

MEDICAL MALPRACTICE ISSUES ARISING FROM THE PRACTICE OF PRESCRIBING MEDICATIONS ONLINE

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I. INTRODUCTION

*"It's a wonderful tool, this Internet...[w]hat I'm doing is ethical and, as far as I know, legal."*¹ – Piotr Hitzig, M.D., 1998.

So spoke one-time Baltimore physician Piotr Hitzig, referring to his practice of providing prescription medications to patients via the Internet.² Unfortunately, the federal courts did not agree with Dr. Hitzig's conclusions, and in 2001 he was convicted by a Maryland District Court on thirty-four counts of illegally dispensing controlled substances, a violation of federal law under 21 U.S.C. § 841(a)(1).³ Hitzig was sentenced to concurrent terms of forty-five months imprisonment for each of the counts in a decision which was subsequently upheld by the Fourth Circuit in an unpublished per curiam opinion.⁴ In October, 2003, the United States Supreme Court denied Hitzig's writ of certiorari.⁵

The self-proclaimed "father of Fen/Phen,"⁶ Hitzig first gained the interest of federal authorities in the 1990's by writing countless off-label prescriptions for the once-

1. Michael James & Joan Jacobson, *Physician Keeps a Practice Online Investigation: A Baltimore doctor Prescribes Drugs to Patients Around the World*, BALT. SUN, Sept. 3, 1998, at 1A.

2. *Id.*

3. 21 U.S.C. § 841(a)(1) states: "Except as authorized by this title, it shall be unlawful for any person knowingly or intentionally...to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance."

4. *United States v. Hitzig*, 63 Fed. Appx. 83, 83-85 (2003), *cert. denied*, 124 S. Ct. 263 (2003).

5. *Hitzig v. United States*, 124 S. Ct. 263 (2003).

6. James & Jacobson, *supra* note 1, at 1A.

popular diet drug combination fenfluramine and phentermine, better known as Fen/Phen.⁷ By 1993, Hitzig's medical practice was limited exclusively to prescribing the drug combination, which he touted as a kind of universal remedy for an assortment of maladies.⁸ After DEA raids of his home and office in 1997 effectively crippled his practice, Hitzig continued to prescribe medications via his website.⁹ He reportedly prescribed Fen/Phen to over eight thousand patients in numerous states and several foreign countries prior to his eventual arrest.¹⁰

Many of the patients who received the medication were never physically seen by Hitzig, a fact which caught the attention of the Maryland Board of Physician Quality Assurance in 1998.¹¹ The Board suspended Hitzig's license and issued a 59-page complaint alleging, inter alia, that Hitzig had been "...handing out various kinds of pills 'like candy.'"¹² However, the executive director of Maryland's Board of Physician Quality Assurance recognized the legal difficulties posed by Hitzig's use of the Internet to prescribe medications: the laws governing medical practice in the state, he said, "...were developed for disciplining doctors before there was an Internet."¹³

Numerous complaints and medical malpractice suits were filed against Hitzig in connection to his controversial prescription writing.¹⁴ Hitzig eventually surrendered his

7. *Hitzig*, 63 Fed. Appx. at 83-84. Off-label drug use is defined as the "use of a medication for a purpose other than that approved by the FDA." *STEDMAN'S MEDICAL DICTIONARY* 892 (27th ed. 2000).

8. *Hitzig*, 63 Fed. Appx. at 84. Dr. Hitzig claimed that Fen/Phen could be used to treat, among other things, "...cancer, AIDS, psychiatric illness, asthma, lupus, multiple sclerosis, and Gulf War syndrome." *Id.*

9. *New Study Finds Heart Valve Damage in 25% of Diet Drug Users*, 1 No. 3 *Andrews Diet Drugs Litig. Rep.* 17, 17 (1997).

10. *Id.*

11. *Maryland Suspends Dr. Hitzig's MD License, Issues Charges*, 2 No. 5 *Andrews Diet Drugs Litig. Rep.* 13, 13 (1999).

