

June 2001

Cybermedicine and Virtual Pharmacies

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Recommended Citation

Ronald L. Scott, *Cybermedicine and Virtual Pharmacies*, 103 W. Va. L. Rev. (2001).
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CYBERMEDICINE AND VIRTUAL PHARMACIES

*Ronald L. Scott**

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I. INTRODUCTION

Some of the evidence in this case strongly suggests that some companies operating in the area of the Internet may have a misconception that, because their technology is somewhat novel, they are somehow immune from the ordinary applications of laws of the United States They need to understand that the law's domain knows no such limits.¹

Consider the following scenario: John is a 58 year-old overworked trial lawyer, married for 25 years to Susan. Susan calls John at work on January 4, 2004, their wedding anniversary, and strongly implies she is looking forward to a romantic encounter in the evening. John has been avoiding intimacy for some time, after suffering more than an occasional inability to perform sexually, yet he dearly loves Susan and wants to remain close to her in every way. John remembers that his health plan has recently added a new Virtual Preferred Provider Organization (VPPO) benefit, allowing cyber-consultations with a network of providers throughout the country for a \$20 co-payment. John is not particularly concerned about the cost, but litigation deadlines make it difficult for him to arrange time to visit his family practice physician.

Based on direct-to-consumer (DTC) advertising and some other health information he obtained via the Internet, John feels he is a good candidate for

¹ UMG Recordings, Inc. v. MP3.Com, Inc., 2000 WL 1262568, *6 (S.D.N.Y. Sep. 6, 2000) (No. 00 CIV. 472 JSR) (federal district court judge Jed S. Rakoff ruling that the online music start-up company MP3.com had willfully infringed the copyrights of Universal Music Group)

Pfizer's anti-impotence drug, Viagra. He logs on to his health plan's website, and conducts a search for urologists participating in the VPPO. He finds Dr. Carter, whose biographical information indicates that he specializes in diagnosing and treating erectile dysfunction. With a click of his mouse, he views Dr. Carter's licensing profile maintained by the state medical board, and is pleased to find that Dr. Carter graduated from Harvard Medical School and has no reported disciplinary or malpractice incidents. Going back to the health plan website, he views Dr. Carter's cyber-consultation appointments calendar, and finding a convenient opening for 3:00 p.m. the same afternoon, he books the appointment online.

At the scheduled time, John closes his office door, hangs a "conference call" sign on his door, logs into Dr. Carter's secure website, and begins a voice dialog with Dr. Carter while they are viewing each other on a computer camera. John's identity is confirmed by a retinal scan transmitted to Dr. Carter. Dr. Carter briefly inquires about the nature of John's problem, explains the diagnostic and treatment limitations inherent in cyber-consultations, and asks John if he would like to proceed. John confirms his agreement to a special informed consent document transmitted by Dr. Carter, and also agrees that Dr. Carter may access John's medical and pharmaceutical records maintained at another secure site. While viewing John's medical records on a separate monitor, Dr. Carter asks John a series of questions about the general state of his health, and the questions and answers are converted to text via voice recognition software and automatically entered into John's medical record. Dr. Carter notices in the medical record that, because John is an amateur pilot, he obtained a Federal Aviation Administration (FAA) Class 1 physical about three months ago showing John to be in good general health with normal blood pressure. John's pharmaceutical records indicate that he is not currently taking any other prescription medications.

Nonetheless, out of an abundance of caution, Dr. Carter asks John to transmit his current blood pressure and heart rate via the computer's telemetrics interface using the monitoring device John already wears while exercising. Satisfied with the results, Dr. Carter agrees to prescribe Viagra, but suggests that because it is not effective in every case, John may wish to first obtain a trial prescription of five 50mg tablets. Dr. Carter advises John that his health plan will not pay for "lifestyle" drugs such as Viagra, so John provides Dr. Carter with the account number and access code for his tax-deferred medical spending account² (MSA) maintained at Charles Schwab.

With a click of his mouse, Dr. Carter transmits the prescription and payment information to a virtual pharmacy that in turn transmits the request to an

² See 26 U.S.C. § 220 (2000). MSAs are tax-free accounts set up to pay for routine medical expenses. Contributions to MSAs are tax-deductible and may be made by individuals or by their employers. Withdrawals from MSAs for qualifying medical expenses are not taxed, and MSA balances carry over from year to year and may earn interest that is also tax-free provided it is used only for qualified medical expenses or remains in the account until the holder is age 65 or disabled. Under a four-year pilot project beginning in 1996, medical savings accounts (MSAs) are available to self-employed individuals and employees of participating small employers. A limited number of participants are part of a study scheduled to end in the year 2000. See *id.* MSAs are part of an effort to empower health care consumers by allowing an alternative means to pay for health care. However, demand for MSAs has been less than anticipated.

automated pharmacy dispensing machine located near John's home address. Dr. Carter deducts the \$20 copayment from John's MSA, and electronically bills the health plan for the consultation. Dr. Carter also updates John's online medical and drug records, maintained separately since a pharmacist will only have access to the drug record. Before signing off, Dr. Carter reminds John that the FAA may not approve of him flying while taking Viagra, since one side effect of the drug is to cause some patients to experience difficulty distinguishing blue from green.³

The consultation, prescription, insurance billing and collection are completed in fifteen minutes. After the consultation, John enters the payment information into his Quicken software for a possible tax deduction next year. He also enters the information on his calendar at the date of his next FAA flight physical, to remind him to accurately advise the FAA of the consultation and prescription information as required by FAA regulations. On the way home, John drives by the automated pharmacy, has his identity again verified by retinal scan, and the machine dispenses five pills together with a drug information sheet. John and Susan have a wonderful anniversary evening.

The above scenario takes place in 2004, yet virtually all the technology described was already available in 2000. And the technology is quickly getting better. A combination of seemingly unrelated factors has driven up the demand for cybermedicine. For example, the growth of content available on the Internet⁴, and specifically the World Wide Web, has been exponential. In addition, the quantity of health information has perhaps grown even more than other information, since many users are quick to access health care information via the Internet. Also, the quality of health care information freely available is impressive—but only for the sophisticated user who can distinguish peer-reviewed journals from quackery.

Many states are providing Internet access to physician profiles, allowing users a glimpse at information once available only to state boards of medicine, hospitals, health care plans, and peer review organizations. Digital signatures have lessened security concerns for some transactions, and companies are already offering storage of medical records on the web. The Health Insurance Portability and Accountability Act⁵ (HIPAA) is finally focusing attention on privacy, security and confidentiality issues. And yes, people are getting prescriptions for Viagra and

³ Such an inability could present a serious problem for pilots trying to distinguish runway access lights from taxiway lights at night.

⁴ See THE BLUEBOOK: A UNIFORM SYSTEM OF CITATION § 17.3.3 (16th ed. 1996); cf. THE BLUEBOOK: A UNIFORM SYSTEM OF CITATION § 18.2 (17th ed. 2001) (expanding and clarifying the rules for the citation of Internet sources); see also Candace Elliott Person, *Citation of Legal and Non-legal Electronic Database Information* (last modified June 24, 1997) <<http://www.michbar.org/publications/citation.htm>>. The author is familiar with the *Bluebook's* admonition to avoid citation to Internet sources unless the materials are unavailable in printed form or are difficult to obtain in their original form. The *Bluebook* adopts this approach because of the transient nature of Internet sources. Nonetheless, given the subject matter of this article, the author is relatively unapologetic about the plethora of Internet citations used herein. Many state and federal agencies are publishing important policies solely on the Internet. This approach is good because it allows much easier access to governmental information to a broader group of people. However, it can be a nightmare for a researcher who might wish to track changes in a given policy over time - the previous version might simply disappear when a revised policy is published.

⁵ See Pub. L. No. 104-191, 110 Stat. 1936 (codified in various sections of the U.S.C.).

other “lifestyle drugs” via the Internet by filling out simple questionnaires (and providing valid credit card information) despite attempts by federal and state regulators and prosecutors to curb such conduct.

Managed care has made us comfortable enough to engage in transactions with remote mail-order pharmacies. Even more significantly, it has forever changed the physician-patient relationship. It has lowered our expectations of the once-revered relationship by limiting the duration of examinations and causing us to change physicians whenever a list of preferred providers is amended. Managed care has also forced patients to become more active in managing their medical care, with patients believing that one must be—or have—an effective advocate to obtain proper medical care, accelerating a trend that may have begun in earnest with the publication of *How To Be Your Own Doctor (Sometimes)* in 1977.⁶ The book exhorted us to become “activated patients” by taking a more direct role in, and taking more responsibility for, our health care.⁷ Furthermore, DTC advertising for prescription drugs has whetted our appetite for particular drugs, and medical information available on the Internet has allowed us to become more informed patients and consumers of health care.

Cyber-consultations will not soon replace a majority of in-person visits to physicians; however, developed and developing technologies offer promise that for

⁶ See KEITH W. SEHNERT, *HOW TO BE YOUR OWN DOCTOR (SOMETIMES)* (1977).

⁷ See 65 Fed. Reg. 24,704-05 (Apr. 27, 2000); see also 21 C.F.R. § 330.10 (a)(4); FDA, *Questions and Answers Over-the Counter Drug Products* (visited Oct. 10, 2000) <<http://www.fda.gov/cder/meeting/otcqa-600.htm>>. The U.S. Food and Drug Administration (FDA) has moved to make more formerly-prescription drugs available over-the-counter (OTC), in part because we are more activated patients. The FDA notes that “[i]n light of the continuously changing health care environment, including the growing self-care movement, the agency continues to examine its overall philosophy and approach to regulating [OTC] drug products.” The FDA held public hearings on July 28-29, 2000, to debate the FDA’s approach to regulating over-the-counter (OTC) drug products. The FDA also solicited comments concerning criteria to be considered in decisions on OTC availability, classes of drug products that should (or should not) be made available OTC, consumer understanding of the benefits and risks of OTC availability, and the FDA’s role in switching drugs from prescription to OTC status. The criteria for determining whether a drug should be available only by prescription were originally established in 1951 by the Durham-Humphrey amendments to the federal Food, Drug and Cosmetic Act (Act). The Act requires that drugs that cannot be used safely without professional supervision be dispensed by prescription only. Such drugs may be considered unsafe for OTC sale because they are addictive, toxic, have too many potentially harmful side effects, or are for the treatment of medical conditions that cannot be readily self-diagnosed. All other drugs may be sold OTC. A number of drugs have changed from prescription to OTC status with the FDA’s approval, including: antidiarrheals (loperamide), topical antifungals (clotrimazole, terbinafine HCL), antihistamines (clemastine fumarate, diphenhydramine), vaginal antifungals (clotrimazole, miconazole nitrate), analgesics (ketoprofen, naproxen sodium), acid reducers (cimetidine, famotidine), hair growth treatments (minoxidil) and smoking cessation drugs (nicotine polacrilex). The FDA considers whether labeling can be written that allows consumers to safely self-medicate before allowing prescription drugs to be sold OTC. Labeling is usually re-written when a drug changes from prescription to OTC status, and sometimes the OTC version of a drug may be marketed at a lower dose than the prescription version. Consumers generally benefit from OTC status by having access to safe and effective drugs that can be taken without a physician’s supervision. Cost of drugs typically drops considerably when they switch to OTC status. The issue of whether more drugs should be available OTC is complex, involving issues of patient safety, freedom of patients to self-medicate, drug costs, insurance reimbursement, and pharmaceutical company profits. Appropriate public policy is clearer for certain classes of drugs. For example, antibiotics should not be sold OTC, since they may become less effective and increase pathogen resistance if used too frequently or improperly.

a variety of medical conditions such consultations may be perfectly appropriate and offer a convenient and cost-effective alternative to traditional delivery models. In some limited circumstances, we may be ready to move from Dr. Welby⁸ to drkoop.com.⁹ But there are significant regulatory and other barriers to the growth of cyber-consultations.¹⁰ Currently, the hypothetical introductory consultation could violate a variety of state and federal laws and would also breach ethical principles adopted by organizations such as the American Medical Association (AMA) and Federation of State Medical Boards (FSMB).¹¹

Many of the barriers to the growth of cybermedicine are legitimate, such as concerns about privacy, confidentiality, and security of patient-identifiable information. Other barriers are historical or structural in nature, such as state-by-state licensure of physicians. Cultural barriers and the “digital-divide” can also present formidable obstacles to the growth of health care delivered via the Internet. One thing is clear: the limited regulatory record suggests a strong interest in maintaining the status quo, providing little framework for ethical, appropriate use of new technology in the delivery of health care. State medical boards have responded to real or perceived abuses with quick, knee-jerk regulatory action.¹² Yet they have been silent, or at least very quiet, on the issue of how member physicians might legitimately incorporate the Internet and related technologies into their practices.

No single definition of telemedicine is universally accepted, even though the technology has been available since the mid-1950s.¹³ Some practitioners prefer the terms “telehealth,” believing it to be more inclusive of behavioral telemedicine applications.¹⁴ One recent approach defines telemedicine broadly as “the use of telecommunications and information technology to provide health care to persons

⁸ See The TV series *MARCUS WELBY, M.D.* (1969-76), also known as “Robert Young, Family Doctor”, which was produced in cooperation with the American Academy of Family Physicians. See also Joseph E. Scherger, M.D., M.P.H., Editorial, *Marcus Welby Returns*, 4 *AMERICAN ASSOCIATION OF FAMILY PHYSICIANS, FAMILY PRACTICE MANAGEMENT* (June 1997) <<http://www.aafp.org/fpm/970600fm/editorial.html>>. Dr. Welby was the epitome of a caring old-fashioned pre-managed care family physician willing to spend as much time as necessary with his patients.

⁹ See drkoop.com, available at <<http://www.drkoop.com>>.

¹⁰ See, e.g., *Viagra Prescriptions on the Internet: Is this Telemedicine?*, *HEALTH L. PERSPECTIVES* (May 29, 1998) <<http://www.law.uh.edu/healthlawperspectives/Food/980520Viagra.html>>. Some material in this article has been adapted from a series of short “op-ed” articles on e-health issues web-published by the author as *Health Law Perspectives*.

¹¹ See, e.g., *AMERICAN MEDICAL ASSOCIATION, CODE OF MEDICAL ETHICS: CURRENT OPINIONS WITH ANNOTATIONS* (1997).

¹² Several medical boards prohibit most Internet prescribing. See discussion *infra* part V.E.

¹³ See Florida Department of Health, *Task Force on Telehealth*, Jan. 12, 2000, at 7 <<http://www.doh.state.fl.us/mqa/medical/Telehealth.pdf>> (Definitions are difficult because of the complexity of the telecommunication technology and equipment, which is continuing to evolve, providing more application opportunities.).

¹⁴ See Marlene M. Maheu, *Telehealth: The Furthering of Psychology as a Profession* (visited Oct. 20, 2000) <<http://telehealth.net/articles/further.html>>.

who are at a distance from the practitioner.”¹⁵ Although many definitions of telemedicine are broad enough to include telephone, e-mail, and facsimile communications, some states have narrowed the definition by statute to exclude such items.¹⁶ Telemedicine has traditionally used a variety of technologies such as real-time, two-way video and data conferencing (including electronic instruments such as electronic stethoscopes), as well as “store and forward” technology that can, for example, allow a radiologist to review digital images from a remote location.¹⁷ For purposes of this article, cybermedicine is limited to a subset of telemedicine practiced via the Internet. However, the Internet will eventually be the preferred platform for delivery of all telemedicine services, since it provides an affordable, external architecture that can be used for transfer of voice, data, and video images.¹⁸

Part II of this article will review current modes of cybermedicine, including video teleconferencing, behavioral health consultations, physician-patient e-mail communications, and “consultations” based solely on medical questionnaires completed by the patient. Part III will examine Internet resources that support cybermedicine, including the maintenance of physician profiles and medical records on the Internet, and evolving technologies that buttress cybermedicine. Part IV will consider patient and regulatory barriers to the growth of cybermedicine including privacy concerns, licensure and other regulatory issues, insurance reimbursement challenges, and emerging liability concerns. Part V will look at DTC advertising of prescription drugs, a phenomenon that has greatly increased demand for online prescribing, and will address regulation of Internet pharmacies and Internet prescribing, including enforcement actions against pharmacies and physicians. In Part VI, I conclude that ill-considered regulatory efforts could severely thwart the development of cybermedicine, even though cybermedicine has the potential to deliver quality medical care in a cost-effective and convenient manner. Nonetheless, despite these ill-considered regulatory efforts, consumer demand for accessible health care and pharmaceuticals should eventually cause licensure and other issues to be resolved in an acceptable manner.

II. MODES OF CYBERMEDICINE

Regulatory efforts have focused on the most limited type of Internet “consultations,” where a patient completes a questionnaire which is reviewed by a

¹⁵ See *Task Force on Telehealth*, *supra* note 13, at 7. The same report defines telehealth more broadly as “the off-site provision of a wide array of health-related activities, such as professional continuing education, professional mentoring, community health education, public health activities, research and health services administration, as well as consultative and diagnostic health care.” *Id.*

¹⁶ See, e.g., CAL. BUS. & PROF. CODE § 2290.5 (a)(1) (West 1997).

¹⁷ See M. Kevin Outtersson, *e-Health: Advising Clients in the Race to the Promised Land*, presentation at the ABA e-Health Law 2000 seminar, Chicago, Illinois (Oct. 6-7, 2000).

¹⁸ See *id.*

physician who prescribes medication solely on the basis of the questionnaire, often without regard for the answers given by the patient. However, many physicians provide Internet consultations in a more ethical manner, ranging from the simple use of e-mail with established patients to video teleconferencing consultations via the Internet with no physical patient contact. Psychologists and other mental health practitioners seem to have embraced tele-consultations more than other health care providers, perhaps due to the nature of their practices.

A. *Video Teleconferencing*

CyberDocs¹⁹ is the currently available website that comes closest to offering the kind of consultation described in the introductory scenario. CyberDocs offers virtual consultations via NetSpeak's Webphone, which allows real-time, full-duplex voice communications combined with real-time video.²⁰ CyberDocs's physicians charge a fee of \$50 to \$75 per consultation conducted either through video teleconferencing or e-mail.²¹ Physicians will prescribe medications based on the virtual consultations for routine conditions and ailments such as allergies and high blood pressure.²² The site allows scheduling of virtual appointments via e-mail, and the participating physicians carry malpractice insurance.²³ The site seeks to provide "realtime, online, confidential medical advice, and, in selected circumstances initial medical care to patients on the Internet."²⁴ However, the site recommends that all patients seek appropriate medical follow-up with another physician in person.²⁵

The CyberDocs website suggests that virtual consultations may be appropriate in a variety of circumstances, including: (1) where patients are away from home, at school, or experiencing minor symptoms for which they would like medical advice and/or initial treatment, (2) where patients live in a geographic area that does not allow immediate access to a physician's office or clinic, or (3) where patients do not have an established relationship with a primary care physician.²⁶

¹⁹ See CyberDocs (visited Oct. 16, 2000) <<http://www.cyberdocs.com>>.

²⁰ See Webphone (visited Oct. 16, 2000) <<http://www.webphone.com/product/features.html>>.

²¹ See CyberDocs (visited Oct. 16, 2000) <<http://www.cyberdocs.com>>.

²² See Ian Morrison, *The Future of Physicians' Time*, 132 ANNALS INTERNAL MED. 80, 80-84 (Jan. 4, 2000).

²³ *Id.*

²⁴ See CyberDocs, *Frequently Asked Questions* (visited Oct. 16, 2000) <www.cyberdocs.com/faq.com>. The "Frequently Asked Questions" (FAQ) page provides background on when a cyberconsultation may be appropriate and how the site works. Since the site uses frames, it is not possible to go directly to this link; instead, click the FAQ link from the home page. Since it is impossible to give page-specific citations, please note that all the following information about CyberDocs may be found on their website unless another source is indicated.

²⁵ See *id.*

²⁶ See *id.*

Patients choose a physician by clicking on a map of their home state: for Texas, the site lists three physicians, Juan Nieto (Emergency Medicine), Jerry Morris (Family Practice) and Alfredo Santesteban (Pediatrics).²⁷ The site allows patients to view a photo of the physician and verify the physician's credentials online using the AMA's "Physician Select" database or a site maintained by the American Board of Medical Specialties.²⁸ Checking the physicians' credentials through Docboard.org confirmed that all three physicians are indeed licensed in Texas and have no reported disciplinary actions on file.²⁹ Oddly, one of the physicians, Dr. Morris, appears to live only in cyberspace. The search results on Docboard showed Dr. Morris's zip code as "0" and his address as *locum tenens*.³⁰ CyberDocs has registered with Verisign, Inc., a company that provides digital signatures and site verification services, and the site displays the Verisign Authentic Site seal.³¹ CyberDocs appears to respect state licensing laws, by listing for each state only those physicians licensed to practice medicine in the state.³² Some participating physicians offer videoconferencing, some offer keyboard "chat," and some offer both.³³

It is possible to seek an immediate medical consultation with an emergency physician via CyberDocs' website.³⁴ However, a patient must first enter credit card information, complete a registration form with personal information and medical history and questions relating to the immediate medical concern.³⁵ Obviously, the site is not a good choice for a seriously injured patient if alternative emergency medical treatment is available. Additionally, if a patient suffers serious symptoms, such as chest pains, he will be advised to get offline and immediately visit an emergency room.³⁶ Using online services for emergency care requires some common sense. Tom Caffrey, founder and CEO of CyberDocs noted that "[i]f you cut yourself with a chainsaw, don't bleed [on] the keyboard. Head to the emergency room."³⁷

²⁷ See *id.*

²⁸ See *id.*

²⁹ See Docboard.org (visited Oct. 16, 2000) <<http://docboard.org>>.

³⁰ See Merriam-Webster (visited Oct. 16, 2000) <<http://www.m-w.com>> ("One filling an office for a time or temporarily taking the place of another").

³¹ See CyberDocs, *Frequently Asked Questions* (visited Oct. 16, 2000) <www.cyberdocs.com/faq.com>; see *supra* note 24.

³² See CyberDocs, *Frequently Asked Questions* (visited Oct. 16, 2000) <www.cyberdocs.com/faq.com>.

³³ See *id.*

³⁴ See *id.*

³⁵ See *id.*

³⁶ See Marissa Melton, *Online Diagnoses, Finding More Than A Doc-In-The-Box*, U.S. NEWS ONLINE (June 21, 1999) <<http://www.usnews.com/usnews/issue/990621/nycu/drugs.b.htm>>.

³⁷ *Id.*

For non-emergency consultations, patients make an appointment online, again completing credit card and personal information, past medical history and the nature of the medical problem.³⁸ After making an appointment, patients are given a user ID and an appointment ID.³⁹ CyberDocs claims that all patient information is fully encrypted through SSL encryption.⁴⁰ Prior to the online consultation, the physician reviews the medical and personal information.⁴¹ After the consultation, if the physician believes initiation of treatment is warranted, the physician will either call the prescription in to a pharmacy near the patient, or the prescription may be filled with the appropriately-named CyberPharmacy⁴² and delivery can be arranged within twenty-four hours.⁴³ However, the site contains a long list of prescriptions that CyberDocs says are inappropriate to be prescribed through an online consultation, including barbiturates, muscle relaxants, narcotics, sedatives, and stimulants/appetite suppressants.⁴⁴ Viagra is not on the “inappropriate” list, so is presumably available online.⁴⁵

Patients who have scheduled an appointment with a doctor on CyberDocs or have had an online consultation in the past may upload clinical files, so that their CyberDocs physician can access the information for clinical review purposes.⁴⁶ For example, a patient could upload pictures of a skin rash, a scanned electrocardiogram (ECG), or a scanned x-ray in a variety of supported digital formats. As a matter of practice, CyberDocs recommends that all patients should obtain an in-person follow-up visit with a physician, and further notes that they do not intend to be a substitute for conventional in-person medical care.⁴⁷ CyberDocs does about half its business outside the U. S., and schedules 3,000 online visits per day.⁴⁸

Caffrey argues that some medical tasks can be performed more efficiently

³⁸ See CyberDocs, *Frequently Asked Questions* (visited Oct. 16, 2000) <www.cyberdocs.com/faq.com>; see also *supra* note 24.

³⁹ See CyberDocs, *Frequently Asked Questions* (visited Oct. 16, 2000) <www.cyberdocs.com/faq.com>

⁴⁰ See *id.*

⁴¹ See *id.*

⁴² See CyberPharmacy (visited Oct. 16, 2000) <<http://www.cyberpharmacy.com>>.

⁴³ See CyberDocs, *Frequently Asked Questions* (visited Oct. 16, 2000) <www.cyberdocs.com/faq.com>; see also *supra* note 24.

⁴⁴ See CyberDocs, *Frequently Asked Questions* (visited Oct. 16, 2000) <www.cyberdocs.com/faq.com>.

⁴⁵ See *id.*

⁴⁶ See *id.*

⁴⁷ See *id.*

⁴⁸ See Melton, *supra* note 36.

online than in person, and that most of what a physician does is talk to a patient.⁴⁹ Online, Dr. Caffrey has diagnosed a case of shingles, advised a patient with heart disease to go to the emergency room, and refilled blood pressure medication.⁵⁰ As Dr. Caffrey notes, “say you’re at work, you’re feeling sick. Do you have four hours to go to the emergency room? Can you get an appointment with your doctor who is jerking you around: Here’s a way for patients and doctors to talk again.”⁵¹

Not surprisingly, CyberDocs is not without its critics. Some critics argue that it is inappropriate to diagnose a patient’s illness without a physical examination and at least simple tests such as blood pressure, and that a physician needs to touch, feel, and smell a patient to make an accurate diagnosis.⁵² Dr. Thomas Reardon, president of the AMA says that “[i]n five or 10 minutes face to face I can find out more about you than I can in an hour on the computer.”⁵³

However, even critics of cybermedicine recognize that technology may eventually make online diagnosis and treatment more acceptable. Dr. Arthur Caplan, director of the Center for Bioethics at the University Pennsylvania, notes that at present, on some sites, a patient may be getting advice on allergies from a pathologist, or psychological help from a gastroenterologist, but predicts that these problems will be erased by technology, and that “[w]e will have certification and standards for doctors, link-ups to televised images and readouts from microchips that may be in your body. I think that world will come, but it ain’t here by a long shot.”⁵⁴ CyberDocs may not “be there” yet, but they represent a serious attempt to begin practicing cybermedicine ethically. CyberDocs does not deny that its physicians are “practicing medicine.”⁵⁵ However, at the other end of the spectrum, sites like Ask the Doc⁵⁶ allow patients to have private online conversations with its 100 physicians, but claim they are not practicing medicine. The site makes this claim because the physicians will not diagnose illness, prescribe medication, keep a medical record of the conversation or even reveal their identity.⁵⁷

Additionally, as an alternative for physicians who do not wish to practice

⁴⁹ See Claudia Kalb and Deborah Branscum, *Doctors Go Dot.Com*, NEWSWEEK.COM (Aug. 16, 1999) (also available from the Cyberdocs media link at <http://www.cyberdocs.com/mediapress/newsweek_08169htm>).

⁵⁰ See Sheryl Gay Stolberg, *Technology, Need A Doctor in a Hurry? How About MD.com?*, N. Y. TIMES (July 4, 1999) (also available from the Cyberdocs media link at <http://www.cyberdocs.com/mediapress/nytimes_070499.htm>).

⁵¹ *Id.*

⁵² *See id.*

⁵³ Stolberg, *supra* note 50.

⁵⁴ *See* Kalb and Branscum, *supra* note 49.

⁵⁵ *See* CyberDocs, *Frequently Asked Questions* (visited Oct. 16, 2000) <www.cyberdocs.com/faq.com>; *see also supra* note 24.

⁵⁶ *See* Ask the Doc (visited Oct. 16, 2000) <<http://www.americasdoctor.com>> (access from this home page through “Meet the Research Physician” to “Ask the Doctor”).

⁵⁷ *See* Stolberg, *supra* note 50.

cybermedicine with patients they have never seen, CyberDocs allows physicians to register and use the infrastructure to communicate with their established patients.⁵⁸ However, it is not clear from the site how successful this approach has been. To access the service, a patient must input the physician's name, rather than selecting from the list of cyber-physicians.

Although CyberDocs' structure respects state licensing laws, several state medical boards and some state legislatures have essentially decreed that prescribing drugs online without a face-to-face consultation is in violation of state medical practice acts and constitutes inappropriate conduct subject to disciplinary sanctions including loss of licensure.⁵⁹ While the current structure does not comply with these decrees, it is unclear from the site whether CyberDocs complies with specialized telemedicine informed consent laws enacted by several states.⁶⁰

B. *Tele-psychology and Psychiatry Consultations*

Mental health professionals may embrace cybermedicine more enthusiastically than physicians in other specialties. "Psychiatry, a specialty that does not require touch during examination of the patient, is a branch of medicine eminently suited to the use of telecommunications technology."⁶¹ Suicide and crisis-intervention hotlines have used telephone counseling for decades.⁶² Two-way interactive television has been used for telepsychiatry since 1959,⁶³ but advances in Internet videoconferencing technology should be a boon to mental health online consultations. Psychologists and other mental health professionals have coined the terms "telehealth" and "behavioral telehealth" as being less restrictive than "telemedicine."⁶⁴ Behavioral telehealth is the largest and fastest growing area of telemedicine, dominated by psychiatry, nursing, and social work.⁶⁵ Because patients may form close bonds with mental health professionals, telehealth may be particularly helpful for patients prematurely terminating therapy due to relocation, childcare difficulties, or post-surgical restrictions.⁶⁶ Some psychologists believe that "[t]elehealth seems well suited to support the assessment and decision-making

⁵⁸ See CyberDocs, *Frequently Asked Questions* (visited Oct. 16, 2000) <www.cyberdocs.com/faq.com>; see also *supra* note 24.

⁵⁹ See discussion *infra* part V.E.; see, e.g., Texas Internet Prescribing Policy, *infra* note 623

⁶⁰ See, e.g., ARIZ. REV. STAT. § 36-3602 (2000); see generally Jay Katz, *Informed Consent - Must It Remain A Fairy Tale?*, 10 J. CONTEMP. HEALTH L. & POL'Y 69 (1993).

⁶¹ See Elisabeth Liebson, *Telepsychiatry: Thirty-Five Years' Experience*, 2 MEDSCAPE MENTAL HEALTH (July 8, 1997) <<http://www.medscape.com>>.

⁶² See *id.*

⁶³ See *id.*

⁶⁴ See Marlene M. Maheu, *Telehealth: The Furthering of Psychology as a Profession* (visited Oct. 20, 2000) <<http://telehealth.net/articles/further.html>>.

⁶⁵ See *id.*

⁶⁶ See *id.*

role envisioned for doctoral-level psychologists in certain emerging areas of the health care marketplace.”⁶⁷

C. *Physician-Patient E-mail Communication*

Most physicians may not be prepared to communicate with their patients via video conferencing, but an increasing number of physicians are beginning to use e-mail to communicate with their patients.⁶⁸ According to an October 1999 survey conducted by the law firm of McDermott Will & Emery, 85% of physicians are now online, 63% of physicians use e-mail for some purpose, and 33% of physicians communicate with patients via e-mail.⁶⁹ If this survey is accurate in concluding that one-third of physicians communicate with patients online, the recent increase in use of e-mail by physicians has been exponential. Compare the 1999 numbers with a 1995 study that found only about 1% to 2% of physicians offered patients this option.⁷⁰

As with telephone calls, communication via e-mail is unlikely to be reimbursed by health insurance plans.⁷¹ Therefore, economically, physicians may be reluctant to allow such communication, believing it may simply extend their workday without producing any additional revenue. In fact, patients may seek advice to avoid a visit to the physician’s office. Less problematical is the use of e-mail to schedule appointments or deliver test results. Surely an e-mail is more secure than leaving a patient’s test results on a telephone answering machine, and more productive than playing telephone “tag.”⁷² E-mail may be the lower-tech cousin of telemedicine, but it is clearly embraced by most legal definitions of telemedicine, that often include all “telephone, video, and electronic transmissions via telephone lines or digital connections.”⁷³

However, recognizing the ubiquitous nature of e-mail, some states have limited the application of telemedicine-specific informed consent procedures to e-mail communications. For example, the California statute specifically excludes both telephone and e-mail communications from such requirements.⁷⁴ Physicians

⁶⁷ Kathleen M. Kirby et al, *Telehealth and the Evolving Health Care System: Strategic Opportunities for Professional Psychology*, *Professional Psychology*, 29 RESEARCH AND PRACTICE 527-535 (Dec. 1998) <<http://www.apa.org/journals/pro/pro296527.html>>.

