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The Taming of E-Health: Asserting U.S. Juridiction over Foreign and Domestic Websites

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THE TAMING OF E-HEALTH: ASSERTING U.S. JURISDICTION OVER FOREIGN AND DOMESTIC WEBSITES

Melissa K. Cantrell*

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I. INTRODUCTION

The Internet is one of the fastest growing markets in the world today. The number of American adults with Internet access grew from roughly 88 million to more than 104 million in the last half of 2000. The number of Internet users worldwide is predicted to grow from 400 million in 2000 to 977 million in 2005. In the United States alone, consumers will spend over \$700 billion purchasing

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See More Online, Doing More: 16 Million Newcomers Gain Internet Access in The Last Half of 2000 As Women, Minorities, And Families With Modest Incomes Continue to Surge Online, PEW INTERNET AND AMERICAN LIFE, (Feb. 18, 2001) http://www.pewinternet.org/reports/reports.asp?Report=30&Section=ReportLevel1&Field=Level1ID&ID=105 (The results of this report were based on data taken from two surveys conducted by Princeton Survey Research Associates. The first was between May 2 and June 30, 2000, of some 4,606 adults 18 and older, 2,277 of them being Internet users. The second took place between November 22 and December 21, 2000, and some 3,493 adults were interviewed, 2,038 of them being Internet users.).

² See Troy Wolverton, Sites Aren't Ready For E-Business Explosion (visited Apr. 28, 2001) http://news.cnet.com/news/0-1007-200-5712022.html?tag=mn hd>.

goods and services online by 2005.3

The health care industry has not taken a backseat in this new medium, and the Internet community has eagerly embraced its presence. According to a Harris Poll released on April 18, 2001, almost 97 million American adults use the Internet to find health-related information.⁴ These adults look for health information on average 3.3 times a month.⁵ But this growing community is hungry for more. For example, many of these consumers would like to see their physicians using the Internet to provide them better quality health care. In a survey released January 8, 2001, 81% of the online population surveyed said they would like to receive e-mail reminders for preventive care, and 83% would like to see follow-up e-mails from their physician after a visit.⁶ While well over half of practicing physicians in America use e-mail, only about 25% use it to communicate with their patients.⁷ Many physicians, however, work in practices that have websites that could easily be adapted to address this consumer need.⁸

Physicians are not the only health care providers to hang out a shingle on the Internet superhighway. Hospitals, pharmacies, pharmaceutical companies, medical device manufacturers and health plans have all joined the rush to tap into this growing web-based patient population.

As with any venture, be it "virtual" or "bricks and mortar," it is vital to understand the risks associated with conducting that business before jumping into the fray. Executives need to know their potential liabilities so they can accurately price their product or service. A crucial part of understanding potential business liability is understanding the legal concept of jurisdiction. Jurisdiction dictates which legislature, court or agency can exert authority over a business and its activities—whether foreign or domestic. If a court can assert jurisdiction over a company, then agencies can enforce their rules and regulations through that court

³ See IDC eWorld 2001 Challenges Accuracy of Current Market Assumptions (visited Apr. 28, 2001) http://www.idc.com/itover/press/IT042401pr.stm (IDC is a leading global market intelligence and advisory firm and its IDC eWorld 2001 Survey was conducted through 27 countries polling the three major subsections of the ebusiness world: CIO/IT managers, business executives, and consumers.).

See Trends & Timelines EHealth: 75% of Adults Use Internet for Health Information, 6 Am. POLITICAL NETWORK 9 (2001).

⁵ See id.

See Harris Interactive, Study Reveals Big Potential For The Internet To Improve Doctor-Patient Relations, 1 HEALTH CARE NEWS, Jan. 8, 2001, available at http://www.harrisinteractive.com/about/healthnews/HI HealthCareNews-V1-Issue1.pdf.

According to an American Medical Association study released on May 9, 2001, about 25% of physicians who use the Internet send e-mail to their patients. See E-Health: AMA Finds Surge in Use of Internet by Physicians, 12 Health Care Report (BNA) 522 (May 11, 2001). Because the study found that 70% of doctors use the Internet, this implies that about 17.5% of all doctors e-mail their patients. See id; but see Harris Interactive, New Data Shows Internet, Web site and Email Usage by Physicians All Increasing, 1 HARRIS INTERACTIVE HEALTH CARE NEWS, Feb. 26, 2001, at 2, available at http://www.harrisinteractive.com/about/healthnews/HI_HealthCareNews2001Vol1_iss8.pdf (reporting that 93% of physicians are currently online, but only 13% of physicians who use e-mail to communicate send e-mail to their patients).

s See id.

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and thereby exercise authority over that business. Agencies have other weapons as well, such as the authority to grant or revoke a license or to prevent the entry of foreign goods into domestic commerce. Once it is clear who has authority, a company can develop a business model that complies with all applicable laws and regulations and limits company exposure to government enforcement or civil actions. Executives will also be able to determine what taxes are due, what consumer protection laws to apply, what licenses to secure, and what privacy protections to incorporate.

Companies doing business on the Internet, whether based in the U.S. or abroad, need to understand their potential risk for criminal prosecution or civil liability here in the United States. No country is an island when it comes to webbased commerce. With the World Wide Web comes a wide world of potential liability. It will serve e-health executives well to understand the role of jurisdiction in this new frontier.

This article explores some recent actions by the U.S. government against domestic and foreign e-health websites and their operators. It also touches on other sanctions that e-health executives should be aware of and guard against. After a look at what can happen to a rogue site, the article explores, in both the domestic and foreign context, how U.S. courts can assert jurisdiction over these sites in order to pursue these actions. The article ends with a warning to anyone involved in an e-health venture: the Internet is not a shield for illegal activity—if it is illegal in the "bricks and mortar" world, then it will be illegal in the "virtual" world.

II. U.S. ACTIONS AGAINST DOMESTIC WEBSITES

Life in the Internet age may move at break-neck speed, but the law has not been left behind. It may be difficult for the courts, Congress, and even attorneys in the trenches to keep up, but keep up they will—keep up, they have. As the court in *UMG Recordings* recently noted, "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." A Department of Justice official said at an American Health Lawyers Association conference on November 3, 2000, "The Internet is not an enforcement-free zone. We try to make sure that what is illegal in the bricks-and-mortar world is equally illegal in the Internet world."