12. *Id.*

13. James & Jacobson, *supra* note 1, at 1A.

14. *Id.*; *See also Maryland Class Action Names Doctors, Seeks \$3 Million Per Plaintiff*, No. 1 *Andrews Diet Drugs Litig. Rep.* 5, 5 (1997).

medical license,¹⁵ but his ill-fated words asserting the belief that his actions were legal have proven to be more than erroneous. Indeed, Hitzig's statements may have foreshadowed the arrival of the modern legal dilemmas confronting physicians, pharmacists, legislators, and agencies who engage in the practice or regulation of online prescribing.¹⁶ The use of the Internet as a medium for this purpose has produced a particularly troublesome set of legal issues, several of which remain unsettled.¹⁷

II. METHODS OF UTILIZING THE INTERNET TO PRESCRIBE MEDICATIONS

Currently, medications may be obtained online via any of four general methods, three of which involve the actions of a medical practitioner on some level.¹⁸ These include: (1) authorized refill prescriptions presented to pharmacies via the Internet, where the refill stems from an original prescription that was written by the patient's physician and previously presented to a brick and mortar pharmacy; (2) prescriptions provided by patients or by their personal physicians directly to pharmacies that exist exclusively online; and (3) prescriptions provided by an online physician who is directly affiliated with an online pharmacy, where no prior patient-physician relationship exists.¹⁹ The fourth method, which circumvents the role of the physician entirely, typically involves only two entities: the consumer, who seeks prescription medications, and a website operator/drug distributor, frequently located outside of the United States.²⁰ No

15. *Hitzig*, at 84 n.1.

16. For the purposes of this article, the term "physician" will be used for simplicity, although of course malpractice issues involving prescriptions may extend to the full spectrum of medical practitioners who prescribe medications, including dentists, optometrists, and the like.

17. See John D. Blum, J.D., M.H.S., *Internet Medicine and the Evolving Legal Status of the Physician-Patient Relationship*, 24 J. LEGAL MED. 413, 439 (2003).

18. *Id.* at 440.

19. *Id.*

20. *Id.*

physicians are involved and no prescriptions are written. Although this method is not relevant to a discussion of medical malpractice, it is worthwhile to note that such websites, which commonly specialize in trendy, highly-publicized lifestyle drugs, are both illegal and ubiquitous.²¹

The first two methods impart little additional risk of malpractice upon the prescribing physician, provided that the original prescription was given under appropriate circumstances. Despite the use of the Internet, these methods essentially resemble traditional prescribing practices. The focus of this discussion will be on the third method, which carries the greatest risk of liability for practitioners and generates the most legal discussion.

The third method is distinct in that although a physician is involved, there is no physical encounter between the patient and the physician. In this scenario, a consumer visits an online pharmacy where he or she is asked to fill out a questionnaire, and this serves as the basis for a medical consultation by a physician affiliated with the website.²² The physician reviews the information provided by the patient and then authorizes the online pharmacy to dispense the medication sought by the patient.²³ When the use of this consult-and-dispense method results in harm to a patient, legal issues arise which present challenges to the application of conventional models of medical malpractice.

21. Ross D. Silverman, *The Changing Face of Law and Medicine in the New Millennium*, 26 AM. J.L. & MED. 255, 266 (2000). Contemporary examples of such medications include Viagra®, Propecia®, Levitra®, and Cialis®.

22. Blum, *supra* note 17 at 440.

23. *Id.*

III. APPLYING TRADITIONAL THEORIES OF MEDICAL MALPRACTICE

The issue of whether traditional models of medical malpractice can be applied to a physician's use of the Internet has been extensively explored in the literature.²⁴ The two most vocal areas of legal concern which are raised in regard to prescribing medications via the Internet are: (1) whether a doctor-patient relationship is established in this form of practice, and correspondingly, whether prescribing medication in the absence of such a relationship is appropriate; and (2) to what extent, if any, a physician may prescribe electronically outside of the jurisdiction in which he or she is licensed.²⁵

A. The Doctor-Patient Relationship

The first issue has presented the most complex questions. At first blush, a unique legal conundrum appears to exist: in a given case where a patient has suffered harm through the use of an improperly prescribed medication, the demonstration of the existence of a doctor-patient relationship is ordinarily the injured party's first step in seeking damages for malpractice. It is generally agreed that the existence of this relationship is a prerequisite to any malpractice suit against a physician.²⁶ Absent this relationship, the duty element is not met.²⁷ However, in the context of online prescribing, it may be difficult to show that a doctor-patient relationship exists because the patient and physician have had no direct contact and no physical examination of the patient has been performed by the physician. Thus, while the failure of the physician to properly examine

24. See Ruth Ellen Smalley, *Will a Lawsuit a Day Keep the Cyberdocs Away? Modern Theories of Medical Malpractice as Applied to Cybermedicine*, 7 RICH. J.L. & TECH. 29, 36-42 (2001); See Blum, *supra* note 17 at 437-39; See also Jessica W. Berg, *Ethics and E-Medicine*, 46 ST. LOUIS U. L.J. 61, 61-63 (2002) (arguing that professional ethical standards should serve as a guideline for the appropriate use of new technologies, rather than traditional evaluative mechanisms such as legal standards of care).