⁶⁸ See generally Alissa R. Spielberg, *Online Without A Net: Physician-Patient Communication By Electronic Mail*, 25 AM. J.L. & MED. 267 (1999).

⁶⁹ See Susan Huntington, *Emerging Professional Liability Exposures For Physicians On The Web*, presentation at the ABA e-Health Law 2000 Seminar, Chicago, Illinois (Oct. 6-7, 2000).

⁷⁰ See Tom Ferguson, *Digital Doctoring—Opportunities and Challenges in Electronic Patient-Physician Communication*, 280 JAMA 1361 (1998).

⁷¹ See generally Morrison, *supra* note 22, at 80.

⁷² See Spielberg, *supra* note 68, at 270.

⁷³ *Id.*

⁷⁴ See CAL. BUS. & PROF. CODE § 2290.5(c) and 2290.5(a)(1) (West 1998) (California, Arizona,

should be concerned about the security of e-mail transmissions, including compliance with HIPAA standards. However, evidence derived from attorneys' experience with unencrypted e-mail suggests that physicians should not be overly concerned. For lawyers at least, most states' legal ethics committees have concluded that communicating with or about clients using unencrypted e-mail is usually appropriate.⁷⁵

Of course, e-mail communications should be afforded the same confidentiality protections as other forms of patient-physician communication. E-mail communications are more troubling to some physicians than telephone conversations because a clear written record is created indicating exactly what the patient and physician communicated. Other physicians may take comfort that their advice is better documented, with less chance it could be misconstrued in a later malpractice action. In either case, good practice, medical malpractice risk management, and sometimes the law, dictate that e-mail communications should become part of the medical record.⁷⁶ Even if the physician deletes his or her copy of an e-mail communication, the patient may have retained a copy, or the message may in some cases be retrieved from a hard drive or Internet service provider.⁷⁷

If a physician decides to communicate with patients via e-mail, clear guidelines on the use of e-mail must be provided to the patient. For example, the use of e-mail may be limited to scheduling of appointments, insurance reimbursement issues, and other non-clinical matters. The physician may wish to advise patients that e-mails will be accepted involving minor medical questions, but that the patient should call rather than communicate via e-mail for urgent matters. The patient should be advised: (1) that e-mails become a part of the medical record, (2) of the pros and cons of communicating by e-mail, (3) who has access to the messages, and (4) that if the patient sends an e-mail from work, her employer may have access to the message.⁷⁸

Physicians sometimes post their e-mail addresses on websites or elsewhere, allowing non-patients the opportunity to send an unsolicited e-mail to the physician. A study conducted between December 1997 and January 1998 sent unsolicited e-mails from a fictitious patient to physicians seeking advice for a "skin problem."⁷⁹ The request tried to suggest a herpes zoster infection.⁸⁰ Of the 50% of

Texas and some other states require a specific form of informed consent prior to engaging in a telemedicine consultation, sometimes including a warning to the patient that confidential information will be transmitted electronically with a possibility that confidentiality may be breached as a result of the transmission.; see also Spielberg, *supra* note 68.

⁷⁵ See William Freivogel, *Legal and Ethical Ramifications of Lawyers Communicating with Unencrypted E-Mail*, presentation at the ABA e-Health Law 2000 Seminar, Chicago, Illinois (Oct. 6-7, 2000) (citing D.C. Op. 281 (1998); Ill. Op. 96-10 (1997); Mass. Op. 00-1 (2000); N. Y. Op. 709 (1998), and ABA Op. 99-413 (1999)).

⁷⁶ See generally Spielberg, *supra* note 68.

⁷⁷ See *id.*

⁷⁸ See Susan Huntington, *What Every Healthcare Lawyer Needs to Know*, presentation at the ABA e-Health Law 2000 Seminar, Chicago, Illinois (Oct. 6-7, 2000).

⁷⁹ See Gunther Eysenbach and Thomas L. Diepgen, *Responses to Unsolicited Patient E-mail*

physicians who responded, 93% advised the fictitious patient to see a physician, and surprisingly, most of those responding also mentioned a diagnosis.⁸¹ The authors of the study concluded that the “legal consequences of providing incorrect, incomplete, or inappropriate advice under these circumstances are unclear” and advised websites posting physicians’ e-mail addresses to also post a disclaimer advising that unsolicited patient e-mail may not be answered and should not be a substitute for obtaining in-person medical care.⁸²

D. Consultations Using Questionnaires

The most controversial “consultations” are those where a physician prescribes a drug such as Viagra on the basis of a medical history questionnaire completed by the prospective patient. The patient often completes the questionnaire at an Internet pharmacy site, and the pharmacy forwards it to a physician for “review.”⁸³ Typically, the patient will not even know what physician he is “seeing” in cyberspace. The patient is usually charged a physician fee of \$50 to \$75, payable only if the prescription is approved.⁸⁴ Ordinarily, the patient never sees the prescription—nor does he have the ability to fill the prescription at a local pharmacy, which could perhaps be less expensive than the cyberpharmacy.⁸⁵ This conduct has attracted the most attention from state medical boards, attorneys general, the FDA, the Federal Trade Commission and other regulatory bodies as discussed *infra* in part V.

Newspapers are filled with accounts of a dog, cat, or child successfully obtaining Viagra over the Internet. One researcher pretended to be a 69-year old woman giving a sexual history of “no orgasm” and suffering from obesity, coronary artery disease and hypertension.⁸⁶ She also advised that she was taking captopril, pravachol, atenolol, and erythromycin.⁸⁷ The research identified 22 pharmacies of three types: two required a prescription from a physician of the patient’s choosing; nine dispensed the drug without requiring any prescription, and 11 provided an online prescription based on alleged physician review of an online

Requests for Medical Advice on the World Wide Web, 280 JAMA 1333 (1998).

⁸⁰ See *id.* at 1334.

⁸¹ See *id.* (Seven of those who advised the patient to see a physician gave no additional advice, but 18 of the 20 remaining respondents mentioned a diagnosis, and 17 specifically mentioned herpes zoster).

⁸² See *id.* at 1335.

⁸³ See Bernard S. Bloom & Ronald C. Iannacone, *Internet Availability of Prescription Pharmaceuticals to the Public*, 131 ANNALS INTERNAL MED. 830 (1999).

⁸⁴ See Morrison, *supra* note 22 at 82; Claudia Kalb & Deborah Branscu, *Doctors Go Dot.Com*, NEWSWEEK (Aug. 16, 1999).

⁸⁵ See Bloom, *supra* note 83 (stating that the median cost is 15% higher than that for general practice visits).

⁸⁶ See Gunther Eysenbach, *Online Prescribing of Sildenafil (Viagra®) on the World Wide Web*, 1 J. MED. INTERNET RES. e10 (1999) <<http://www.jmir.org/1999/2/e10/index.htm>>.

⁸⁷ See *id.*

order form containing medical history questions.⁸⁸ However, a “surprisingly high number of Internet pharmacies declined delivery.”⁸⁹ The study found that prescriptions were issued in 30% of the cases, even though clear contraindications existed.⁹⁰ Further, in two of the three cases where Viagra was delivered, physicians had approved the prescriptions, but the name of the consulting physician was revealed in only two cases.⁹¹ Interestingly, the average price charged was quite high at \$17 per pill, and the great majority of the pharmacies failed to include proper labeling with the shipment.⁹²

The near-incestuous physician-pharmacy relationship raises additional legal concerns. Anti-kickback and anti-referral laws at the federal and state level have long sought to eliminate physician’s monetary connections with pharmacies.⁹³ Prior to the enactment of such laws, physicians could own the pharmacy to which they sent patient’s prescriptions.⁹⁴ Alternatively, physicians could receive a rebate (or kickback) based on referrals to a pharmacy, or in some cases directly from a pharmaceutical company for prescribing its drugs.⁹⁵ In the other direction, it is also ethically and legally inappropriate for a physician to pay a “referral fee” to anyone for sending a patient his way.⁹⁶ Therefore, any arrangements where a pharmacy keeps a portion of the reviewing physician’s fee could be subject to regulatory scrutiny.⁹⁷

It is easy to see why regulators have rushed to quash online prescribing. However, the too-simple question being asked is “how do we stop this” rather than “how do we regulate this.” Defining the issue goes a long way towards determining the outcome. Rather than rationally discussing whether it may sometimes be appropriate for a physician to write a prescription based only on a patient-completed questionnaire, we are focusing on pharmacies and physicians that are

⁸⁸ *See id.*

⁸⁹ *See id.*

⁹⁰ *See id.* Viagra is not approved for females, special caution has to be taken with patients who have a history of cardiovascular disease, and the fictitious patient was taking multiple drugs that could interact with Viagra.

⁹¹ *See* Gunther Eysenbach, *Online Prescribing of Sildenafil (Viagra ®) on the World Wide Web*, 1 J. MED. INTERNET RES. e10 (visited Sept. 4, 2000) <<http://www.jmir.org/1999/2/e10/index.htm>>.

⁹² *See id.*

⁹³ *See* 42 U.S.C. § 1395nn (2000) (codifying the Stark I and Stark II Statutes); *see e.g.* TEX OCC. CODE § 102.001 (1999).

⁹⁴ *See generally* HHS ISSUES FINAL RULE ADDRESSING PHYSICIAN SELF-REFERRALS, HHS NEWS, Jan. 3, 2001 (visited May 2, 2001) <<http://www.house.gov/stark/stark2/Stark2info.html>> (legislative history of self-referral legislation); *see also generally* Fed. Reg. 856-59 (Jan. 4, 2001), *available at* <<http://www.house.gov/stark/stark2/Stark2info.html>> (legislative history of self-referral and anti-kickback legislation).

⁹⁵ *See id.*

⁹⁶ *See, e.g.*, TEX OCC. CODE § 121.001(a) (1999).

⁹⁷ *See infra* part V and the accompanying footnotes.

ignoring medical histories provided by patients, which is clearly inappropriate, as a basis for blanket prohibitions. Two other points seem to be lost in the current one-sided “debate.” First, a large majority of the inappropriate prescribing cases that have been the basis for newspaper articles, regulatory investigations, and academic journal articles has involved fictitious patients who suffered no real harm. Second, the idea that physicians could diagnose and prescribe to a patient solely on the basis of a patient-provided history is not new. Rather, it hails back to a time when physicians preferred to base their diagnosis on their patient’s written description of symptoms.⁹⁸

III. INTERNET RESOURCES FOR CYBERMEDICINE

A. *Health Information Available on the Web*

1. Consumer Perspective

The unique nature of the Internet makes finding health information much easier than in the past. An “activated patient” in the 1970s had to be very activated indeed, since medical research required not only visiting a medical library, but a fair understanding of medical terminology.⁹⁹ An uninformed reader might not think of reading *Oncology Today* for information about research breakthroughs in cancer treatment. Today a simple search of the word cancer will result in over 8 million hits.¹⁰⁰ As of 1997, forty-three percent of adult Internet users were searching for health information online.¹⁰¹

Because the Internet contains an extensive array of medical information, separating the peer-reviewed science from quackery or from marketing may challenge the average user. Although the ability to locate cutting-edge research is often touted, the Internet is even more useful to locate established medical information. For example, a patient diagnosed with osteoporosis may want more detailed information than that available from a short consultation with a physician. Many websites provide information about prescription drugs once available only to subscribers of the *Physician’s Desk Reference*.¹⁰² Interactive tools allow patients to enter current prescription drugs they are taking and see whether an unfavorable drug interaction is likely.¹⁰³ The key to determining the quality of any information

⁹⁸ See Spielberg, *supra* note 68, at 268 (“During the seventeenth and eighteenth centuries, physicians valued patients’ descriptions of their illness above a physical examination when making medical diagnosis.”).

⁹⁹ See SEHNERT, *supra* note 6.

¹⁰⁰ A search of the Internet search engine Google for the word cancer found 8,310,000 documents (visited June 2, 2001) <<http://www.google.com/>>.

¹⁰¹ See Robert Mittman & Mary Cain, *The Future of the Internet in Healthcare*, CAL. HEALTHCARE FOUNDATION (Jan. 1999) <<http://www.chcf.org>>.

¹⁰² See PHYSICIANS DESK REFERENCE (2001).

¹⁰³ See, e.g., [drkoop.com](http://www.drkoop.com), *Personal Drugstore* (visited Nov. 9, 2000) <<http://www.drkoop.com/>>

located via an Internet search may be as simple as looking at the ubiquitous uniform resource locator (URL), *i.e.*, the Internet “address.”¹⁰⁴ For example, a search of governmental (.gov) domains would arguably produce information with less bias, or at least a different bias, than information obtained from a search of commercial (.com) domains.¹⁰⁵

Another method to evaluate the quality of health care information is to consider the perspective of the organization posting the information.¹⁰⁶ Whenever possible, it is helpful to try to locate organizations with differing perspectives on a given issue. An organization such as the Foundation for Osteoporosis Research and Education¹⁰⁷ or the National Osteoporosis Foundation¹⁰⁸ would perhaps be more bullish on bone density testing than the governmental Agency for Healthcare Research and Quality (formerly the Agency for Health Care Policy and Research.)¹⁰⁹

Some websites attempt to filter information available within their sites. For example, the National Institutes of Health (NIH) National Library of Medicine (NLM) offers part of the MEDLINE database containing abstracts of articles from 3,900 medical journals.¹¹⁰ Additionally, the site includes links to responsible organizations, publications, medical dictionaries, libraries, and directories for finding physicians and hospitals.¹¹¹ A search within MEDLINE differs from other Internet searches in one important respect: the NLM has selection guidelines for

hcr/drugstore>.

¹⁰⁴ See Google <<http://www.google.com>>. Sophisticated search engines such as Google allow a user to specify the “domain” where a search will be conducted.

¹⁰⁵ Even within commercial domains, information posted by a reputable drug manufacturer, *e.g.*, is likely more medically accurate than information posted by a website selling “nutritional supplements” to ostensibly treat medical conditions. For the skeptic, information posted by a website directly selling anything may be suspect on the basis of *caveat emptor*. Further, a manufacturer using a website as a marketing tool, even without direct selling, may present a less objective perspective than a more neutral source. A visit to Pfizer, the manufacturer of Viagra (available at <<http://www.viagra.com>>), will not likely reveal the level of drug interaction details that may be found at the Food and Drug Administration site (available at <<http://www.fda.gov>>). One commercial site (sponsored by several drug companies) that offers fairly detailed medical information on a wide variety of conditions is the *Doctor's Guide to the Internet* (visited Sept. 20, 2000) <<http://www.pslgroup.com/docguide.htm>>.

¹⁰⁶ See American Medical Association (visited Sept. 20, 2000) <<http://www.ama-assn.org/home.htm>> (under the heading “Physicians”). For example, when visiting the American Medical Association’s website also visit the “Policy and Advocacy” section to better understand the organization’s goals on health policy issues. See American Medical Association, *Policy and Advocacy* (visited Sept. 20, 2000) <<http://www.ama-assn.org/advocacy.htm>>.

¹⁰⁷ See Foundation for Osteoporosis Research and Education (visited Sept. 20, 2000) <<http://www.fore.org>>.

¹⁰⁸ See National Osteoporosis Foundation (visited Sept. 20, 2000) <<http://www.nof.org>>.

¹⁰⁹ See Agency for Healthcare Research and Quality (visited Sept. 20, 2000) <<http://www.ahrpr.gov>>.

¹¹⁰ See National Library of Medicine (visited Sept. 20, 2000) <<http://www.nlm.nih.gov/medlineplus/>>.

¹¹¹ See *id.*

evaluating whether to include web pages, in an attempt to include only appropriate, authoritative health information sources. In fact, much of the information available at the site is from NLM itself or the NIH.¹¹² The selection criteria exclude web pages that are selling a product or service.¹¹³ Also, NLM reviews pages for quality, authority and accuracy of content.¹¹⁴ Even lists of links are “quality-filtered.”¹¹⁵

2. Practitioner/Clinical Perspective

Not surprisingly, physicians also turn to the Internet for medical information.¹¹⁶ And even with their medical expertise, they experience similar difficulties faced by lay patients. Physicians sometimes avoid accessing resources such as MEDLINE, textbook collections, full-text journal articles and drug databases because electronic retrieval systems “are still difficult to use and do not provide clinically expedient information.”¹¹⁷ Some physicians have a “vision of a unified information network that delivers frequently updated, clinically relevant, highly valid, and deeply integrated medical information over the Internet.”¹¹⁸ Lay consumers would be equally appreciative of such a system with an additional translation feature to allow non-medically trained consumers to understand the information retrieved.¹¹⁹

3. Standards for Websites

Some health websites have been criticized for ethical lapses. For example, a *New York Times* article examined criticism of former Surgeon General Dr. C. Everett Koop in connection with the Drkoop.com website.¹²⁰ On September 6, Koop indirectly responded to the criticism in an editorial, noting that websites

¹¹² First-time or casual users may find the MEDLINE database (an index to medical literature, and to some full-text publications produced by NIH) a bit daunting, requiring more than a modicum of medical knowledge, or at least an understanding of medical terminology. Also, the MEDLINE database contains mostly abstracts of articles rather than full text, and will primarily interest serious researchers only. A feature called *Loansome Doc* allows registered users to order full-text copies of articles from a local medical library, but the site warns that local fees and delivery methods may vary. However, MEDLINE is only a small part of the site. The remaining areas of the site will be useful to a wide variety of consumers seeking accurate, authoritative health information.

¹¹³ See National Library of Medicine (visited Sept. 20, 2000) <<http://www.nlm.nih.gov/medlineplus/>>.

¹¹⁴ See *id.*

¹¹⁵ See *id.*

¹¹⁶ See William R. Hersh & David H. Hickam, *How Well Do Physicians Use Electronic Information Retrieval Systems?, A Framework for Investigation and Systematic Review*, 280 JAMA 1347 (1998).

¹¹⁷ R. Robert Hubbs et al, *Medical Information on the Internet*, 280 JAMA 1363 (1998).

¹¹⁸ *Id.*

¹¹⁹ It would also be nice to eliminate the banner advertisements.

¹²⁰ See *Hailed as a Surgeon General, Koop Is Faulted on Web Ethics*, N.Y. TIMES (Sept. 5, 1999).

“have a profound responsibility to clearly delineate advertising from editorial, and to provide credible, unbiased information.”¹²¹ Users of medical information websites are faced with a number of challenges in evaluating any health information. Even if the information is unbiased, it may be out-of-date given the speed of advances in medical science. In some cases, it is impossible to determine the date information was posted—and an article could have been published years before it is posted on the Internet. However, the issue of web ethics is subtly different than from other “reliability” issues.

Critics of Koop charged that he engaged in activities that constituted a conflict of interest, or at least the appearance of a conflict, e.g., by allowing links on his website to advertisers (“partners”) that pay the website “referral fees” when visitors from Koop’s website order goods or services from the partner.¹²² In fairness to Koop, critics should separate Dr. Koop (the individual) from drkoop.com (the business). Even though the business is benefiting from the individual, and vice versa, it is unrealistic to expect a publicly traded concern to act as altruistically as a respected individual. After all, the business also has obligations to its shareholders. However, Koop has altered his arrangement with the website so that he will no longer receive a percentage of revenues from services or products sold through the site.

The proper ethical balance is exactly as stated by Koop: the business has a responsibility to carefully and accurately delineate between advertising and editorial content. Sites should follow the good journalistic practice of labeling content as “advertising” when it may not be clear from the context. The “dot com” suffix gives fair warning to visitors that the Internet site is a for-profit concern. Although commercial, Koop’s site is excellent. From the home page, a visitor can obtain information about health topics ranging from anorexia to stroke.¹²³ The innovative “drug checker”¹²⁴ feature allows comparison of drug/drug (and in some cases drug/food) interactions for a wide variety of medications. Finally, the online medical encyclopedia can be helpful in understanding information obtained from this or other health information websites.

Responding to ethical criticism of cybermedicine, the Internet Healthcare Coalition¹²⁵ (IHC) seeks to develop and promote a code of conduct through its e-Health Ethics Initiative¹²⁶ The initiative addresses ethical principles relevant to

¹²¹ Dr. C. Everett Koop, *Medical Content on the Internet* (Sept. 6, 1999) <<http://drkoop.com/aboutus/koop>>.

¹²² See Holcomb B. Nobile, *Hailed as a Surgeon General, Koop Critized on Web Ethics*, N. Y. TIMES, Sept. 4, 1999.

¹²³ See drkoop.com (visited Nov. 9, 2000) <<http://drkoop.com>>.

¹²⁴ See drkoop.com, *Drug Checker* (visited Nov. 9, 2000) <<http://www.drkoop.com/hcr/drugstore/interactions>>.

¹²⁵ See Internet Healthcare Coalition (visited Nov. 9, 2000) <<http://www.ihealthcoalition.org>>.

¹²⁶ See Internet Healthcare Coalition, *e-Health Ethics Initiative* (visited Nov. 9, 2000) <<http://www.ihealthcoalition.org/ethics/ethics.html>>.

online, interactive health care communications.¹²⁷ The IHC is seeking the consensus of industry, academic, government, patients, and consumer leaders. The initiative will address quality of content; commercial behavior; privacy, security and confidentiality; and use of the Internet in the practice of health care. According to its mission statement, the IHC seeks “a self-regulated Internet in which voluntary guidelines provide effective means for the legitimate dissemination of accurate healthcare information.”¹²⁸ Sponsors of IHC include non-profit philanthropic organizations as well as commercial entities such as Glaxo Smithkline and drkoop.com. The IHC only accepts donations on an “unconditional and unrestricted basis.”¹²⁹ The IHC has introduced an international code of ethics based on the principles of candor, honesty, quality, informed consent, privacy, professionalism in online health care, responsible partnering, and accountability.¹³⁰

In addition, the AMA has released guidelines applicable to all AMA websites.¹³¹ The AMA guidelines are more extensive and detailed than the IHC code. For example, the AMA guidelines require clear disclosure of site registration requirements, and payment information where charges are made for document delivery, pay per view, or subscription, etc.¹³² The AMA guidelines even address Internet irritations by providing that sites should not prevent viewers from returning to a previous site and should not redirect viewers to a site the viewer did not intend to visit.¹³³ Both the IHC and AMA efforts are laudable. The discussion and debate arising from these codes should help define the privacy and other protections needed by patient-consumers when accessing health care websites. However, it remains to be seen whether “voluntary” and “self-regulating” codes will offer sufficient protection.

B. *Physician Profiles Available on the Web*

1. State Resources

In the introductory scenario, John checked the credentials of Dr. Carter via

¹²⁷ See *id.*

¹²⁸ See Internet Healthcare Coalition, *Mission Statement* (visited Nov. 9, 2000) <<http://www.ihealthcoalition.org/about/mission.html>>.

¹²⁹ See Internet Healthcare Coalition, *Sponsorship Information* (visited Nov. 9, 2000) <<http://www.ihealthcoalition.org/ethics/sponsorship-eHES.html>>.

¹³⁰ See Internet Healthcare Coalition, *Code of Ethics* (visited Nov. 9, 2000) <<http://www.ihealthcoalition.org/ethics/code0524.pdf>>.

¹³¹ See Margaret A. Winker et al., *Guidelines for Medical and Health Information Sites on the Internet, Principles Governing AMA Web Sites*, 283 JAMA 1600 (Mar. 22, 2000).

¹³² See *id.*

¹³³ See *id.*

the Internet.¹³⁴ Finding a good doctor is important in a VPPO or in today's Preferred Provider Organization (PPO). A consumer needs to ask several questions in evaluating a physician, but where can one find the answers to such questions? For example, a consumer may want to know whether a physician is board certified. Other things being equal, a board-certified physician is desirable. Board certification requires several years of post-medical school training in a specialty, as well as passing a rigorous examination.¹³⁵

A consumer may want to review what medical school a physician attended, and her date of graduation to determine how many years' experience she has. It could also be useful to determine whether a physician has been subject to any disciplinary actions. Insurers and health plans have long had access to such information, which they use in a sophisticated "credentialing" process to evaluate physicians. Now individual consumers are beginning to have access to such information via the Internet, courtesy of state licensing boards, and in some cases, state legislators. For example, DocFinder¹³⁶ provides physician profiles for eighteen participating states.¹³⁷ The website is maintained by Administrators in Medicine (AIM), the Association of State Medical Board Executive Directors.¹³⁸ One need only enter the name of a physician in the database to gain access to a wealth of useful information, including license status, number, and type (e.g. M.D. or D.O.), address, date of birth, original license date, license expiration date, education, and specialty.¹³⁹ The screen also indicates whether information is on file as to any disciplinary actions, at least as of the date the database was created or last modified.¹⁴⁰

In the future, even more profiles of physicians and other health care providers and more extensive information should be available on the Internet, since several states have enacted or are considering legislation mandating consumer

¹³⁴ See *supra* part I.

¹³⁵ See American Medical Association, *Physician Education, Licensure and Certification* (visited June 1, 2001) <<http://www.ama-assn.org/aps/physcred.html>>.

¹³⁶ See Association of State Medical Board Executive Directors, *DocFinder* (visited Oct. 9, 2000) <<http://www.docboard.org/>>.

¹³⁷ See *id.* (Alabama, Arizona, California, Colorado, Iowa, Kansas, Maine, Maryland, Massachusetts, Minnesota, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, Texas and Vermont).

¹³⁸ See *id.*

¹³⁹ See *id.*

¹⁴⁰ See *id.* The American Board of Medical Specialties (ABMS) maintains another service, the "CertifiedDoctor Verification Service." The site contains all physicians certified by an ABMS member board, and allows one to verify the board certification status, location by city and state, and specialty of physicians certified by any of the 24 member boards of ABMS. The result screen will confirm, e.g., whether a primary care physician's certificates include "Family Practice." The site contains a good description of the board certification process, and the training required for certification in a specialty or subspecialty. The site also allows one to search by geographic area and specialty for a board certified physician through the "CertifiedDoctor Locator Service," but the site makes clear that listings are of those physicians who have subscribed to be listed in the service, not all certified physicians as contained in the verification service. See CertifiedDoctor Locator Service (visited Oct. 9, 2000) <<http://www.certifieddoctor.org/>>.

access to such information. For example, although Texas was already participating in the DocFinder site, Texas passed legislation in 1999 mandating the availability of even more extensive physician profile information.¹⁴¹ The statute significantly increased the types of information and the level of detail that must be made available to the public.¹⁴² The statute requires that the Texas Board of Medical Examiners create a profile of each physician licensed in Texas.¹⁴³ The statute specifically provides that the physician profiles must be made available on the Internet.¹⁴⁴

Some states have mandated that additional information be disclosed in physician profiles. For example, Indiana requires disclosure of percentage of ownership in certain health care facilities.¹⁴⁵ Florida, Maine, Rhode Island and Tennessee list publications by physicians, and Tennessee and Virginia require profiles to list those managed care organizations that are accepted by a physician.¹⁴⁶

2. The National Practitioner Data Bank

Disciplinary information reported in physician profiles is largely derived from information maintained in the National Practitioner Data Bank (NPDB). The Health Care Quality Improvement Act of 1986 (HCQIA)¹⁴⁷ established the NPDB as a central information clearinghouse to collect and release information related to the professional conduct and competence of physicians, nurses, dentists and other

¹⁴¹ See TEX. OCC. CODE § 160.002 (West 1999).

¹⁴² See *id.*

¹⁴³ *Id.* § 512(a).

¹⁴⁴ Profiles must include the name of each medical school attended and the dates of graduation; a description of all graduate medical education in the United States or Canada; any specialty certification held by the physician; the number of years the physician has actively practiced medicine in the United States or Canada, and in Texas; the name of each hospital in Texas in which the physician has privileges; the physician's primary practice location; the type of language translating services, including translating services for a person with impairment of hearing, that the physician provides at the physician's primary practice location; whether the physician participates in the Medicaid program; a description of any criminal conviction involving moral turpitude during the 10-year period preceding the date of the profile; a description of any charges reported to the Board during the 10-year period preceding the date of the profile to which the physician has pleaded no contest, for which the physician is the subject of deferred adjudication or pretrial diversion, or in which sufficient facts of guilt were found and the matter was continued by a court of competent jurisdiction; a description of any disciplinary action against the physician by the Board during the 10-year period preceding the date of the profile; a description of any disciplinary action against the physician by a medical licensing board of another state during the 10-year period preceding the date of the profile; a description of the final resolution taken by the Board on medical malpractice claims or complaints required to be reviewed by the Board under the Medical Practice Act; whether the physician's patient service areas are accessible to disabled persons, as defined by federal law; and a description of any formal complaint against the physician initiated and filed under the Medical Practice Act and the status of the complaint. See *id.*

¹⁴⁵ See Stephanie Norris, *Issue Brief: Provider Profiles*, Health Pol'y Tracking Service (Oct. 3, 2000) <<http://www.hpts.org>>.

¹⁴⁶ See *id.*

¹⁴⁷ Health Care Quality Improvement Act of 1986, Title IV, P.L. 99-660; see also NPDB regulations, 25 C.F.R. § 60.

health care practitioners.¹⁴⁸ The NPDB contains information about health care practitioners' malpractice payments, adverse licensure actions, restrictions on professional membership, and negative privileging actions by hospitals.¹⁴⁹ As a national database, the NPDB helps prevent incompetent practitioners from moving between states without discovery of the practitioners' incompetent performance.¹⁵⁰

The NPDB specifically applies to physicians, including doctors of medicine or osteopathy legally authorized by a state to practice medicine or surgery, and dentists legally authorized to practice dentistry by a state.¹⁵¹ However, only eligible entities are entitled to participate in the NPDB; except as contained in physician profiles, information on individual practitioners contained in the NPDB is not available to the public.¹⁵² Some critics of the current structure of the NPDB believe that the database should be accessible to the public. House Commerce Committee Chairman Thomas Bliley is considering legislation to allow public access to the NPDB.¹⁵³ The AMA opposes such access because the physician organization does not believe malpractice information is related to competency.¹⁵⁴ Although the AMA originally supported a version of the NPDB (without

¹⁴⁸ See generally Laura-Mae Baldwin et. al., *Hospital Peer Review and the National Practitioner Data Bank*, 282 JAMA 349 (1999).

¹⁴⁹ The stated intent of HCQIA is to support professional peer review by encouraging hospitals, state licensing boards, professional societies, and other health care entities to identify and discipline health care practitioners who engage in unprofessional conduct. HCQIA offers limited immunity from damages in civil suits under Federal or State law for peer review bodies and individual participants assisting such bodies if two conditions are met. First, the peer review action must be taken in the reasonable belief that the action was in the furtherance of quality health care. Also, the practitioner must be afforded due process protections, including adequate notice and hearing procedures fair to the practitioner under the circumstances. See *National Practitioner Data Bank Fact Sheet* (visited Sept. 9, 1999) <<http://www.hrsa.dhhs.gov>>.

¹⁵⁰ See *id.*

¹⁵¹ Additionally, the NPDB applies to other practitioners who are licensed or otherwise authorized (*i.e.*, certified or registered) by a state to provide health care. See *National Practitioner Data Bank Guidebook, Section C. Practitioners* (Jan. 1999) <<http://www.npdb.com/guidebook.htm>>.