UMG Recordings, Inc. v. MP3.Com, Inc., No.00 CIV. 472(JSR), 2000 WL 1262568, at *6 (S.D. N.Y. Sept. 6, 2000).

DOJ Official Warns Online Pharmacies to Play by Rules or Risk Prosecution, 8 Health Care Policy Report (BNA) 1821 (Nov. 13, 2000) (quoting Ethan M. Posner, Deputy Assistant Associate Attorney General, U.S. Dep't of Justice).

A. Federal Initiatives

Beginning in the 1990's, federal agencies in the United States and abroad started to regulate and prosecute health-related websites. The U.S. Food and Drug Administration ("FDA") has been particularly vigilant in policing e-health sites that sell or promote medical products. In November 1998, the owner of an Internet site selling bogus HIV test kits, Lawrence "Larry" Greene of Los Banos, California, was convicted of six counts of mail fraud and eleven counts of wire fraud in federal court and sentenced to over five years in prison. Greene's "kit" consisted of a plain white cardboard box with a computer-generated label on it containing an opened Band-Aid for placing a drop of blood, a stylus for pricking the finger and another small Band-Aid for covering the prick site. Consumers returned the Band-Aid with a drop of blood on it to Greene for interpretation, but no medical testing was done—according to Greene's wife, he simply held the sample up to the light to determine whether the person was HIV positive or not. Although this is a particularly egregious example, FDA is avidly surfing the Internet for other unscrupulous sites that can potentially harm the public.

In July 1999, the FDA developed an Internet Drug Sales Action Plan that has expanded and improved the agency's ability to address illegal sales of drugs over the Internet. The agency is concerned about sites selling unapproved drugs, or products making unproven claims regarding cancer treatment and miracle weight loss. The problem with these products is that not only may they fail to work, but also they can prevent a person from seeking life-saving medical care in a timely fashion. There is also no guarantee that these products are developed or packaged in a sanitary way, or that they are free of toxic substances. Because of the many health risks associated with these unapproved drugs, the FDA sends warning letters to companies advising them to cease advertising that their supplements cure certain diseases and informing them of the criminal and civil penalties they can face if they

See Paula Kurtzweil, Internet Sales of Bogus. HIV Test Kits Result in First-of-Kind Wire Fraud Conviction, FDA CONSUMER MAG. (July-Aug. 1999) https://www.fda.gov/oc/buyonline/fdacir.html; see also U.S. Dep't of Justice, Press Release, New Jersey Man Admits Distributing Unapproved HIV Home Test Kits (last modified Oct. 25, 2000) https://www.usdoj.gov/criminal/cybercrime/hivtest.htm (pleading guilty to fraud charges the man faced a maximum sentence of three years in prison, a \$250,000 fine, and the possibility of paying restitution and the costs of prosecution).

See Kurtzweil, supra note 11.

See id.

See Jane E. Henney, M.D., E-Regulation and Public Health, Address Before the 2000 Leonard Davis Institute of Health Economics University of Pennsylvania Health Policy Seminar Series (Sept. 29, 2000), available at http://www.fda.gov/oc/speeches/2000/ecommerce.html (last visited Apr. 13, 2001).

¹⁵ See id.

See id.

¹⁷ See id.

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The FDA is also concerned about the sale of approved drugs, in particular Viagra and Xenical, to consumers without prescriptions based solely on the consumers' responses to a simple online questionnaire. The potential for deadly reactions or drug interactions when prescription drugs are taken without the supervision of a licensed physician is considerable. Four individuals from Alabama and Florida were arrested and charged in July 2000, along with a pharmaceutical supply firm, for illegally selling prescription drugs over the Internet. Consumers were told that their questionnaire answers would be reviewed, for a fee, by a physician who would write them a prescription for the drug they wanted. In truth, no medical review took place. Jane E. Henney, M.D., Commissioner of Food and Drugs, said "[t]he investigation of this case and the resulting charges demonstrate FDA's commitment and determination to protect Americans from unscrupulous operators of websites that illegally prescribe, promote, and sell prescription drugs."

From July 1999 to May 2000, the U.S. Department of Justice ("DOJ") filed ten cases in U.S. courts and opened approximately thirty cases involving the sale of drugs on the Internet, twenty of which involved the sale of prescription drugs by online pharmacies.²⁴ The FDA's Action Plan announced that the agency will continue monitoring websites and will make appropriate referrals for criminal or civil actions against those that are violating the law.²⁵

Recently, FDA has begun issuing electronic warning letters, or "cyber" letters, over the Internet to websites that offer to sell online prescription drugs illegally. These letters warn website operators that they may be engaged in illegal activities and inform them of the laws that govern prescription drug sales.²⁶ The agency sent fifty-eight cyber letters in 2000 and forty-five in the first four months

See, e.g., Food and Drug Administration, Warning Letter to John C. Dowd, President, Solocare Pharmaceuticals, Inc. (visited Apr. 30, 2001) http://www.fda.gov/foi/warning-letters/m3883n.pdf.

See Henney, supra note 14.

See U.S. Dep't of Justice, Press Release, Indictment in Internet Sale of Prescription Drugs (Aug. 7, 2000) http://www.usdoj.gov/opa/pr/2000/August/460civ.htm.

²¹ See id.

See id.

²³ *ld*.

See U.S. Dep't of Justice, Testimony of Ethan M. Posner, Deputy Associate Attorney General, Before the Subcomm. on Oversight and Investigations of the House Comm. on Commerce (May 25, 2000) http://www.usdoj.gov/criminal/cybercrime/posner.htm.

²⁵ See Henney, supra note 14.

