



Case Strategy: How to Investigate an Internet Pharmacy

Benjamin Gluck
Bird Marella

National Association of Boards of
Pharmacy
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Thesis

- “Things should always be made as simple as possible, but no simpler.”

Albert Einstein



Thesis

- Most existing laws are poorly suited to harshly prosecute internet prescribers
- Most existing laws:
 - Do not set bright lines
 - Do implicate medical judgment



Thesis

- Internet prescribers:
 - Range from those that are almost indistinguishable from corner drug dealers to those that are almost indistinguishable from typical medical care
- Put together:
 - Non-bright-line laws and varying facts make enforcement very difficult because it requires reinventing the wheel for each case



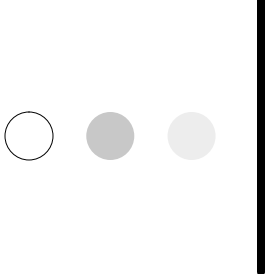
Thesis

- Therefore:
 - Don't assume it is enough to prove that internet prescribing was going on
 - Make sure to gather evidence that will specifically prove lack of “usual course of medical practice”
 - Consider other statutes



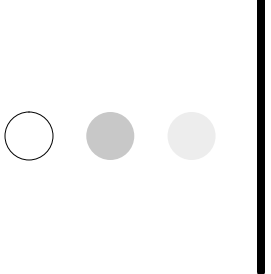
Outline

- The varied types of internet prescribing schemes
- The legislative schemes addressing (or used to address) internet prescribing
- Application of the laws to the schemes
- Lesson: Don't assume it's simpler than it is
- Pause: Do we want to do what we're trying to do?



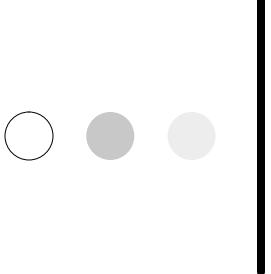
The varied types of internet prescribing schemes

- “Brown bag” sites
 - No doctors
 - No prescriptions
 - Offshore
 - Foreign drugs
 - Mailed in to country



The varied types of internet prescribing schemes

- Online questionnaire site
 - U.S. Doctors
 - U.S. Drugs
 - Medical questionnaire
 - Disclosures/disclaimers



The varied types of internet prescribing schemes

- Online questionnaire+ sites

- U.S. Doctors

- U.S. Drugs

- Medical questionnaire

- Medical records with existing prescription

- Telephone contact with customer



Non-Internet parenthetical: Coverage scenario

- When your doctor is out
 - U.S. Doctor
 - U.S. Drugs
 - Medical records – available, even if not reviewed
 - Telephone contact
 - Existing doctor/patient relationship with medical group



Non-Internet Parenthetical: Call centers

- Large HMO call centers
 - U.S. Doctors
 - U.S. Drugs
 - Medical records
 - Telephone contact
 - Existing doctor/patient relationship with someone in “privity” with call center doctor



The law

- Virginia – very simple
 - “Prescriptions may be issued only to persons . . . with whom the practitioner has a bona fide practitioner-patient relationship”
 - A bona fide relationship requires that the practitioner “perform or have performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically”
 - Virginia Code § 54.1-3303



The law

- California – not so simple
 - Unprofessional conduct to prescribe drugs “without a good faith prior examination”
 - Cal. Bus. & Prof. Code § 2242



Federal Statutes

- Require a “medical purpose”
 - “currently accepted medical use” – 21 U.S.C. § 812(b)
 - “medical purpose” – 21 U.S.C. § 829(c)
 - “legitimate medical purpose” – 21 U.S.C. § 830(b)(3)(A)(ii)
- “Course of practice”
 - “course of professional practice” – 21 U.S.C. § 802(21)



Federal Regulations

- “Legitimate medical purpose”
- “Usual course of professional practice”
 - Responsibility “is upon prescribing practitioner, but a corresponding responsibility rests with the pharmacist” 21 C.F.R. § 1306.04(a)



Violation Of Other Statutes

Does Not Invalidate Prescription

- *United States v. Hitzig*, 2003 WL 1871051 (4th Cir.)
 - “A physician’s conduct may constitute a violation of applicable professional regulations as well as applicable criminal statutes. However, a violation of a professional regulation does not in and of itself establish a violation of the criminal law.”