¹⁵² Entities eligible to query the NPDB include state licensing boards, hospitals, and other health care entities that provide health care services provided they also follow a formal peer review process, and professional societies that follow a formal peer review process. Practitioners are also permitted to "self-query" the NPDB for their own records only. Entities eligible to report to the NPDB include entities that make medical malpractice payments for the benefit of a health care practitioner, state licensing boards, health care entities that take adverse privileging actions as a result of professional peer review, and professional societies that take adverse membership actions based on peer review. Payers of medical malpractice claims must report such payments to the NPDB and state licensing boards within 30 days of payment. Hospitals, professional societies, and other health care entities must submit reports to the NPDB and state licensing boards within fifteen days of an adverse action. See *id.* §§ D (Queries), E (Reports).

¹⁵³ On September 7, 2000, House Commerce Committee Chairman Thomas Bliley, R-Va., introduced H.R. 5122 to allow access by the public to all information reported to the NPDB. It has recently been reported that Bliley wants to pass his bill before he retires in December and has offered a compromise. Under the compromise, public access could be limited to information on hospital and state medical board disciplinary actions. The provision for access to raw malpractice information available—the most contentious part of the bill—would be dropped.

¹⁵⁴ See *New Data Bank Focuses on Fraud* (visited Dec. 1999) <http://www.ama-assn.org/sci-pubs/amnews/pick_99/gvta1122.htm>.

malpractice information), it now favors abolishing the NPDB because it contains malpractice information.¹⁵⁵

In addition to the NPDB, hospitals and other entities use a number of other practitioner data banks when credentialing physicians and other health care practitioners.¹⁵⁶ For example, another relatively new database containing physician fraud and abuse information is the Healthcare Integrity and Protection Data Bank.¹⁵⁷

C. *Maintaining Medical Records on the Internet*

In the introductory scenario, Dr. Carter was able to access John's medical record from a flight physical examination and use the information contained therein for a quite different purpose. Presently, it is difficult for physicians to share medical record information with one another even where the physicians are located in the same town. First, the record must be copied. The physician must then generally obtain the patient's consent to the release of medical information in accordance with state law. It may be difficult and expensive to copy items such as x-rays, CAT scans, or other visual records, and a secure delivery method must be found. Physicians may opt to unnecessarily repeat (or forego) a medical test rather than wait for receipt of the files.¹⁵⁸ In our mobile society, patients may have lived in multiple states or international locations, presenting even more formidable

¹⁵⁵ See *id.*

¹⁵⁶ The Federation of State Medical Boards maintains a Board Action Data Bank containing disciplinary actions including license revocations, probations, suspensions, consent orders, and Medicare sanctions. Other data banks include the Physician Masterfile of the American Medical Association, the Drug Enforcement Administration Controlled Substances Act Registration Database, and the Chiropractic Information Network/Board Action Databank (CINBAD). See *How to Use Practitioner Data Banks* (visited Sept. 30, 1999) <<http://www.credentialinfo.com>>.

¹⁵⁷ The Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, established the national Healthcare Integrity and Protection Data Bank (HIPDB). The HIPDB was created to combat fraud and abuse in health insurance and health care delivery. Beginning in the fall of 1999, the HIPDB will contain information regarding civil judgments, criminal convictions, or actions by Federal or State licensing agencies against a health care provider, supplier, or practitioner related to the delivery of a health care item or service. The HIPDB will also contain information relating to the exclusion of a health care provider, supplier, or practitioner from participation in Federal or State health care programs. All licensing boards and some reporting entities are required to report to both the HIPDB and the NPDB. However, reports on medical malpractice payments, clinical privileges actions, and professional society membership actions will only be in the NPDB. Civil judgments and criminal convictions will only be contained in the HIPDB. The HIPDB will collect and maintain some licensure actions, e.g., adverse licensure actions from August 21, 1996 must be reported to HIPDB. Access to information in the HIPDB will not be available to the public, but will be available to Federal and State government agencies, health plans, and via self-query similar to the NPDB. A joint website has been established for NPDB-HIPDB. See NPDB-HIPDB, *Home Page* (visited Sept. 30, 1999) <http://www.npdb-hipdb.com>; see also U.S. Department of Health & Human Services, Health Resources & Services Administration, *Introducing the Healthcare Integrity and Protection Data Bank*, NPDB NEWS, July, 1999; U.S. Department of Health & Human Services, Health Resources & Services Administration, *Comparing the NPDB to the HIPDB*, NPDB NEWS, July, 1999.

¹⁵⁸ Of course, due to the time-critical nature of treating heart attacks, most physicians would probably opt to repeat an electrocardiogram (ECG) and initiate treatment rather than wait several hours for the staff of the patient's regular physician to fax the most recent ECG for evaluation.

obstacles. For many medical conditions, a long-running longitudinal record would be very helpful in confirming a diagnosis or preparing a treatment plan. For example, a relatively young man with a low bone density may be suffering from osteoporosis, or he may have simply been born with less-dense bone tissue than average. A patient exhibiting high blood pressure could be better treated if the physician could see a historical record of the patient's blood pressure readings dating back for twenty years. A pattern of sinusitis could help indicate whether surgery or standard antibiotic therapy is medically indicated.

Dr. Welby may have treated the same patient (and her parents) for a lifetime, but such a long-term relationship is unlikely today. Increased mobility of patients, managed care organizations' changes in preferred providers, and use of a plethora of specialists result in an often-inaccessible, fragmented medical record of little use to the patient or physician. Also, emergency room physicians could benefit from access to the medical records of unconscious patients they have never seen. At present, they may have to rely on a low-tech bracelet to advise them of a patient's allergic reaction to a class of drugs.

An ideal medical record would be Internet-based, but only available to physicians upon consent of the patient or in a *bona fide* emergency. The record could be electronically segregated into sections allowing various health care providers and others access on a "need to know" basis. The patient should have full "read-only" access to the official record, and only licensed health care providers should be able to enter information in the record, to ensure the accuracy of the record. The record could however contain a patient section allowing the patient to enter self-recorded weight and blood pressure, frequency and severity of headaches, and other similar information. Such information could even be entered electronically via biometrics devices.

Although we are years away from such a comprehensive online medical record, a number of commercial websites currently offer storage and Internet access for medical records.¹⁵⁹ They typically promote such storage for a variety of reasons. For example, in an emergency, an attending physician can have access to critical information such as drugs being taken, allergic reactions to drugs, conditions such as heart problems or diabetes, and other important medical information.¹⁶⁰ Such information can arguably be available even where the patient is too ill to communicate the history to emergency staff. Storing children's immunization records makes them accessible even if a parent changes jobs, insurers or physicians. Advance directive storage available at some sites allows individuals to ensure that physicians and other family members know such individuals' wishes in the event of an accident or serious illness.¹⁶¹ Most sites at present rely on patient input of medical records,¹⁶² but some health care providers may be reluctant to rely on the

¹⁵⁹ See, e.g., 4healthylife.com, *Welcome to 4HealthyLife* (visited Oct. 12, 2000) <<http://www.4healthylife.com>>.

¹⁶⁰ See *id.*

¹⁶¹ See *id.*

¹⁶² See *id.*

accuracy and completeness of such records. Such records are likely to be better than a short oral medical history, but less comprehensive than medical records created and maintained by medical professionals.

Some sites are offering Internet storage of physician-created records. For example, MedicaLogic provides an “ambulatory electronic medical record” (EMR) and supporting Internet services to member physicians.¹⁶³ MedicaLogic allows patients to review their own medical records, but only clinicians can alter the records.¹⁶⁴ Audit trails are maintained on the website of all access to and modification of personally identifiable medical information.¹⁶⁵ A patient must agree before even de-identified information is provided to a third party.¹⁶⁶

It is not clear how websites such as MedicaLogic will face the challenge of complying with varying state laws on disclosure of medical information. For example, in order to be effective, Texas law requires that a consent for the release of confidential medical information must have at least five essential elements: 1) it must be in writing; 2) it must be signed by the patient or the patient’s authorized representative; 3) it must specify the information covered by the release; 4) it must specify the purpose of the release; and 5) it must specify the person or persons to whom the information is to be released.¹⁶⁷ Regulatory, security, and privacy concerns present serious barriers to maintenance of Internet-based medical records. However, if these concerns can be addressed adequately, the benefits to patients could be enormous. Ultimately, federal privacy standards issued in accordance with HIPAA¹⁶⁸ should provide clearer guidance to medical records storage companies, patients, and clinicians.¹⁶⁹ The proposed standards would not, however, preempt more stringent state standards.¹⁷⁰

163 See MedicaLogic (visited Oct. 12, 2000) <<http://www.medicallogic.com>>.

164 See *id.*

165 See *id.*

166 See *id.*

167 TEX. OCC. CODE § 159.005 (West 1999).

168 Pursuant to Section 264 of Pub.L. 104-191, the Secretary of Health and Human Services submitted to the Committee on Labor and Human Resources and the Committee on Finance of the Senate, and the Committee on Commerce and the Committee on Ways and Means of the House of Representatives, detailed recommendations on standards with respect to the privacy of individually identifiable health information. The privacy standards are codified at 45 C.F.R. § 160 (2000).

169 See generally Barbara J. Williams, *Virtual Web Wave of the Future: Integration of Healthcare Systems on the Internet*, 76 N.D. L. REV. 365, 372-75 (2000).

170 See Mary R. Anderlik, *Proposed Privacy Standards: Background and Overview*, HEALTH L. PERSPECTIVES (Nov. 11, 1999) <<http://www.law.uh.edu/healthlawperspectives/Privacy/991109Proposed.html>>.

D. *Evolving Technologies for Cybermedicine*

1. Home Health Monitoring

A number of existing and evolving technologies are making cybermedicine more feasible.¹⁷¹ For example, home health monitoring is now available via the Internet.¹⁷² Twice daily, while sitting in her dining room, Gloria Belisle confronts a machine that asks her “how can I help you” and then proceeds to measure blood pressure, heart rhythms, and a variety of other diagnostic criteria to help maintain cardiac health.¹⁷³ The machine, called HANC (home-assisted nursing care) is linked to a home health care agency, and allows her to perform an electrocardiogram with three electronic leads to her chest.¹⁷⁴ It also enables her to check her blood pressure by slipping her arm into a cuff, and to check pulse and blood-oxygen levels by inserting her finger in a sleeve.¹⁷⁵ HANC can also handle an electronic stethoscope to provide remote examination of the heart and lungs.¹⁷⁶ Finally, HANC stores the information and relays it to nurses at the home care agency monitoring her condition.¹⁷⁷

Additionally, home laboratory diagnostic testing could be combined with information appliances to better deliver health care via the Internet. Patients already have (or will soon have) access to self-tests for prostate cancer, onset of menopause, osteoporosis, allergies, thyroid and liver problems.¹⁷⁸ Drug tests¹⁷⁹ and

¹⁷¹ See generally DOUGLAS E. GOLDSTEIN, *E-HEALTHCARE* 189-210 (2000). *E-Healthcare* addresses the impact of the Internet and related emerging technologies on the provision of health care. It is divided into four sections. It focuses on the electronic trends that are revolutionizing health care through Internet technology. It describes how current models of care delivery, disease management, and demand management are evolving into what the author says are care support and “e-care” models that allow patients to better guide their own care. The author predicts that telemedicine will grow in frequency with web-enabled applications and net devices. Chapter 7, *Telemedicine Becomes a Reality with Web-Enabled Applications and Net Devices* does an excellent job of describing telemedicine applications and technology. In keeping with the high-tech subject matter, the book ships with a very useful CD-ROM version in PDF format, allowing links to the numerous websites discussed in the book to be easily accessed without typing in the URL. *E-healthcare* should be read (or used as a reference) by anyone involved in the provision of health care via the Internet. Its discussion of trends and predictions for the future are valuable, and its description of current and emerging technology is clear and useful. *Id.* See my complete review of the book in Ronald L. Scott, *eHealthcare*, XIV HEALTH L. NEWS (Sept. 2000) (book review), available at (visited Oct. 13, 2000) <<http://www.law.uh.edu/healthlawnews/09-2000.html>>.

¹⁷² See Eric Nagourney, *Visiting the Doctor, via the Dining Room*, N. Y. TIMES, Apr. 6, 1999, at F7.

¹⁷³ See *id.*

¹⁷⁴ See *id.*

¹⁷⁵ See *id.*

¹⁷⁶ See *id.*

¹⁷⁷ The machine costs about \$12,000, but physicians have been getting good results from machines sometimes costing less than \$1,000. See *id.*

¹⁷⁸ See Tara Parker-Pope, *Home Testing Expands To Include a Range Of Serious Conditions*, WALL ST. J., Sept. 22, 2000, at B1.

pregnancy tests have been available for some time, but tests intended to diagnose serious conditions including diabetes and Hepatitis C are now available.¹⁸⁰

The FDA has the authority to regulate medical devices¹⁸¹ used in telemedicine.¹⁸² An FDA working group concluded that devices used in a number of telemedicine activities are subject to the FDA's medical device regulatory authority, including software and hardware devices used in: (1) direct clinical, preventative, diagnostic and therapeutic services and treatment, (2) consultative and follow-up services, (3) remote monitoring, including the remote reading and interpretation of results of patient's procedures, and (4) rehabilitative services.¹⁸³ The FDA even asserts jurisdiction over devices used for patient education provided in the context of delivering health care services to patients.¹⁸⁴ Furthermore, the FDA has regulated some telemedicine devices, including medical image devices used in teleradiology applications, electronic stethoscopes, and heart monitors.¹⁸⁵ However, the FDA has not formulated a clear position or regulations on how most telemedicine software and hardware should be regulated.¹⁸⁶

2. Biometrics

Another area of developing technologies for cybermedicine is biometrics. A biometrics system may be used for identification or verification.¹⁸⁷ Identification (used by law-enforcement) is labor intensive, since a system must compare an individual sample with all possible candidates.¹⁸⁸ Security systems using biometrics may identify an individual user by her or his fingerprint, iris, voice, retina, face

179 Tests are available for marijuana, tobacco, and cocaine. *See id.*

180 *See id.*

181 "Device" is defined as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is: (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action..." 21 U.S.C. § 321(h) (2000).

182 *See generally* Center for Devices and Radiological Health, Food and Drug Administration, *Telemedicine Related Activities* (last modified Aug. 5, 1997) <<http://www.fda.gov/cdrh/telemed.html>>.

183 *See id.*

184 Patient education may be regulated when the "education" is medical device labeling information. *See id.*

185 *See id.*

186 *See* Ann K. Schooley, *Allowing FDA Regulation of Communications Software Used in Telemedicine: A Potentially Fatal Misdiagnosis?*, 50 FED. COMM. L.J. 731, 744 (1998).

187 *See* Frederick M. Avolio, *Buyers Guide: Biometrically Speaking*, NETWORK COMPUTING (Aug. 23, 1999) available in Lexis, News/Mags.

188 *See id.*

geometry, hand geometry, signature and perhaps even by DNA.¹⁸⁹ Where the system is only needed to verify an identity, the software looks up the template related to a user name and compares the new sample against it to determine whether there is a match.¹⁹⁰ This type of system is used in biometrics-automated teller machines (ATMs) and would be appropriate for most health care applications.¹⁹¹ For example, physicians on the staff at Sarasota Memorial Hospital access the hospital's electronic health care data via a finger scanning biometrics security system.¹⁹²

Biometrics technology is much more secure than passwords, which can sometimes be easily guessed—or stolen.¹⁹³ Typically a sensor device captures the data, for example a scanner could capture a fingerprint, or a camera could capture the image of an iris.¹⁹⁴ Some ATMs are already using iris or fingerprint scans to prevent fraud in monetary transactions. Yet the technology holds even more potential for health care. In the introductory scenario, Dr. Carter verified John's identity using biometrics, which also allowed Dr. Carter to associate the cybervisitor with the correct medical record, and the automated dispensing pharmacy verified John's identity using an iris scan.¹⁹⁵ Another application for health care providers is identifying those who may access medical records. Physicians are notorious for giving their passwords to secretaries, nurses and other support staff. However, it will be much harder for the physician to loan her finger or iris, which will, *e.g.*, help ensure the accuracy of medical records by limiting—and identifying—those who access and alter the medical record. These applications will be made more possible as the costs are coming down. For example, the fingerprint scanning system used at Sarasota Memorial costs about \$300 per workstation, down from \$2000 only a few years earlier, and would probably be much cheaper today.¹⁹⁶

Lakeland Area Health Services and an associated hospital have implemented biometrics technology for patient registration and identification, ensuring that the correct, unique, medical record is associated with each patient.¹⁹⁷ Another approach, using iris scan technology, is being adopted by a childrens' health care project in Florida. The project's goal is to allow authorized health care

¹⁸⁹ See *Health Care Starts to Eye Biometrics Technology*, HEALTH DATA MANAGEMENT (September 1997) available in Lexis, News/Mags.

¹⁹⁰ See Avolio, *supra* note 187.

¹⁹¹ See *id.*

¹⁹² See *Health Care Starts*, *supra* note 189.

¹⁹³ See *id.*

¹⁹⁴ See *id.*

¹⁹⁵ See *supra* part I.

¹⁹⁶ See *Health Care Starts*, *supra* note 189.

¹⁹⁷ See *id.*

providers access to children's Internet-based medical records.¹⁹⁸ Using the iris scan technology, providers will be able to identify the child and link to the appropriate medical record even if the child cannot communicate.¹⁹⁹ However, in addition to complying with legislation specifically directed at medical records, such projects might have to contend with federal laws relating to privacy of education records, depending on where the records are maintained. Health care lawyers may be unfamiliar with the Family Educational Rights and Privacy Act (FERPA)²⁰⁰ and the Individuals with Disabilities Education Act (IDEA).²⁰¹ Both statutes contain provisions addressing the collection, maintenance, distribution, and destruction of education records.²⁰² In these statutes, the definition of "education records" is broad enough to include students' medical records maintained by an educational institution.²⁰³

3. Smart Cards

"Smart" cards incorporating microchip processors can store significantly more information than their magnetic-stripe counterparts, and are therefore being used to store medical information.²⁰⁴ The cards can carry insurance information, drug sensitivities, and dialysis records and prescriptions for kidney patients.²⁰⁵ Smart cards have been used in Europe for years in lieu of the credit cards commonly used in the U.S. For example, France switched to such cards in the mid-1980s to combat credit card fraud.²⁰⁶ Germany has begun to issue all its citizens smart cards carrying their basic health insurance information, and France is using the cards for kidney patients with expansion of use likely.²⁰⁷ Smart cards offer a portable alternative to Internet-based medical records, and can serve as a repository

198 *See id.*

199 *See id.*

200 *See* 20 U.S.C. § 1232g (2000).

201 *See id.* §§ 1400 *et seq.* (2000).

202 *See id.* §§ 1232, 1412, 1415.

203 FERPA (also known as the Buckley Amendment) is the primary statute protecting the confidentiality of education records. FERPA applies to any educational institution that receives federal funds, and protects privacy by generally prohibiting disclosure of "education records" and "personally identifiable information" from those records without the consent of parents for students under 18 years of age. FERPA defines "education records" as "... those records, files, documents, and other materials which: (1) contain information directly related to a student; and (2) are maintained by an educational agency or institution or by a person acting for such agency or institution." 20 U.S.C. § 1232g (2000).

204 *See id.*

205 *See id.*

206 Carol H. Fancher, *Smart Cards*, SCIENTIFIC AMERICAN (Aug. 1996) <<http://www.sciam.com/0896issue/0896fancher.html>>.

207 *See id.*

for digital signatures.²⁰⁸ A smart card used for identification purposes could have a photograph, signature, digital signature, and a catalogue of biometrics identifiers including voiceprints, fingerprints, retina scans and iris scans.²⁰⁹ The ultimate smart card could eventually contain information about individuals' DNA, allowing futuristic compounding pharmacies to capitalize on developments in pharmacogenomics to concoct individualized pharmaceuticals.

4. Electronic Signatures

Recent legislation at both the federal and state level should facilitate Internet-based health care transactions using smart cards or other encryption technology. The federal Electronic Signatures in Global and National Commerce Act ("E-sign") recognizes electronic signatures and records as legally binding and provides a common legal framework for interstate electronic commerce.²¹⁰ At the state level, the Uniform Electronic Transactions Act (UETA) is similar to E-sign and has been adopted in 21 states.²¹¹ Many of the state laws are based on digital signatures, a subcategory of electronic signatures considered the most secure way to transfer documents over the Internet, and such laws typically address quality and trustworthiness of digital certificate authorities.²¹² The federal law is technology-neutral, and does not favor any particular encryption or verification technology.²¹³

However, some have warned that physicians "should be careful before they zap their electronic John Hancock around cyberspace."²¹⁴ The concern is that the E-sign law has low security standards allowing electronic signatures to be easily replicated.²¹⁵ Health care may require stronger security standards than the minimum standards provided in the law, particularly if the proposed HIPAA standards are enacted in their present form.²¹⁶

IV. BARRIERS TO CYBERMEDICINE

A number of barriers may affect the continued growth and viability of cybermedicine. Patient barriers include security, privacy and confidentiality

208 *See id.*

209 *See id.*

210 *See* Kate Marquess, *Sign on the Dot-Com Line*, ABA J., Oct. 2000, at 74.

211 (as of July, 2000) *See id.*

212 *See id.* at 75.

213 *See id.*

214 Tyler Chin, *Electronic Signatures: Digital Scrawl*, AM. MED. NEWS, Aug. 28, 2000, available at <http://www.ama-assn.org/sci-pubs/amnews/pick_00/tesa0828.htm>.

215 *See id.*

216 *See id.*

concerns. Cultural barriers and the digital divide may prevent computer-illiterate patients and others from seeking help online. Other barriers include current ethical codes as well as multiple federal and state laws that discourage physicians from offering their services online. As one attempt to address these barriers, the newly enacted HIPAA regulations will tighten security requirements, and will regulate online patient privacy at the federal level.

A. *Privacy Concerns*

A report by the California Healthcare Foundation found that consumers are reluctant to shop online for fear that their financial information might get into the hands of the wrong parties, and the report noted, "If there's one thing people are even more guarded about than their financial information, it's private information about their health."²¹⁷ Patients are rightfully concerned about the privacy of their medical information, whether the information is in the hands of a physician, insurer, employer, pharmacist, or Internet service provider.

California and some other states' laws that regulate the privacy of medical records impose confidentiality obligations on a variety of individuals and institutions, including "health care providers" who are not physicians, insurers, plan administrators, or employers.²¹⁸ In addition, California has imposed additional requirements on physicians and these other health care providers who maintain patient records electronically. However, these additional requirements do not apply to patient records if hard copy versions of the patient records are also retained.²¹⁹ In California, providers maintaining electronic records "shall ensure the safety and integrity of those records at least to the extent of hard copy records."²²⁰ Providers must also use an "offsite backup storage system, an image mechanism that is able to copy signature documents, and a mechanism to ensure that once a record is input, it is unalterable."²²¹ Where records have been stored electronically in accordance with these requirements, original hard copies may be destroyed.²²² Additionally, providers using electronic records must "develop and implement policies and procedures to include safeguards for confidentiality and unauthorized access to electronically stored patient health records, authentication by electronic signature keys, and systems maintenance."²²³ Although the additional requirements may discourage some health care providers from maintaining records

²¹⁷ See Robert Mittman and Mary Cain, *The Future of the Internet in Health Care: Five-Year Forecast, Executive Summary*, at 2 (Jan. 1999) <<http://www.chcf.org>>.

²¹⁸ See e.g. California's Confidentiality of Medical Information Act, CAL. CIV. CODE §§ 56-56.37 (Deering 2000).

²¹⁹ CAL. HEALTH & SAFETY CODE § 123149 (a) (West 1996)

²²⁰ *Id.* § (b)

²²¹ *Id.* § (b)

²²² *Id.* § (c)

²²³ *Id.* § (g)

electronically, the statute does not prohibit health care providers from maintaining or retaining patient records electronically.²²⁴ States also have pharmacy practice acts, which in some cases contain provisions regulating the disclosure of confidential patient-identifiable information by pharmacists.²²⁵ Some states have adopted insurance code privacy protections, regulating the disclosure of medical information by health insurers.²²⁶

Most states recognize the physician-patient testimonial privilege, which provides protection from disclosure during litigation of confidential communications.²²⁷ Where applicable, a physician generally may not testify about confidential communications with his patient during the course of treatment unless the patient waives the privilege.²²⁸ The initial statutory privilege statutes were concerned solely with testimony at trial, and were not intended to impose civil liability for a breach of physician-patient confidentiality. Although civil liability for breach of confidentiality was first imposed in 1917, the trend toward imposing civil liability gained momentum only in the 1960s.²²⁹ The information that courts consider as falling within the ambit of confidentiality varies from state to state.²³⁰

224 CAL. HEALTH & SAFETY CODE § 123149 (i) (West 1996).

225 See, e.g., Illinois Pharmacy Practice Act of 1997, ILL. COMP. STAT. ANN. ch. 225, para. 85/1-39 (West 2000).

226 See, e.g. ILL. COMP. STAT. ANN. ch. 215, Act 5, Art. XL (West 2000).

227 See e.g. TEX R. EVID. Rule 509m (2001).

228 See generally Robert M. Gellman, *Prescribing Privacy: The Uncertain Role of the Physician in the Protection of Patient Privacy*, 62 N.C. L. REV. 255 (1984). The physician-patient privilege usually applies to all confidential communications, and in that sense is broader than state statutes regulating privacy of medical records that generally prohibit disclosure of "medical" information. See Betty F. Lay, *Healer-Patient Privilege: Extending The Physician-Patient Privilege to Alternative Health Practitioners in California*, 48 HASTINGS L. J. 633, 651 (1997). Historically, common law did not recognize physician-patient communications as privileged. The first exception to this rule occurred in the context of physician testimony at trial. To protect patients' confidentiality, states began to enact testimonial privilege statutes that prohibited a physician from being compelled to testify, without the patient's consent, regarding the information acquired in attending the patient in a professional manner. The privilege is not absolute, e.g., a physician may testify about being consulted by a particular individual, and about facts that are not necessary for the physician to act in a professional capacity. See generally Bernard Friedland, *Physician-Patient Confidentiality: Time to Re-Examine a Venerable Concept in Light of Contemporary Society and Advances in Medicine*, 15 J. LEGAL MED. 249, 251-252 (1994).

229 Imposition of civil liability for a breach of physician-patient confidentiality has been imposed on a variety of different grounds. Some courts use the testimonial privilege, either by itself, or in conjunction with other laws as the basis for imposing liability. Some states do not impose liability on the basis of the testimonial privilege statute (although they do impose liability on other grounds) even in the face of an identical statute. Courts also have used the law of contracts as a basis for imposing civil liability, holding that there exists a contract between physician and patient and, as part of this contract, the physician impliedly promises not to reveal confidential information. See *id.* Some courts have used state licensing statutes as a basis for imposing liability. See, e.g., *Hammonds v. Aetna Casualty & Surety Co.*, 243 F. Supp. 793 (N.D. Ohio 1965).

230 Some states mandate that physicians owe a duty not to disclose medical information about their patient, while others prohibit the unauthorized revelation of any confidential communication given in the course of treatment. Further, several states recognize a cause of action for invasion of privacy relating to confidential medical records either by common law, statute, or state constitutional provision. Courts have

In determining whether patients have a reasonable expectation of privacy, courts may look to general ethical principles and specific ethical codes such as those adopted by the AMA²³¹ or even the more ancient example of the Hippocratic Oath.²³² Some courts have imposed tort liability partly on the basis of a physician's breach of an ethical code of conduct.²³³ Also, courts may consider the nature of the harm caused by the unwanted disclosure.²³⁴

In addition to personal privacy of individual medical records, Internet users are also concerned about improper use of demographic information. Some state medical or insurance confidentiality statutes specifically address the disclosure of "demographic" information. For example, Illinois and Ohio have enacted versions of the National Association of Insurance Commissioners model Insurance Information and Privacy Protection Act.²³⁵ A Washington case held that a patient's name and consumer number were "health care information" regulated by statute.²³⁶ In the context of health care, one writer has recognized that "there is no . . . easy resolution of the conflict between the need for information and the need for

generally held physicians liable for unauthorized disclosure of confidential information concerning the patient on the ground that such disclosure constitutes an actionable invasion of the patient's right of privacy. See generally Judy E. Zelin, Annotation, *Physician's Tort Liability for Unauthorized Disclosure of Confidential Information About Patient*, 48 A.L.R. 4th 668 (1987). A cause of action for invasion of privacy generally requires a plaintiff-patient to establish each of the following elements: (1) a legally protected privacy interest; (2) a reasonable expectation of privacy in the circumstances; and (3) conduct by defendant constituting a serious invasion of privacy. See e.g., *Heller v. Norcal Mutual Insurance Co.*, 876 P.2d 999, 1006 (Cal.), cert. denied, 513 U.S. 1059 (1994).

²³¹ The American Medical Association Principles of Medical Ethics provide: "[I]nformation disclosed to a physician during the course of the relationship between physician and patient is confidential to the greatest possible degree. The patient should feel free to make a full disclosure of information to the physician in order that the physician may most effectively provide needed services The physician should not reveal confidential communications or information without the express consent of the patient, unless required to do so by law." (quoted in Betty F. Lay, *Healer-Patient Privilege: Extending The Physician-Patient Privilege to Alternative Health Practitioners in California*, 48 HASTINGS L.J. 633, 657 (1997)).

²³² "Physicians have a fundamental ethical obligation to protect the confidentiality of information obtained from patients during the course of treatment or diagnosis. This ethical obligation finds its earliest expression in the Hippocratic Oath, which states in part: 'What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of man, which on no account one must spread abroad, I will keep to myself holding such things shameful to be spoken about.'" *Id.* at 656.

²³³ See *Hammonds v. Aetna Casualty & Surety Co.*, 243 F. Supp. 793 (N.D. Ohio 1965).

²³⁴ For example, a particular disclosure may deserve moral and legal protection simply because personal information is unjustifiably disclosed, or alternatively the disclosure may result in actual economic harm to the patient, e.g. loss of a job or loss of insurability. See Lay, *supra* note 231, at 656.

²³⁵ See, e.g., definition of "personal information" in ILL. CODE STAT. ANN. ch. 215, para. 5/1003. (T) "Personal information" means any individually identifiable information gathered in connection with an insurance transaction from which judgments can be made about an individual's character, habits, avocations, finances, occupation, general reputation, credit, health or any other personal characteristics. "Personal information" includes an individual's name and address and "medical-record information" but does not include "privileged information." ILL. CODE STAT. ANN. ch. 215, para. 5/1003.

²³⁶ See *Doe v. Group Health Cooperative of Puget Sound, Inc.*, 932 P.2d 178 (Wash. Ct. App. 1997). A 1975 Ohio case refused to enjoin publishers from selling subscription lists to direct mail advertisers, finding the practice constitutionally permissible. See *Shibley v. Time, Inc.*, 341 N.E.2d 337 (Ohio Ct. App. 1975); see generally Joel Smith, Annotation, *Invasion of Privacy By Sale or Rental of List of Customers, Subscribers, or the Like, To One Who Will Use It For Advertising Purposes*, 82 A.L.R. 3d 772 (1978).

privacy.”²³⁷

Two reported settlement agreements illustrate the risks associated with misuse of patient information. One settlement included an agreement by the pharmacy chain Rite-Aid to restrict its disclosure procedures in the future.²³⁸ The settlement calls for Rite Aid “to implement new prescription billing procedures to protect HIV sufferers” from having their names linked with the HIV-related medications they purchase.²³⁹ In another settlement regarding marketing practices for prescription drugs, the settlement required that the company Medco must advise consumers about the extent to which information in Medco’s consumer files will remain confidential, including the fact that medical histories and prescription drug usage could be made available to consumers’ employers.²⁴⁰

Although some state laws require disclosure to the patient of the risks associated with the electronic transfer of medical information, HIPAA is the first comprehensive attempt to regulate the security and privacy of electronic medical records at the federal level. Five key requirements are mandated by HIPAA: (1) access to electronically stored health information must be limited to those who have a legitimate business need to access the data, (2) health care providers must obtain a patient’s authorization prior to allowing anyone to use or disclose the information, (3) health care providers must insure the integrity of the data (*e.g.*, requiring a physician’s digital signature to enter data), (4) health care providers must confirm that entities they communicate with are who they claim to be (*e.g.*, by using biometrics technology), and (5) health information transmitted over open networks must be protected from interception.²⁴¹

Although state and federal regulations are being promulgated to help ensure confidentiality, evidence suggests that consumers should be leery of the privacy promises and protections offered by most current health websites. A recent report concluded:

Although health web sites now provide a wide range of clinical and diagnostic information; opportunities to purchase products and services; interactions among consumers, patients, and health care professionals; and the capability to build a personalized

²³⁷ See Lawrence Gostin, *Health Information Privacy*, 80 CORNELL L. REV. 451, 455 (1995); see also Scott Shoor, *Personal Information Contracts: How to Protect Privacy Without Violating the First Amendment*, 80 CORNELL L. REV. 1756 (1995) (proposing a theory of property and contract rights in personal information).