^{26 .} See Food and Drug Administration, Center for Drug Evaluation and Research, "Cyber" Letters 2000, (visited Apr. 30, 2001) http://www.fda/gov/cder/warn/cyber/cyber2000.htm; Food and Drug Administration, Center for Drug Evaluation and Research, "Cyber" Letters 2001, (visited Apr. 30, 2001) http://www.fda/gov/cder/warn/cyber/cyber2001.htm.

of 2001.²⁷ John M. Taylor, Senior Advisor for Regulatory Policy, Office of Regulatory Affairs has said, "FDA has made Internet surveillance an enforcement priority and the agency plans to take legal actions if appropriate."²⁸

The Federal Trade Commission ("FTC") has also played a significant role in prosecuting unfair and deceptive acts and practices by e-health sites. As early as 1997, the agency joined several foreign and domestic consumer protection agencies in conducting "Surf Days" aimed at identifying e-health sites with potentially false or deceptive advertising claims.²⁹ The agency has sent out hundreds of e-mail messages to websites and newsgroups to inform them that without evidence to back up their claims, they are violating the FTC Act and the agency can bring legal action to halt the violations and possibly recover money for consumers deceived by the advertisements.³⁰

In 1999, the FTC joined forces with the FDA to bring charges against several websites selling ineffective and unapproved HIV test kits. Cyberlinx and its president, Jeffrey S. Stein, agreed in a settlement with the FTC to a lifetime ban from marketing any HIV home test kits and to pay back money received from the sale of the kits after the FDA found that the test kits consistently failed to detect the presence of HIV antibodies.³¹ In March 2000, the agency announced a settlement with Medimax and its president, David M. Rothbart, for representing on their website that their HIV tests accurately detected HIV infection in blood.³² In a stipulated final order, Medimax and Rothbart are permanently banned from marketing any HIV test kit and must pay back all the money received from sales of these tests.³³

The FTC's most recent initiative, "Operation Cure.All," is an ongoing federal and state law enforcement effort as well as a consumer education campaign launched in June 1999 to target bogus health claims on the Internet. As of June 2000, the agency had filed seven law enforcement actions and sent over 800 letters to Internet companies advising them they were making questionable health claims

See supra note 26.

Federal Trade Commission, Press Release, FTC Hits Internet Health Fraud in Continuation of Operation Cure.All: New Cases Target Deceptive Hi-Tech Marketing Techniques (Apr. 5, 2000) http://www.ftc.gov/opa/2000/04/cure-all2.htm.

See Federal Trade Commission, Press Release, North American Health Claim Surf Day Targets Internet

Ads, Hundreds of E-mail Messages Sent (Nov. 5, 1997)

http://www.ftc.gov/opa/1997/9711/hlthsurf.htm.

³⁰ See id.

See Federal Trade Commission, Press Release, FTC and FDA Warn Consumers About Ineffective and Unapproved HIV Test Kits; Announce Joint Law Enforcement Actions (Nov. 17, 1999) http://www.ftc.gov/opa/1999/9911/cyberlinx.htm.

See Federal Trade Commission, Press Release, FTC Settles Charges Against Second Internet Marketer of Inaccurate HIV Tests (Mar. 30, 2000) https://www.ftc.gov/opa/2000/03/medimax3.htm.

³³ See id.

³⁴ See FTC Hits Internet Health Fraud, supra note 28.

as a result of Operation Cure.All.³⁵ One particularly high-profile case involved a one million dollar judgment against Lane Labs and its president, Andrew J. Lane, for making false and unsubstantiated claims regarding shark cartilage.³⁶ The complaint also alleged that the company illegally embedded terms such as "cancer treatment" and "cancer therapy" in its website's metatags,³⁷ which are used by search engines to identify sites related to the term a consumer has used to conduct an Internet search.

Other federal enforcement agencies that can assert jurisdiction over an ehealth website include the Federal Bureau of Investigation ("FBI"), the Office of the Inspector General in the Department of Health and Human Services ("OIG"), and the U.S. Postal Service. Now that President Bush has directed the Secretary of Health and Human Services to allow the proposed privacy regulations to take effect April 14, 2001,³⁸ the Department of Health and Human Services, Office of Civil Rights will also have authority to regulate the compliance of e-health sites with these regulations.³⁹

B. State Initiatives

States are also asserting authority over e-health websites. Several national associations of state entities have led the charge, including the National Association of Attorneys General, the National Association of State Medical Boards, and the National Association of Boards of Pharmacy.

The Kansas Attorney General took an early lead in prosecuting online pharmacies illegally selling prescription drugs over the Internet. In February 1999, Lifestyle USA, Inc. was sued by the Attorney General and the Kansas Board of Pharmacy for deceptive advertising and selling prescription drugs with little or no evaluation of consumer's physical conditions.⁴⁰ The company eventually accepted a permanent injunction and a civil fine of \$9,000.⁴¹ In June 1999, the Attorney

See Federal Trade Commission, Press Release, "Operation Cure.All" Nets Shark Cartilage Promoters: Two Companies Charged with Making False and Unsubstantiated Claims for Their Shark Cartilage and Skin Cream as Cancer Treatments (June 29, 2000) http://www.ftc.gov/opa/2000/06/lanelabs.htm>.

³⁶ See id.

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See White House, Press Release, President's Statement on Medical Privacy Information (Apr. 12, 2001) http://www.whitehouse.gov/news/releases/2001/04/20010412-1.html; Jeff Tieman, Privacy Surprise: Bush Backs Tough Medical-data Standards, MODERN HEALTHCARE, Apr. 16, 2001, at 4.

Office for Civil Rights, Statement of Delegation of Authority, 65 Fed. Reg. 82,381 (Dec. 28, 2000).

See Kansas Attorney General, Press Release, Attorney General Stovall and Kansas Board of Pharmacy File Lawsuit Against Company Selling Viagra on the Internet (Feb. 25, 1999) http://www.ink.org/public/ksag/contents/news-releases/news99/viagra.htm.

See Kansas Attorney General, Press Release, Attorney General Stovall Reaches Settlement With Company Selling Viagra Online (June 16, 2000) http://www.ink.org/public/ksag/contents/news-releases/2000news/lifestyle-settlement.htm>.