Violation Of Other Statutes

Does Not Invalidate Prescription

- “Outside usual course” means it is not medical care at all
- Violations of other statutes or rules of professional conduct are not necessarily outside the usual course
 - *United States v. Goldstein*, 695 F.2d 1228 (10th Cir. 1983)



Federal law

- Uses normative standards
- Norm:
 - “A pattern or trait taken to be typical in the behavior of a social group”
 - “A widespread or usual practice, procedure, or custom”



Federal law

- Normative standards do not make for easy criminal enforcement
 - Need to prove the standard in each case
 - Create constitutional problems
 - Vagueness
 - Lenity

- ● ● | Normative Standard
| Montana's Speed Limit

SPEED LIMITS

DAY ——— REASONABLE & PRUDENT

TRUCK ————— 65

NIGHT — ALL VEHICLES — 65



Federal Law - DEA's Position

**DEA Guidance 66 FR 211810-01, April 27,
2001**

- “Where a doctor/patient relationship exists, you may use the Internet to receive requests for treatment.”
(Including prescriptions)



Federal Law - DEA's Position

- DEA Guidance 66 F.R. 211810-01, April 27, 2001
 - “Under federal and state law, for a doctor to be acting in the usual course of professional practice, there must be a bona fide doctor/patient relationship. . . .”
 - “Completing a questionnaire that is then reviewed by a doctor hired by the Internet Pharmacy could not be considered the basis for a doctor/patient relationship.”



Federal Law - DEA's Position

- DEA Guidance 66 FR 211810-01, April 27, 2001
 - “It is illegal to receive a prescription for a controlled substance without the establishment of a legitimate doctor/patient relationship, and it is ***unlikely*** for such a relationship to be formed through Internet correspondence alone.”



Federal Law - DEA's Position

- Open to debate whether the DEA got the normative standard wrong:
 - At least a portion of the medical, legal, and legislative community apparently does not deem all internet prescribing outside “legitimate medical purpose” and “usual course of professional conduct”



The Community Does Not Reflect DEA's Position

- If the DEA's position is correct, we should find a well-accepted, clear consensus that online prescribing is --
 - not just unprofessional
 - not just grounds for discipline
 - but so far outside the usual course of practice as to render the prescription invalid and expose the practitioner to liability as a drug dealer
- But defendants will argue that there is no such consensus. Quite the contrary --



Federation Of State Medical Boards

- FSMB – April 2002

- “Although the Board recognizes that it may be difficult in some circumstances, particularly in an online setting, to define precisely the beginning of the physician-patient relationship, it tends to begin when an individual seeks assistance from a physician with a health-related matter for which the physician may provide assistance.”

(continued)



Federation Of State Medical Boards

- FSMB – April 2002

- “However, the relationship is clearly established when the physician agrees to undertake diagnosis or other treatment of the patient and the patient agrees, whether or not there has been a personal encounter between the physician (or other supervised health care practitioner) and the patient.”



Nat'l Assoc. Of Boards Of Pharmacies

- NABP – December 2001

- “What’s wrong with using a prescribing site?

Most regulatory authorities and professional organizations regard online prescribing to be unprofessional, and in some states it is illegal, unless it is done pursuant to a valid, ongoing patient-prescriber relationship that has included an in-person physical examination.”



Nat'l Assoc. Of Boards Of Pharmacies

- NABP – December 2001

- “Completing only an online questionnaire does not establish a valid patient-prescriber relationship. Moreover without a physical examination you could receive inappropriate medication and worsen an underlying, undiagnosed, serious medical condition.”



American Medical Assoc.

- *Trustees Report on Internet Prescribing: AMA Position on Using the Internet for Prescribing and Dispensing Drugs, 1999*
 - “The Board of Trustees recommends: That our AMA vigorously oppose the use of the Internet . . . to prescribe medications in the absence of safeguards that ensure: an adequate medical history is taken; full disclosure of risks, side-effects and limitations is provided; and where appropriate, additional interventions and follow-up care are provided.”



American Medical Assoc.

- *AMA Ethics Policy, December 2002*
 - “Email should not be used to establish a patient-physician relationship. Rather email should supplement other, more personal, encounters.”



American Medical Assoc.