²³⁸ See 22 Pension and Benefits Reporter (BNA) 33 (Jan. 2, 1995).

²³⁹ However, the agreement applies only to Rite-Aid’s 389 Pennsylvania pharmacies, although Rite-Aid also operates pharmacies in 22 other states. See *id.*

²⁴⁰ See National Association of Attorneys General, *Seventeen Attorneys General Reach \$1.9 Million Prescription Drug Practices Settlement With Merck-Medco Health Conglomerate*, CONSUMER PROTECTION REP. 10, 11 (Nov. 1995).

²⁴¹ See Lisa L. Dahm, *The Health Insurance Portability and Accountability Act of 1996*, HEALTH L. NEWS, Dec. 1999, at 8. HIPAA regulations were not yet finalized at the time this paper was written (Nov. 2000). See generally Williams, *supra* note 169.

health record, they have not matured enough to guarantee the quality of the information, protect consumers from product fraud or inappropriate prescribing, or guarantee the privacy of individuals' information.²⁴²

The report, which was widely publicized in the media, found that: (1) visitors to health websites are not anonymous, although they may think they are, (2) health websites recognize user's concern about the privacy of their personal health information, but established privacy policies fail to provide adequate safeguards, (3) an inconsistency exists between the privacy policies and the actual practices of health websites, (4) the security of personal health information may not be adequate for consumers using health websites to better manage their health, and (5) health websites with privacy policies that disclaim liability for the actions of third parties on the site negate those very policies by not holding third parties to the standards they espouse.²⁴³

B. *Informed Consent*

Many patients still have an expectation of confidentiality more in line with the Hippocratic Oath than the reality of modern medical practice. This gap suggests that physicians should have a duty to advise patients of the limits of confidentiality in order to obtain "informed consent."²⁴⁴ Historically, physicians evidence a reluctance to provide their patients with adequate information.²⁴⁵ Some physicians treat informed consent as a form of "defensive medicine" to reduce legal liability.²⁴⁶ Physicians sometimes complain that legalistic requirements for obtaining informed consent are just an example of lawyers forcing them "to do silly

²⁴² See Janlori Goldman and Zoe Hudson, *Report on the Privacy Policies and Practices of Health Web Sites* (Jan. 2000) <<http://ehealth.chcf.org>>.

²⁴³ See *id.* at 4,5.

²⁴⁴ See generally Jay Katz, *Informed Consent - Must It Remain A Fairy Tale?*, 10 J. CONTEMP. HEALTH L. & POL'Y 69, (1993).

²⁴⁵ We routinely quote the Hippocratic Oath for principles of confidentiality and statements such as the physician shall do no harm, etc. The Oath also says "I will follow that . . . regimen which . . . I consider for the benefit of my patients . . ." The patient's judgment does not *seem* to deserve consideration. In the Hippocratic Corpus, physicians are admonished "to conceal most things from the patient while attending to him; to give necessary orders with cheerfulness and serenity, . . . revealing nothing of the patient's future or present condition." The AMA's first Code of Ethics was adopted twenty-five centuries later (1847), and also scolded patients that their "obedience . . . to the prescriptions of their physician should be prompt and implicit. They should never permit their own crude opinions . . . to influence their attention to their physicians." *Id.* at 73 (citations omitted).

²⁴⁶ It is an obligation imposed by the legal system rather than a valued medical concept of joint decision-making. Its value to physicians can be seen in the way informed consent is obtained, *i.e.*, a form that the nurse has the patient sign. Katz observed that "translating the ingredients of [the informed consent] process into legal and useful medical prescriptions that respect patients' wishes to maintain and surrender autonomy, as well as physicians' unending struggles with omnipotence and impotence in the light of medical uncertainty, is a difficult task [which the medical profession] has not pursued . . . in any depth." *Id.* at 79.

things.²⁴⁷

However, within the patient-physician relationship, the Hippocratic Oath is still often cited as the source of the idea that a physician should retain in confidence matters related to his patients. As a concise statement of the underlying ethical principle of medical confidentiality, the Hippocratic Oath remains valid today. However, Hippocrates did not have to provide guidance concerning genetic databases, “smart” credit card sized cards that can hold a megabyte or more of a patient’s medical records, patient files maintained on the Internet, or group practices of physicians that maintain centralized computerized filing allowing access from multiple offices. Since the era of Hippocrates, the opportunity for both inadvertent and intentional disclosure of a patient’s confidential information has grown exponentially.

To address such risks of disclosure, some states have enacted specialized “informed consent” requirements for telemedicine encounters, usually focusing, *inter alia*, on the risk that data may somehow be lost or confidentiality breached during the encounter.²⁴⁸ This specialized informed consent statutorily mandated for telemedicine encounters is unusual in the sense that informed consent is ordinarily associated with more invasive procedures. For example, where a physician conducts a physical examination or gives a patient an injection, she may informally seek the patient’s consent, but will not ordinarily obtain written consent.²⁴⁹ Any oral consent will not become part of the patient’s medical record, but rather consent in such situations is largely presumed.²⁵⁰ In the context of telemedicine, or where electronic transmission of medical records is contemplated, physicians are often required to obtain a specific written consent by statute or to document oral consent where oral consent is allowed by the statute.²⁵¹

Specific telemedicine requirements vary by state, and an interstate telemedicine encounter may require that a physician comply with both state’s statutes.²⁵² Although requirements vary, several elements are commonly required for consent to be legally effective. The patient should be given a description of the

²⁴⁷ Katz said that “physicians must embark on a prolonged period of self-examination about how to interact with patients in new ways in an age of medical science and informed consent. Physicians must cease to complain about lawyers forcing them ‘to do silly things.’ . . . [I]nformed consent in today’s world, is largely a charade which misleads patients into thinking that they are making decisions when indeed they are not. Any meaningful change in Hippocratic decision-making practices first requires a new and revolutionary commitment to one principle: that physicians must respect patients as autonomous persons. *See id.* at 84.

²⁴⁸ . *See, e.g.*, ARIZ. REV. STAT. § 36-3602 (2000).

²⁴⁹ *See e.g.* T.L. BEAUCHAMP & JAMES CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 142 (1994) (writing that “physicians and investigators must obtain the informed consent of patients and subjects prior to any *substantial* intervention” (emphasis added)).

²⁵⁰ *See id.*

²⁵¹ *See* ARIZ. REV. STAT. § 36-3602.

²⁵² For example, the Arizona statute applies to the practice of telemedicine “within the State of Arizona” and so would presumably apply to out-of-state consultations conducted from within Arizona. *See id.* § 36-3603. The physician would additionally need to comply with the law of the state where the patient is located. *See e.g.*, TEX. OCC. CODE § 151.056 (a).

telemedicine arrangement, describing the participants and their anticipated roles.²⁵³ The patient should be advised that his or her confidential health information will be electronically recorded, stored, and transmitted.²⁵⁴ The patient should be told who will have access to the patient's health information.²⁵⁵ The consent should include a description of the risks and benefits of electronic recordation, storage, and transmission, and an acknowledgement that electronic transmission does not alter the confidential status of the information.²⁵⁶ Furthermore, there should be no dissemination of the patient's medical information to researchers or others external to the physician-patient relationship without the patient's express consent.²⁵⁷ Finally, the patient should be cautioned that, notwithstanding all reasonable security measures, the confidentiality of the information may be compromised by electronic transmission.²⁵⁸

Some or all of the above elements are contained in state statutes addressing telemedicine informed consent, but variations do exist among such statutes. For example, Texas requires written telemedicine consent only for "out-of-state" consultations and excludes consultations by telephone or facsimile, but does not specifically exclude e-mail.²⁵⁹ Texas and some other states provide that a physician who fails to obtain informed consent may be subject to disciplinary action.²⁶⁰ Arizona allows oral or written consent, but requires that the consent be documented in the patient's medical record.²⁶¹ The Arizona statute does not specifically exclude e-mail and telephone consultations, but telemedicine is defined for purposes of the statute as "the practice of health care delivery, diagnosis, consultation, treatment and transfer of medical data through interactive audio, video or data communications that occurs in the physical presence of the patient."²⁶² The Arizona

²⁵³ See Barry B. Cepelewicz, *Telemedicine Liability: Strategies to Minimize Risk*, 15 MED. MALPRACTICE LITIG. & STRATEGY 1, 3 (Dec. 1997).

²⁵⁴ See *id.* at p. 6-7.

²⁵⁵ See *id.*

²⁵⁶ See *id.*

²⁵⁷ See *id.*

²⁵⁸ See generally Cepelewicz, *supra* note 253; see also TEX. ADMIN. CODE tit. 22, § 174.10 (1997), which provides in part: "Written informed consent shall be obtained from any patient who is the subject of out-of-state consultation by electronic means other than telephone or telefacsimile. Such informed consent shall include an explanation by the consulting physician or, in the absence of a consulting physician, by the physician consulted. The written informed consent shall include an acknowledgment by the patient that confidentiality of medical information may be compromised by electronic transmission for purposes of consultation."

²⁵⁹ See *id.*; see also TEX. ADMIN. CODE tit. 22, § 174.10 (1997).

²⁶⁰ "Failure to obtain written informed consent . . . shall be grounds for revocation or limitation of a special purpose license . . . and, if the person is licensed by the board, grounds for disciplinary action . . ."
Id.

²⁶¹ See ARIZ. REV. STAT. ANN. § 36-3602 (West 1997).

²⁶² Audio or video communications sent to a health care provider for diagnostic or treatment consultation also constitute telemedicine for the purpose of this article. See ARIZ. REV. STAT. ANN. § 36-

statute applies to the practice of telemedicine “within the state of Arizona,” so it would presumably apply to both in-state and out-of-state consultations.²⁶³ California’s statute provides that “[n]either a telephone conversation nor an electronic mail message between a health care practitioner and patient constitutes ‘telemedicine’ for purposes of this section.”²⁶⁴ Interestingly, the California statute requires that both verbal and written consent be obtained by the practitioner “who has ultimate authority over the care or primary diagnosis of the patient”²⁶⁵ prior to the delivery of health care via telemedicine. Further, the patient must be advised that he retains an option to withhold or withdraw consent “without affecting the right to future care or treatment nor risking the loss or withdrawal of any program benefits to which the patient . . . would otherwise be entitled . . .”²⁶⁶ Oklahoma has a similar provision in its less-extensive telemedicine statute.²⁶⁷

C. *The Digital Divide*

What has been termed the “digital divide” may pose yet another barrier to the widespread adoption of cybermedicine technology. Not everyone has a computer, and even those that do may lack the software, hardware, and technical expertise to conduct two-way video teleconferencing with companies such as CyberDocs. A sophisticated personal computer and high speed Internet access are beyond the reach of many individuals, but economics is not the only reason for the digital divide: some senior citizens may have adequate financial resources, but are simply overwhelmed by the complexity and unreliability of home computers.

Presently, those accessing the Internet for health care information and services are what the California HealthCare Foundation christens “new consumers,” *i.e.*, those who are actively involved in making choices about the health care they receive, utilizing the Internet in the process.²⁶⁸ According to the Foundation, the three characteristics that distinguish these new consumers from more traditional consumers are cash, college, and computers.²⁶⁹ These new consumers have annual household incomes of more than \$50,000, have attended at least a year of college, are more likely to seek information about health and health care choices than traditional consumers, and have access to and experience in using

3601 (West 1997).

²⁶³ The statute also provides that “[n]othing in this article shall be construed to expand, reduce or otherwise amend the health care provider licensing requirements of title 32.” ARIZ. REV. STAT. ANN. § 36-3603 (West 1997).

²⁶⁴ CAL. BUS. & PROF. CODE § 2290.5(a)(1) (Deering 1998 & Supp. 2000).

²⁶⁵ CAL. BUS. & PROF. CODE § 2290.5(c) (Deering 1998).

²⁶⁶ CAL. BUS. & PROF. CODE § 2290.5(c)(1) (Deering 1998).

²⁶⁷ OKLA. STAT. ANN. tit. 36, § 6804 (West 1999).

²⁶⁸ See Robert Mittman & Mary Cain, *The Future of the Internet in Healthcare*, at 9 (Jan. 1999) <<http://www.chcf.org>>.

²⁶⁹ See *id.*

computers at home, work, or both.²⁷⁰ The Foundation estimates that in 1998, new consumers constituted more than 40% of the U.S. population, and forecasts they will comprise about one-half of the population by the end of 2000.²⁷¹ Not everyone will be a new consumer, and the disparity between the technologically sophisticated and the technologically illiterate will leave many behind, correlated closely with demographics such as income, education, and ethnicity.²⁷²

Even those with the financial means to purchase computers and pay for Internet access may face barriers of language, literacy, and education, or simply choose not to go online.²⁷³ For this last group, however, a number of recent developments offer hope. MyGait installs specially modified computers for senior citizens in Houston retirement communities.²⁷⁴ The computers come with 19-inch monitors, digital video cameras, special software, broadband Internet access, technical support and maintenance, and on-site training.²⁷⁵ The screens, icons and fonts are large and easy to see; a track ball is used in place of a mouse for easier manipulation by arthritic hands; and the color yellow has been eliminated from the screens since yellow starts to blur for seniors with deteriorating retinas.²⁷⁶ As another example, the Huffington Center on Aging at Houston's Baylor College of Medicine provides health newsletters online that address concerns sent in e-mail to "Dr. Baylor."²⁷⁷

Another approach to bridging the digital divide is through "net devices" that are not personal computers or laptops, yet connect patients to the Internet.²⁷⁸ These devices include Palm type handheld computers, two-way pagers, set-top boxes and interactive televisions, smart phones, smart houses and appliances.²⁷⁹ Internet access devices such as WebTV and smart phones such as iPhone offer the most hope of delivering cybermedicine in the home without a typical personal computer.²⁸⁰ Smart phones allow Internet access via easy to use touchscreens, and can be connected to a monitoring site where physicians and other health care

270 *See id.* at p. 9-10.

271 *See id.* at p. 10.

272 *See id.* at p. 11.

273 *See id.*

274 *See Mary Sit-DuVall, ELDERS/Silver Surfing/Start-up Offers Retirement Homes Its Special PCs For Senior Citizens, HOUSTON CHRONICLE (Oct. 15, 2000) available in Westlaw, database HSTNCHRON 4, 2000 WL 24518700.*

275 *See id.*

276 *See id.*

277 *Id.*

278 *See GOLDSTEIN, supra note 171, at 194.*

279 *See id.*

280 *See id.* at p. 199.

professionals monitor data to manage diseases and symptoms.²⁸¹ Currently available uses include cardiac monitoring and rehabilitation, glucose monitoring, support services for home infusion therapy, and patient education and reminders for osteoarthritis, Alzheimer's, and smoking cessation.²⁸²

D. Insurance Reimbursement

Another significant barrier to the growth of telemedicine is the difficulty physicians and other health care providers face in getting paid for their time online. Unlike attorneys, accountants, and other professionals, physicians have not historically billed directly for their time, although an extensive office visit is billed at a higher rate than a standard or follow-up visit.²⁸³ When attorneys spend fifteen minutes on the phone with their clients, the time spent on the call is added to the client's bill. Similarly, if an attorney consults with another partner over the phone, the client is charged for both attorneys' time. Unlike attorney consultations, however, traditional telemedicine has faced enormous reimbursement struggles, according to the following statement by an industry spokesperson:

Despite many years of successful telemedicine demonstrations and the rapidly expanding deployment of telemedical services in the private sector and in other countries, the U.S. lags behind in recognizing and paying for medical services provided via telemedicine. Medicare currently reimburses for several different types of remote services including teleradiology, remote patient monitoring and live video consultations with patients residing in remote Health Professional Shortage Areas. However, broad reimbursement for telemedicine services is still unavailable.²⁸⁴

Much of the reimbursement debate has centered on the extent to which the government should reimburse providers for telemedicine services provided under governmental programs such as Medicare and Medicaid. Under Medicare, if the standard of care for medical practice does not require personal contact between a patient and health professional, then Medicare will reimburse for the service, such as in the case of teleradiology.²⁸⁵ Since Medicaid is a joint federal/state program,

²⁸¹ See *id.*

²⁸² See *id.* at p. 199-200.

²⁸³ See generally Morisson, *supra* note 22.

²⁸⁴ Hearing on Telemedicine Technologies before the Senate Committee on Commerce, Science and Transportation Subcommittee on Science, Technology and Space (1999) (testimony of Ronald K. Poropatich, Member, Board of Directors, American Telemedicine Association) (visited Oct. 21, 2000), available at <<http://www.ctl.org/assets/images/tmh hearing.pdf>>.

²⁸⁵ See U. S. DEP'T OF COMMERCE, TELEMEDICINE REPORT TO CONGRESS, (1997) (visited Oct. 21, 2000), available at <<http://www.ntia.doc.gov/reports/telemed/payment.htm>> [hereinafter TELEMEDICINE REPORT].

health professionals and services that are covered vary greatly by state.²⁸⁶ For example, California reimburses for telemedicine services under the Medi-Cal program, although reimbursement is not provided for consultations via telephone or facsimile, and as previously noted California excludes e-mail from the definition of telemedicine.²⁸⁷

Little information exists about private payor coverage of telemedicine, but the limited evidence suggests that few insurance companies or health plans pay for telemedicine consultations, with the exception of radiology and similar imaging services.²⁸⁸ CyberDocs, discussed *supra* part II.A, does not accept insurance for its services, but will provide a receipt for medical services to those optimists who wish to seek reimbursement from their insurance companies.²⁸⁹ Because many insurers balk at paying for services provided via telemedicine, several states including California, Hawaii, Louisiana, Oklahoma and Texas have passed laws requiring reimbursement for telemedicine services.²⁹⁰ The state of Georgia has even negotiated arrangements with Medicaid and the insurance industry, and as of August 1999, 150 private providers were reimbursing for most telemedicine services in Georgia.²⁹¹

The California statute provides that “[i]t is the intent of the Legislature to recognize the practice of telemedicine as a legitimate means by which an individual may receive medical services from a health care provider without person-to-person contact with the provider”²⁹² and that “no health care service plan contract that is issued, amended, or renewed shall require face-to-face contact between a health care provider and a patient for services appropriately provided through telemedicine, subject to all terms and conditions of the contract agreed upon between the enrollee or subscriber and the plan.”²⁹³ However, health care plans are not required to pay for consultation provided by the health care provider via telephone or facsimile machines.²⁹⁴ Oklahoma has a similar statute, requiring private and Medicaid reimbursement “[f]or services that a health care practitioner determines to be appropriately provided by means of telemedicine.”²⁹⁵ Texas also provides that certain health care plans must not exclude a service from coverage

²⁸⁶ See *id.*

²⁸⁷ See CAL. WELF. & INST. CODE §§ 14132.72(c)(1), 14132.72(d) (Deering Supp. 2001); CAL. BUS. & PROF. CODE § 2290.5(a)(1) (Deering Supp. 2001).

²⁸⁸ See TELEMEDICINE REPORT, *supra* note 285.

²⁸⁹ See CyberDocs (visited Oct. 16, 2000) <www.cyberdocs.com/faq.com>.

²⁹⁰ See Heather Hayes, *Flatlining, Funding and Policy Barriers Plague Rural Telemedicine* (Jan. 10, 2000) <<http://www.fcw.com/civic/articles/telemed011000.asp>>.

²⁹¹ See *id.*

²⁹² CAL. HEALTH & SAFETY CODE § 1374.13 (a) (Deering Supp. 2001).

²⁹³ *Id.* § 1374.13(c).

²⁹⁴ *Id.* § 1374.13(d).

²⁹⁵ OKLA. STAT. ANN. tit. 36 § 6803(A) (West 1998).

under a plan solely because the service is provided through telemedicine and not provided through a face-to-face consultation.²⁹⁶ Texas further provides that any “deductible, copayment, or coinsurance applicable to a particular service provided through telemedicine may not exceed the deductible, copayment, or coinsurance required by the health benefit plan for the same service provided through a face-to-face consultation.”²⁹⁷

E. *Fraud, Abuse and Anti-Referral Statutes*

Federal and state statutes enacted to address abusive referral and self-dealing practices by physicians present barriers to the growth of cybermedicine. If a “business model” exists for Internet businesses, it is based almost solely on payment for referrals. The idea behind such a model is that individuals will not pay to obtain information online, but will grudgingly accept “banner” advertisements that irritatingly appear together with the sought-after content. When a visitor clicks on an advertisement link, the referring site is paid a fee. Of course, the individual business arrangements are more complex, but at present a majority of Internet businesses are based on this model. Using this model, a web designer creating a pharmacy’s website might, for example, wish to include links to physicians where consumers could obtain necessary prescriptions. For virtually all non-health care sites, the person receiving the benefit of the referral would pay a fee to the referring site.

Physicians, pharmacies, and other health care providers may be legally precluded from such a financial arrangement. First, physicians’ ability to advertise is limited by legal and ethical constraints.²⁹⁸ Also, physicians generally cannot pay referral or finders’ fees as a way to solicit patients.²⁹⁹ Furthermore, federal laws regulating such conduct require a governmental payor, *e.g.*, Medicare, Medicaid, or some other governmental program reimbursing the physician.³⁰⁰ Additionally, state statutes sometimes prohibit such referrals even where no governmental or other third-party payor is involved.³⁰¹

Physicians may also violate ethical standards by payment of a referral fee.³⁰² Clearly, “fee-splitting” by a physician is unethical according to the AMA’s Code of Medical Ethics. Opinion 6.02 states in part:

²⁹⁶ See TEX. INS. CODE ANN. Art. 21.53F § (3)(a) (West 2001)

²⁹⁷ *Id.* 21.53F § (3)(b).

²⁹⁸ See Texas State Board of Medical Examiners, *Statement on Ethical Advertising* (1994) (visited June 2, 2001) < <http://www.tsbme.state.tx.us/policy/sea.htm5>>.

²⁹⁹ See *e.g.* TEX OCC. CODE § 121.001(a) (1999).

³⁰⁰ See *e.g.*, 42 U.S.C. § 1320a-7(a)(3) (2000).

³⁰¹ See *e.g.* TEX OCC. CODE § 121.001(a) (1999).

³⁰² See AMERICAN MEDICAL ASSOCIATION, COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, CODE OF MEDICAL ETHICS: CURRENT OPINIONS WITH ANNOTATIONS, Opinion 6.03. (1997).

Fee Splitting. Payment by or to a physician solely for the referral of a patient is fee splitting and is unethical. A physician may not accept payment of any kind, in any form, from any source . . . for prescribing or referring a patient to said source. In each case, the payment violates the requirement to deal honestly with patients and colleagues. The patient relies upon the advice of the physician on matters of referral.³⁰³

Opinion 6.03 further provides:

Fee Splitting: Referrals to Health Care Facilities. Clinics, laboratories, hospitals, or other health care facilities that compensate physicians for referral of patients are engaged in fee splitting, which is unethical. Health care facilities should not compensate a physician who refers patients there for the physician's cognitive services in prescribing, monitoring, or revising the patient's course of treatment. Payment for these cognitive services is acceptable when it comes from patients, who are the beneficiaries of the physician's services, or from the patient's designated third-party payer.³⁰⁴

The principal laws restricting payment of referral fees are the federal and state anti-kickback laws, which not only prohibit payment or receipt of referral fees, but also limit or prohibit "self-referral" by a physician to certain designated facilities where the physician has any kind of financial interest.³⁰⁵ Federal law prohibits kickbacks and self-referrals because they create conflicts of interest that tend to corrupt the exercise of a medical professional's independent judgment.³⁰⁶ Federal law provides that "whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind . . . in return for referring an individual to a person . . . shall be guilty of a felony."³⁰⁷ Conviction may result in a fine of \$25,000 and five years imprisonment.³⁰⁸ It is also a crime to *offer* a kickback, bribe, or rebate.³⁰⁹ Federal law also prohibits so-called self-referrals, for example, a

³⁰³ *Id.*, Opinion 6.02.

³⁰⁴ *Id.*, Opinion 6.03.

³⁰⁵ See 42 U.S.C. § 1395nn (2000) (codifying the Stark I and Stark II statutes).

³⁰⁶ See John T. Bentivoglio, Address to the Symposium on Healthcare Internet and E-Commerce: Legal, Regulatory and Ethical Issues, Washington, D.C. (Mar. 27, 2000), available at <<http://www.cybercrime.gov/healthsp.htm>>.

³⁰⁷ 42 U.S.C. § 1320a-7b(b) (2000).

³⁰⁸ See *id.*

³⁰⁹ See *id.*

physician could not refer a patient to a pharmacy owned by the physician.³¹⁰

State laws also restrict payment of referral fees. For example, Texas law prohibits physicians from paying or receiving referral fees, although Texas has not specifically targeted “self-referral” by physicians.³¹¹ Unlike the federal prohibitions, the Texas law applies even when no government reimbursement is present. The Texas Occupations Code provides that “[a] person commits an offense if the person knowingly offers to pay or agrees to accept, directly or indirectly, overtly or covertly any remuneration in cash or in kind to or from another for securing or soliciting a patient or patronage for or from a person licensed, certified, or registered by a state health care regulatory agency.”³¹² Based on a very similar earlier anti-referral statute,³¹³ the Texas Attorney General interpreted Texas law as prohibiting a physician from entering into a contract with a referral service to pay or promise to pay a fee for each patient such service would generate for the physician.³¹⁴

The payment of referral fees can result in additional problems where the health care is covered by insurance. For example, Texas has enacted legislation to address insurance fraud.³¹⁵ The statutory provisions on insurance fraud could be relevant if a broker and/or a physician mischaracterized the nature of the health

³¹⁰ See 42 U.S.C. § 1395nn (2000) (codifying the Stark I and Stark II statutes).

³¹¹ See TEX OCC. CODE § 102.001 (1999).

³¹² *Id.*

³¹³ The statute was previously contained in the Medical Practice Act, TEX REV. CIV. STAT. ART. 4495b §3.07. Section (c) provided that “[a] physician or surgeon may not employ or agree to employ, pay or promise to pay, or reward or promise to reward any person, firm, association of persons, partnership, or corporation for securing, soliciting, or drumming patients or patronage. A physician or surgeon may not accept or agree to accept any payment, fee, reward, or anything of value for securing, soliciting, or drumming for patients or patronage for any physician or surgeon.” *Id.*

³¹⁴ The Texas Board of Medical Examiners submitted a sample of a referral service contract to the Texas Attorney General. The Board asked whether a physician would violate Texas law by entering into an agreement that provided for the referral service to bill the practitioner based upon the number of patients referred during the previous month. The contract stated that the purpose of the referral service was to generate new patient appointments for health care professionals, and to “match the right patient with the right practitioner.” The Attorney General’s opinion stated that where a physician was promising to pay the referral service a fee for each patient referred, then a physician who enters into such a contract would violate the referral statute. The Attorney General was also asked whether a hospital could make a similar agreement. The opinion said that the same statute did not apply to hospitals, but that other laws could be violated, depending upon the terms under which the hospital entered into the agreement. Finally, the opinion cautioned that a physician could not avoid a violation of the statute by paying the referral fee to a hospital rather than to a referral service. See Op. Tex. Att’y Gen. JM-752 (July 17, 1987).

³¹⁵ See TEX. PENAL CODE, § 35.01-04 (1999). The statute provides that a person commits an offense if, with intent to defraud or deceive an insurer, the person causes to be prepared or presents to an insurer in support of a claim for payment under a health policy a statement that the person knows contains false or misleading information concerning a matter that is material to the claim, and the matter affects a person’s right to payment or the amount of payment to which a person is entitled. This restriction includes information concerning: (1) whether health care goods or services were provided; (2) whether health care goods or services were medically necessary under professionally accepted standards; (3) the nature of the health care goods or services provided; (4) the date on which health care services were provided; (5) the medical record of goods or services provided; (6) the condition treated or diagnosis made; and (7) the identity and applicable license of the provider or the recipient of health care goods or services. See *id.* § 35.02.

care goods or services provided in order to recoup the referral fee. Physicians would need to review any contractual agreements with insurers to see whether such agreements contain any prohibitions on payment of referral fees with respect to patients covered by such insurers, as a violation of contractual restrictions could arguably result in a violation of the insurance fraud statute.

Furthermore, the anti-referral statutes present difficulties for a variety of Internet referral businesses. For, example, Medicine Online (MOL) allows prospective patients to search for and select physicians and other health care providers to perform elective, aesthetic procedures including cosmetic surgery, cosmetic dentistry, laser vision correction surgery, and podiatric surgery.³¹⁶ MOL allows prospective patients to solicit bids for surgery using “reverse auction” technology.³¹⁷ In a reverse auction, a prospective purchaser advertises a need for services or products (in this case, surgical health care), and individuals willing to provide the services or products “bid” for the right to provide such services or products.³¹⁸ Under the MOL business model, patients receive a free face-to-face consultation with one or more physicians under consideration, and either the patient or physician may reject the surgery without obligation.³¹⁹ Although MOL currently does not charge either patients or physicians, eventually it plans to charge patients for its service.³²⁰ MOL may have decided to charge patients rather than physicians to avoid ethical and legal prohibitions against physicians paying referral fees or splitting fees with non-physicians.

F. *Emerging Liability and Malpractice Issues*

Cybermedicine raises new questions of when and to what extent a physician or e-health website should be liable under existing principles of medical malpractice.³²¹ Physicians may find that their medical malpractice insurance does not extend to cyberspace. For example, The Doctors’ Company (TDC), a California malpractice insurer, sent physicians a letter warning that those participating in bidding systems may be vulnerable to suits for breach of contract, and that such

³¹⁶ See *MedicineOnline.com* (visited Oct. 23, 2000) <<http://www.medicineonline.com>>.

³¹⁷ See *id.*

³¹⁸ Thirty years ago, professional fees charged by physicians and attorneys were not negotiable. It is still rare for physicians, dentists and other health care providers to advertise their fees, although lately some advertisements are appearing for cosmetic or elective services such as cosmetic dentistry and laser vision correction, *i.e.*, procedures that are usually not paid for by health insurance plans. Negotiating fees for health care services has been the exclusive province of insurers or other payors such as employers. Even discussing fees with physicians has been culturally taboo. Now e-healthcare via the Internet is challenging the notion that consumer/patients should not consider fees charged when selecting a physician or dentist. It is unclear whether physicians will embrace the concept of bidding for patients. For now, MOL is a pilot project operating primarily in southern California.

³¹⁹ See *MedicineOnline.com*, (visited Oct. 23, 2000) <<http://www.medicineonline.com>>.