25. *Id.*

26. BARRY R. FURROW ET AL., HEALTH LAW 271 (4th ed. 2001).

27. Blum, *supra* note 17 at 424.

a patient may lead to a medication error, it could theoretically also relieve the physician of any duty beyond ordinary care because a doctor-patient relationship is never formed.

However, the concept of the doctor-patient relationship has been gradually refined by courts, legislators, and regulatory bodies over time.²⁸ While at one time the prevailing belief held that direct contact between the patient and physician is necessary to establish this relationship, case law has evolved in which the courts have carved out several exceptions to this rule.²⁹ Although the elements required to form this relationship vary from jurisdiction to jurisdiction, it can be generally said that the formation of a doctor-patient relationship requires actions on the part of both the physician and the patient, whether express or implied.³⁰ The patient seeks medical treatment and the physician agrees to provide it, either explicitly or implicitly.³¹ Circumstantial evidence surrounding the interaction of the two parties may further assist fact finders in determining whether the relationship was truly formed.³²

Modern cases provide examples of relationships formed in the absence of face-to-face encounters between the physician and the patient. For instance, a simple telephone call to a physician's office for the purpose of initiating treatment was held to be adequate to create a doctor-patient relationship where the physician gave medical advice and the patient relied upon it.³³ Similarly, cases involving consultations between two physicians have been held to create a relationship between the patient and the outside consultant,

28. Michael A. McCann, *Message Deleted? Resolving Physician-Patient E-Mail Through Contract Law*, 5 YALE J.L. & TECH. 103, 111 (2002/2003).

29. *Id.*; See also Blum, *supra* note 17 at 437.

30. Blum, *supra* note 17 at 437-38.

31. *Id.*

32. *Id.*

33. *Bienz v Central Suffolk Hosp*, 557 N.Y.S.2d 139, 139-140 (App. Div. 1990).

even where the consultant never directly examined or interacted with the patient.³⁴ However, a relationship in these consultation cases was typically established only when the outside consultant offered advice based upon a formal review of the patient's records, medical history, and diagnostic items such as radiographs, lab results, or pathological specimens.³⁵ Less-formal consultations in which the treating physician merely sought the advice of the consulting physician absent diagnostic tools were typically held not to establish the relationship between the patient and the consultant.³⁶

The challenge before the courts will be to decide which of these models of modern case law is most persuasive in deciding whether a doctor-patient relationship has been formed in the context of online prescribing. Clearly, arguments could be made for both. Online prescribing resembles the interaction between a physician and patient via telephone in that a patient seeking some remedy may telephone a physician, and the physician may respond by providing a recommendation founded solely in his interpretation of the information provided by the patient in the conversation. Similarly, the consultation model may be applicable in that the physician has a limited amount of information regarding the patient's condition available to him, and the determination of whether the relationship is formed may depend upon the quantity or manner in which this information is provided.

Case law which reaches these issues is essentially non-existent; most malpractice cases related to online physician activity have been tried on other grounds or resulted in

34. Patricia Kuszler, *Telemedicine and Integrated Health Care Delivery: Compounding Malpractice Liability*, 25 AM. J.L. & MED. 297, 311-13 (1999).

35. *Id.*

36. *Id.*

settlements prior to trial.³⁷ Cases which may have touched on these issues have been tried for violations of federal law, as in the *Hitzig* case described above.³⁸ The Federal Trade Commission has pursued actions against online pharmacies and physicians under federal unfair or deceptive practices laws.³⁹ Finally, a series of suits filed by the Kansas Attorney General against several website operators and affiliated prescribing physicians were tried exclusively under consumer protection laws in 2002 and 2003.⁴⁰

Notably, lawmakers in the individual states have increasingly bypassed the doctor-patient relationship issue by implementing legislation that requires a physical examination of the patient by the physician prior to prescribing, and physicians have been prosecuted under these laws.⁴¹ This would seem to resolve this issue by nullifying the legitimacy of all consult-and-dispense online pharmacies in those jurisdictions.

