in the retail but not the general law: physicians and pharmacists acting for legitimate medical reasons within the usual course of practice are, as we have argued, already exempt from the general paraphernalia law because they are authorized to prescribe and dispense by the Pharmacy Act. The special exemption was only necessary in the retail law because it deals with display of paraphernalia, a matter not addressed in the Pharmacy Act and for which the Pharmacy Act therefore does not provide an authorization.

18 However, this argument may also be undermined by the exemption allowed by Cal. Health & Safety Code § 11364(c). If local governments authorize it, individuals may carry up to 10 syringes acquired from an authorized source for personal use. This seems to undercut the idea of “zero tolerance.”
It has the defects of its strengths. It side-steps basic rules of construction, and ignores what evidence there is of legislative intent. The interpretation leads to some strange results in addition to the basic conflict described above. Consider, for example, a physician whose insulin-dependent patient is also an IDU. On this interpretation, the physician’s or pharmacists’ knowledge that the patient will probably use the syringe to inject drugs would make providing the syringe a crime, despite the indisputable medical need arising from the patient’s diabetes.

**Conclusion:** Dispensing sterile injection equipment to known IDUs does not violate California law, although the contrary conclusion is not unreasonable.

III. How Might California Law Be Changed or Clarified to Promote Access to Sterile Injection Equipment for IDUs Through the Health Care System?

This Memorandum has concluded that physicians may prescribe and pharmacists may dispense sterile injection equipment to IDUs as a health-care intervention to prevent the transmission of blood-borne pathogens. Nevertheless, several legal measures would add clarity to the legal situation or otherwise protect public health by enhancing access to safe injection equipment.

**A. Changes in Statutes or Regulations**

1. The Legislature should repeal the prescription requirement state-wide and amend the paraphernalia law to legalize the over-the-counter sale of injection equipment under all circumstances.

2. The Medical and Pharmacy Boards have the power to and should issue regulations explicitly stating that providing sterile injection equipment to IDU patients in order to prevent transmission of a serious communicable disease is an acceptable medical practice. Cal. Bus. & Prof. Code §2018 (Medical Board); Cal. Bus. & Prof. Code §4005 (Pharmacy Board.)

3. The Medical and Pharmacy Boards should require training in the theory and practice of harm reduction as part of mandated continuing education. Cal. Code Regs. Tit. 16, §1355 (medical); Cal. Code Regs. Tit. 16, §1732.5(a) (pharmacy).

**B. Declaratory Judgment**

A practitioner wishing to prescribe or dispense injection equipment could also consider bringing an action for a declaratory judgment. Cal. C.C.P. §1060. Declaratory judgments aim to
enable a party to secure a declaration of his or her rights or duties under state law. Id.; see, e.g., Winter v. Gnaizda, 90 Cal.App.3d 750, 152 Cal.Rptr. 700(1979). For purposes of standing, a person or group seeking declaratory relief must be able to show that the person is threatened by a genuine and justiciable controversy, ripe for declaratory relief. A declaratory judgment would thus probably be available to test the legality of prescribing and dispensing syringes to prevent the spread of HIV among IDU’s.

C. Attorney General’s Opinion

State agencies, but not individual citizens, can request an opinion of the attorney general on the proper interpretation of a statute. Cal. Gov. Code §12519.