General announced she had filed suits against seven companies, six doctors, four individuals doing business under fictitious names, and three out-of-state pharmacies—the Board of Healing Arts joined in one case for the unauthorized practice of medicine and the Board of Pharmacy joined in four for the unauthorized practice of pharmacy.⁴²

The Arizona Attorney General has also sued several e-health sites for consumer fraud on the Internet.⁴³ The Texas and Pennsylvania Attorneys General have charged unlicensed online pharmacies with illegally selling prescription drugs over the Internet,⁴⁴ and the West Virginia Attorney General sued a pharmacy and Internet prescription drug business for selling drugs online to consumers who simply filled out a medical questionnaire that was reviewed by a Romanian doctor who wrote a prescription for those drugs.⁴⁵

Physicians practicing medicine over the Internet need to be sure they are complying with state medical board licensure rules. The Arizona Board of Medical Examiners recently ordered a "virtual" physician to stop prescribing over the Internet without performing a medical examination of those patients. ⁴⁶ If a physician is treating a patient located in a state other than the one where that physician is licensed to practice medicine or dentistry, the physician may be required to comply with the licensure requirements of the state where the patient is located. The Oklahoma Attorney General decided in September 2000 that the Oklahoma Board of Dentistry could regulate out-of-state individuals who practice

See Kansas Attorney General, Press Release, Attorney General Files Lawsuits to Prohibit Internet Drug Sales (June 9, 1999) http://www.ink.org/public/ksag/contents/news-releases/news1999/internetdrugsales.htm>.

See Arizona Attorney General, Press Release (June 21, 2000), (visited Apr. 13, 2001) http://www.attorney_general.state.az.us/press_releases/june/062100.html (filing a consumer fraud lawsuit against A Fresh Life, Inc., a Nevada-based company, for offering consultations and prescriptions over the Internet without a medical examination); Arizona Attorney General, Press Release (Nov. 17, 2000), (visited Apr. 13, 2001) http://www.attorney_general.state.az.us/press_releases/nov/111700.html (settling a consumer fraud lawsuit with an Arizona-based Internet company, a Virginia pharmacy, and an Ohio physician for prescribing and selling prescription drugs over the Internet without a full medical exam; the pharmacy, Choice Rx, Inc., is prohibited from advertising or doing business in Arizona and the pharmacy and physician will jointly pay the State \$5,500 in attorney's fees and costs); Arizona Attorney General, Press Release (Dec. 18, 2000) http://www.attorney_general.state.az.us/press_releases/dec/121800.html (settling with HealthSquare.com for deceiving customers into believing that their interactions with the website would be kept confidential; the company must now clearly state in its privacy policy if it uses cookies, how it uses cookies, and what cookies are, as well as pay \$1,500 in attorney's fee and costs).

See Texas Attorney General, Press Release, Cornyn Sues Online Pharmacies (Aug. 9, 2000), (visited Apr. 13, 2001) http://www.oag.state.tx.us/newspubs/releases/2000/20000809.online.pharm.htm (seeking an injunction against two out-of-state websites, ExpressToday.com and MedPrescribe.com, for selling dangerous drugs and controlled substances based only on a virtual consultation); 8 Health Care Pol'y Rep. (BNA) 790 (May 15, 2000) (suing three online pharmacies for violating Pennsylvania licensing and consumer protection laws).

See West Virginia Attorney General, Press Release, Attorney General Darrell V. McGraw, Jr., Sues West Virginia Pharmacy, An Internet Prescription Drug Business, For Unlawfully Selling Drugs Online to Consumers (Sept. 27, 2000) http://www.state.wv.us/wvae/press/2000/sept/27.htm.

See State Moves to Restrict Physician From Prescribing Drugs Over Internet, 8 Health Care Pol'y Rep. (BNA) 738 (May 8, 2000).

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dentistry in Oklahoma via the World Wide Web.⁴⁷ "Virtual" physicians should also beware of the corporate practice of medicine doctrine, still strong in several states.

E-health sites should also be concerned about state consumer protection laws that protect citizens against deceptive practices and advertisements. For example, many consumer protection acts mandate that companies divulge any material fact to a consumer that is not otherwise readily available. Information about who is getting your personal information, how it is collected, and what is being done with it can be considered a material fact, ⁴⁸ but merely posting a privacy policy is not enough. Failure to comply with a privacy policy posted on your website may invoke the wrath of not only state Attorneys General, but the Federal Trade Commission as well.

III. JURISDICTION OVER DOMESTIC WEBSITES

A. Subject Matter Jurisdiction

Before a court can hear a case, it must be established that the court has the competency to hear the case—this is known as subject matter jurisdiction. Any judgment rendered by a U.S. court lacking subject matter jurisdiction is void. This issue can be raised at any point in the judicial process, and is not an issue the parties to a case can waive. If a court lacks subject matter jurisdiction there is no discretion for it to hear the case. The Constitution of the United States gives very limited judicial power to the federal courts, but Congress has given the federal courts exclusive jurisdiction over several types of actions such as those arising under the patent and trademark or civil rights laws. This results in the vast

See Digest of Opinions of Attorney General W.A. Drew Edmondson, 36 Dig. ATT'Y GEN. Op. (Oklahoma) 3, Opinion 00-41 (Sept. 6, 2000), available at http://www.oag.state.ok.us/ ("Under appropriate facts, the Oklahoma Board of Dentistry has aut[h]ority to regulate individuals physically located outside the State who practice dentistry... in the State of Oklahoma via the Internet.").

Several Attorneys General brought actions against Double Click, Inc. for using "cookies," or electronic surveillance files, to compile consumer profiles without telling site visitors that a cookie would be installed on their hard drive or getting visitor's consent. See, e.g., South Carolina Attorney General's Office, Press Release, Condon Announces Investigation of Double Click, Inc. (Mar. 16, 2000) http://www.scattorneygeneral.com/scattorneygeneral/press_release.nsf/ frmPressRelease?CreateDocument&unid=072297C32CEE4EB7852568A8005C9307>; Jennifer M. Granholm, Michigan Attorney General, Press Release 00-007 (Feb. 17, 2000) http://www.ag.state.mi.us/.