However, there exists a school of thought which disagrees with this legislative approach. Many physicians consider it common practice to prescribe medications via telephone to patients whom they have never physically examined, as in the case of physicians who share after-hours emergency call with one another. This was the argument of David L. Bryson, M.D., a Texas physician whose license was suspended for providing prescriptions via the telephone to numerous patients whom he had never

37. Smalley, *supra* note 24, at 39; Cf. Phyllis Forrester Granade, *Medical Malpractice Issues Related to the Use of Telemedicine - An Analysis of the Ways in Which Telecommunications Affects the Principles of Medical Malpractice*, 73 N. DAK. L. REV. 65, 67-68 (1997) (asserting the proposition that despite a lengthy history, the use of telemedicine by physicians had spawned no medical malpractice cases which were decided by the courts).

38. *Hitzig*, 63 Fed. Appx. 83.

39. See, e.g., *FTC v. Sandra L. Rennert*, complaint and settlements filed in U. S. District Court for the District of Nevada, available at <http://www.ftc.gov/os/2000/07/index.htm#12>.

40. *State ex rel. Stovall v. Alivio*, 275 Kan. 169 (2003); *State ex rel. Stovall v. DVM Enterprises*, 275 Kan. 243 (2003); *State ex rel. Stovall v. Confimed.com*, 272 Kan. 1313 (2002).

41. Blum, *supra* note 17 at 443.

seen.⁴² Bryson argued that this practice is no different than what physicians who are on call do routinely.⁴³ When a physician is on vacation, his or her patients telephone the call service and are directed to the covering physician; this physician, who has likely never examined the patient, may then provide a prescription.⁴⁴

The American Medical Association appears to agree with the states. In June, 2003, the AMA adopted a new set of guidelines for Internet prescribing.⁴⁵ These guidelines state plainly that physicians should not only obtain a medical history from their patients prior to prescribing, but they should also perform a physical exam prior to prescribing any medications online.⁴⁶ Such a broad pronouncement by the AMA, an organization that typically advocates bare-minimum practice standards, is indicative of the need for safe prescribing practices felt by the medical community.

B. Jurisdictional Issues

Under the Tenth Amendment to the U.S. Constitution, the states are granted the power to create legislation in order to regulate the health, safety, and welfare of their people.⁴⁷ The authority to regulate the practice of medicine falls within this power, and this includes a state's power to limit such practice to those licensed within its own jurisdiction.⁴⁸ However, in the context of online prescribing, new questions develop.

42. Tyler Chin, *Rx Surveillance: Watch out for Prescribing over the Internet*, AMERICAN MEDICAL NEWS, ¶ 28 (Oct. 22, 2001) at <http://www.ama-assn.org/amednews/2001/10/22/tesa1022.htm>.

43. *Id.*

44. *Id.*

45. *AMA Adopts New Guidelines to Help Physicians Ensure Safe and Secure Internet Prescribing*, AMERICAN MEDICAL NEWS (June 19, 2003), at <http://www.ama-assn.org/ama/pub/article/1616-7802.html>.

46. *Id.*

47. U.S. CONST. amend. X. The Tenth Amendment states: "The powers not delegated to the United States by the Constitution, nor prohibited by it to the states, are reserved to the states respectively, or to the people." *Id.*

48. McCann, *supra* note 28 at 128.

When a physician prescribes a medication, most if not all states agree that the act constitutes the practice of medicine.⁴⁹ Yet, when a physician writes a prescription for a patient who is physically located in another state, it may be difficult to say where the practice of medicine actually takes place. Does the practice occur where the physician resides, or where the patient receives the prescription?

If, as discussed above, a physician may not write a prescription without first physically examining the patient, then this issue is less troublesome. In this case, the patient and physician will necessarily have engaged one another in the same jurisdiction in the course of treatment. Further, since the medical examination must serve as the basis for writing the prescription, the location where the exam took place would likely be considered the place where the practice of medicine occurred. This comports with the result reached by the Ninth Circuit in *Wright v. Yackley*.⁵⁰ In that case, which involved a traditional hand-written prescription, a patient sued her physician for injuries purportedly stemming from the medication prescribed.⁵¹ Prior to the suit, the patient and the physician were both located in South Dakota, where the patient was being treated.⁵² Several months after relocating to Idaho, the patient contacted her physician to request that an existing prescription refill authorization be transferred to an Idaho pharmacy, and the physician agreed.⁵³ Later the patient filed suit against the physician in an Idaho District Court, but the District Court declined to extend the state's long-arm statute and dismissed the case for lack of jurisdiction over the physician.⁵⁴ The Ninth Circuit

49. See Blum, *supra* 17 at 418, 423-24.

50. *Wright*, 459 F.2d 287 (1972).