- *AMA Guidance for Physicians on Internet Prescribing, H-120.949 2003*
 - “Physicians who prescribe medications via the Internet shall establish, or have established, a valid patient-physician relationship, including, but not limited to the following components:



American Medical Assoc.

- *AMA Guidance for Physicians on Internet Prescribing*, H-120.949
2003
 - “The physician shall (i) obtain a reliable medical history and perform a physical examination, adequate to establish the diagnoses for which the drug is being prescribed. . . . Exceptions to the above criteria exist in the following specific instances: treatment provided in consultation with another physician who has an ongoing professional relationship with the patient . . . and on-call or cross-coverage situations.”



The Legal Community Disagrees With The DEA

- Holds that a physician-patient relationship can be established without a face-to-face meeting
- Holds that online prescribing is not per se illegal



Irvin v. Smith

Kansas Supreme Court

- “Generally, a physician-patient relationship is created only where the physician personally examines the patient.

A physician's indirect contact with a patient, however, does not preclude the finding of a physician-patient relationship.”



Irvin v. Smith

- o *Adams v. Via Christi Regional Med. Center*, 270 Kan. 824, 835 (2001). *McKinney*, 118 Ohio App.3d at 336 (lack of direct contact between physician and patient does not preclude the finding of a physician-patient relationship); *Cogswell*, 672 N.Y.S.2d 460 (physician-patient relationship can be established by a telephone call to physician); *Millard*, 14 S.W.3d at 49 (Mo.) (physician-patient relationship may be found even in the absence of contact between the physician and patient); *St. John*, 901 S.W.2d at 424 (Tex.) (physician-patient relationship does not require a formal contract and may be implied by the circumstances).

Other Government Sources

Indicate Online Prescribing Is Not Illegal

- Current statutes
- Medicare reimbursement rules
- Congressional hearings
- Proposed statutes in Congress

21 U.S.C. § 353(b)(2)

Prescription By Physician; Labeling And Prescription Requirements

- “This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnoses by mail.”

Medicare Provider

Reimbursement Manual

§ 270

- “Effective October 1, 2001, coverage and payment for Medicare telehealth includes consultation . . . and pharmacologic management delivered via telecommunications system.

Asynchronous ‘store and forward’ technology may be used in delivering those services when the originating site is a Federal telemedicine demonstration project in Alaska or Hawaii.”



Drugstores On The Net: The Benefits And Risks Of On-line Pharmacies

- Subcomm. on Oversight and Investigations, 106-51, July 30, 1999, p.19
 - “In talking with state and federal agencies and lawmakers over who is responsible for regulating on-line prescription drug sales, we found there seems to be confusion. In fact, it doesn’t seem to be against the law.”



Congressional Research Service Report

Legal Issues Related to Prescription Drug Sales on the Internet

May 24, 2005



CRS Report, May 24, 2005

- “Some rogue sites operate in a legal gray area in which the online pharmacy, as mandated by federal law, requires a prescription before dispensing prescription drugs, but allows patients to secure a prescription by completing an online questionnaire that is reviewed by a doctor who never examines or speaks to the patient. This practice, though potentially unsafe for patients who may be diagnosed incorrectly, is not necessarily illegal.”



The Detroit News

- *Internet Drugstore Laws Differ*, May 18, 2005
 - “Can I legally get a prescription online without meeting in person with a doctor?”

Legality is determined by the situation. Federal and some state laws do not specifically require patients seeking prescriptions to meet in person with a doctor. Proposed federal legislation would require such meetings. Some states already do.”



Louisville Courier-Journal

- *Internet Pharmacies*, May 2, 2005
 - “Federal law now requires only that prescriptions be issued ‘for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.’”
 - “Whether a doctor-patient relationship can be established online remains unclear. Kentucky authorities have said recipients of drugs from internet pharmacies are subject to prosecution only if they give a false name or address or are receiving drugs from multiple doctors.”
- KY statute and board say it is unethical and unprofessional – but authorities say it is not illegal



Louisville Courier-Journal

- *Internet Pharmacies*, May 2, 2005
 - “A 2001 policy statement by the DEA said a questionnaire filled out by a customer and reviewed by a doctor hired by an Internet pharmacy ‘could not be considered the basis for a doctor-patient relationship.’ DEA spokesman Bill Grant said federal law conveys the illegality of such relationships ‘without describing it in words.’”