See Pennoyer v. Neff, 95 U.S. (5 Otto) 714, 732-33 (1877).

See FED. R. CIV. P. 12(h)(3) ("Whenever it appears by suggestion of the parties or otherwise that the court lacks jurisdiction of the subject matter, the court shall dismiss the action."); ef. CAL. CIV. PROC. CODE § 430.80(a) (West 2001); MINN. STAT. ANN. § 12.08(c) (West 2000).

See Cutler v. Rae, 48 U.S. 729, 731 (1849) ("But the consent of parties cannot give jurisdiction to the courts of the United States, in cases where it has not been conferred by the Constitution and laws.").

See U.S. CONST. art. III, § 2.

⁵³ See 28 U.S.C. § 1338 (1994 and Supp. IV 1998).

majority of cases being heard in state courts.

The first step in determining which court, federal or state, is competent to hear a case is to look at the relevant statute that is being enforced. In particular, the Food, Drug and Cosmetic Act explicitly vests authority over violations of the Act in the federal courts. However, many states have similar laws regulating these substances and devices and violations of these laws would be redressed in state court. If the statute is ambiguous, then the second step would be to look at the Constitutional grant of power to federal courts in Article III of the U.S. Constitution. If authority is not exclusively reserved to the federal courts, then the case may be heard in state court.

B. Personal Jurisdiction

For domestic websites doing business in the United States, it is fairly obvious that a federal court would be able to assert personal jurisdiction over any person or organization on American soil. The analysis gets a little more complicated, however, when one state is trying to assert personal jurisdiction over a nonresident entity or individual.

The first step in a personal jurisdiction analysis is to determine if there is a legislative grant of authority for a court to exercise jurisdiction over a defendant. If the action is brought in state court, one must look to that state's long-arm statute to determine when the court can assert jurisdiction over a nonresident of that state.⁵⁷ If the case is filed in federal court, first look at the applicable statute for a specific authorization for nationwide service of process and if that is not available, in the case of civil actions, look to the "long-arm" statute of the State in which the court is located.⁵⁸ In federal criminal actions, a warrant can be served anywhere in the United States.⁵⁹

The second step is to determine if the exercise of personal jurisdiction is constitutional under the Due Process clauses of the Fifth Amendment⁶⁰ and Section 1 of the Fourteenth Amendment.⁶¹ In the early days of American commerce, once it was established that a particular court had the authority to hear a case (and thus subject matter jurisdiction was satisfied), personal jurisdiction was easily

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<sup>54</sup> See 28 U.S.C. § 1343 (1994).
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⁵⁵ See 21 U.S.C. § 332(a) (1994).

See, e.g., TEX. HEALTH & SAFETY CODE ANN. § 431.047(a) (West 1992) (Texas Food, Drug, and Cosmetic Act).

⁵⁷ See, e.g., N.Y. C.P.L.R. § 302 (McKinney 1990 & Supp. 2000) (New York long-arm statute).

⁵⁸ See FED. R. CIV. P. 4(k).

⁵⁹ See FED. R. CRIM. P. 4(d)(2), 9(c)(1).

U.S. CONST. amend. V ("No person shall . . . be deprived of life, liberty, or property, without due process of law. . . .").

U.S. CONST. amend. XIV, § 1 ("nor shall any State deprive any person of life, liberty, or property, without due process of law...").

determined using geographic boundaries.⁶² If a business was located within a forum, that forum had jurisdiction.⁶³ Specifically, a court of a particular state could get jurisdiction if real property was located in that state (*in rem* jurisdiction) or if the parties were located in that state (*in personam* jurisdiction).⁶⁴ If a business was located in the United States, federal agencies generally had the authority to regulate that business. Physical presence in a forum continues to be a conventional basis for jurisdiction,⁶⁵ but as American commerce matured, geographic boundaries became obsolete.

The United States Supreme Court noted in 1958 that "[a]s technological progress has increased the flow of commerce between States, the need for jurisdiction over nonresidents has undergone a similar increase." A new framework for evaluating jurisdiction arose in the landmark case of *International Shoe Co. v. Washington*, which established the "minimum contacts" test for asserting jurisdiction over an out-of-state defendant. Courts apply the "minimum contacts" standard using a two-step approach. First, a determination regarding the existence of minimum contacts is made, and then the court will consider if asserting jurisdiction comports with "traditional notions of fair play and substantial justice."

Today, the Internet ushers in the next step in the evolution of jurisdiction determinations. The United States Supreme Court noted in 1985 that "it is an inescapable fact of modern commercial life that a substantial amount of business is transacted solely by mail and wire communications across state lines, thus obviating the need for physical presence within a State in which business is conducted." The landmark case for Internet jurisdiction analysis, *Zippo Manufacturing Co.*, established a "sliding scale" test to determine when jurisdiction is appropriate based on the content and function of the website.⁷⁰

In the e-health context, it is highly unlikely that the operators of a website will have property in the forum state, so the most likely means of asserting jurisdiction would be over the party itself. There are two broad classes of *in personam* jurisdiction—specific and general. For specific jurisdiction, the suit must

See Pennoyer, 95 U.S. at 722 (holding that states have exclusive authority over persons and property within their territory, but not without their territory).

⁶³ See id.

⁶⁴ See id.

⁶⁵ See Burnham v. Superior Court, 495 U.S. 604, 610 (1990).

⁶⁶ Hanson v. Denckla, 357 U.S. 235, 250-51 (1958).

^{67 326} U.S. 310, 316 (1945).

⁶⁸ World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 291-92 (1980).

Burger King Corp. v. Rudzewicz, 471 U.S. 462, 476 (1985) (observing that jurisdiction is not avoided just "because the defendant did not *physically* enter the forum state.").

