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Nicolas P. Terry

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NICOLAS P. TERRY*

INTRODUCTION

When a politician hails the importance of a global economy[1] or a popularizer[2] reports that our social and economic worlds have been flattened,[3] patients, health care providers, and health lawyers may nod sagely in agreement. In their hearts, however, they know that health care is in denial. And they have good reason to be skeptical. Domestic health care seems resistant to market functioning and there is little evidence it is ready to take its place in the global economy. Doctors are subjected to state rather than national licensure and discouraged from reaching beyond state or national borders with the Internet technologies used by every other industry. Hospitals are hampered by immigration policies when they seek to overcome physician shortages. Patients are denied access to drugs or treatments that are cheaper across nearby borders.

Yet, health care is becoming more global in ways that patients and even some providers do not realize. Modern health care may still appear to be local, but how many patients know that, increasingly, their prescription drugs are being tested on foreign populations, that there is little tracking of exactly where or by whom the

* Chester A. Myers Professor of Law, Co-Director, Center for Health Law Studies, Professor of Health Management & Policy, Saint Louis University, e-mail: terry@slu.edu. I thank Professor Margaret H. McDermott, SLU Law Library, and Natalie Kean, SLU J.D. candidate, for their enthusiastic and valuable research assistance and Michael Henderson, SLU J.D./M.H.A. candidate, for his editorial suggestions. Sandra Johnson, Tim Jost, Tom McLean, Kevin Outterson, and Kandis Scott were exceptionally generous with their time in making suggestions or commenting on earlier drafts.

1. *See, e.g.*, *Address Before a Joint Session of the Congress on the State of the Union*, 42 WKLY. COMP. PRES. DOC. 145, H17 (Jan. 31, 2006), *available at* http://www.gpoaccess.gov/sou/06sou.pdf ("With open markets and a level playing field, no one can out-produce or out-compete the American worker.").

2. *See Confusing Columbus*, THE ECONOMIST, Mar. 31, 2005, at 77.

3. THOMAS L. FRIEDMAN, THE WORLD IS FLAT: A BRIEF HISTORY OF THE TWENTY-FIRST CENTURY (2005).

history they just gave their doctor is being transcribed and processed, or that their CAT scan performed in a U.S. emergency room is analyzed a few minutes later by a radiologist on the other side of the world?

This Article examines two intersecting phenomena: medical tourism and the outsourcing of health care goods and services. "Medical Tourism" (Part I) involves the resident of one state or country physically experiencing health care in another place. "Outsourcing" (Part II) involves care that appears domestic but has been disaggregated to allow some components to be performed non-domestically. Frequently the patient (or in the case of final beneficiaries of a clinical trial, a domestic user of a subsequently approved drug) does not know that care has been outsourced.

These two phenomena currently operate outside, and may be disruptive of, contemporary Western health care regulation. While health care, particularly in the U.S., is our most highly regulated industry, medical tourism and outsourcing appear to operate outside our traditional regulatory matrix. Having examined the extent to which this is an accurate intuition, this Article questions (in Part III) the extent to which we do or will enjoy increased trading of health services and addresses some of the issues that must be considered in approaching any regulatory questions posed by medical tourism and outsourcing.

I. MEDICAL TOURISM

The terms "medical tourism" and "health tourism" refer to treatments or surgery that have been planned in advance to take place outside a patient's usual place of residence.[4] Originally, such tourism literally and rather quaintly applied to vacations at European spas. As communications and travel improved, medical tourism was used, somewhat pejoratively, to describe the travel of patients from less-developed countries seeking superior health care in industrialized countries—a transfer that continues today with

4. Atul D. Garud, *Medical Tourism and its Impact on Our Healthcare*, 18 NAT'L MED. J. INDIA 318, 318-19 (2005).

major medical centers in Europe[5] and the U.S.,[6] attracting high profit self-payers from other countries.[7]

Today, however, it is more likely that the journey is reversed, as patients travel from industrialized countries to less-developed nations.[8] Such patients are attracted by the lower costs of procedures in less-developed countries, the opportunity to avoid their home country's health care rationing (e.g., waiting lists for certain surgical procedures),[9] the need for a procedure still under regulatory review in their home country,[10] or a belief in the healing potential of alternative procedures or medicines such as laetrile.[11] Patients who fall ill while visiting abroad (e.g., "snowbirds") are generally not viewed as medical tourists. There are, however, some unplanned scenarios that raise similar issues to those raised by planned medical tourism—for example, the accident victim who

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5. *See, e.g.*, Munich Airport, Doctors and Health Insurers, http://www.munich-airport.de/EN/Areas/Consumer/Service/aerzte_und_Krankenkassen/index.html (last visited Mar. 18, 2007) (listing available medical services on the Munich International Airport website).