³²⁰ See *id.*

³²¹ See generally Patricia Kuszler, *Telemedicine and the Changing Face of the Doctor-Patient Relationship*, HEALTH L. NEWS, Dec. 1999, at 4.

suits are not covered by TDC's professional liability policies.³²² Mark Gorney, TDC's executive vice president for medical affairs, has said "[i]ts medicine, not plumbing . . . the idea of establishing a contract for potentially life-threatening services with a patient you've never laid eyes on absolutely makes no sense to us."³²³ Some auction websites and the malpractice insurer have received conflicting legal advice on when the physician-patient relationship first exists and whether disclaimers will prevent an accepted bid from being construed as a legally binding contract.³²⁴ The auction sites argue that the physician-patient relationship begins at the time of a face-to-face consultation, and that an accepted bid does not rise to the level of a contract until after the consultation.³²⁵ However, "neutral" attorneys have advised TDC that courts would generally view bids as contracts, regardless of disclaimers contained on the auction site.³²⁶

Most modern medical malpractice claims are tort claims, based on breach of the standard of care rather than breach of contract. The starting point for such claims is proving the existence of a physician-patient relationship in order to establish the requisite "duty" owed by the physician.³²⁷ The closest analogy that case law can provide to cybermedicine consultations is the earliest form of telemedicine, *i.e.*, telephone consultations. In *Bienez v. Central Suffolk Hospital*,³²⁸ the question on appeal "was whether a telephone call to a physician's office for the purpose of initiating treatment is [sufficient] to create a physician-patient relationship."³²⁹ The physician argued that such communication is insufficient as a matter of law to create the "sort of physician-patient relationship which [sic] is necessary in order to support a medical malpractice cause of action."³³⁰ The court found the argument unpersuasive: it said that a medical malpractice cause of action may be based on a physician's negligent advice to his patient as to what course of treatment to pursue.³³¹ The court then held that whether the physician's giving of advice provides a sufficient basis to find the existence of a physician-patient relationship is ordinarily a question of fact for the jury.³³²

³²² See Linda O. Prager, *Doctors May Face Liability Risks In Bidding For Patients On Web Auction Sites*, AMERICAN MEDICAL NEWS, Sept. 4, 2000, at 11-12, available at <http://www.ama-assn.org/sci-pubs/amnews/pick_00/prsa0904.htm>.

³²³ *Id.*

³²⁴ *See id.*

³²⁵ *See id.*

³²⁶ *See id.*

³²⁷ *See e.g.* Clanton v. Von Haam, 340 S.E. 2d 627, 630 (Ga Ct. App. 1986).

³²⁸ 163 A.D.2d 269 (N.Y. App. Div. 1990).

³²⁹ *Id.* at 270.

³³⁰ *Id.*

³³¹ *See id.*

³³² *See id.*

In *Cogswell v. Chapman*, a patient was seen in emergency room with an eye injury, and the emergency room physician's assistant consulted an ophthalmologist by telephone about the patient's injury.³³³ The ophthalmologist was on the courtesy/consulting staff of the hospital and would sometimes answer questions from emergency room staff over the telephone.³³⁴ He had never received payment for any such consultation, and did not see the patient at the emergency room.³³⁵ He rendered an "informal" telephone opinion without examining the patient, taking a history, or otherwise treating the patient.³³⁶ The court said that a physician-patient relationship can be established by a telephone call "when such a call 'affirmatively advise[s] a prospective patient as to a course of treatment' and it is foreseeable that the patient would rely on the advice."³³⁷ The court held that whether a physician-patient relationship was created through the telephone consultation was an issue of fact precluding summary judgment.³³⁸

However, a Michigan court was unwilling to find the existence of a physician-patient relationship where a prospective patient called to schedule an appointment but did not have a prior relationship with the physician and did not seek or obtain medical advice during the conversation.³³⁹ Whether a physician-patient relationship exists involves "concepts of a contractual nature rather than expert medical principles."³⁴⁰ Therefore, the patient's perspective as to the existence of such a relationship is as important as the physician's perspective. Where the relationship and negligence are established, a sponsoring website should be concerned about vicarious liability and direct corporate liability.³⁴¹

What about liability for a physician's e-mail to a patient? As the "telephone call" cases illustrate, very little is required to establish a physician-patient relationship for malpractice purposes. Even where no previous physician-patient relationship exists, a physician who gives advice as to what course of treatment a patient should pursue has probably created the requisite relationship.³⁴² It is doubtful that courts will give great weight to disclaimers on websites that proclaim physicians are not practicing medicine by answering medical questions. Courts will also be unlikely to relieve a physician from liability simply because she

333 249 A.D.2d 865 (N.Y. App. Div. 1998)

334 *See id.*

335 *See id.* at 866.

336 *Id.*

337 *Id.* (quoting *Miller v. Sullivan*, 214 A.D.2d 822, 823 (N.Y. App. Div. 1995)).

338 *Id.* at 866-867.

339 *Weaver v. Univ. of Michigan Bd. of Regents*, 506 N.W.2d 264 (Mich. Ct. App. 1993).

340 *See Clanton v. Von Haam*, 340 S.E.2d 627 (Ga. Ct. App. 1986) (doctor's conclusory statements as to existence of physician-patient relationship not admissible as expert testimony, because questions within comprehension of average layman).

341 *See, e.g., Shannon v. McNulty*, 718 A.2d 828 (Pa. Super. Ct. 1998)

342 *See Spielberg, supra* note 68, at 292.

did not receive payment for a consultation. Rather, the issue may be whether the physician answered the questions correctly, or whether she should have answered them at all. Evidence of what was recommended during a consultation will be fully documented by the e-mail copies rather than being a source of argument and conjecture in court.

The problem physicians have with e-mail from a liability (and licensure) standpoint is that patients do not ask “generic” questions such as “what treatments can help lower blood pressure.” Patients are more likely to ask self-specific questions such as “how can I lower my blood pressure.” If a physician answers such a specific question with generic advice, problems may result. For example, a patient with very high blood pressure may have a stroke while following a physician’s e-mail advice to “watch your diet and exercise more.” In such a case, several factors could work against the physician. First, any violation of licensing restrictions or state medical board’s rules on cybermedicine consultations could be powerful evidence of negligence, or a violation of a statute may even rise to negligence per se. Generally, the “physician should not rely on any less information than a face-to-face consultation would require in conducting the medical assessment because the standard of care remains the same.”³⁴³ Another problem physicians online may encounter is liability resulting from breach of confidentiality where e-mail communications are not afforded sufficient security or confidentiality.³⁴⁴

Arguing that there is no physician-patient relationship, and therefore characterizing patient interactions as informational only, may result in unintended adverse consequences.³⁴⁵ If the responses are merely informational rather than part of medical care, few health insurance policies are ever likely to pay for such transactions.³⁴⁶ More importantly, most currently available medical malpractice insurance policies may not provide coverage on the basis that the physician was not rendering medical care.³⁴⁷ Even where the physician admits she is “practicing medicine” in cyberspace, medical malpractice insurance may not be sufficiently broad to cover the practice of cybermedicine. The problem is that most medical malpractice policies either do not cover “Internet Activities” or exclude coverage for Internet activity claims arising out of bodily injury or death, making such policies useless for cyberphysicians.³⁴⁸ Policies also typically contain exclusions for coverage where any claim is brought about or contributed to by a willful violation by the insured of any law, statute, rule, or regulation.³⁴⁹

343

Id.

344

See id.; see also *supra* discussion part IV.A and accompanying notes.

345

See Susan Huntington, Emerging Professional Liability Exposures, supra note 69.

346

See id.

347

See id.

348

Id.

349

See id.

Once it is shown that a physician-patient relationship is established, a medical malpractice plaintiff must still establish that a physician breached the requisite standard of care.³⁵⁰ A variety of tests have been used to establish the necessary standard. Some courts have compared a particular physician's performance to other physicians in the same or similar locality.³⁵¹ Another approach holds specialists to the same standard as others in the same specialty, usually resulting in a "national" standard of care.³⁵² If cybermedicine becomes commonplace across state lines, courts may have to rethink the requisite standard of care. The gold standard for telemedicine is that it should provide a "qualified substitute for the traditional medical process it seeks to replace."³⁵³ Perhaps, however, we should consider a lower standard of care for cybermedicine, essentially recognizing its place within medicine while also recognizing the limitations of diagnosing and treating patients online. As patients, we routinely decide to see a general practitioner rather than a specialist partly for reasons of cost and convenience. Should we not have the same right to make the decision to seek a cyber-consultation in spite of its limitations? If we allow cyber-consultations while recognizing inherent limitations, perhaps a new standard of care will ultimately develop, based on what a reasonable cyberphysician would have done under the circumstances.

The *Perez* case shows us that courts are willing to consider the evolution of health care in determining liability.³⁵⁴ Although the physician in *Perez* was not relieved of all liability, the pharmaceutical company shared the exposure since the physician's role was changed by the evolution of health care.³⁵⁵ Cyber-consultations will surely change the nature of the physician-patient relationship,³⁵⁶ and logically should shift more responsibility to the properly informed patient, reducing the physician's exposure. One commentator noted that "[t]elemedicine presents the opportunity for the courts to recast the provider-patient relationship, and the duty that flows from it, in a more elastic fashion."³⁵⁷

G. *State Licensure for Interstate Consultations*

State licensure is by far the most significant legal barrier inhibiting the growth of cybermedicine. Licensure has also presented a challenge to more

350 See e.g. *White v. Wah*, 789 S.W.2d 312, 315 (Tex. App.--Houston [1st Dist.] 1990, no writ).

351 See e.g. *Shilkret v. Annapolis Emergency Hosp. Ass'n*, 349 A2d 245, 249-252 (Md. 1975) (discussing strict locality, similar locality, and national standard).

352 See *id.* at 250-252.

353 Spielberg, *supra* note 68, at 292.

354 See *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245 (N.J. 1999).

355 See *id.*

356 See Kuszler, *supra* note 321, at 4.

357 *Id.*

traditional forms of telemedicine, but perhaps to a lesser degree since in practice many telemedicine centers have been established to allow patients in rural areas to access specialists in urban or regional hospitals within the same state.³⁵⁸ Whether for telemedicine or its new cousin cybermedicine, licensure severely restricts physicians from offering their services across state borders, and the trend may be to tighten rather than relax such restrictions.

1. The FSMB Model Act & Licensure

In 1996, the Federation of State Medical Boards adopted as policy a report of the Ad Hoc Committee on Telemedicine that included a model act to regulate the practice of medicine across state lines.³⁵⁹ The report noted that managed care, politics, and technological advances including telemedicine are rapidly transforming traditional medical practice.³⁶⁰ The report acknowledged potential benefits of telemedicine including better access for underserved areas, utilization of specialty expertise, faster availability of medical records, and potentials for reduced cost.³⁶¹ The report recognized that “[t]here are; however, as yet unresolved issues surrounding telemedicine, including the regulation of physicians who practice across state boundaries.”³⁶² The report concluded that it is unacceptable to require physicians practicing across state lines to maintain a full and unrestricted license for each state, but concluded that leaving the practice unregulated was equally unacceptable.³⁶³

Therefore, the Model Act allows physicians who wish to practice telemedicine across state lines to obtain a special “limited license” that would only apply to telemedicine practice.³⁶⁴ The limited license would not allow a physician to physically enter the state for the purpose of practicing medicine.³⁶⁵ This approach would leave the physician subject to the jurisdiction of the state where the patient resides.³⁶⁶ Under the Model Act, a physician holding “a valid, unrestricted license in one state should be given every consideration for expedient issuance of a special license . . . in other states.”³⁶⁷ Under the Model Act, patient records,

³⁵⁸ See National Rural Health Association, *The Role of Telemedicine in Rural Health Care* (Feb. 1998) (visited June 2, 2001) <<http://www.nrharural.org/dc/issuepapers/ipaper7.html>>.

³⁵⁹ See FEDERATION OF STATE MEDICAL BOARDS, REPORT OF THE AD HOC COMMITTEE ON TELEMEDICINE (approved Apr. 1, 1996) <<http://www.fsmb.org/telemed.htm>>.

³⁶⁰ *Id.* § I.

³⁶¹ *See id.*

³⁶² *Id.*

³⁶³ *See id.*

³⁶⁴ *See* FEDERATION OF STATE MEDICAL BOARDS, *supra* note 359.

³⁶⁵ *See id.* § III.

³⁶⁶ *See id.* § V.

³⁶⁷ *See id.* § IV.

wherever located, must be maintained in accordance with the laws of the patient's state.³⁶⁸ The Model Act does not require a special license for physicians who practice across state lines in an emergency, informally without compensation, or on an "irregular or infrequent" basis.³⁶⁹ The physician will be deemed to qualify for the irregular or infrequent exemption if her practice occurs less than once monthly, or involves fewer than ten patients annually, or comprises less than 1% of her practice.³⁷⁰

Only six states have adopted versions of the FSMB Model Act: Alabama, California, Montana, Oregon, Tennessee and Texas.³⁷¹ Some states including Maryland, North Dakota and Wisconsin have considered legislation based on the Model Act but rejected it.³⁷² Therefore, a large majority of states still require a full, unrestricted license in order to practice telemedicine either explicitly per statute or by default.³⁷³ Not only has the FSMB's Model Act met with little success, "there has been significant backlash against initiatives to relax licensure standards for telemedicine practitioners."³⁷⁴ For example, Georgia and Illinois recently passed laws barring telemedicine advice or treatment absent a full, unrestricted license.³⁷⁵ Some states that have not enacted the special licensure requirements of the Model Act have nonetheless varied their definitions of "practicing medicine" or "practicing medicine across state lines" to allow for occasional consulting without violating the state's medical practice act.

The Texas statute is based on the FSMB Model Act, and provides:

A person who is physically located in another jurisdiction but who, through the use of any medium, including an electronic medium, performs an act that is part of a patient care service initiated in this state, including the taking of an x-ray examination or the preparation of pathological material for examination, and that would affect the diagnosis or treatment of the patient, is considered to be engaged in the practice of medicine in this state and is subject to appropriate regulation by the board.³⁷⁶

However, this section does not apply to a medical specialist located in another

³⁶⁸ See *id.* § VI.

³⁶⁹ See FEDERATION OF STATE MEDICAL BOARDS, *supra* note 359, at § VII.

³⁷⁰ See *id.*

³⁷¹ See Laura Keidan Martin, *Not So Fast, It's Regulated*, BUS. L. TODAY, Sept./Oct. 2000, at 12.

³⁷² See *id.*

³⁷³ See The Riner Group, Inc., *Telemedicine Licensing Update* (last modified Oct. 6, 2000) <<http://www.rinergroup.com/Pulse041700.htm>>.

³⁷⁴ Martin, *supra* note 371, at 12.

³⁷⁵ See *id.*

³⁷⁶ TEX. OCC. CODE ANN. § 151.056 (2000 Pamphlet).

jurisdiction who provides only “episodic”³⁷⁷ consultation services at the request of a Texas-licensed physician if both the out-of-state physician and the Texas physician practice in the same specialty.

The Texas Administrative Code regulates the issuance of a special limited license based on the FSMB Model Act. First, a physician applying for the “special purpose license” must be licensed to practice medicine in another state that is recognized by the Texas medical board, with no restrictions for disciplinary actions.³⁷⁸ The physician must then be certified in a medical specialty and must pass the Texas Medical Jurisprudence Examination.³⁷⁹ A holder of a special purpose license is not authorized to physically practice medicine in the state of Texas,³⁸⁰ but she must “maintain, safeguard, and release patient medical records of Texas patients in a manner consistent with the laws of the state of Texas.”³⁸¹ Furthermore, either the consulting physician or the physician consulted must obtain the specialized informed consent required for out-of-state consultations by electronic means other than via telephone or facsimile.³⁸² Informal consultations performed infrequently outside the context of a contractual relationship without compensation or expectations of compensation are also exempt.³⁸³ Finally, an applicant for a special purpose license must pay an initial fee of \$800 and a renewal fee of \$300 annually.³⁸⁴

2. AMA Policy on Licensure

The AMA disagrees with the FSMB position, and recommends that states require full and unrestricted licenses for the practice of telemedicine, as follows:

It is the policy of the AMA that medical boards of states and territories should require a full and unrestricted license in that state for the practice of telemedicine, unless there are other appropriate state-based licensing methods, with no differentiation by specialty, for physicians who wish to practice telemedicine in that state or territory. This license category should adhere to the following principles: (a) application to situations where there is a

³⁷⁷ In the implementing regulations, episodic consultation is defined as “[c]onsultation on an irregular or infrequent basis involving no more than 24 patients of a physician’s diagnostic or therapeutic practice per calendar year. Multiple consultations may be performed for one or more patients up to 24 patients per calendar year.” TEX. ADMIN. CODE tit. 22, § 174.2 (1997).

³⁷⁸ *Id.* § 174.3.

³⁷⁹ *See id.*

³⁸⁰ *See id.* § 174.4.

³⁸¹ *Id.* § 174.9.

³⁸² TEX. ADMIN. CODE tit. 22, § 174.10 (1997).

³⁸³ *See id.* § 174.13.

³⁸⁴ *See id.* § 174.15.

telemedical transmission of individual patient data from the patient's state that results in either (i) provision of a written or otherwise documented medical opinion used for diagnosis or treatment or (ii) rendering of treatment to a patient within the board's state.³⁸⁵

However, the AMA policy does recommend an exemption for "curbside consultations," meaning traditional informal physician-to-physician consultations that are provided without expectation of compensation.³⁸⁶ The policy also allows consultations without a license in emergency situations.³⁸⁷

Most states have intentionally or by default adopted the AMA's view. Because the definition of "practicing medicine" is usually broad enough to cover telemedicine encounters, full licensure is implicitly required even where a statute does not specifically address telemedicine. Several states have nonetheless amended their licensing statutes to define the "practice of medicine" in a manner that encompasses telemedicine. For example, the Oklahoma statute defines the practice of medicine to include "performance by a person outside of this state, through an ongoing regular arrangement, of diagnostic or treatment services through electronic communications for any patient whose condition is being diagnosed or treated within this state."³⁸⁸ Also, a person who performs telemedicine as defined above submits himself or herself to the jurisdiction of the Oklahoma courts for any cause of action resulting from the functions performed.³⁸⁹ The Oklahoma telemedicine informed consent statute appears to be based on a very traditional model of telemedicine, since it requires that "prior to the delivery of health care via telemedicine, the health care practitioner who is in *physical contact* with the patient shall have the ultimate authority over the care of the patient . . ."³⁹⁰

Similarly, the Georgia statute provides that a person who is "physically located in another state or foreign country" and who, "through . . . electronic, radiographic, or other means of telecommunication, through which medical information or data is transmitted, performs an act that is part of a patient care service located in this state . . . that would affect the diagnosis or treatment of the patient . . ." is engaged in the practice of medicine in Georgia.³⁹¹ The statute requires any person providing such telemedicine services including radiology and

³⁸⁵ AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES, THE PROMOTION OF QUALITY TELEMEDICINE, RESOLUTION H-480.689 (1996).

³⁸⁶ *Id.*

³⁸⁷ *See id.*

³⁸⁸ OKLA. STAT. ANN. tit. 59, § 492(c)(3)(b) (West 1999).

³⁸⁹ *See id.*

³⁹⁰ OKLA. STAT. ANN. tit. 36, § 6804 (West 1999) (emphasis added).

³⁹¹ GA. CODE ANN. § 43-34-31.1 (1997).

pathology to have a full Georgia license.³⁹² Practitioners must also agree to be subject to regulation by the Georgia board. Further, “out-of-state or foreign practitioners shall not have ultimate authority over the care or primary diagnosis of a patient who is located in this state.”³⁹³

3. Consultation Exemptions

Whether states require a full license, or allow for a special purpose license, most do allow for a consultation exemption from licensure requirements. These exceptions generally allow physicians licensed in other states to consult on patient cases, but require the consulting physician to work in tandem with or provide services at the request of a physician licensed in the state where the patient is located.³⁹⁴ The exceptions are premised on the infrequency of the consultations or final decision-making by the in-state physician.³⁹⁵ For example, Mississippi requires telemedicine practitioners to hold a full license unless the evaluation, treatment and/or the medical opinion of the out-of-state physician are requested by a physician licensed in Mississippi who has already established a physician-patient relationship with the patient to be evaluated or treated.³⁹⁶ Some states such as Texas require that the consulting physician be licensed in the same specialty as the physician requesting the consultation, and that the consultations be infrequent.³⁹⁷ Some state’s consultation exceptions may not be broad enough to allow for telemedicine consultations due to restrictions placed on consultations, perhaps inadvertently, by states’ efforts to address the telemedicine licensing “problem.”³⁹⁸ As Representative Ron Wyden has noted:

[C]onsultations are often required to be limited in duration, and a number of states which possess them are acting to close them for telemedicine practitioners. In 1995, Colorado, South Dakota, and Texas have considered amendments to their consultation statutes prohibiting out-of-state telemedicine practitioners from “entering” without being licensed in their state. Utah repealed its consultation exception effective in 1993, and the Kansas Board of Healing Arts passed a regulation (which conflicts with its statutory consultation exception) which requires out-of-state telemedicine practitioners to be licensed in Kansas. Additionally, a number of states prohibit

³⁹² See *id.*

³⁹³ *Id.*

³⁹⁴ See Martin, *supra* note 371, at 10.

³⁹⁵ See *id.*

³⁹⁶ See MISS. CODE ANN. § 73-25-34 (3) (West 2000).

³⁹⁷ TEX. ADMIN. CODE tit. 22 § 174.2 (2000 Pamphlet).

³⁹⁸ See Shannon B. Hartsfield, *Keeping Your Telehealth Venture Legally Healthy*, presentation at the ABA e-Health Law 2000 Seminar, Chicago, Illinois (Oct. 6-7, 2000).

out-of-state consultants from establishing regularly used hospital connections. If consultants cannot use telemedical facilities at out-of-state hospitals, this limits the availability of specialized healthcare to underserved areas. The “consultation exceptions” are simply not useful or dependable for the future of telemedicine.³⁹⁹

4. Proposals for Reform

Given the barriers that state licensing presents to telemedicine, does state licensing serve a useful purpose? Those within the emerging industry believe the answer is “no” for a number of reasons. For example, during the past 30 years, there has been “[a] remarkable convergence in licensing requirements stipulated by states to license physicians.”⁴⁰⁰ Every state requires that a physician pass the United States Medical Licensing Examination (USMLE) in order to practice medicine.⁴⁰¹ Specialty board certification is given by national organizations based on national standards.⁴⁰² Medical schools and residency programs are nationally accredited, and all states recognize their credentials.⁴⁰³ Traditionally, the practice of medicine has been local in nature, but “telemedicine introduces a distance independent variable that is, by definition, neither local nor traditional.”⁴⁰⁴

The American Telemedicine Association (ATA) policy position calls for less than full national licensure, but attempts to address certain state imposed barriers to telemedicine. Under the ATA position, a virtual encounter with an out-of-state physician should be outside the purview or jurisdiction of the state where the patient is located.⁴⁰⁵ The ATA argues that since states cannot restrict physical travel by patients, they should not be able to restrict virtual travel.⁴⁰⁶ The “medical event” subject to regulation would be anchored to the physician’s location, not the patient’s.⁴⁰⁷ However, one compromise in the ATA’s policy severely restricts cyber-consultations. Under the proposal, the telemedicine request must originate from a licensed provider in the patient’s state, and the patient and requesting physician must have a physical face-to-face encounter.⁴⁰⁸ Also, the responsibility

³⁹⁹ 141 CONG. REC. E1392-01 (daily ed. June 30, 1995) (Statement of Rep. Wyden).

⁴⁰⁰ American Telemedicine Association Board of Directors, *Policy Regarding State Medical Licensure* (May 21, 1999) <<http://www.atmeda.org/news/060199a.html>>.

⁴⁰¹ *See id.* The USMLE consists of three separate examinations during the course of medical training.

⁴⁰² *See id.*

⁴⁰³ *See id.*

⁴⁰⁴ *Id.*

⁴⁰⁵ *See American Telemedicine Association Board of Directors, supra note 400.*

⁴⁰⁶ *See id.*

⁴⁰⁷ *See id.*

⁴⁰⁸ *See id.*

for medical care remains with the requesting physician, and thus care never transfers to the out-of-state physician.⁴⁰⁹ The requesting physician is always the “attending” physician.⁴¹⁰ While the ATA proposal would benefit traditional telemedicine, it would be of little help in breaking down the barriers to cybermedicine.

Only two models would effectively allow cyber-consultations to flourish. National licensure at the federal level seems logical and appropriate, particularly if coupled with a national disciplinary system. However, national licensure seems to attract more interest from academics than practitioners or regulators.⁴¹¹ The other model is mutual recognition of licensure between states based on the concept of reciprocity, similar to the automatic reciprocity that allows a holder of a driver’s license from one state to drive in every other state.⁴¹²

The National Council of State Boards of Nursing has developed and promoted the Interstate Nurse Licensure Compact.⁴¹³ Under the compact, which has already been adopted by at least ten states, a nurse licensed in one compact state may practice in any other compact state without obtaining a license in the second state.⁴¹⁴ The compact provides for states to cooperate in disciplinary matters, and requires each state to participate in a multi-state database of all licensed nurses.⁴¹⁵ It is striking that many state legislatures seem so willing to allow for mutual recognition of nurses yet remain so adamantly opposed to such a licensing scheme for physicians. One possible reason may be economic. Nurses are in great demand, and states are struggling to fill available openings with qualified applicants, so

409 *See id.*

410 *See American Telemedicine Association Board of Directors, supra note 400.*

411 Licensure requirements for military physicians have followed the trend of requiring full licensure in a state before the physician may practice therein. The federal statute provides that a military physician “may not provide health care independently as a health-care professional ... unless the person has a current license to provide such care.” 10 U.S.C. § 1094 (a)(1) (2000). Further, a 1999 amendment to the statute provides that “the physician may not provide health care as a physician ... unless the current license is an unrestricted license that is not subject to limitation on the scope of practice ordinarily granted to other physicians for a similar specialty by the jurisdiction that granted the license.” *Id.* The Secretary of Defense may waive the above licensing requirement with respect to any person in “unusual circumstances.” *Id.* § 1094 (a)(2). Some states do accommodate military physicians by allowing waivers of certain licensing requirements. Kansas provides for a “federally active license” category that exempts military physicians from requirements to maintain medical malpractice insurance, so long as the physician’s practice is limited to practice in connection with official duties. *See KAN. STAT. ANN. § 65-2809 (West 2000); see also FLA. STAT. ANN. § 458.320 (5)(a) (West 2000).*

412 *See American Telemedicine Association Board of Directors, supra note 400.*

413 *See generally* National Council of State Nursing Boards Inc. (visited Nov. 1, 2000) <<http://www.ncsbn.org>>.

414 *See, e.g.,* TEX REV. CIV STAT ART. 4528b (West 2000). Other states adopting the compact include Arkansas, Delaware, Iowa, Maryland, Mississippi, Nebraska, North Carolina, South Dakota, Utah and Wisconsin. *See* National Council of State Nursing Boards Inc., *State Compact Bill Status* (visited Nov. 1, 2000) <<http://www.ncsbn.org/files/mutual/billstatus.asp>>.

415 *See* National Council of State Nursing Boards Inc. (visited Nov. 1, 2000) <<http://www.ncsbn.org>>.

adoption of the compact may help states recruit nurses in short supply.⁴¹⁶

A constitutional challenge is a possibility if state licensing laws are not modified to accommodate telemedicine and cybermedicine.⁴¹⁷ Article I of the U.S. Constitution limits state's abilities to erect unnecessary barriers against activities that are inherently national in scope.⁴¹⁸ The Commerce Clause grants the United States Congress the power "to regulate commerce with foreign nations, and among the several States."⁴¹⁹ The purpose of the Commerce Clause is to prevent a state from "establishing an economic barrier against competition with the products of another state or the labor of its residents."⁴²⁰ In balancing the objective and purpose of a state law against the burden that it imposes on interstate commerce, courts may begin to find that the burden imposed by state licensing outweighs the benefits provided by these laws.⁴²¹

Before telemedicine and cybermedicine, the burden of state regulation was more limited. A physician living near the border of two states might wish to establish offices in two states, but even in that case the licensing burden was not exceptional.⁴²² The introduction of telemedicine increased the burden imposed by state licensing statutes, and cybermedicine has increased the burden exponentially. Today, thousands of cyberphysicians and patients are potentially affected by the burden of state licensure, making a successful constitutional challenge more viable. Two other factors related to the benefits of state licensing laws may weaken the states' case as well. First, as noted above, the licensing requirements of the various states are almost identical.⁴²³ Second, states that have enacted the Interstate Nurse Licensure Compact have by implication admitted that a health care professional can be adequately regulated in a manner that protects the public's interest with a system far less restrictive and burdensome than the existing system.

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⁴¹⁶ Dr. Michael Ewer, a student at the University of Houston Law Center, suggested this economic explanation for the difference in physician and nurses licensing during a conversation in October 2000.

⁴¹⁷ See generally American Telemedicine Association Board of Directors, *supra* note 400.

⁴¹⁸ See *id.*

⁴¹⁹ U.S. CONST., art. I, § 8, cl. 3.

⁴²⁰ *City of Philadelphia v. New Jersey*, 437 U.S. 617, 624 (1978).

⁴²¹ See generally American Telemedicine Association Board of Directors, *supra* note 400.

⁴²² See generally *Slocum v. City of Fredonia*, 8 P.2d 332 (Kan. 1932) (holding that a nonresident travelling physician who examined patients in Fredonia, Kansas and sent medicine to patients through mail from his office in Missouri was practicing medicine within Fredonia's licensing ordinance, and court rejected challenge under commerce clause to licensing ordinance).

⁴²³ See American Telemedicine Association Board of Directors, *supra* note 400.

V. VIRTUAL PHARMACIES

A. DTC Advertising of Prescription Drugs

Internet pharmacies have facilitated the demand for online prescribing. Patients seeking the convenience of filling their prescriptions online may also seek to *obtain* such prescriptions online. The explosion in DTC advertising of new drugs has fueled demand for online prescribing. Pharmaceutical companies spent \$1.8 billion on DTC advertising in 1999, more than thirty-three times the \$55 billion spent on such ads in 1991.⁴²⁴ DTC advertising has driven consumer demand for drugs such as Viagra for erectile dysfunction, Xenical and Meridia for obesity, and Propecia for male pattern baldness, as these “lifestyle” drugs ranked in the top twelve for promotional expenditures in 1999.⁴²⁵ Lifestyle drugs may deserve special marketing attention by pharmaceutical companies since the costs of such drugs are not reimbursed by many health insurance plans.

In 1997, the FDA issued a draft guidance⁴²⁶ clarifying rules for DTC advertising, which may account for the increases in DTC advertising expenditures and sharp increases in retail spending on prescription drugs in 1998 and 1999.⁴²⁷ The FDA has the authority to regulate labeling and advertising for prescription drugs under the Food Drug and Cosmetic Act (FDCA).⁴²⁸ Pursuant to such authority, the FDA has issued regulations on prescription drug advertising.⁴²⁹ Although the FDCA defines labeling to include written, printed, or graphic materials “accompanying” prescription drugs, the FDA has long asserted that their regulatory authority is not limited to materials that physically accompany a product.⁴³⁰

In *Kordell v. United States*, the Supreme Court in 1948 addressed the meaning of “accompanying” with the FDCA and held that “[o]ne article or thing is accompanied by another when it supplements or explains it, in the manner that a committee report of the Congress accompanies a bill. No physical attachment one to the other is necessary. It is the textual relationship that is significant.”⁴³¹ However, the distinction between “labeling” and “advertising” is not always clear. The FDA considers brochures, calendars, price lists, motion picture files, sound

⁴²⁴ See National Institute for Health Care Management, *Prescription Drugs and Mass Media Advertising* (visited Sept. 24, 2000) < <http://www.nihcm.org/DTCbrief.pdf> > [hereinafter NIHCM].

⁴²⁵ See *id.* at 2.

⁴²⁶ See 62 Fed. Reg. 43,171 (1997).

⁴²⁷ Retail spending increased from \$78.9 billion in 1997 to \$93.4 billion in 1998, rising to \$111.1 billion in 1999. See *id.*

⁴²⁸ See 21 U.S.C. § 321(m) (2000).

⁴²⁹ See 21 C.F.R. § 202.1 (2000).

⁴³⁰ See 60 Fed. Reg. 42,581 (1995) (proposed Aug. 16, 1995).