⁷⁰ See Zippo Mfg. Co. v. Zippo Dot Com, Inc., 952 F. Supp. 1119, 1124 (W.D. Pa. 1997).

arise out of or be related to the defendant's contact with the forum⁷¹ and this contact must meet the "minimum contacts" test articulated in *International Shoe* so that "traditional notions of fair play and substantial justice" are satisfied.⁷² Specific jurisdiction also requires either isolated or occasional contacts purposefully directed toward the forum, and that the exercise of jurisdiction be reasonable.⁷³ For suits that do not arise out of or relate to a defendant's contact with a forum, the court may assert general jurisdiction as long as the defendant's contacts with the forum state are "systematic and continuous" enough to make the assertion of jurisdiction just.⁷⁴ Courts have found both specific and general jurisdiction in cases involving a website.

In the context of Internet defendants, U.S. courts have generally held that states cannot assert jurisdiction over passive websites that merely post information, however, jurisdiction is appropriate if the provider facilitates the transaction of business on the site. In *Cybersell Inc. v. Cybersell, Inc.*, the appellate court held there must be something more than an Internet advertisement "to indicate that the defendant purposefully (albeit electronically) directed his activity in a substantial way to the forum state." ⁷⁵ The leading case in this area is *Zippo Manufacturing Co.*, which established the "sliding scale" test for personal jurisdiction analysis in an attempt to synthesize the various results of different courts. ⁷⁶ At one end of the spectrum, a website clearly conducting business over the Internet would be subject to personal jurisdiction in a forum, and at the other end, a defendant simply posting information on the site would not. ⁷⁷ In the middle of the sliding scale, a user exchanges information with a website and the level of interactivity and the commercial nature of this exchange determines whether asserting jurisdiction is appropriate or not. ⁷⁸

Although typically a "passive" website that simply posts information would not invoke personal jurisdiction, there is a minority view that continuous advertising over the Internet would be sufficient. Most courts, however, require

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71 See CompuServe, Inc. v. Patterson, 89 F.3d 1257, 1267 (6th Cir. 1996).
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⁷² International Shoe, 326 U.S. at 316.

⁷³ See Bancroft & Masters v. Augusta Nat'l, Inc., 223 F.3d 1082, 1086 (9th Cir. 2000) (finding that specific jurisdiction is appropriate where the defendant has purposely availed himself of the forum, the suit arises out of the defendant's activities in the forum, and the exercise of jurisdiction is reasonable).

⁷⁴ See Helicopteros Nacionales de Colombia, S.A. v. Hall, 466 U.S. 408, 414-15, n.9 (1984).

^{75 130} F.3d 414, 418 (9th Cir. 1997).

⁷⁶ Zippo, 952 F. Supp. at 1124.

⁷⁷ See id.

⁷⁸ See id.

See Telco Communications Group, Inc. v. An Apple a Day, Inc., 977 F. Supp. 404, 406-07 (E.D. Va. 1997) (holding that posting press releases on the Internet satisfied the Virginia long-arm statute); Inset Systems, Inc. v. Instruction Set, Inc., 937 F. Supp. 161, 165 (D. Conn. 1996) (holding that consistent and repetitive advertising on the Internet, which included a toll-free number, was soliciting business in Connecticut for purposes of asserting personal jurisdiction).

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"something more." In a recent e-health case, *Bradley v. Mayo Foundation*, the court held that a Kentucky resident who was treated in Minnesota at the Mayo Clinic could not sue the Clinic in Kentucky simply because the Clinic operated two websites accessible by Kentucky residents. However, the court implied that if the patient's treatment had occurred in Kentucky over the Internet the result would be different. E2

IV. U.S. ACTIONS AGAINST FOREIGN WEBSITES

An increasing percentage of online drug sales are conducted through websites based in foreign countries.⁸³ When a foreign-based online pharmacy sells prescription drugs to consumers in the United States without a prescription it not only violates U.S. law, but also the United Nations Convention Against Illicit Traffic in Narcotics and Psychotropic Substances.⁸⁴ Any operator of an offshore online pharmacy that illegally sells controlled substances or unapproved drugs to U.S. residents can be prosecuted in the U.S. upon entering the country.⁸⁵

The FDA recognizes that the global nature of the Internet is making law enforcement more difficult; the agency has said that it plans to "work extremely closely with foreign governments to share information and to develop mechanisms for cooperative law enforcement." Its 1999 Internet Drug Sales Action Plan included working with foreign governments to prosecute foreign individuals who sell unapproved drugs in the United States. The internet is making law enforcement in plans to "work extremely closely with foreign governments to prosecute foreign individuals who sell unapproved drugs in the United States.

The FDA has issued several warning letters to international websites reminding them of their legal obligations if they market to consumers in the United States. The following example addresses how international companies selling both devices that are approved by the FDA and devices that are not approved can advertise on the Internet:

Since your company holds 510(k)s and an IDE in the US, the international site at xxx in order to be in compliance, would need to have a US icon and a European or International icon that would

Cybersell, 130 F.3d at 418; see also Uncle Sam's Safari Outfitters, Inc. v. Uncle Sam's Army Navy Outfitters-Manhattan, Inc., 96 F. Supp. 2d 919, 922-23 (E.D. Mo. 2000).

See No. CIV.A.97-204, 1999 WL 1032806, at *19-20 (E.D. Ky. Aug. 10, 1999).

See id. at *10 (discussing McGee v. Riekhof, 442 F. Supp. 1276 (D. Mont. 1978), where the cause of action arose from a telephone diagnosis originating in Utah and received by the patient in Montana).

⁸³ See DOJ Official Warns Online Pharmacies, supra note 10, at 1822.

See Testimony of Ethan M. Posner, supra note 24, at *9.

⁸⁵ See id.

Henney, supra note 14, at *4.

⁸⁷ See id.

separate the FDA cleared information that appears for the US devices. International information, which I assume would include information on uses and devices that have not received FDA clearance, cannot be promoted to a US customer. In looking at your international site there is no clear distinction between devices intended for the US.[sic] audience and those intended for other than the US. xxx although headquartered in (foreign country) still has to meet the same requirements as any other company that promotes and advertises devices that have received marketing clearance in the US.

We therefore suggest that the international site be revised.