States Do Not Reflect the DEA's Purported Consensus

- Previously showed that at a national level, there is no consensus agreeing with the DEA's position
- Individual states do not reflect it either



Utah Expressly Permits Online Prescriptions

- KwikMed has won permission from the state of Utah to operate legally as long as it adheres to a strict set of guidelines. That makes it the only online prescription Web site in the U.S. that has won explicit approval from a state, according to the Federation of State Medical Boards.
 - *Wall Street Journal Online*, November 16, 2004



States Do Not Reflect The DEA's Purported Consensus

- 29 states (58%) have medical board policies addressing online prescribing
 - Some only say things like “use of Internet does not change standards of care” (NY)
 - Most merely deem it “unprofessional”
 - None of these say it is outside the course or an invalid prescription



States Do Not Reflect The DEA's Purported Consensus

- 15 states (30%) have statutes addressing online prescribing
 - Some merely address cross-border licensing issues
 - Most merely deem it “unprofessional”
 - Only NV and VA prohibit it



The Climate Summary

- The medical community does not reflect the consensus the DEA purports to rely upon
- The legal community similarly does not reflect the purported consensus
- Congress and other government sources do not reflect it
- The broader community does not reflect it
- Individual states do not reflect it either
- While some sources, though certainly not all, deem online prescribing unprofessional, the overwhelming majority do not treat it as outside the usual course to the extent that results in an invalid prescription



Gonzalez v. Oregon

- Physician-assisted-suicide is not grounds for revoking a DEA number.
 - DEA/DOJ has no authority to define “medical purpose” or “usual course of professional practice”
 - Court discusses extraordinary breadth of “usual course”



Gonzalez v. Oregon

- “All would agree, we should think, that the statutory phrase ‘legitimate medical purpose’ is a generality, susceptible to more precise definition and open to varying constructions and thus ambiguous in the relevant sense.”
 - *Oregon*, 126 S.Ct. 904, 916.



Gonzalez v. Oregon

- “The Government contends ordinary usage of these words ineluctably refers to a healing or curative art, which by these terms cannot embrace the intentional hastening of a patient’s death. It also points to the teachings of Hippocrates, the positions of prominent medical organizations, the Federal Government, and the judgment of the 49 States that have not legalized physician-assisted suicide as further support for the proposition that the practice is not legitimate medicine.”⁵⁴



Gonzalez v. Oregon

- “On its own, this (*i.e.*, the Government’s) understanding of medicine is at least reasonable.”
- “The primary problem with the Government’s argument, however, is its assumption that the CSA impliedly authorizes an Executive officer to bar a use simply because it may be inconsistent with one reasonable understanding of medical practice.”

Per Oregon, this does not represent a sufficient consensus to deem physician assisted suicide outside the “usual course”