⁴³¹ 335 U.S. 345, 350 (1948).

recordings, and literature as “labeling” and interprets “advertising” to mean information other than labeling “that is sponsored by a manufacturer and is intended to supplement or explain a product.”⁴³²

In 1995, the FDA issued a notice of public hearing and request for comments on consumer-directed broadcast advertisements.⁴³³ In the notice, the FDA outlined the history of DTC advertising. Prior to 1980, pharmaceutical companies usually limited promotion of prescription drugs to physicians and other health care professionals.⁴³⁴ DTC advertising began in the early 1980s, and shortly after drug companies started DTC promotions, the FDA called for a moratorium on the practice in a September 2, 1983 policy statement.⁴³⁵ The voluntary moratorium was lifted in September 1985, based on the FDA’s finding that then-current regulations governing prescription drug advertising provided sufficient safeguards to protect consumers.⁴³⁶

In August 1999, the FDA issued its current guidance for industry on consumer-directed broadcast advertisements.⁴³⁷ The FDCA requires that drug advertisements contain “information in brief summary relating to side effects, contraindications, and effectiveness.”⁴³⁸ The FDA refers to such disclosure as the brief summary. Print advertisements must contain the brief summary, but broadcast advertisements must include a lesser disclosure called the major statement, disclosing only the drug’s major risks.⁴³⁹ In addition to the major statement, broadcast advertisements must make “adequate provision . . . for dissemination of the approved or permitted package labeling,”⁴⁴⁰ the so-called adequate provision requirement.

Drug advertisers may comply with the adequate provision requirement in a variety of ways acceptable to the FDA. The advertisement may include a toll-free telephone number where the consumers may obtain a copy of the labeling, or even have the labeling information read to them over the telephone.⁴⁴¹ The advertisement may direct consumers to print advertisements containing more complete labeling

⁴³² *Id.* (citing 21 C.F.R. § 202.1 (1) (2) (2000)).

⁴³³ *See* 60 Fed. Reg. 42,581 (1995) (proposed Aug. 16, 1995).

⁴³⁴ *See id.* at 42,582.

⁴³⁵ *See id.*

⁴³⁶ *See id.*

⁴³⁷ *See* Food and Drug Administration, *Guidance for Industry, Consumer-Directed Broadcast Advertisements* (visited Sep. 25, 2000) <<http://www.fda.gov/cder/guidance/1804fnl.htm>> [hereinafter *FDA Guidance 1999*].

⁴³⁸ 21 U.S.C. § 352(n) (2000).

⁴³⁹ *See FDA Guidance 1999, supra* note 437, at 1.

⁴⁴⁰ 21 C.F.R. § 202.1(e)(1) (2000).

⁴⁴¹ *See FDA Guidance 1999, supra* note 437, at 2.

disclosures,⁴⁴² e.g., “See our advertisement in Reader’s Digest for complete product information.” Finally, the advertisement may direct consumers to a URL address that provides the package labeling, or may advise consumers to seek additional product information from pharmacists, physicians or other health care providers.⁴⁴³ The FDA notes that the adequate provision requirement must be designed in a way that will allow “most of a potentially diverse audience to have reasonably convenient access to the . . . approved labeling.”⁴⁴⁴ Thus, a televised advertisement could not reasonably meet the adequate provision standard by including only a link to a URL. Of course, for banner or other Internet advertising, full compliance by an advertiser could be as simple as providing a link to the drug manufacturer’s website.

The FDA divides DTC promotion of prescription drugs into the following three categories: (1) “product-claim” advertisements mention specific drugs and contain safety and efficacy claims; (2) “help-seeking” advertisements contain information about a disease or medical condition and advice to the consumer to consult a physician, but do not discuss specific treatments or drugs; and (3) “reminder” advertisements contain the name of the drug but do not discuss the conditions the drug treats.⁴⁴⁵ The brief summary, major statement, and adequate provision disclosure requirements apply only to product-claim advertisements. Reminder and help-seeking advertisements are not subject to disclosure requirements.⁴⁴⁶

Critics of DTC advertising argue that they are inappropriately creating demand for new prescription drugs, in some cases causing patients to ask their physicians for newer, more-expensive drugs where less expensive drugs are perfectly adequate.⁴⁴⁷ However, DTC advertising may provide consumers with important information about medical conditions, make them aware of treatment options, and facilitate dialogue between physicians and their patients.⁴⁴⁸ A 1999 survey found that 31 percent of respondents had talked with their physician about a prescription drug they had seen advertised, and those that asked their physician for a specific advertised drug usually received the requested prescription.⁴⁴⁹ This does not mean that organized medicine supports DTC advertising. Rather, most major medical organizations including the AMA, the American College of Physicians and the American Society of Internal Medicine oppose DTC advertising, at least in its

⁴⁴² *Id.* at 3.

⁴⁴³ *See id.*

⁴⁴⁴ *Id.* at 2.

⁴⁴⁵ *See* 60 Fed. Reg. 42,581, 42,582 (1995) (proposed Aug. 16, 1995).

⁴⁴⁶ *See id.* at 42,583.

⁴⁴⁷ *See* NIHCM, *supra* note 424, at 2.

⁴⁴⁸ *See id.*

⁴⁴⁹ *See id.* at 3.

current form.⁴⁵⁰

As noted above, the FDA distinguishes between print and broadcast advertisements, requiring only a major statement disclosure for broadcast advertisements. Further, no disclosure is required for reminder advertisements. The FDA has not specifically addressed where Internet advertisements fit into the regulatory scheme. Presumably, a banner ad on a web page listing only the drug's name would be a reminder advertisement, but the Internet allows for a wide variety of advertising approaches that defy interpretation under the existing regulatory scheme. A consumer visiting a health website may find a pulsing banner asking "[i]s Flonase right for you? Find out and save \$5."⁴⁵¹ With a click on the banner, consumers are transported to a site sponsored by Glaxo Smithkline describing Flonase as a cutting edge allergy remedy, and offering the \$5 incentive coupon.⁴⁵²

A study conducted by the Science Advisory Board found that 54% of 1,000 online consumers had visited a pharmaceutical site to learn more about a specific prescription drug.⁴⁵³ Another study conducted by Cyber Dialogue found that Internet ads aimed at getting consumers to request a particular drug from their physician have been "stunningly effective compared to other media."⁴⁵⁴ The study found that a pharmaceutical company spent \$14 on Internet advertising per customer that requested the advertised drug, and that to obtain the same response through television ads cost \$197 per customer, with print ads even more expensive at \$220 per customer.⁴⁵⁵

Because drug companies are currently spending considerably more advertising revenue on TV and print ads, more customers are influenced to request a particular drug by such ads.⁴⁵⁶ However, estimates of pharmaceutical spending for online ads vary widely. For example, the Cyber Dialogue study estimated that \$10 million, or about one percent, of advertising budgets was spent online for 1999.⁴⁵⁷ Another study estimated that drug companies' cyberspace expenditures were less than \$1 million in 1999.⁴⁵⁸ Yet a third study by McKinsey estimates the drug

⁴⁵⁰ See American College of Physicians and the American Society of Internal Medicine, *Direct to Consumer Advertising for Prescription Drugs*, at 6, 9-10 (visited Sept. 27, 2000) <<http://www.acponline.org/hpp/pospaper/dtcads.htm>>.

⁴⁵¹ Koren L. Capozza, *The Brave New World of Drug Ads*, at 1 (Jan. 4, 2000) <<http://www.office.com/global/0,,301-15085,FF.html>>.

⁴⁵² See *id.*

⁴⁵³ See *id.* at 2.

⁴⁵⁴ Pamela Parker, *Internet Drug Ads Show Stunning ROI* (visited Sept. 27, 2000) <http://www.internetnews.com/IAR/article/0,,12_293331,00.html>.

⁴⁵⁵ See *id.*

⁴⁵⁶ See *id.*

⁴⁵⁷ See *id.*

⁴⁵⁸ See NIHCM, *supra* note 424, at 7.

industry will spend \$30 to \$50 million in 1999 targeting consumers online.⁴⁵⁹

Not all expenditures are specifically for DTC advertising, however. The top fifteen pharmaceutical companies currently sponsor 300 to 400 websites, including branded product websites that communicate product benefits and collect customer information.⁴⁶⁰ The companies also sponsor unbranded and general health care sites.⁴⁶¹ Health portals such as drkoop.com rely heavily on such advertising revenue, and should benefit from increased expenditures.⁴⁶²

Noting that “many manufacturer-sponsored drug websites fall into the gray area between labeling and advertising,” one article suggests that the FDA should regulate the structure of such websites.⁴⁶³ The authors propose that the home page of such websites should contain a major statement, and include a link that satisfies the adequate provision requirement, with side bars on each of the secondary pages containing links to “side effects” and to the full prescribing information contained in current package insert labeling.⁴⁶⁴ Although interesting, the proposal may be criticized on two grounds. First, it is not technologically neutral. In the future, links may be more intuitive or even automatic, perhaps using a more consumer-friendly version of those irritating frames that sometimes automatically open at some sites. Second, the proposal simply imposes the existing regulatory scheme for broadcast and print advertisements on Internet content. Any attempt by the FDA to regulate Internet advertising would likely be more complex, including, for example, attempts to address disclosure of financial arrangements between drug companies and health portals.

In addition to potential barriers pharmaceutical companies may face by Internet-specific DTC marketing rules, the companies are already exposed to increased liability exposure as a result of the 1999 decision in *Perez v. Wyeth Laboratories, Inc.*⁴⁶⁵ The *Perez* court addressed whether the law regarding a drug manufacturer’s liability to patients should “follow these [DTC advertising] changes in the marketplace or reflect the images of the past.”⁴⁶⁶ The court said the following:

We believe that when mass marketing of prescription drugs seeks to influence a patient’s choice of a drug, a pharmaceutical

⁴⁵⁹ See Ronald S. Rogers, *Drug Companies Link to Consumers*, CHEMICAL AND ENGINEERING NEWS BUSINESS (July 12, 1999) <<http://pubs.acs.org/hotartcl/cenear/990712/7728bus3.html>>.

⁴⁶⁰ See *id.*; see also, e.g., <<http://vioxx.com>> (Merck), <<http://viagra.com>> (Pfizer), <<http://www.celebrex.com>> (Searle), and <<http://claritin.com>> (Schering-Plough).

⁴⁶¹ Pfizer is estimated to support more than 40 websites. See Rogers, *supra* note 459.

⁴⁶² See Parker, *supra* note 454.

⁴⁶³ See Patrick Moore & Michael Newton, *Prescription Drug Advertising on the Internet: A Proposal for Regulation*, 2 W. VA. J. L. & TECH. 1, 5 (Feb. 14, 1998) <<http://www.wvjolt.wvu.edu/v2i1/moore.htm>>.

⁴⁶⁴ See *id.* at 4.

⁴⁶⁵ 734 A.2d 1245 (N.J. 1999).

⁴⁶⁶ *Id.* at 1247.

manufacturer that makes direct claims to consumers for the efficacy of its product should not be unqualifiedly relieved of a duty to provide proper warnings of the dangers or side effects of the product.⁴⁶⁷

In *Perez*, patients who had undergone surgical implantation of Norplant contraceptive capsules brought a product liability action against Wyeth, the manufacturer of Norplant.⁴⁶⁸ Plaintiffs alleged that Wyeth instituted a massive advertising campaign for Norplant directed at women rather than at their physicians, including advertisements in women's magazines such as *Glamour*, *Mademoiselle* and *Cosmopolitan*.⁴⁶⁹ Plaintiffs further alleged that the advertisements did not warn of any dangers posed by Norplant, including side effects such as pain and permanent scarring attendant to removal of the implants.⁴⁷⁰ The trial court entered summary judgment against the patients, and on appeal, the Superior Court, Appellate Division, affirmed.⁴⁷¹ On further appeal, the New Jersey Supreme Court held that the "learned intermediary" doctrine does not apply to DTC marketing of prescription drugs to consumers.⁴⁷² Further, when a drug manufacturer has advertised its drug directly to consumers, the role of a physician in prescribing the drug does not break the chain of causation for the manufacturer's failure to warn patients of harmful side effects.⁴⁷³ However, the court found that a rebuttable presumption exists that when the manufacturer complies with FDA advertising, labeling, and warning requirements, the manufacturer has satisfied its duty to warn consumers about potentially harmful side effects of its drugs.⁴⁷⁴

Under the learned intermediary doctrine, a pharmaceutical manufacturer generally discharges its duty to warn to ultimate user of dangers associated with prescription drugs by supplying physicians with appropriate information about the drug's dangerous propensities.⁴⁷⁵ Thus, the physician's role as a "learned intermediary" may break the chain of causation so that the manufacturer is not liable for injuries suffered by the ultimate user.⁴⁷⁶ However, there are instances where the manufacturer has been held not to be relieved of a duty to warn. For example, a manufacturer of a polio vaccine was held to have a duty to warn consumers directly because the vaccine was provided at immunization clinics with

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Id.

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See id.

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See id. at 1248.

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See id.

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713 A.2d 520 (N.J. 1998).

472

See Perez, 734 A.2d at 1257.

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See id. at 1261-63.

474

See id. at 1258-60.

475

See id. at 1250.

476

See Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966).

no physician present to advise the patients of the risks and benefits of the vaccine.⁴⁷⁷ The *Perez* court noted that the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY has left resolution of the issue of a manufacturer's duty to directly warn consumers to "developing case law."⁴⁷⁸ With DTC advertising resulting in a consumer demanding a particular drug from his physician, the physician may be in a "much-diminished role as an evaluator or decisionmaker"⁴⁷⁹ and it becomes appropriate to impose a duty on the manufacturer to warn the patient directly.

The rationale behind the learned intermediary doctrine is based on four considerations: (1) courts do not wish to intrude upon the physician-patient relationship, (2) physicians are in a superior position to convey meaningful information to their patients, and must do so to obtain necessary informed consent, (3) pharmaceutical manufacturers lack effective means to communicate directly with consumers, and (4) the complexity of risk information together with consumer's comprehension problems make it difficult for drug companies to translate physician labeling into labeling understandable by lay patients.⁴⁸⁰ The *Perez* court found that the first three premises, and possibly the fourth, are absent in the case of DTC advertising.⁴⁸¹ Therefore, the learned intermediary doctrine, "itself an exception to the manufacturer's traditional duty to warn consumers directly of the risk associated with any product, simply drops out of the calculus, leaving the duty of the manufacturer to be determined in accordance with general principles of tort law."⁴⁸²

The court's decision in *Perez* to reduce the effectiveness of the "learned intermediary" defense is particularly noteworthy because it found that in the case of Norplant, "[t]he role of the physician can never be insubstantial because only a physician may implant the device."⁴⁸³ An issue left undecided in *Perez* is what proof a consumer must establish to defeat the rebuttable presumption that when the manufacturer complies with FDA advertising, labeling, and warning requirements, the manufacturer has satisfied its duty to warn consumers about potentially harmful side effects of its drugs. A plaintiff could argue that a drug company's huge DTC advertising budget coupled with sponsorship of multiple websites promoting its drugs should increase the company's responsibility to find ways to effectively communicate dangers associated with its drugs. Perhaps drug companies could devote a tiny percentage of the advertising budget to effectively translating complex physician labeling into something understandable by lay consumers. Trial

⁴⁷⁷ See, e.g., *Davis v. Wyeth Laboratories, Inc.* 399 F.2d 121 (9th Cir. 1968).

⁴⁷⁸ See *Perez*, 734 A.2d at 1253.

⁴⁷⁹ *Id.* (quoting RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6d cmt. b (1997)).

⁴⁸⁰ See *id.* at 1255.

⁴⁸¹ See *id.*

⁴⁸² *Id.* at 1256 (quoting *Edwards v. Basel Pharms.*, 116 F.3d 1341, 1343 (10th Cir. 1997) (adequacy of nicotine patch warning under Texas law)).

⁴⁸³ See *Perez*, 734 A.2d at 1263-64.

lawyers routinely find ways to present complex technical information to lay jurors. Perhaps pharmaceutical manufacturers will be inspired by the holding in *Perez* to redouble efforts in this regard.

B. Types of Internet Pharmacies

The General Accounting Office (GAO) released a report on Internet pharmacies on October 20, 2000, finding that there are currently between 200 and 400 Internet pharmacies.⁴⁸⁴ The GAO identified 190 websites that sold drugs directly to consumers.⁴⁸⁵ Of the 190 pharmacies, twenty-five Internet pharmacies did not require a prescription, fifty-four would provide a prescription based on an online questionnaire, and 111 required a prescription from a physician.⁴⁸⁶ The twenty-five websites that did not require a prescription were located outside the United States, making enforcement extremely difficult.⁴⁸⁷ Further, 185 of the online pharmacies did not disclose their state licensure status, and thirty-seven did not provide a telephone number or address to allow patients to discuss problems with a pharmacist if necessary.⁴⁸⁸ The GAO contacted pharmacy boards in the twelve states with the largest numbers of licensed Internet pharmacies (a total of seventy) to verify their licensure status.⁴⁸⁹ Twenty-two of the sixty-four pharmacies requiring a prescription before dispensing were not licensed in one or more of the states in which they dispensed drugs.⁴⁹⁰ The report urged Congress to pass legislation to require that Internet pharmacies disclose who they are, where they are licensed, and how they will ensure the privacy of patient's personal health information.⁴⁹¹ Consequently, the Internet Prescription Drug Consumer Protection Act of 2000, S 3208, was introduced on October 17, 2000 to regulate Internet pharmacies.⁴⁹² The bill would require Internet pharmacies to reveal their street address, telephone number, and the states in which they are licensed.⁴⁹³

A student of mine christened the categories of Internet pharmacies as "the good, the bad and the ugly."⁴⁹⁴ Good Internet pharmacies may simply be traditional

⁴⁸⁴ See *Studies and Surveys, Online Pharmacies: Congress Should Amend FDCA To Require Web Pharmacies To Reveal Identifying Data*, 8 Health Care Pol'y Rep. (BNA) 1779 (Oct. 30, 2000).

⁴⁸⁵ See *id.*

⁴⁸⁶ See *id.*

⁴⁸⁷ See *id.*

⁴⁸⁸ See *id.*

⁴⁸⁹ See *Online Pharmacies*, *supra* note 484, at 1779.

⁴⁹⁰ See *id.*

⁴⁹¹ See *id.*

⁴⁹² See *News, Health Care Policy, Congressional Roundup: White House Threatens Veto of Medicare Provider Payments Bill*, 9 Health L. Rep. (BNA) 1604 (Oct. 19, 2000).

⁴⁹³ See *id.*

⁴⁹⁴ Rujul H. Desai, a student in my Health Legislation Seminar at the University of Houston Law

“brick and mortar” pharmacies such as Walgreens, Rite Aid, PharMor, and Drug Emporium with a website that allows users to refill prescriptions online with a valid prescription from a physician, and then pick up medications at a drive-through window or at the pharmacy counter. Such pharmacies are licensed in each state they do business, and the web extensions to their business have triggered little controversy or regulatory scrutiny. Many of these sites do not accept new prescriptions via their websites.⁴⁹⁵

Some purely Internet pharmacies are also licensed in each state where they do business. PlanetRx⁴⁹⁶ is an example of a “good” purely Internet pharmacy. A physician may fax or call in a prescription or the patient may send in the physician’s written prescription. The AMA recognizes that the Internet can be a valuable source for prescription medications, and that some online pharmacies are legitimately dispensing medications pursuant to valid prescriptions.⁴⁹⁷ Legitimate benefits of online pharmacies include: (1) computer order entry and online transmission of prescriptions, (2) mechanisms allowing the patient or physician to order refills, and (3) electronic consultations between the physician and patient resulting in a prescription.⁴⁹⁸

The FDA also recognizes a number of benefits from online pharmacies, including greater availability of drugs for those in rural areas with few pharmacies, and for those who may have difficulty traveling to a pharmacy due to limited mobility.⁴⁹⁹ In addition, it is easier to comparatively shop among Internet pharmacies, and Internet drug shopping may save consumers money.⁵⁰⁰ Online shopping may be more convenient for harried consumers, and the online pharmacies may have a greater variety of products.⁵⁰¹ Internet pharmacies also offer easier access to written product information than traditional storefront pharmacies.⁵⁰² Finally, consumers may order products and consult with a

Center used the “good, bad and ugly” moniker to describe online pharmacies in his unpublished paper, *Travels Along the E-Health Frontier: On-Line Prescription Issues* (May 1998) (unpublished manuscript on file with author).

⁴⁹⁵ See *Virtual Pharmacies Boast Easy Access, Privacy Safeguards*, AM. J. HEALTH-SYSTEM PHARMACY NEWS (June 15, 1999), available at <<http://www.ashp.org>> [hereinafter *Virtual Pharmacies*].

⁴⁹⁶ See PlanetRx (visited Nov. 4, 2000) <<http://www.planetrx.com>>.

⁴⁹⁷ See AMERICAN MEDICAL ASSOCIATION, *AMA STATEMENT ON THE RISKS AND BENEFITS OF ON-LINE PHARMACIES* (submitted by Herman I. Abromowitz to the Subcommittee on Oversight and Investigations of the House Commerce Committee) (July 30, 1999) <<http://www.ama-assn.org>> [hereinafter *AMA STATEMENT*].

⁴⁹⁸ See *id.*

⁴⁹⁹ See John Henkil, Food and Drug Administration, *Buying Drugs Online: It's Convenient and Private, but Beware of 'Rogue Sites'* (June 2000) <http://www.fda.gov/fdac/features/2000/100_online.html>.

⁵⁰⁰ See *id.* (citing a survey in the fall of 1999 by Consumer Reports showing that buyers could save as much as 29% by obtaining certain drugs online).

⁵⁰¹ See *id.*

⁵⁰² See *id.*

pharmacist from the privacy of their own homes.⁵⁰³

Legitimate pharmacies collect information from the consumer on drug allergies, current medical condition, and other medications, and establish a profile on the web that the patient can access.⁵⁰⁴ They use the information to check for possible drug interactions and allergic reactions.⁵⁰⁵ The legitimate sites sometimes accept insurance reimbursement, or may require the consumer to pay for the prescription and seek reimbursement from the insurer.⁵⁰⁶ Some sites provide a library of pharmaceutical and health care information, allowing consumers to find answers to questions about their prescription drugs and other disease management concerns.⁵⁰⁷

Legitimate Internet pharmacies and their trade organizations have mounted a public relations campaign to distinguish themselves from illegitimate sites, but they face an uphill battle, since the vast majority of online pharmacies are not operating legally.⁵⁰⁸ The ratio of "bad" to "good" pharmacies is about 400 to six.⁵⁰⁹ Especially troubling are the sites offering a "package deal" of both prescriptions and drugs. Certainly, the marketplace has shown creativity in this instance. For example, to minimally comply with the FDA data sheet's recommendation of a physical examination before receiving Viagra, a website may ask whether potential customers have had a recent physical examination showing general good health. The U.S. pharmacies that have received the most attention from regulators and legislators are those that provide lifestyle drugs such as Viagra via this method. Typically, a site will promote the privacy and convenience advantages of buying via the Internet.⁵¹⁰ The site will require the purchaser to accept a waiver of liability, choose the quantity of pills to be purchased, and fill out a short questionnaire.⁵¹¹ Critics argue that the questionnaires are inadequate because they only request a minimal medical history and sometimes use medical terminology beyond the understanding of a layperson.⁵¹²

Critics also complain that there is no mechanism to see whether a

503 *See id.*

504 *See Virtual Pharmacies, supra* note 495.

505 *See id.*

506 *See id.*

507 *See id.*

508 *See* Kansas Attorney General Carla J. Stovall (Testimony before the Health, Education, Labor, & Pensions Committee Hearing) *E-Drugs: Who Regulates Internet Pharmacies* (Mar. 21, 2000) <<http://www.ink.org/public/ksag/contents/testimony/senate-test.htm>> [hereinafter Stovall Testimony].

509 *See id.*

510 *See* AMA STATEMENT, *supra* note 497.

511 *See id.*

512 *E.g.*, nitrates, arrhythmia, unstable angina, retinitis pigmentosa. *See id.*

purchaser has deliberately or inadvertently provided incorrect information.⁵¹³ By far the largest concern is that prescriptions are being issued without a physical examination.⁵¹⁴ Most of the rogue sites are not licensed in the states they ship to, and they (or their consultant physicians) often ignore the information provided by patients.⁵¹⁵ For example, one 16-year-old Kansas boy ordered and received Viagra, Meridia and Phentermine, even though he accurately provided his date of birth.⁵¹⁶ A woman ordered and received Viagra, although in one instance she was asked to re-order using a man's name before they would fill the prescription.⁵¹⁷

Although the "bad" websites may provide a less than adequate prescription, some domestic and international pharmacies completely dispense with prescriptions.⁵¹⁸ International pharmaceutical sites offer even greater concerns, since they may operate beyond the jurisdiction of U.S. regulators. These "ugly" pharmaceutical sites may ship drugs banned in the U.S. or drugs that otherwise fail to meet regulatory requirements, for example, inadequately labeled prescriptions.⁵¹⁹ Consumers may seek out these websites precisely because they can be used to eliminate the inconvenience of obtaining a prescription, or to circumvent a physician's refusal to supply a particular drug.⁵²⁰

C. Regulation of Internet Pharmacies

Although both pharmacies and pharmacists are licensed by the states for the practice of pharmacy within a state's borders, federal law also regulates aspects of the practice of pharmacy.⁵²¹ The federal Food, Drug, and Cosmetic Act⁵²² (FDCA) prohibits the manufacture and distribution of misbranded and adulterated drugs, mandates labeling standards, and requires that drugs be handled in a manner

⁵¹³ See *id.*

⁵¹⁴ See *id.*

⁵¹⁵ See Stovall Testimony, *supra* note 508.

⁵¹⁶ See *id.*

⁵¹⁷ See *id.*

⁵¹⁸ See *The Electronic Frontier: The Challenge of Unlawful Conduct Involving the Use of the Internet*, A REPORT OF THE PRESIDENT'S WORKING GROUP ON UNLAWFUL CONDUCT ON THE INTERNET, APPENDIX D (March 2000) <<http://www.usdoj.gov/criminal/cybercrime/append.htm#D>> [hereinafter President's Report].

⁵¹⁹ See *id.*

⁵²⁰ See *id.*

⁵²¹ All states have a board of pharmacy that requires pharmacists to be licensed or registered to practice pharmacy. The requirements vary among the states, but generally, pharmacists must: have a degree from an accredited college of pharmacy; complete a residency or internship program; pass a licensing examination; and meet continuing education requirements for practicing pharmacists in most states. See Melanie Margolis, *You Can Get Anything You Want: Internet Pharmacies Overstep Boundaries*, HEALTH L. PERSPECTIVES (Jan. 10, 2000) <<http://www.law.uh.edu/healthlawperspectives/Internet/20000110Pharmacies.html>>.

⁵²² See 21 U.S.C. § 301 (1994).

that will prevent contamination or misuse.⁵²³ The regulatory scheme is designed to protect the public from abuses arising from the sale of prescription drugs.⁵²⁴ Section 353 of the FDCA provides that “[a] drug intended for use by man which is . . . not safe for use except under the supervision of a practitioner licensed by law to administer such drug . . . shall be dispensed only . . . upon a written prescription of a practitioner licensed by law to administer such drug.”⁵²⁵ The regulatory scheme relies on both a physician and a pharmacist to protect patients from intentional or accidental misuse of prescription drugs.⁵²⁶ Further, the FDCA provides that dispensing a prescription drug contrary to the provisions of Section 353(b)(1) “shall be deemed to be an act which results in the drug being misbranded”⁵²⁷ Section 331 of the FDCA prohibits the introduction or delivery of misbranded drugs into interstate commerce.⁵²⁸

Clearly, an online pharmacy providing drugs without any prescription would be introducing or delivering “misbranded” drugs in violation of Section 331. For pharmacies that offer a prescription based on a questionnaire or knowingly accept a prescription from a physician that does not have an established physician-patient relationship, the issue is whether a valid prescription exists under Section 353.⁵²⁹ The federal law does not specifically address the validity of such prescriptions, so resolution of the issue may be dependent on state law.⁵³⁰ Furthermore, pharmaceutical sites selling controlled substances are subject to stricter requirements, and could be charged with drug trafficking.⁵³¹

⁵²³ See *President's Report*, *supra* note 518.

⁵²⁴ See *id.*

⁵²⁵ 21 U.S.C. § 353(b)(1) (1994).

⁵²⁶ See *President's Report*, *supra* note 518.

⁵²⁷ 21 U.S.C. § 353(b)(1) (1994).

⁵²⁸ See 21 U.S.C. § 331(a) (1994). A criminal or civil action may be brought to prevent the distribution of misbranded drugs, which includes distribution of drugs without a valid prescription. See *President's Report*, *supra* note 518. If a defendant acts with intent to defraud or is a repeat offender the government may obtain a felony conviction. See *id.*; see also 21 U.S.C. § 333(a) (1994). No proof of intent to defraud or mislead is required for civil cases and misdemeanor prosecutions. See *President's Report*, *supra* note 518.

⁵²⁹ See *President's Report*, *supra* note 518.

⁵³⁰ See *id.* One argument for the requirement that a physician-patient relationship must exist to have a “valid” prescription is based on the successful federal prosecution of physicians who improperly prescribed steroids in the absence of a legitimate physician-patient relationship. See *id.*

⁵³¹ See *id.*; see also 21 U.S.C. §§ 822, 829, 841, 958 (1994); 21 C.F.R. § 1306.04 (2000) (providing in part that “[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. 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. An order purporting to be a prescription issued not in the usual course of professional . . . is not a prescription . . . and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.”).

The Federal Trade Commission Act⁵³² (FTCA) may also be invoked to protect consumers from deceptive acts or practices including false advertising of drugs.⁵³³ An action could be brought against websites under the FTCA where the site misrepresented the safety of a product, the confidentiality of data collected by the site, or the nature of a physician's review of an online questionnaire.⁵³⁴ A presidential report on unlawful conduct on the Internet concluded the following:

Existing federal law appears generally adequate to encompass the unlawful sale of prescription drugs over the Internet. The same substantive legal requirements that apply to the sale of prescription drugs from the corner pharmacy, by mail order, or by the telephone also apply to such sales over the Internet. The Internet simply provides another means of communication.⁵³⁵

On December 28, 1999, the Clinton administration nonetheless concluded that the federal government does not have sufficient authority to regulate abuses at Internet pharmacy sites.⁵³⁶ The Clinton proposal would give the FDA greater oversight powers over online pharmacies, including the authority to certify Internet pharmacies before they can sell prescription drugs, and would provide additional funding to go after the rogue sites.⁵³⁷ The proposal would allow sanctions to be imposed against pharmacy sites that operate without FDA approval, and online pharmacies that sell prescription drugs without a valid prescription could be fined a civil penalty up to \$500,000 for each violation.⁵³⁸ Further, the FDA would be able to issue subpoenas in support of its investigations, a power it currently lacks.⁵³⁹ The proposal also includes \$10 million in new funding to fund the FDA's efforts to investigate and prosecute illegitimate websites.⁵⁴⁰

Initial reaction from an industry group and the chair of the House Commerce Committee was mixed at best. Committee Chairman Thomas Bliley's spokesman said that Bliley is "very reluctant to set a precedent" for Internet regulation, and that "Chairman Bliley greets the White House proposal with skepticism and is alarmed that it may be a precedent for regulation of the Internet by politicians who not only do not understand the technology, but could not turn on

532 See 15 U.S.C. § 45 (1994).

533 See *President's Report*, *supra* note 518; see also 15 U.S.C. §§ 45(a), 52 (1994).

534 See *President's Report*, *supra* note 518.

535 See *id.*

536 See *Pharmacies: Clinton Proposes Greater FDA Authority Over Online Pharmacies; Reactions Skeptical*, 8 Health Care Pol'y Rep. (BNA) 5 (Jan. 3, 2000).