Office of Compliance Promotion and Advertising Policy Staff⁶⁸

In addition to identifying which devices are and are not approved in the U.S., it will also be important to verify that U.S. citizens are not purchasing unapproved devices. A disclaimer on the site could state that unapproved devices will not be sent to U.S. addresses, and then any orders for unapproved devices that come from the U.S. should be discarded. In the name of good customer service, a reply e-mail could remind the customer that the product ordered is not approved by the FDA and may not be shipped to a U.S. address.

The FDA issued fifty-eight "cyber" letters in 2000 and forty-five as of April 2001 to operators of Internet sites illegally selling online prescription drugs without a prescription—half of these were foreign-based sites. ⁸⁹ The letters warn these website operators they may be engaged in illegal activities, provide them with an explanation of the statutory provisions that govern interstate commerce of drugs in the United States, and warn them of possible detention and refusal of entry of their product into this country. ⁹⁰ Copies of these letters are sent to regulatory drug officials in the country from which the sites are operated and the U.S. Customs Service through an Import Alert. ⁹¹

In the fall of 2000, consumer protection agencies from eight countries, six U.S. agencies including the FTC and the Department of Justice, and twenty-one

Food and Drug Administration, Advertising of Medical Devices on the Internet (last modified Feb. 15, 2001) http://www.fda.gov/cdrh/devadvice/21xxx.html#top.

See Food and Drug Administration, Center for Drug Evaluation and Research, "Cyber" Letters 2000 (visited Apr. 30, 2001) http://www.fda/gov/cder/warn/cyber/cyber2000.htm; Food and Drug Administration, Center for Drug Evaluation and Research, "Cyber" Letters 2001 (visited Apr. 30, 2001) http://www.fda/gov/cder/warn/cyber/cyber2001.htm.

See supra note 88.

See Food and Drug Administration, FDA Talk Paper, FDA Launches "Cyber" Letters Against Potentially Illegal, Foreign-based On-line Drug Sites (Feb. 2, 2000) http://www.fda.gov/bbs/topics/ ANSWERS/ANS01001.html>; Food and Drug Administration, Center for Drug Evaluation and Research, "Cyber" Letter to Mr. Juergen Schneider (Mar. 12, 2001) http://www.fda.gov/cder/warn/cyber/2001/Cyber094.pdf>.

state Attorneys General participated in "Operation Top Ten Dot Cons." Health care claims were ranked among the top ten scams taken from FTC databases. The FTC has also been active in the development of international guidelines to protect consumers; on December 9, 1999, the Committee on Consumer Policy of the Organization for Economic Cooperation and Development ("OECD") released a set of general guidelines to protect consumers participating in business-to-consumer electronic commerce. These guidelines were meant to ensure that consumers have just as much protection when shopping online as they do when shopping in a store or by catalog. The FTC is also currently serving as president of the International Marketing Supervision Network, an association of consumer protection agencies from twenty-nine countries. These agencies are working together to combat fraud and deception on the Internet.

V. JURISDICTION OVER FOREIGN WEBSITES

The Internet is changing how international law is formed and enforced. The Internet invites new forms of regulation, as lawmakers struggle to extend their jurisdiction over Internet conduct that has effects within their territory. In order for a U.S. court to assert jurisdiction over a foreign-based website, it must satisfy the requirements of both subject matter jurisdiction and personal jurisdiction.

A. Subject Matter Jurisdiction

When determining if a U.S. court has subject matter jurisdiction over a case against a foreign website operator, the first thing to consider is where the action or offense takes place. If in the United States, then the same analysis for

Office of Maryland Attorney Gen. J. Joseph Curran, Jr., News Release, Curran Targets "Top 10"
Online Scams: Joins Consumer Protection Cops Tackling Internet Fraud (Oct. 31, 2000)
http://www.oag.state.md.us/Press/2000/103100.htm.

⁹³ See id.

See Organization for Economic Cooperation and Development, OECD Guidelines for Consumer Protection in the Context of Electronic Commerce (visited May 7, 2001) http://www.oecd.org/dsti/sti/it/consumer/prod/guidelines.htm>.

See id.

See Federal Trade Commission, Speech by Robert Pitofsky, Chairman of the Federal Trade Commission, at the American Bar Association 2000 Annual Meeting Plenary Session on Cyberspace Jurisdiction, Balancing The New Powers and Interests of Consumers and Business in Cyberspace Commerce (visited Apr. 13, 2001) http://www.ftc.gov/speeches/pitofsky/abaremarks.htm; see also International Marketing Supervision Network (IMSN), (visited May 7, 2001) http://www.imsnricc.org/.

⁹⁷ See Speech by Robert Pitofsky, supra note 96, at n.5.

See Henry H. Perritt, Jr., The Internet is Changing the Public International Legal System (visited May 7, 2001) http://www.kentlaw.edu/cyberlaw/perrittnetchg.html>.

⁹⁹ See id.

domestic sites should apply. When conducting business in the U.S., a foreign organization will be subject to the same laws as a domestic organization. ¹⁰⁰ The advent of the Internet, however, challenges this determination because it is difficult to localize the legally relevant conduct that occurs on the Internet. ¹⁰¹ In Internet gambling cases, U.S. courts have identified the location of the action or offense as the place of downloading. ¹⁰² In a recent New York case, the court rejected World Interactive Gaming's argument that the gambling on its website occurred in Antigua, not New York, because its servers were located in Antigua. ¹⁰³ The court made clear that a "computer server cannot be permitted to function as a shield against liability." ¹⁰⁴

Since this is an emerging area of the law, however, should a court find that the locus of activity is the overseas server, the law at issue can only be applied extraterritorially. To do this, a court would have to determine that Congress has mandated such extraterritorial application and the effect of the action on the United States justifies exercising jurisdiction in this case. The Commerce Clause of the U.S. Constitution gives Congress the power to enact laws that operate extraterritorially. Some laws specifically preclude certain acts in foreign commerce, such as the Wire Act, which prohibits certain communication in interstate or foreign commerce. This specific language suggests that Congress intended courts to have extraterritorial jurisdiction over violators of this Act. If extraterritorial application of a U.S. law is not possible, an agency can look to international treaties for a basis of asserting jurisdiction over a foreign defendant.