51. *Id.* at 288.

52. *Id.*

53. *Id.*

54. *Id.*

affirmed, stating: “If the appellee was guilty of malpractice, it was through acts of diagnosis and prescription performed in South Dakota. The mailing of the prescriptions to Idaho did not constitute new prescription.”⁵⁵

However, the Ninth Circuit distinguished this view in *Cabbage v. Merchant*.⁵⁶ In that case, a California District Court’s jurisdiction over an Arizona physician was held to be reasonable because the defendant physician’s actions constituted “...continuing efforts to provide services...” as part of “...voluntary, interstate economic activity... directed at another state in order to benefit from effects sought there...”⁵⁷ Unlike the physician in *Wright*, the defendant physician in *Cabbage* had sought to avail himself of the benefits of treating patients from an adjacent jurisdiction.⁵⁸ Despite the fact that the treatment was rendered in the physician’s state, the Ninth Circuit felt that due process would not be offended in exerting jurisdiction over the defendant in light of defendant’s contacts in the forum state.⁵⁹

Using these cases as a model for malpractice suits which arise from the act of prescribing medications online, the courts will once again be presented with the challenge of deciding which model case is more comparable to the online prescribing case at bar. Ignoring, for the moment, the fact that regulations in most jurisdictions have traditionally limited or prohibited physicians and pharmacies from prescribing/dispensing medications across state lines, the question becomes valid.

In a case similar to *Wright*, it seems likely that a court would reach the same decision that the Ninth Circuit did in that case, regardless of whether the prescription was

55. *Wright*, 459 F.2d 287 at 288.

56. *Cabbage*, 744 F.2d 665 (1984).

57. *Id.* at 669 (citations omitted).

58. *Id.*

59. *Id.*

written in the traditional manner or provided via the Internet. In other words, if a patient is examined or treated in the physician's state and that patient later relocates to another jurisdiction, an isolated incidence of prescribing to that patient via the Internet would not likely justify an assertion of jurisdiction over the physician by the foreign state.

However, the case might be different where a physician actively seeks to avail himself of the benefits of prescribing to patients in other jurisdictions, particularly when the physician acts for economic benefits. In such a case, a court might be more strongly persuaded by the reasoning in *Cabbage*. Thus, the actions of a Texas physician who prescribes online to a patient in Ohio might be considered adequate to allow an Ohio court to assert jurisdiction over the physician.

This issue may become more prevalent in the future. Some states already have statutes in place which permit prescribing across borders in exceptional circumstances, for example, in emergency situations.⁶⁰ Additionally, a model act known as the Model Legislation Regarding Licensure has already been adopted by several states.⁶¹ This act allows a physician licensed in one state to apply for a limited license to practice across state lines by electronic means, among other things.⁶² Thus, it is foreseeable that a relaxation of jurisdictional boundaries in the context of online prescribing may actually lead to more questions about the application of traditional medical malpractice models for the courts.

CONCLUSION

60. Barbara J. Williams, *On-Line Prescriptions and Drug Sales: An Overview of Emerging Issues*, 1 HOUS. J. HEALTH L. & POL'Y 147, 156 (2001). The Model Act may be found on the American Medical Association's website, available at <http://www.ama-assn.org/ama/pub/article/2378-2752.html>.

61. Williams, *supra* note 59 at 156.

62. *Id.*

As practitioners endeavor to embark on pathways which embrace the benefits that new technology offers to the practice of medicine, the legal boundaries are often unclear. When these practitioners stray onto questionable pathways and engage in actions which are redolent of traditional medical malpractice, governing and regulatory bodies are often slow or simply abortive in their efforts to adapt traditional legal models to novel issues which emerge through the use of new technologies. The effect is to protect the public, but also to hinder its access to new forms of medical care. In simple terms, a balance must be struck: protecting the health, safety, and welfare of the community must be met by an equivalent effort to embrace technologies which will promote these aims. Public policy considerations require that our laws do not neglect the needs of the individual. The *Wright* Court, perhaps ahead of its time, summarized this sentiment well in 1972:

[T]he forum state's natural interest in the protection of its citizens is here countered by an interest in their access to medical services whenever needed. In our opinion, a state's dominant interest on behalf of its citizens in such a case as this is not that they should be free from injury by out-of-state doctors, but rather that they should be able to secure adequate medical services to meet their needs wherever they may go.⁶³

63. *Wright*, 459 F.2d 287 at 290-91.