537 See *id.*

538 See *id.*

539 See *id.*

540 See *id.*

a fax machine.”⁵⁴¹ The National Association of Boards of Pharmacy (NABP), creator of the Verified Internet Pharmacy Practice Sites (VIPPS) certification program, supports broader state regulation but not greater authority for the FDA.⁵⁴² The NABP believes that states should have the sole authority to regulate pharmacies and that it would be a mistake to transfer such authority to the FDA.⁵⁴³ However, the NABP is now supporting the Clinton proposal, including adoption of a mandatory, federalized version of its VIPPS seal.⁵⁴⁴ There is no preemption of any state law by the proposal, an original concern of NABP.⁵⁴⁵

To combat growing public concerns about online pharmacies, the NABP created the VIPPS certification program. To be VIPPS-certified, a pharmacy must comply with the licensing and inspection requirements of each state in which they operate or dispense pharmaceuticals.⁵⁴⁶ Pharmacies displaying the VIPPS seal on their sites “have demonstrated to NABP compliance with VIPPS criteria, including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists.”⁵⁴⁷ Fifteen pharmacies have received the VIPPS certification as of November 5, 2000.⁵⁴⁸ The VIPPS program is being considered at the federal level and internationally.⁵⁴⁹ It will soon be adopted by New Zealand, and is under consideration in Australia, Canada, and by representatives from the International Pharmaceutical Federation, representing pharmacies throughout the world.⁵⁵⁰

States are also considering changes to their pharmacy laws based on VIPPS. In a draft report issued August 24, 2000, the Task Force on Internet Pharmacies and Prescribing stated that principles outlined in VIPPS “should be the basis of any changes to pharmacy regulations.”⁵⁵¹ The report recommends that Michigan consider amending statutes that limit the ability of Michigan-based

541 *See Clinton Proposes Greater FDA Authority, supra* note 536, at 5.

542 *See id.*

543 *See id.*

544 *See Outlook, Drugs And Devices: Drug Costs To Fuel Medicare Debate; Online Drug Sales, Patient Safety On Agenda*, 8 Health Care Pol’y Rep. (BNA) 153 (Jan. 24, 2000).

545 *See id.*

546 *See* National Association of Boards of Pharmacy (visited Nov. 5, 2000) <<http://www.nabp.net/vipps/intro.asp>>.

547 *Id.*

548 *See* National Association of Boards of Pharmacy, *VIPPS Database Search Results* (visited Nov. 5, 2000) <<http://www.nabp.net/vipps/consumer/listall.asp>>.

549 *See Federal News, Pharmacies: Senate Committee Examines E-Pharmacy; Some Question Need For Federal Regulation*, 8 Health Care Pol’y Rep. (BNA) 474 (Mar. 27, 2000).

550 *See id.*

551 *State News, Michigan: Panel Urges Verification Standards for Licensing of Internet Pharmacies*, 8 Health Care Pol’y Rep. (BNA) 1493 (Sep. 11, 2000).

pharmacies to ship prescriptions out-of-state, allowing them to compete with online pharmacies.⁵⁵² The task force concluded that the Michigan Public Health Code does not address the verification of patient identity, the need for an established diagnosis, and the need for a provider to be available for follow-up or emergency care.⁵⁵³ The report recommended that each of these issues be addressed by statutory modifications.⁵⁵⁴ Adoption of the VIPPS criteria by the Michigan task force, together with potential adoption in some form federally, establishes the VIPPS program as a potential national standard for Internet pharmacies. The only serious criticism of VIPPS is that it is presently a voluntary program, lacking regulatory consequences for violations. It will be difficult for the NABP to oppose successfully efforts to make the voluntary requirements mandatory by statute at the state or federal level.

Some states have already enacted laws regulating Internet pharmacies. Indiana requires Internet pharmacies providing medications to its residents to comply with Indiana's licensure and drug substitution laws.⁵⁵⁵ A mail order or Internet based pharmacy is defined as a pharmacy that is either located in Indiana or is a nonresident pharmacy that dispenses prescription drugs to patients in Indiana through postal or other delivery services or after receiving a request for prescription drugs through the Internet.⁵⁵⁶ A "mail order or Internet based pharmacy" must comply with the licensure laws of the state in which the mail order or Internet based pharmacy is domiciled and with the drug substitution laws of Indiana.⁵⁵⁷ Illinois amended its pharmacy practice act to allow the Department of Professional Regulation to regulate the dispensing of medications by Internet pharmacies.⁵⁵⁸ The statute requires that nonresident pharmacies register with the state subject to several conditions.⁵⁵⁹ The nonresident pharmacy must be "licensed in the state in which the dispensing facility is located and from which the drugs" are dispensed.⁵⁶⁰ It must disclose the location, names, and titles of all principal corporate officers and all pharmacists who are dispensing drugs to Illinois residents.⁵⁶¹ The pharmacy must maintain adequate records, "and must provide a toll free telephone number not less

⁵⁵² *See id.*

⁵⁵³ *See Report on Task Force on Internet Pharmacies and Prescribing* (last modified Aug. 28, 2000) <<http://eshare1.fullscope.com:8080/documents/INTERNETPHARM.htm>>.

⁵⁵⁴ *See id.*

⁵⁵⁵ *See* IND. CODE ANN. § 25-26-18-2 (West 2000).

⁵⁵⁶ *See* IND. CODE ANN. § 25-26-18-1 (West 2000). "Nonresident pharmacy" is defined as a pharmacy located outside Indiana that dispenses drugs or devices through the United States Postal Service or other delivery services to patients in Indiana. IND. CODE ANN. § 25-26-17-2 (West 2000).

⁵⁵⁷ IND. CODE ANN. § 25-26-18-2 (West 2000).

⁵⁵⁸ *See* ILL. REV. STAT. ch. 225 para. 85/16a (a) (West 2000).

⁵⁵⁹ *Id.* para. 85/16a (b).

⁵⁶⁰ *Id.*

⁵⁶¹ *See id.*

than 6 days per week to facilitate communication between Indiana patients and a pharmacist at the pharmacy who has access to the patients' records.⁵⁶²

New Hampshire has amended its statute to include Internet pharmacies in the definition of mail-order pharmacies, and to require such pharmacies to register with the state and obtain a permit before delivering drugs within New Hampshire.⁵⁶³ As a final example, California has amended its pharmacy practice act to provide that no person or entity may dispense or furnish a prescription drug on the Internet for delivery to any person in California without a prescription "issued pursuant to a good faith prior examination if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination"⁵⁶⁴ A violation of the statute may subject the person or entity to a fine or civil penalty of up to \$25,000 per occurrence.⁵⁶⁵

D. *Enforcement Actions Against Internet Pharmacies*

The FDA has been active in both civil and criminal investigations of online pharmacies. Civilly, the FDA has taken action against more than fifty websites and the agency has fifty-four more under investigation.⁵⁶⁶ The FDA has issued thirty-eight warning letters and seventeen "cyber letters" to foreign countries.⁵⁶⁷ Five injunctions have been sought or obtained, and twelve seizures of drugs have occurred.⁵⁶⁸ The FDA has obtained eleven recalls, eighteen voluntary destructions of shipments of drugs, and has issued seventeen import alerts.⁵⁶⁹ Criminally, the FDA has 132 investigations underway, eighty-six of which are active, open criminal investigations and forty-six more preliminary investigations.⁵⁷⁰ Forty-nine investigations involve online pharmacies that use questionnaires, and 83 involve the selling of unapproved drugs.⁵⁷¹ The FDA has obtained forty-three arrests and twenty-two convictions, and has referred at least eleven cases to states that are taking action independently.⁵⁷²

562

Id.

563

See N.H. REV. STAT. ANN. § 318:1, 318:37 (West 2000).

564

CAL. BUS. & PROF. CODE § 4067 (a) (West 2000 update).

565

Id. § 4067 (b).

566

See Gene Therapy: Hearing Before the Subcommittee on Oversight and Investigations of the House Committee on Commerce, 106th Cong., 2d Sess., Serial No. 106-112 (May 25, 2000) (Testimony of William K. Hubbard, Senior Associate Commissioner of Policy, Planning, and Legislation, U.S. Food and Drug Administration) [hereinafter Gene Therapy].

567

See id.

568

See id.

569

See id.

570

See id.

571

See Gene Therapy, supra note 566.

572

Id.

The FDA has sent “cyber” letters electronically via the Internet to operators “of foreign-based Internet sites that offer to sell online prescription drugs” to U.S. residents without a prescription.⁵⁷³ The letters warn the website operators that they may be engaged in activities that violate the laws governing prescription drug sales in the U.S.⁵⁷⁴ The cyber letters are similar to traditional “warning” or “untitled” letters, which the FDA has long sent to organizations or individuals it believes may be violating the law.⁵⁷⁵ “These letters outline the nature of the alleged violation and request a formal response.”⁵⁷⁶ They also provided foreign operators with an explanation of the laws that govern interstate commerce of drugs in the United States, and warn that future shipments of their products to this country may be detained and subject to refusal of entry.⁵⁷⁷ The Department of Justice has also filed “several cases involving sales of drugs on the Internet.”⁵⁷⁸ Additionally, the agency opened approximately thirty cases involving the sale of drugs on the Internet, of which approximately twenty involve online prescription drugs sales.⁵⁷⁹ At least sixty different websites are involved in those twenty investigations.⁵⁸⁰

As federal and state regulators step up efforts to control Internet sales by pharmacies in the U.S. and abroad, international entrepreneurs are selling record amounts of drugs to customers in the U.S. via the Internet. Effective enforcement and regulation requires cooperation among all domestic and foreign regulating bodies because Internet commerce crosses state, national and international boundaries. Jurisdictional issues can be particularly difficult where the U.S. wishes to prosecute website operators located outside of the U.S.⁵⁸¹ Last year, U.S. Custom’s inspectors seized 9,725 packages containing prescription drugs—up from

⁵⁷³ See Food & Drug Administration, *Press Release, FDA Launches “Cyber” Letters Against Potentially Illegal, Foreign-Based Online Drug Sites* (Feb. 2, 2000) <<http://www.fda.gov/bbs/topics/ANSWERS/ANS01001.html>>.

⁵⁷⁴ See *id.*

⁵⁷⁵ See *id.*

⁵⁷⁶ *Id.*

⁵⁷⁷ See *id.*

⁵⁷⁸ See *Internet Pharmaceutical Sales: Hearing Before the Subcommittee on Oversight and Investigations of the House Committee on Commerce*, 106th Cong., 2d Sess., Serial No. 106–112 (May 25, 2000) (Prepared Statement of Ethan M. Posner, Deputy Associate Attorney General, U.S. Department of Justice).

⁵⁷⁹ See *id.*

⁵⁸⁰ See *id.*

⁵⁸¹ See generally American Bar Association Global Cyberspace Jurisdiction Project, *Achieving Legal and Business Order in Cyberspace: A Report on Global Jurisdiction Issues Created by the Internet* (visited Sept. 4, 2000) <<http://www.kentlaw.edu/cyberlaw/docs/drafts/draft.rtf>>; see also Melissa K. Cantrell, *The Taming of E-Health: Asserting U.S. Jurisdiction Over Foreign and Domestic Web Sites*, 103 W. VA. L. REV. 573 (2001).

2,148 in 1998.⁵⁸² Seized drugs included steroids, hormones, aphrodisiacs, impotency medications, anticancer drugs, painkillers and tranquilizers.⁵⁸³ The drugs were sent from locations in the Asia-Pacific region, Europe, Central America, and elsewhere.⁵⁸⁴

Politically, the issue of restricting international sales is sensitive since some politicians have criticized pharmaceutical companies for charging higher prices in the U.S. than in other countries. Some patients are simply taking advantage of “gray-market” importing to save money on legitimate prescriptions. Practically, effective regulation is nearly impossible. The U.S. could step up customs enforcement actions in the U.S.—but such action is analogous to going after the small user rather than the kingpin-distributor in the “war on drugs.” The U.S. government can probably count on some regulatory support from countries such as England that regulate prescription drugs as rigorously as the U.S. However, it may be difficult for the U.S. to obtain the cooperation of countries that allow the sale of most drugs without prescriptions. By offering assistance with enforcement of more stringent U.S. standards, such countries could negatively affect the economy and citizens of the country where the sales occur.

However, the U.S. has been successful in obtaining cooperation from some fairly unlikely allies. Recently, agents of the United States Customs Service joined Thai authorities in raiding Thailand-based Internet pharmacies, a major overseas source of steroids, tranquilizers and other drugs requiring a prescription in the U.S.⁵⁸⁵ Twenty-two arrests were made in Thailand for violation of Thai drug and export laws.⁵⁸⁶ Six arrests were made in the U.S., of those accused of buying drugs from a Thai Internet pharmacy.⁵⁸⁷ U.S. officials received excellent cooperation from Thai authorities.⁵⁸⁸ U.S. and Thai officials raided offices and warehouses used by Internet pharmacies in Thailand, seizing twenty computers and 245 parcels ready for shipment to the U.S. containing more than 2.5 million doses of drug products.⁵⁸⁹ The drugs included anabolic steroids, Valium, Viagra, fen-phen, Tylenol with codeine, Xanax, and Rohypnol, a sedative commonly used as a “date rape” drug.⁵⁹⁰

States have been even more active and successful in actions against online pharmacies than the federal government. Illinois has filed complaints against

⁵⁸² See Robert Pear, *Thais Help U.S. Stem Internet Sales of Medicines* (June 26, 1999) <<http://www.prm.usm.my/headline/others.html>>.

⁵⁸³ See *id.*

⁵⁸⁴ See *id.*

⁵⁸⁵ See *id.*

⁵⁸⁶ See *id.*

⁵⁸⁷ See Pear, *supra* note 582.

⁵⁸⁸ See *id.*

⁵⁸⁹ See *id.*

⁵⁹⁰ *Id.*

several out-of-state Internet pharmacies, alleging that the pharmacies did not tell their patients that the physicians and pharmacies were not legally registered or licensed in Illinois.⁵⁹¹ The state Attorney General is seeking a permanent injunction to bar the companies from prescribing, promoting, or distributing prescription drugs to Illinois patients.⁵⁹² Kansas has sought temporary and permanent restraining orders, penalties and fees from at least seven pharmacies and physicians associated with the pharmacies.⁵⁹³ Michigan has pursued actions against several pharmacies, and even where the issues have not yet been resolved in court, many of the sites are no longer making shipments to Michigan.⁵⁹⁴ New Jersey has sought cease and desist orders, investigative costs and civil penalties under its consumer fraud act against at least nine online pharmacies, and has settled with one defendant.⁵⁹⁵ Missouri has obtained permanent injunctions and penalties against two pharmacies. Pennsylvania and Texas also have actions pending against online pharmacies.⁵⁹⁶

In addition, the National Association of Attorneys General (NAAG) has been active in coordinating state enforcement actions against Internet pharmacies. The NAAG believes that states should retain primary enforcement authority over physicians and pharmacies.⁵⁹⁷ However, given the difficulties they face in halting the unlawful activities of out-of-state defendants, the NAAG would prefer laws allowing state attorneys general to bring enforcement actions in federal court and obtain federal injunctive relief.⁵⁹⁸

E. Regulation of Internet Prescribing

The FSMB adopted recommendations regarding Internet prescribing in April 1999.⁵⁹⁹ The FSMB recommends that state medical boards "consider it unprofessional conduct for a physician to provide treatment recommendations, including issuing a prescription . . . unless the physician has obtained a history and [adequate] physical evaluation of the patient."⁶⁰⁰ A report of the FSMB's Special

⁵⁹¹ See Claire Hackney, *Issue Brief, On-Line Pharmacy*, Health Pol'y Tracking Service, Oct. 3, 2000, available at <<http://hpts.org>> (password-protected material on file with author).

⁵⁹² *Id.*

⁵⁹³ *Id.*

⁵⁹⁴ *Id.*

⁵⁹⁵ *Id.*

⁵⁹⁶ See Hackney, *supra* note 591.

⁵⁹⁷ See *Thirty-four Attorneys General File Comments Stressing the States' Role in Policing Online Commerce* (visited Nov. 5, 2000) <<http://www.naag.org/legislation/inetcommerce.html>>.

⁵⁹⁸ See *id.*

⁵⁹⁹ See Federation of State Medical Boards, *The Report of the Special Committee on Professional Conduct and Ethics, § IV, Internet Prescribing* (visited Nov. 1, 2000) <<http://www.fsmb.org>> [hereinafter *FSMB Report*].

⁶⁰⁰ *Id.*

Committee on Professional Conduct and Ethics⁶⁰¹ found that the prevalence of websites that offer prescriptions without an adequate evaluation by a physician poses a threat to public health and safety.⁶⁰² The report concluded that online prescribing of medications based solely on a medical questionnaire “clearly fails to meet an acceptable standard of care and is outside the bounds of professional conduct.”⁶⁰³ The FSMB proposed a four-part test a physician must meet in order to establish an acceptable standard of practice.⁶⁰⁴ A physician must conduct a documented patient evaluation, including a physical examination adequate to establish the diagnosis and to identify contraindications to any proposed drug therapy.⁶⁰⁵ The physician must also discuss treatment options and the risk and benefits of treatment with the patient. The physician must follow the patient’s progress to review the efficacy of treatment and to assess therapeutic outcome.⁶⁰⁶ Finally, the physician must maintain a contemporaneous medical record “that is readily available to patients and their other health care professionals.”⁶⁰⁷ The FSMB would allow exceptions for emergencies, consultations, and on-call or cross-coverage situations where the physician has access to the patient’s medical records.⁶⁰⁸ The FSMB recommends that state medical boards require all physicians to disclose identifying information such as name, practice location, states where the physician is licensed, and financial interest in any products recommended.⁶⁰⁹

The AMA has adopted a policy on Internet prescribing that ostensibly supports the use of the Internet to prescribe “with appropriate safeguards to ensure that the standards for high quality medical care are fulfilled.”⁶¹⁰ However, the

⁶⁰¹ See *id.*

⁶⁰² See *id.* (“The increasing prevalence of Internet websites that allow consumers to obtain prescriptions, medications, and/or medical treatments without an adequate evaluation by a physician poses an immediate threat to the public health and safety. Health risks to the public include (1) adverse drug reactions and/or interactions, (2) misdiagnosis or delay in diagnosis, and (3) failure to identify complicating conditions. Regulators are challenged due to difficulties in discerning the identity and location of participating physicians thereby making jurisdictional determinations difficult.”).

⁶⁰³ *Id.*

⁶⁰⁴ See *FSMB Report, supra* note 599.

⁶⁰⁵ See *id.*

⁶⁰⁶ See *id.*

⁶⁰⁷ *Id.*

⁶⁰⁸ See *id.*

⁶⁰⁹ See *FSMB Report, supra* note 599.

⁶¹⁰ “Our AMA will: (1) develop principles describing appropriate use of the Internet in prescribing medications; (2) support the use of the Internet as a mechanism to prescribe medications with appropriate safeguards to ensure that the standards for high quality medical care are fulfilled; (3) work with state medical societies in urging state medical boards to ensure high quality medical care by investigating and, when appropriate, taking necessary action against physicians who fail to meet the local standards of medical care when issuing prescriptions through Internet websites that dispense prescription medications; (4) work with the Federation of State Medical Boards and others in endorsing or developing model state legislation to establish limitations on Internet prescribing; (5) continue to work with the National Association of Boards of

policy provides that the AMA will work with the FSMB in “endorsing or developing model state legislation to establish limitations on Internet prescribing.”⁶¹¹ The Board of Trustees report leading up to the AMA’s policy statement recommended that the “AMA vigorously oppose the use of the Internet as a mechanism 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”⁶¹²

State medical boards have reacted to the “threat” of Internet prescribing in a variety of ways. Some state medical boards have too-literally adopted the FSMB’s recommendations by issuing “policy” or “position” statements on Internet prescribing without reference to their state medical practice acts or other state law. The North Carolina Medical Board has a position statement that states, “Prescribing drugs to an individual the prescriber has not personally examined is usually inappropriate.”⁶¹³ The position statement does recognize circumstances when prescribing for a patient whom the physician has not personally examined may be appropriate. Examples “include admission orders for a newly hospitalized patient, prescribing for a patient of another physician for whom the prescriber is taking call, or continuing medication on a short-term basis for a new patient prior to the patient’s first appointment.”⁶¹⁴ Also, the statement recognizes that “established patients might not require a new history and/or physical examination for each new prescription.”⁶¹⁵ The statement condemns as “inappropriate and unprofessional” prescribing drugs to individuals the physician has never met based solely on a patient questionnaire, “as is common in Internet or toll-free telephone prescribing.”⁶¹⁶

Mississippi’s policy statement provides that “[e]ssential components of proper prescribing and legitimate medical practice requires that the physician obtains a thorough medical history and conducts an appropriate physical

Pharmacy and support their “Verified Internet Pharmacy Practice Sites” program so that physicians and patients can easily identify legitimate Internet pharmacy practice sites; (6) work with federal and state regulatory bodies to close down Internet websites of companies that are illegally promoting and distributing (selling) prescription drug products in the United States; and. (7) keep pace with changes in technology by continually updating standards of practice on the Internet.” See American Medical Association, *H-120.956 Internet Prescribing*, (BOT Rep. 35, A-99) (visited Nov.3, 2000) < <http://www.ama-assn.org/meetings/public/annual99/reports/onsite/bot/rtf/bot35.rtf>>.

⁶¹¹ See *id.*

⁶¹² American Medical Association, *Board of Trustees Report* (visited Nov. 3, 2000) < <http://www.ama-assn.org/meetings/public/annual99/reports/onsite/bot/rtf/bot35.rtf>>.

⁶¹³ See North Carolina Medical Board, *Position Statement, Contact With Patients Before Prescribing* (Nov. 1999) < <http://www.docboard.org/nc/pos2.htm>>.

⁶¹⁴ *Id.*

⁶¹⁵ *Id.*

⁶¹⁶ *Id.*

examination before prescribing any medication for the first time.”⁶¹⁷ The policy allows exceptions similar to the North Carolina position statement. The Mississippi policy statement provides “that prescribing drugs to individuals that the physician has never met based solely on answers to a set of questions . . . is inappropriate, fails to meet a basic standard of care that potentially places patients’ health at risk and could constitute unprofessional conduct punishable by disciplinary action.”⁶¹⁸

These mere policy or position statements are problematical. They are conclusory in nature, with little discussion or support for the conclusions, and do not even cite or discuss the state’s medical practice acts. Also, since they were not adopted through formal rule-making procedures, any opposing viewpoints were perhaps not even considered. Some states including Texas and Louisiana have at least provided more analysis for their still-informal policy statements.

The Texas Board of Medical Examiners established a policy regarding Internet prescribing in December 1999.⁶¹⁹ The board notes that the state medical practice act⁶²⁰ authorizes the Board to discipline a Texas physician for unprofessional conduct, including conduct that is likely to deceive, defraud, or injure the public. The statute defines unprofessional or dishonorable conduct to include “prescrib[ing] or administer[ing] a drug or treatment that is nontherapeutic in nature or nontherapeutic in the manner the drug or treatment is administered or prescribed.”⁶²¹ It is also unprofessional conduct to prescribe or dispense a drug in a manner inconsistent with public health and welfare.⁶²² Based on its interpretation of the above sections, the board has determined that it is “unprofessional conduct for a physician to initially prescribe any dangerous drugs or controlled substances without first establishing a proper physician-patient relationship.”⁶²³ The board establishes four minimum criteria to determine whether a proper relationship has been established. A physician must: (1) verify that the person requesting the medication is in fact who he or she claims to be, (2) establish a diagnosis using accepted medical practices such as a patient history, physical examination, and diagnostic and laboratory testing, (3) discuss the diagnosis and the risks and benefits of various treatment options with the patient, and (4) insure availability of the physician or coverage for the patient for appropriate follow-up care.⁶²⁴ Based on the above criteria, the Board has determined that “an online or telephonic

⁶¹⁷ See Mississippi State Board of Medical Licensure, *Policy Statement Regarding Internet Prescribing* (visited Nov. 3, 2000) <<http://www.msbl.state.ms.us/internet%20prescribing%20policy.htm>>.

⁶¹⁸ *Id.*

⁶¹⁹ See Texas State Board of Medical Examiners, *Internet Prescribing Policy* (Dec. 8-11, 1999) <<http://www.tsbme.state.tx.us/policy/ipp.htm>>.

⁶²⁰ See TEX. OCC. CODE § 164.053 (West 2000).

⁶²¹ *Id.* § 164.053 (a)(5).

⁶²² See *id.* § 164.053 (a)(6).

⁶²³ Texas State Board of Medical Examiners, *Internet Prescribing Policy* (Dec. 8-11, 1999) <<http://www.tsbme.state.tx.us/policy/>>.

⁶²⁴ See *id.*

evaluation by questionnaire is inadequate.”⁶²⁵

Louisiana issued a statement of position on Internet/telephonic prescribing on May 24, 2000.⁶²⁶ The statement provides that it is a violation of the state medical practice act⁶²⁷ for a physician to prescribe medication if the physician has not established a physician-patient relationship.⁶²⁸ The Louisiana statement also addresses issuance of prescriptions by out-of-state physicians. It provides that “the issuance of a prescription or order to dispense medication to individuals who are residents of or physically located in the state of Louisiana constitutes the practice of medicine and may only be undertaken by a physician licensed to practice medicine in this state.”⁶²⁹ The statement warns that unlicensed out-of-state physicians are “practicing medicine”⁶³⁰ within the statutory definition, and they may be referred to the Louisiana Attorney General for criminal prosecution and incarceration for up to five months for each offense.⁶³¹ The statement adds that prescribing in the absence of a physical examination and physician-patient contact is contraindicated, and can cause harm to patients who are “required to engage in self-assessment.”⁶³² Further, the statement condemns online evaluation of a patient the physician has never seen as inadequate and warns that a Louisiana licensed physician who participates in such activities is subject to sanctions, including license revocation.⁶³³

In support of its position, the statement cites a statute allowing the board to revoke the license of a physician who has been found culpable of “[p]rofessional or medical incompetency . . . [c]ontinuing or recurring medical practice which fails to satisfy the prevailing and usually accepted standards of medical practice in this state.”⁶³⁴ The statement does not condemn all Internet prescribing as unlawful, noting the common exceptions for admission orders for newly hospitalized patients, physicians taking calls for another physician, or continuing medication for a new patient prior to the patient’s first appointment.⁶³⁵ The statement concludes that

⁶²⁵ *Id.*

⁶²⁶ See Department of Health and Hospitals, Louisiana State Board of Medical Examiners, *Statement of Position, Internet/telephonic Prescribing* (May 24, 2000) <<http://www.lsbme.org/position/tp.pdf>> [hereinafter Louisiana State Board].

⁶²⁷ See LA. REV. STAT. ANN. §§ 37:1261-1292 (West 2000).

⁶²⁸ See Louisiana State Board, *supra* note 626.

⁶²⁹ *Id.*

⁶³⁰ “[T]he holding out of one’s self to the public as being engaged in the business of, or the actual engagement in, the diagnosing, treating, curing, or relieving of any bodily or mental disease, condition, infirmity, deformity, defect, ailment, or injury in any human being...whether by the use of any drug, instrument or force...or any other agency or means...” LA. REV. STAT. ANN. §§37:1261-61 (West 2000).

⁶³¹ See LA. REV. STAT. ANN. §§ 37:1271, 1286 and 1290 (West 2000).

⁶³² *Id.*

⁶³³ See *id.*

⁶³⁴ See LA. REV. STAT. ANN. §§ 37:1285(A)(12), (14) (West 2000).

⁶³⁵ See Louisiana State Board, *supra* note 626.

issuance of a prescription either in the absence of a physician-patient relationship or by a physician not licensed in Louisiana to residents of Louisiana constitutes “*per se* violations of the Medical Practice Act.”⁶³⁶

Some states have formalized their Internet prescribing positions by properly adopted rules issued pursuant to statutory authority. For example, Alabama’s board has issued Rule 540-X-9.11,⁶³⁷ requiring contact with patients before prescribing. The rule is similar substantively to those issued by Mississippi and North Carolina. Issuance of a formal rule rather than a mere policy or position statement shows more respect for due process.

California now regulates Internet prescribing of “dangerous” drugs by statute. Dangerous drugs are defined as drugs requiring a prescription.⁶³⁸ The statute provides that “[p]rescribing, dispensing, or furnishing dangerous drugs . . . without a good faith prior examination and medical indication therefore, constitutes unprofessional conduct.”⁶³⁹ The statute provides some exceptions, including prescriptions issued by designated physicians temporarily acting for other physicians and prescriptions issued after consultation with a nurse.⁶⁴⁰ The statute was recently amended to more specifically address Internet prescribing. Senate Bill 1828 added section 2242.1 to the Business and Professions Code, to provide that “no person or entity may prescribe, dispense, or furnish . . . dangerous drugs . . . on the Internet for delivery to any person in this state, without a good faith prior examination and medical indication therefore, except as authorized by Section 2242.”⁶⁴¹ Violations are subject to a fine or civil penalty of up to \$25,000 per occurrence.⁶⁴²

Historically, physicians have occasionally and appropriately prescribed medications to their new and existing patients based on telephone “consultations.” As state policy makers develop rules on use of the Internet in practicing medicine, they should not regulate solely as a response to a few bad actors prescribing medications based only on questionnaires. Additionally, they should consider developing the technology.

[Policymakers] must realize there are circumstances when

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Id.

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Alabama Board of Medical Examiners, *Contact with Patient before Prescribing, Rule 540-X-9.11* (April 15, 1997) <http://www.albme.org/New_Folder/chap09.pdf> (issued under authority of ALA. CODE § 34-24-53 (West 2000)); see also Ohio State Medical Board Rule 4731-11-09, *Prescribing To Persons Not Seen By The Physician* (specifically addressing provision of controlled substances and dangerous drugs) (visited Nov. 3, 2000) <<http://www.state.oh.us/med/rules/11-09.htm>>.

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CAL. BUS. & PROF. CODE § 4022 (Deering Supp. 2001) (“ ‘Dangerous drug’ . . . means any drug . . . unsafe for self-use . . . and includes . . . [a]ny drug that bears the legend: ‘Caution: federal law prohibits dispensing without prescription,’ ‘Rx only,’ or words of similar import”).

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CAL. BUS. & PROF. CODE § 2242 (a) (Deering Supp. 2001).

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See id. § 2242 (b).

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California SB 1828, *approved by the Governor Sept. 24, 2000.*

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Id.

providing medical advice over the Internet without an in-person physical examination is appropriate. Further, the increasing use of videoconferencing may mean that it is not as important for a doctor to actually physically examine the patient, particularly if he can see the patient and another practitioner—perhaps a nurse practitioner or a physician’s assistant—is doing the examination under the doctor’s “online” supervision.⁶⁴³

F. *Enforcement Actions Against Physicians*

State licensing boards have disciplined physicians for online prescribing without a prior physician-patient relationship or without a physical examination of the patient, as discussed in the two examples *infra*. Importantly, the disciplinary actions to date involve prescriptions based on a questionnaire completed by the patient intended to elicit a basic medical history and to identify any contraindications. None of the disciplinary actions have involved use of interactive video teleconferencing.

Dr. Danny Ray Johnson was the first person to be formally disciplined by the Texas Board of Medical Examiners.⁶⁴⁴ The Agreed Order contained the following finding of facts. Dr. Johnson is a 43-year-old family physician and has been licensed to practice in Texas for thirteen years.⁶⁴⁵ He had been performing consulting work for two years with ProCare Clinic, a Texas corporation owned by a non-physician.⁶⁴⁶ Patients sought prescription drugs via the Internet through ProCare after completing an online questionnaire.⁶⁴⁷ Johnson prescribed Viagra and Propecia for ProCare patients after reviewing the questionnaires and following-up with a telephone interview to elicit additional patient information.⁶⁴⁸ Johnson did not perform a face-to-face interview or a physician examination of the patients.⁶⁴⁹

Based on the above facts, the Texas Board of Medical Examiners found that Johnson was failing “to practice medicine in an acceptable professional manner consistent with public health and welfare.”⁶⁵⁰ The board publicly reprimanded⁶⁵¹

⁶⁴³ Chad Bowman, *Drugs and Devices: More Regulators Just Say No to Online Drug Prescriptions*, Health Care Daily Rep. (BNA), May 18, 2000 (quoting Mark B. Langdon, of Arent Fox Kintner Plotkin & Kahn PLLC, Washington, D.C.).