B. Personal Jurisdiction

When determining whether a United States court can exercise personal jurisdiction over an international website, the same analysis used for purely domestic cases should be applied. The first case to discuss the issue of specific jurisdiction over a website in an international context was *Minnesota v. Granite Gate Resorts*. *Inc.* ¹⁰⁸ Granite Gate Resorts, Inc., a Nevada corporation, advertised

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          See id.
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          See id.
102
          See Adrian Goss, Jay Cohen's Brave New World: The Liability of Offshore Operators of Licensed
Internet Casinos for Breach of United States' Anti-gambling Laws, 7 RICH. J.L. & TECH. 32, at 34 (2001).
103
          See Vacco v. World Interactive Gaming Corp., 714 N.Y.S.2d 844, 850 (N.Y. App. Div. 1999).
104
          Id.
105
          See United States v. Aluminum Co. of Am., 148 F.2d 416, 443-44 (2d Cir. 1945).
108
          U.S. CONST. art. 1, § 8, cl. 3 ("The Congress shall have the power . . . [t]o regulate commerce with
foreign nations, and among several states, and with the Indian tribes").
107
          See 18 U.S.C. § 1084(a) (1994).
108
          568 N.W.2d 715 (Minn. Ct. App. 1997).
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on a website that was maintained on a web server located in Belize. The Minnesota Court of Appeals held that personal jurisdiction over the defendant was justified because the website was accessible by Minnesota residents, and the defendant had directed its advertisements at customers in the United States, including residents of Minnesota. 110

In 1997, the United States District Court for the District of New Jersey addressed whether a United States court could exercise general personal jurisdiction over a foreign defendant based solely on maintenance of a passive website. The defendant, Jolly Hotels, was located in Italy and maintained a website as an advertisement. The plaintiff, a New Jersey resident, sued the defendant in New Jersey state court for injuries sustained while visiting the Italian hotel, claiming the New Jersey court could assert personal jurisdiction over the defendant based on its website. The court determined that advertising on a website is comparable to advertising in a national magazine and is insufficient to allow the forum court to establish general personal jurisdiction when the injury was not related to the website. The

In Quokka Sports, Inc. v. Cup International, Ltd., a California court found that the foreign defendants were subject to personal jurisdiction based on their Internet activities. The holding of the court focused on the intended audience for its America's Cup website, and the court noted that in this case the defendant set up websites that specifically targeted the United States. The fact that ten banner ads for U.S. companies encouraged visitors to click on and go to those websites led the court to characterize the website's activity as commercial and aimed at U.S. consumers. 117

The global nature of the Internet creates many problems for effective law enforcement. Even if a court is found to have both subject matter and personal jurisdiction and renders a judgment against a foreign website operator, it may be difficult to enforce the judgment against that operator. There are several tools, however, to address the challenges of prosecuting offshore sales and other activities on the Internet. First, the United States must continue working with foreign governments to reduce the use of the Internet for illegal activity. Examples of

¹⁰⁹ See id. at 717.

¹¹⁰ See id. at 721.

See Weber v. Jolly Hotels, 977 F. Supp. 327 (D. N.J. 1997); see also Smith v. Hobby Lobby Stores Inc., 968 F. Supp. 1356, 1365 (W.D. Ark. 1997) (finding no jurisdiction over Hong Kong defendant that merely posted an advertisement on the Internet without selling any goods or services in Arkansas).

¹¹² Weber, 977 F. Supp. at 329.

¹¹³ See id. at 330-31.

¹¹⁴ See id. at 333-34.

⁹⁹ F. Supp. 2d 1105, 1113-14 (N.D. Cal. 1999).

¹¹⁶ See id. at 1112.

¹¹⁷ See id.

international cooperation include the United States' work with the Council of Europe to draft a Cybercrime Convention, 118 and the Group of Eight ("G-8") nations to enhance the abilities of law enforcement to investigate and prosecute computer crimes. 119 Second, the Justice Department and other enforcement authorities can reduce the flow of money to these foreign websites and their operators by enjoining the dissipation of assets, including credit card accounts. 120 "If enforcement agencies and financial institutions can stop even some of the credit card orders used for the illicit sale of controlled substances or prescription drugs, then the operations of some of these 'rogue' online pharmacies may be disrupted significantly." 121 Third, the agency could seek a warrant for the arrest of an offshore website operator, which would prevent that person from traveling to the United States. Finally, to the extent an operator has assets in the United States, the government could seize them. 122

If a warrant is granted against a foreign national, a prosecutor will contact the Office of International Affairs in the Criminal Division of the Department of Justice. 123 This office assists federal, state and local prosecutors with issues related to the extradition of foreign nationals to the United States. 124

VI. CONCLUSION

Foreign and domestic e-health executives need to be aware of the jurisdictional effects of how their websites are designed. Use of a passive website that merely posts information will minimize the risk of being haled into any foreign or domestic court. However, because consumers are demanding more from e-health, it is unrealistic to believe that a company can remain competitive by maintaining a passive website. The more interactive and commercially oriented a site becomes, the more important it will be to consult with legal counsel to ensure that the organization complies with all applicable federal and state laws. Executives must remember that the Internet is not a shield for illegal activity—if it's illegal in the "brick and mortar" world, then it will be illegal in the "virtual" world.

The most recent Draft was released on December 22, 2000 and defines offenses and addresses such topics as jurisdiction, international cooperation, and search and seizure. See European Committee on Crime Problems, Committee of Experts on Crime in Cyber-space, Draft Convention on Cyber-crime, Draft No. 25 Rev. 5 (Dec. 22, 2000) https://conventions.coe.int/treaty/EN/ projets/cybercrime25.htm>.

See Testimony of Ethan M. Posner, supra note 24, at *9.

See DOJ Official Warns Online Pharmacies, supra note 10, at 1822.

Testimony of Ethan M. Posner, supra note 24, at *9.

¹²² See Goss, supra note 102, at *81.

See Department of Justice, Criminal Division, Office of International Affairs (visited May 8, 2001) http://www.usdoi.gov/criminal/oia.html.

See id.