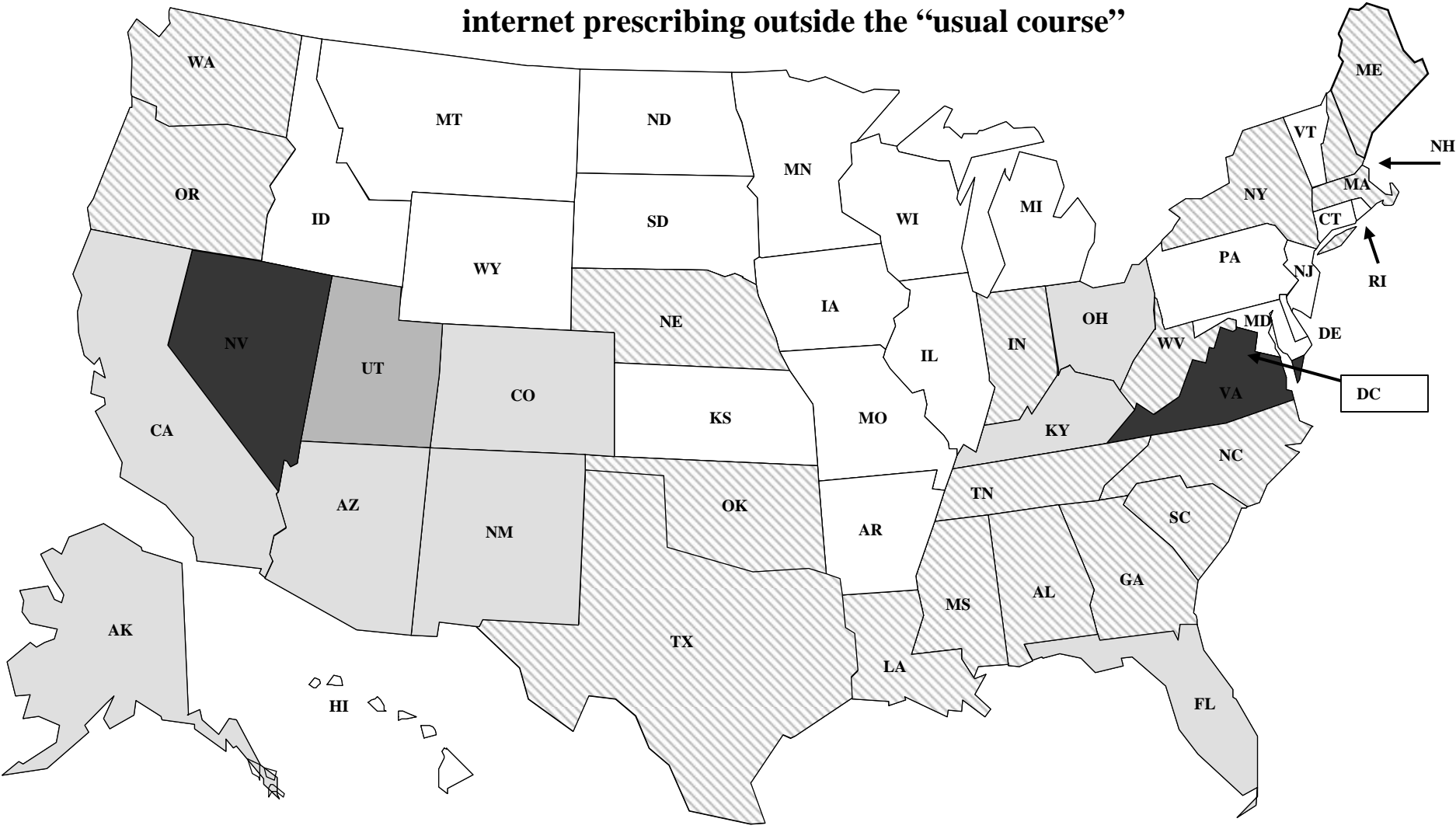


STATE KEY






 = Criminalize Physician Assisted Suicide

 = Permit Physician Assisted Suicide

***A fortiori*, this cannot represent a sufficient consensus to deem internet prescribing outside the “usual course”**



STATE KEY

- | | | | |
|---|--|---|--------------------------------------|
|  | Medical Board Deems Unprofessional |  | Permit Internet Prescribing |
|  | Statute (and sometimes Md. Bd.) Deem Unprofessional |  | No Action |
| | |  | Prohibit Internet Prescribing |



Application of law to facts

- The reason we needed to go through that survey of the various communities is because the law uses normative standards
- Under current laws, defendants have potentially strong defenses to drug trafficking allegations



Takeaway

- If you want to use drug laws for enforcement, don't assume the case is simpler than it really is
 - Depending on your jurisdiction, you probably will have to prove:
 - 1) The “usual” standard, and
 - 2) That this conduct fell outside the “usual” standard



What to do?

- Don't underestimate complexity of case
- Be prepared to prove “outside usual course”
 - Take advantage of computers
 - Show how long the doctor spent on each review
 - Show how many the doctor denied



What to do?

- Consider other statutes
 - Labeling laws
 - Fraud
 - False statements on the web sites about legality
 - False statements on the web sites about business model
 - “Licensed doctors”
 - Sales to minors
 - HIPAA
- Keep in mind that the defense will be “we’re just practicing medicine.” Anything that challenges this claim will help make the case



Long Term Solutions

- Change the laws to explicitly ban non-face-to-face prescribing
- BUT should we?
 - Do we really have any principled reason for prohibiting internet questionnaire+ sites while permitting call center or coverage situations?
 - If we do have such a reason, is it strong enough to justify the expenses associated with prohibiting the sites?