⁶⁴⁴ See Texas State Board of Medical Examiners, In the Matter of the License of Danny Ray Johnson, M.D., Agreed Order H-0499 (Aug. 26, 2000).

⁶⁴⁵ See *id.*

⁶⁴⁶ See *id.*

⁶⁴⁷ See *id.*

⁶⁴⁸ See *id.*

⁶⁴⁹ See Danny Ray Johnson, *supra* note 644.

⁶⁵⁰ *Id.* (citing TEX. OCC. CODE ANN. § 164.051(a)(6) (2000 Pamphlet)).

Johnson, and imposed additional conditions in the Agreed Order. Among other things, he was required to give a copy of the Order to all hospitals, nursing homes and other health care entities where he has privileges, applies for privileges or otherwise practices medicine.⁶⁵² Based on the Agreed Order, the board filed an adverse action report with the NPDB on September 28, 2000.⁶⁵³

Dr. Johnson has also been sanctioned in Missouri: on August 26, 1999, Missouri Attorney General Jay Nixon obtained a temporary restraining order prohibiting Johnson from treating Missourians or prescribing drugs for them.⁶⁵⁴ Nixon said that “[i]t’s wrong and dangerous to dispense prescription drugs on the basis of a prescription issued by a doctor who has never spoken with the patient, and who issues the prescription for a potentially lethal drug solely on the basis of an e-mail.”⁶⁵⁵ A female investigator from Nixon’s office was able to obtain an online medical consultation and prescription for Viagra from Johnson.⁶⁵⁶ However, Johnson was not licensed to practice medicine in Missouri.⁶⁵⁷ On November 29, 1999 Nixon obtained a permanent injunction against Johnson and ordered that Johnson and other defendants pay a total of \$15,000 in civil penalties.⁶⁵⁸ The injunction prohibits Johnson from treating Missourians without being licensed by the state licensing board.⁶⁵⁹

On February 15, 2000, the Board of Medical Examiners of Oregon filed a complaint⁶⁶⁰ against Dr. Steven Gabriel Moos, a physician licensed in Oregon.⁶⁶¹ The board charged Dr. Moos with two violations of the state’s medical practice act. He was charged with “unprofessional or dishonorable conduct.”⁶⁶² “Unprofessional or dishonorable conduct” is broadly defined as conduct unbecoming a person

651 *See id.* at 2.

652 *See id.* at 3.

653 A search of Johnson’s credentials on DocFinder directs the viewer to contact the board for information on disciplinary actions. A link on the Docfinder site allows a visitor to make an “open records” request of the board via the website. A request for Johnson’s disciplinary records resulted in the agreed order in his case being sent as an e-mail attachment within a few hours. No charge was made for the information. *See Docboard* (visited Oct. 31, 2000) <<http://www.docboard.org>>.

654 *See Missouri Attorney General, Press Release* (Aug. 26, 1999) <<http://www.ago.state.mo.us/82699.htm>>.

655 *See id.*

656 *See id.*

657 *See id.*

658 *See Missouri Attorney General, supra* note 654; *see also* 229 Health Care Daily Rep. (BNA), Nov. 30, 1999 (citing *Missouri v. Miles*, Mo. Cir. Ct., No. 99CV217072-Div. 11 (Nov. 29, 1999)).

659 *See id.*

660 *See In the Matter of Steven Gabriel Moos, MD, License No. MD 20201, Oregon State Board of Medical Examiners, Complaint and Notice of Proposed Disciplinary Action* (Feb. 15, 2000).

661 *See id.*; *see also* OR. REV. STAT. § 677.190(1)(a) (West 2000).

662 OR. REV. STAT. § 677.190(1)(a) (West 2000).

licensed to practice medicine or detrimental to the best interests of the public, and includes any conduct or practice contrary to recognized standards of medical ethics or any conduct which could constitute a danger to the health or safety of a patient or the public.⁶⁶³ It also includes willful performance of a medical treatment that is contrary to acceptable medical standards⁶⁶⁴ or otherwise utilizing medical service for diagnosis or treatment that is or may be considered inappropriate.⁶⁶⁵ Moos was also charged with “gross or repeated negligence in the practice of medicine.”⁶⁶⁶ According to the complaint, Moos advertised his medical and prescribing services on a number of Internet sites including *viagramed.org*, *centerformenshealth.com* and *5freeviagra.com*. He prescribed medication based on a medical questionnaire submitted by patients online, and prescribed a variety of drugs including Viagra, Propecia, Xenical, Celebrex and Zyban.

Moos never examined the patients, did not obtain medical records of the patients or confer with their primary care providers, and did not review alternative treatments, risks or side effects with the patients.⁶⁶⁷ He reviewed between 150 and 250 questionnaires per week and either provided prescriptions or directly dispensed prescription drugs from his Oregon office or his Washington clinic.⁶⁶⁸ Investigators for the board successfully ordered Viagra and Propecia by completing online questionnaires.⁶⁶⁹ On March 29, 2000, the board entered a final order in the case.⁶⁷⁰ Under the order, Moos stipulated that he engaged in the conduct complained of, and that his manner of practice endangered the public by exposing patients to treatment that could be contraindicated either by pre-existing conditions or other medications the patients could be taking, and that such weaknesses in his treatment could have been prevented by taking an adequate history, consulting with the patient’s primary care physicians, reviewing their medical records and providing follow-up care.⁶⁷¹ Dr. Moos was fined \$5,000, reprimanded and placed on probation for ten years.⁶⁷² During the ten years of his probation, he is subject to a number of limitations on his practice.⁶⁷³ He agreed that he would not communicate with patients in Oregon or elsewhere via the Internet.⁶⁷⁴ He will not diagnose or

663 *Id.* § 677.188(4)(a).

664 *Id.* § 677.188(4)(b).

665 *Id.* § 677.188(4)(d).

666 *Id.* § 677.190(14).

667 *See Matter of Moos, supra* note 660.

668 *See id.*

669 *See id.*

670 *See id.*

671 *See id.*

672 *See Matter of Moos, supra* note 660.

673 *See id.*

674 *See id.* at 4.

treat a patient he has not seen in a face-to-face clinical setting.⁶⁷⁵ Before prescribing medications to any patient he must verify their identity.⁶⁷⁶ He must report quarterly in person to the medical board, and his patient charts are subject to audit by the board.⁶⁷⁷

The above two physicians are not unique. A physician has been criminally indicted in Ohio for drug trafficking as a result of prescribing and dispensing drugs based only on an online questionnaire; he is being civilly charged in three other states, and he has himself filed a civil suit against the State of Ohio.⁶⁷⁸ State medical boards in California, Colorado, Florida, Hawaii, Illinois, Michigan, Missouri, Nevada, Ohio, Washington, Wisconsin, and Wyoming have also disciplined physicians for writing Internet prescriptions.⁶⁷⁹

G. *Delivery of Prescriptions via the Internet*

A recent editorial in the *Archives of Internal Medicine* noted that “[e]lectronic prescribing is introducing significant changes in how drugs are used and monitored.”⁶⁸⁰ Electronic prescribing can help reduce prescribing errors, dispensing errors, and administration errors.⁶⁸¹ In *Vasquez v. Albertson’s*, a Texas district court jury found a physician negligent for writing an illegible prescription.⁶⁸² The jury attributed the death of Vasquez to the illegibility of the prescription.⁶⁸³ A pharmacist dispensed 20mg Plendil, a drug used to control high blood pressure, rather than Isordil, used to control angina.⁶⁸⁴ The maximum daily dosage of Plendil is 10mg, so the patient not only received the wrong medication,

⁶⁷⁵ See *id.*

⁶⁷⁶ See *id.*

⁶⁷⁷ See Oregon Administrators In Medicine (visited Nov. 3, 2000) <<http://www.bme.state.or.us/search.html>>. A search of his physician profile reveals that a “[p]ublic order [is] on file” and directs the visitor to “[s]ee link for details.” *Id.* One might assume the link would be to the order detailing Dr. Moos’ wrongdoing and imposing sanctions, but instead the link is only to a document that provides licensure definitions. “Public Order on File” is explained as “The Board of Medical Examiners has taken action that has resulted in a Public Order, which relates to the licensee’s right to practice.” *Id.* To obtain a copy of the order, one must file a written request with the board and include a \$10 payment for each licensee. See *id.*

⁶⁷⁸ See Kansas Attorney General Carla Stovall, *Testimony before the U.S. House of Representatives Committee on Commerce Subcommittee on Oversight and Investigations* (May 23, 2000) <http://www.naag.org/legislation/may/stovall_online_pharm.html>.

⁶⁷⁹ See Bowman, *supra* note 643.

⁶⁸⁰ See Edward P. Armstrong, *Electronic Prescribing and Monitoring are Needed to Improve Drug Use*, 160 ARCH. INTERNAL MED. 2713 (Oct. 9, 2000).

⁶⁸¹ See *id.*

⁶⁸² See Linda S. Crawford, *A Bitter Pill To Swallow: Illegible Prescriptions an Ill Excuse for Misfills*, 17 MED. MALPRACTICE LITIG. & STRATEGY, May 2000, at 1 (citing *Vasquez v. Albertson’s Inc.*, No. A-103-02 (Oct. 1999)).

⁶⁸³ *Vasquez*, No. A-103-02.

⁶⁸⁴ See *id.*

but also took an overdose.⁶⁸⁵ One day after taking the medication, the patient suffered a heart attack, and he died a few days later.⁶⁸⁶ Jurors held both the pharmacy and physician liable for the medication error.⁶⁸⁷ The pharmacist admitted that he “merely guessed” at what the doctor had written.⁶⁸⁸ Although physician’s bad handwriting is often the butt of jokes, this case represents the first instance of a physician being found negligent for illegible handwriting.⁶⁸⁹ The error could have been prevented if the prescription had been typed, or transmitted electronically from the physician to the pharmacy. The physician’s attorney, Max E. Wright, said, “This jury clearly questioned why in the electronic age . . . we’re still using this antiquated system based on a 3 ½ -by-5 [inch] piece of paper.”⁶⁹⁰

A recent report by the National Academy of Sciences found a variety of medication errors are common, including those involving drug interactions, nomenclature such as incorrect drug name, dosage form, or abbreviations. The report found that medication errors are often preventable, and that computerized drug order entry systems have much potential to reduce errors.⁶⁹¹ Pharmacy benefit managers are already posting some patients’ medication records on the Internet, accessible to the patients and their physicians.⁶⁹² The benefit managers believe that online prescription records can help ensure that physicians order the appropriate medication and are alerted to potentially dangerous drug interactions.⁶⁹³ Programs that allow physicians to access patients’ prescription histories require physicians to first obtain the consent of their patients.⁶⁹⁴

The AMA and Intel have created an authentication process called Digital Credentials to protect the privacy and confidentiality of medical information during

⁶⁸⁵ See *id.*

⁶⁸⁶ See *id.*

⁶⁸⁷ See *id.*

⁶⁸⁸ See Crawford, *supra* note 682.

⁶⁸⁹ See *id.* (citing Mimi Hall, *Doctor Held Liable for Fatal Handwriting Mix-Up*, USA TODAY, Oct. 21, 1999, at 3A).

⁶⁹⁰ See Linda O. Prager, *Jury Blames Doctor’s Bad Penmanship for Patient Death*, AM. MED. NEWS, (Nov. 22/29, 1999), available at <http://www.ama-assn.org/sci-pubs/amnews/pick_99/pr121122.htm>. Although Vasquez is the first case holding a physician liable for an injury suffered a patient because of an illegible prescription; previous cases have held pharmacists liable for not verifying a poorly written prescription with the physician. See, e.g., Harco Drugs v. Holloway, 669 So.2d 878 (Ala. 1995) (pharmacist misread Tamoxifen prescription and filled it with Tambocor, jury found pharmacist negligent and pharmacy responsible for resulting injuries).

⁶⁹¹ See *To Err is Human* (visited Dec. 1999), available at <<http://www.nap.edu/books/0309068371/html/>>.

⁶⁹² See *id.*

⁶⁹³ See *id.*

⁶⁹⁴ Serious issues of privacy, confidentiality, and potential for misuse of online prescription records remain. However, with adequate controls, the potential benefit to patients is real.

electronic interactions.⁶⁹⁵ The program will offer Digital Credentials for physicians, uniquely identifying them over the Internet.⁶⁹⁶ Programs such as the Digital Credentials program should allow pharmacies to communicate more confidently with physicians.⁶⁹⁷ In any event, a simple e-mail is probably more traceable and less prone to error than the present system, where in many cases an employee in a physician's office calls an answering machine in a pharmacy to order a prescription. Handwritten prescriptions should be relegated to the past. Pharmacies should insist on typed prescriptions at a minimum, and encourage physicians to transmit prescriptions electronically. The physician and pharmacy will have a better record of the medication and dosage prescribed and instructions for use, chances for error (and resulting legal liability) will be reduced, and the electronic transmission will facilitate electronic access to medication records by patients and their physicians.

It is already possible for a physician to directly transfer a prescription to a pharmacy using a Palm handheld device together with a wireless Internet connection. On August 1, 2000, ePhysician, a company that combines secure wireless handheld technology and the Internet, announced that it had successfully sent more than 100,000 electronic prescriptions from a Palm handheld to pharmacies in 48 states through its ePad(TM) service.⁶⁹⁸ The company has partnered with Kaiser Permanente, and physicians from the Mid-Atlantic Permanente Medical Group will be using ePhysician's wireless technology to treat up to 40,000 patients.⁶⁹⁹ ePhysician claims to be the first e-health company to provide physicians with point-of-care tools using a secure wireless connection to the Internet through a handheld device. Using Palm handheld devices, physicians can prescribe medication, schedule patients, and view allergy, drug coverage and critical patient information.⁷⁰⁰ In the future, physicians will be able to order and receive lab results, capture patient charges and diagnoses and dictate notes and reports.⁷⁰¹ Physicians can already store a copy of the *Physicians Desk Reference* pharmaceutical information on their Palm to allow them to check for drug interactions, or a third party service, such as a pharmacy benefit manager, can

⁶⁹⁵ See American Medical Association, *AMA Digital Credential FAQs* (visited Dec. 1999) <<http://www.ama-assn.org/ad-com/releases/1999/digcred.htm>>.

⁶⁹⁶ See *id.*

⁶⁹⁷ See *id.*

⁶⁹⁸ ePhysician's ePad is a commercial service that allows physicians to send prescriptions to pharmacies using a secure wireless connection to the Internet. It operates on a Wide Area Network (WAN), allowing physicians to utilize their Palm handhelds from any location. Stuart Weisman, M.D., CEO and founder of ePhysician believes that "[h]ealthcare professionals nationwide are embracing ePhysician's technology because it reduces medical errors and creates tremendous efficiencies for the practicing physician." See ePhysician, *Press Release* (visited Oct. 10, 2000) <<http://www.ePhysician.com/news/index.asp?id=080100>>.

⁶⁹⁹ See *id.*

⁷⁰⁰ See *id.*

⁷⁰¹ See *id.*

review the information before it is transmitted to the pharmacy.⁷⁰²

Although ePhysician claims to have transmitted prescriptions in 48 states, lingering “quill pen” laws could present barriers to implementation of the technology in some states. For example, Florida law requires that a pharmacist who receives a prescription for a “brand name” drug must substitute a less expensive, generically equivalent drug product “unless the prescriber writes the words ‘MEDICALLY NECESSARY,’ in her or his own handwriting, on the face of a written prescription or unless, in the case of an oral prescription, the prescriber expressly indicates to the pharmacist that the brand name drug prescribed is medically necessary.”⁷⁰³ This statute could limit application of the ePhysician technology at present, because the statutory phrase “in her or his own handwriting” presents the question of whether a digital signature would comport with the statute. Presumably the intent of the statute is to promote less expensive generic drugs over their brand name counterparts by requiring the physician to make the extra effort when writing the prescription. However, it does not appear that the handwriting requirement is an attempt to authenticate the prescriber’s identity or status, which is the clear purpose of digital signatures.

In some cases, regulations requiring that written prescriptions for controlled substances be manually “signed” have thwarted electronic transmission of prescriptions. Kansas requires that written prescriptions for controlled substances shall be dated and manually signed on the day issued.⁷⁰⁴ The regulation provides that “[a] practitioner shall manually sign a prescription in the same manner as he would sign a check or legal document.”⁷⁰⁵ In this instance, sending a digital signature should suffice, since the purpose of the regulation seems oriented towards providing adequate security and authentication for controlled substances. In any event, these examples expose the risk inherent in writing legislation that is not technologically neutral.

New York and a number of other states also regulate the electronic transmittal of prescriptions. New York allows a pharmacist to accept an electronically transmitted prescription⁷⁰⁶ from a prescriber subject to several requirements. The requirements include: (1) the prescription must contain the signature or electronic equivalent of the prescriber’s signature, (2) electronically transmitted prescriptions, other than facsimile transmissions, must be electronically encrypted to prevent unauthorized access, alteration or use, and (3) the pharmacy

702 *See id.*

703 FLA. STAT. ANN. § 465.025 (2) (1997).

704 KAN. ADMIN. REGS. § 68-20-18 (c)(2) (1999).

705 *Id.*

706 An electronically transmitted prescription is defined as “a prescription created, recorded, transmitted or stored by electronic means, including but not limited to facsimile but excluding any such prescription for a controlled substance under article 33 [regulating controlled substances] of the Public Health Law.” N.Y. COMP. CODES R. & REGS. tit 8 § 63.6 (7)(i)(1999).

must maintain a hard copy of the prescription for five years.⁷⁰⁷

H. *Automated Pharmaceutical Dispensing Machines*

In the introductory scenario, John picked up his Viagra at an automated pharmaceutical dispensing machine.⁷⁰⁸ The Army has recently tested such an automated drug dispensing systems, and believes that the following scenario will be possible in the not-too-distant future:⁷⁰⁹

A sick soldier about to be deployed on a mission needs antibiotics. He is stationed in a remote site, and the after-hours clinic he visited was unable to fill his prescription. All the pharmacies in town are closed. The soldier pulls up to an automated teller-like machine on post and enters an access code. The prescription is electronically dispensed by a pharmacist and entered on the soldier's medical record. The soldier simply inserts an identification card and the antibiotics are automatically dispensed. A button on the machine initiates contact with a pharmacist to answer any questions the patient has about drug interactions or side effects.⁷¹⁰

Although the technology is promising, regulatory barriers in many states limit the use of automated dispensing machines. For example, at the request of the Texas State Board of Pharmacy, the Attorney General for Texas recently considered whether Texas law permits the use of an automated dispensing machine to dispense prescription drugs at a nursing home.⁷¹¹ At issue was an automated dispensing system machine designed to mechanically sort and then individually label and package oral medications for administration to patients in nursing homes.⁷¹² A licensed pharmacist would load the machine with bulk medications.⁷¹³ A nurse would input a prescription order into a nursing home computer.⁷¹⁴ An off-site pharmacist would review the prescription order together with the patient's medication record, and send an order to the automated dispensing system at the nursing home instructing the machine to prepare and dispense the prescription.

707 N.Y. COMP. CODES R. & REGS. tit. 8 § 63.6 (7)(ii) (1999).

708 *See supra* part I.

709 *See* D. Lana Kagy, 'ATM' Telepharmacy, 3 MILITARY MEDICAL TECHNOLOGY ONLINE 6 (1999), available at <<http://www.mmt-kmi.com/1999archives.cfm>>.

710 *Id.*

711 *See* Op. Tex. Att'y Gen. JC-0186 (Feb. 24, 2000).

712 *See id.*

713 *See id.*

714 *See id.*

Access to the bulk medications contained in the automated dispensing system (other than those dispensed) would be limited to a licensed pharmacist.⁷¹⁵ Such a system could potentially reduce medical error, save time and money, and allow physicians to easily vary dosage and duration of prescriptions based on a patient's response.⁷¹⁶ Automated dispensing systems are already used in some hospitals that hold a valid pharmacy license.⁷¹⁷ However, nursing homes typically do not hold pharmacy licenses, nor do they have a licensed pharmacist on staff.⁷¹⁸

The Texas Pharmacy Act defines a pharmacy as "a facility at which a prescription drug or medication order is received, processed, or dispensed"⁷¹⁹ Under the act, dispense means "to prepare, package, compound, or label, in the course of professional practice, a prescription drug or device for delivery to an ultimate user or the user's agent under a practitioner's lawful order."⁷²⁰ Deliver or delivery means "the actual, constructive, or attempted transfer of a prescription drug or device or controlled substance from one person to another"⁷²¹ Labeling is defined as "the process of affixing a label . . . to a drug or device container"⁷²² The act defines pharmacist as "a person licensed by the Board to practice pharmacy."⁷²³ Finally, the practice of pharmacy includes, among other things, "being responsible for: (i) dispensing a prescription drug order or distributing a medication order; [and] (ii) compounding or labeling a drug or device."⁷²⁴

Since the machine would label, package, and dispense prescription medications, the Attorney General concluded that the machine is legally a "pharmacy" and thus requires a pharmacy license. Further, a pharmacy license entails having a pharmacist on the premises when the pharmacy is open. The nursing home is prevented from using this promising new technology at present. Regulations in several states limit use of automated dispensing machines. The Automation in Pharmacy Initiative (API), a coalition of pharmacy associations, members of state boards of pharmacy, and representatives from the pharmacy automation industry, proposes adoption by states of amendments to the NABP Model State Pharmacy Act to allow broader use of automatic dispensing machines.⁷²⁵ API has also prepared a "White Paper" that addresses technical and

715 *See id.*

716 *See Op. Tex. Att'y Gen. JC-0186, supra note 711.*

717 *See id.*

718 *See id.*

719 TEX. OCC. CODE § 551.003 (2000 Pamphlet).

720 *Id.* § 551.003 (16) (2000 Pamphlet).

721 *Id.*

722 *Id.*

723 *Id.*

724 *Id.*

725 *See White Paper On Automation In Pharmacy, Appendix 1* (visited Nov. 5, 2000)

regulatory issues associated with automation.⁷²⁶ Automated dispensing machines could reduce medical error and provide cost savings in the delivery of medications. If adopted widely, they could also offer added convenience, particularly for patients presently enduring long lines in understaffed pharmacies.

VI. CONCLUSION & PREDICTIONS

At present, the scenario depicted in the introductory hypothetical is more feasible technologically than legally. Poorly considered regulatory efforts could severely thwart the development of cybermedicine. Yet cybermedicine has the potential to deliver cost-effective, convenient, high-quality medical care. The respective roles of the federal and state governments in regulating health care generally, and cybermedicine specifically, are clearly evolving. The issue is complex, because one must consider not only whether the federal or state government *may* constitutionally regulate a particular area of health care, but also which governmental bodies *should* regulate the area. In many cases overlapping jurisdiction and regulation are inevitable.⁷²⁷ Furthermore, the political nature of state medical boards presents a real threat to the growth of cybermedicine. Until the mid-1960s, boards acted almost exclusively as licensing bodies, and rarely disciplined physicians for misconduct.⁷²⁸ As a result of public concern, medical boards significantly increased the number of disciplinary actions against physicians in the late 1980s and early 1990s.⁷²⁹ In this context, it is perhaps not surprising that boards have moved swiftly to establish Internet prescribing “policies” and threaten or discipline physicians attempting to practice cybermedicine.

However, the boards have not provided an adequate forum for discussion of the complex and evolving issues, often bypassing formal rulemaking procedures in favor of more informal “position statements.” Rather than address the more difficult question of the circumstances under which online consulting and prescribing may be proper and provide adequate medical care, they have essentially attempted to regulate the practice out of existence. Certainly some state boards’ insistence on full licensure to practice telemedicine is myopic. However, the role and nature of state medical boards has changed dramatically in the last thirty years

<<http://www.ascp.com/public/pubs/tcp/1998/mar/appendix1.shtml>>.

⁷²⁶ See *id.*

⁷²⁷ See generally *Assessing the New Federalism*, 17 HEALTH AFFAIRS 3 (May/June 1998), available at <<http://newfederalism.urban.org/html/healthaffairs.html#adifferent>>; see also Jill A. Marsteller & Randall R. Bovbjerg, *Federalism and Patient Protection: Changing Roles for State and Federal Government* (Aug. 1999) <<http://newfederalism.urban.org/html/occa28.html>>.

⁷²⁸ See Ross D. Silverman, *State Medical Boards and the Politics of Public Protections: Carl F. Ameringer*, 21 J. LEGAL MED. 143 (1999) (“From the period 1963 to 1967, an average of only .06% of all physicians were disciplined by state boards per year, the majority of these actions involving charges of drug and alcohol abuse and inappropriate prescribing practices.”).

⁷²⁹ See *id.* at 145.

because of public pressure.⁷³⁰ And public demand will drive the growth of cybermedicine—notwithstanding efforts by organized medicine to maintain the status quo. In spite of organized medicines' opposition, we have recently seen a burgeoning demand for "alternative" medicine.⁷³¹

Patients are more informed and self-sufficient in their choices of medical care, and many seem eager to purchase drugs online rather than visit their family physician, disregarding warnings by the FDA, AMA and others. Such patient/consumers even seem willing to forego possible insurance reimbursement, and in some cases pay more for drugs online than they would pay at a local bricks and mortar pharmacy. Perhaps consumers no longer trust the medical profession's disciplinary efforts. Perhaps state medical boards are acting more out of self-interest than public interest. Even veterinary medicine is enacting barriers to telemedicine ostensibly to protect patients. Oklahoma now defines the practice of veterinary medicine to include telemedicine, requiring an Oklahoma license.⁷³²

Cybermedicine cannot thrive so long as we insist that it perfectly replace the practice of medicine with physical contact. Eventually, courts may be willing to allow a different standard of care for physicians practicing across distances without the current ability to "touch" their patients.⁷³³ *Perez*⁷³⁴ shows us that courts will reconsider longstanding legal concepts based on the changing nature of health care.

The federal government has recognized the benefits the Internet can provide in the provision of health care. In his 1997 State of the Union address, President Clinton said that "[n]ow, we should connect every hospital to the Internet, so that doctors can instantly share data about their patients with the best specialists in the field."⁷³⁵ Although the protections contemplated by HIPAA are necessary and worthwhile, the delay in finalizing certain implementing regulations under HIPAA presents barriers to Clinton's vision happening anytime soon. Hospitals may not be willing to spend significant sums of money creating systems allowing physicians to share medical records until they can be confident that such systems will be HIPAA-compliant. State licensure presents even stronger obstacles.

In its 1997 report,⁷³⁶ the Clinton administration identified five key principles guiding the administration's strategy for fostering increased business and

⁷³⁰ See *id.* at 143.

⁷³¹ See *id.* at 150 (in 1997, 629 million visits were made to alternative medicine practitioners in the United States, exceeding the number of visits to primary care physicians).

⁷³² OKLA. STAT. ANN. tit. 59 § 698.11 (West 1999). As a loving owner of Lady, a 20-year-old cat, I cannot believe this statute is intended to protect her interests, but rather to protect those holding veterinary licenses in Oklahoma from competition. The same may be true for physician licensure.

⁷³³ Even "touch" and "feel" via a computer may be possible in the not-too-distant future. See Robert Hercz, *Seeking Computers That Can Feel*, N.Y. TIMES, Nov. 9, 2000, at D19.

⁷³⁴ See *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245 (N.J. 1999).

⁷³⁵ President Clinton, *State of the Union Address* (Feb. 4, 1997) <<http://www.pub.whitehouse.gov/uri-res/I2R?urn:pdi://oma.eop.gov.us/1997/2/5/6.text.1>>.

⁷³⁶ See White House, *A Framework for Global Electronic Commerce* (1997) <<http://www.whitehouse.gov/WH/New/Commerce/summary.html>>.

consumer confidence in the use of electronic networks for commerce. The principles are: (1) the private sector should lead, (2) governments should avoid undue restrictions on electronic commerce, (3) where governmental involvement is needed, its aim should be to support and enforce a predictable, minimalist, consistent and simple legal environment, (4) governments should recognize the unique qualities of the Internet, and (5) electronic commerce on the Internet should be facilitated on a global basis.⁷³⁷ In the area of Internet health care regulation at the state and federal level, we have failed miserably to honor these principles.

What should be the nature of Internet health care regulation? Legislators at all levels should draft any necessary laws using technologically neutral language.⁷³⁸ Such laws should facilitate rather than impede the growth of cybermedicine.⁷³⁹ They should encourage the use of electronic communications.⁷⁴⁰ Finally, the laws should promote consistency and certainty.⁷⁴¹

As we move into an era of evidence-based medicine, we should evaluate whether the crude early cybermedicine prescriptions based solely on a patient's self-assessing questionnaire have caused any harm. The abundance of research into the practice of prescribing and dispensing online in prestigious journals such as the *Journal of the American Medical Association* and in the press show that "there is virtually nothing in the professional literature on any studies or reports of actual patient harm."⁷⁴² In fact, the reported prosecutions have all been based on "stings" performed at the direction of law enforcement officials.⁷⁴³ When Dr. Daniel Carlin sent self-surgery directions via e-mail to a seriously ill Russian sailor alone in the Atlantic, he was heralded as a hero.⁷⁴⁴ Yet a Seattle orthopedic surgeon was accused of unprofessional conduct when he prescribed Viagra on the Internet.⁷⁴⁵ Physicians routinely prescribe via the telephone after office hours when they lack access to patient records.⁷⁴⁶ One author noted that "[i]n its facelessness and need to rely on patient-reported information, Internet medicine may not differ all that much

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Id.

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DOUGLAS E. GOLDSTEIN, *supra* note 171, at 407.

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See id.

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See id.

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See id.

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Virginia Department of Health Professions, *Study of the Sale of Prescription Drugs via the Internet* § B (1997; visited Nov. 4, 2000) http://www.dhp.state.va.us/BHP/internet_prescribing_study_report.htm (noting that there are anecdotal reports of patient harm but problem impossible to quantify because of privacy sought and given for purchasers).

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See, e.g., supra parts V.D and V.F and accompanying notes.

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See Carol M. Ostrom, *Internet Medicine Opens 'Can of Worms,'* SEATTLE TIMES (May 12, 1999), available at <http://seattletimes.nwsources.com/news/health-science/html98/mail_19990512.html>.

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See id.

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See Maxwell J. Mehlman, *The Doctor Will See You Now* (Jan. 2000) <http://www.thedoctorwillseeyounow.com/meditorial/imed_2/> (reporting that in a two-physician practice, 31% of telephone conversations with patients resulted in prescription, and more than half were not for refills).

from so-called traditional medical practice.”⁷⁴⁷

Patients do have a right to legally enforceable privacy, security, and confidentiality for any medical consultations, including those performed via the Internet. HIPAA will eventually provide the legal framework to ensure that these basic rights are protected.⁷⁴⁸ Physicians have a duty to obtain the patient’s informed consent before embarking on a course of therapy, and in the context of cybermedicine that consent should insure that a patient understands the limitations of a given cyber-consultation. But patients should also have the right to consult with a physician via the Internet if they so choose for reasons of privacy, convenience, or otherwise.

Alan S. Goldberg, noted e-health professor, attorney and commentator, remarking on the law regarding online prescriptions, said that “[i]n the short term, it’s a mess,” but “[i]n the long term, I think the patient will win.”⁷⁴⁹ Goldberg believes that consumer demand for accessible health care and pharmaceuticals will eventually cause licensure and other issues to be resolved in a manner acceptable to medical professionals.⁷⁵⁰ “There is zero doubt in my mind that in a certain amount of time, all this stuff will seem like silliness.”⁷⁵¹

⁷⁴⁷ *Id.*

⁷⁴⁸ This may be an overly optimistic assessment. See Cassie M. Chew, *Privacy: Can HHS Rule Protect Privacy, Promote e-Commerce, Industry Asks*, Health Care Daily Rep. (BNA), Mar. 27, 2000.

⁷⁴⁹ Bowman, *supra* note 643.

⁷⁵⁰ See *id.*

⁷⁵¹ *Id.*