6. *See, e.g.*, Johns Hopkins Int'l, http://www.jhintl.net/jhi/english/default.asp (last visited Mar. 18, 2007); Philadelphia Int'l Medicine, http://www.philadelphiamedicine.com (last visited Mar. 18, 2007); Mayo Clinic, Services for International Patients, http://www.mayoclinic.org/english/services.html (last visited Mar. 18, 2007).

7. Steven Findlay, *U.S. Hospitals Attracting Patients from Abroad*, USA TODAY, July 22, 1997, at 1A, *available at* 1997 WLNR 3052799 (Westlaw) (reporting that generally there were increases in tourism traffic at leading U.S. medical centers, and that specifically, 6,000 medical tourists were treated at Johns Hopkins in 1996, and a projected 7,200 would be treated at the Mayo Clinic in 1997).

8. *See* Peter Foster, *Britons Flock to India for Fast, Cheap Surgery*, DAILY TELEGRAPH (London), Aug. 27, 2005, at 4, *available at* 2005 WLNR 13494018 (Westlaw); Prithi Yelaja, *India Offers Surgery in a Hurry*, TORONTO STAR, June 17, 2006, at A01, *available at* 2006 WLNR 10481733 (Westlaw).

9. *See NHS Waiting Lists at 17-Year Low*, BBC NEWS, Nov. 12, 2004, http://news.bbc.co.uk/2/hi/health/4006181.stm (noting September 2004 wait list of 856,600 people, a decline of 300,000 since March 1997). *But see* Brian Donelly, *Patients Still Wait 234 Days for Hip Operations*, THE HERALD (Scotland), Apr. 24, 2006, *available at* http://www.theherald.co.uk/news/60630.html (noting a delay of up to seven months for hip replacement surgery).

10. Jean P. Fisher, *Hip Patients Find Surgeons Overseas: Delay in FDA Approval for Hip Resurfacing Means Lost Opportunity at Duke*, NEWS & OBSERVER (Raleigh, N.C.), Apr. 10, 2006, *available at* 2006 WLNR 6007736 (Westlaw).

11. *See, e.g.*, Barron H. Lerner, *McQueen's Legacy of Laetrile*, N.Y. TIMES, Nov. 15, 2005, at F5, *available at* 2005 WLNR 18424239 (Westlaw); *Patients, Like King, Seek Hope in Mexico*, FT. WAYNE J. GAZETTE (Fort Wayne, Ind.), Feb. 5, 2006, at A10, *available at* 2006 WLNR 2095649 (Westlaw); *see also* Rutherford v. United States, 616 F.2d 455, 456-57 (10th Cir. 1980) (upholding the FDA's right to prohibit the importation of laetrile).

crosses a nearby national border to benefit from superior emergency services.[12]

Throughout the discussion that follows it bears remembering that there is limited data as to the number of medical tourists (and only slightly more regarding outsourcing). Stories about individuals forced to leave their own countries for better health care are media-friendly and tempting cudgels for policy makers wishing to beat on aspects of health care, immigration, or other domestic policies. After collecting and analyzing data on medical tourism from Canada to the United States, Steven Katz and colleagues note that the phenomenon (and its assumed rationing cause) was used to support U.S. criticisms of universal coverage,[13] Canadian attacks on the under-funding of that country's Medicare system, and Canadian proposals to increase the level of private participation in health care financing (for example, by re-capturing the private dollars spent south of the border).[14] Notwithstanding the many political constituents leveraging the tourism phenomenon, the same researchers found that, for the period of 1994-1998, the numbers of Canadian medical tourists seeking care in the U.S. was "almost indetectible" relative to domestic health care.[15]

A. *International Tourism*

Several regions and countries have explicitly established themselves as destinations for medical tourism.[16] For example, the city of Bogotá, Colombia promotes itself as a high-quality destination for medical tourists in Latin America.[17] South African hospitals offer "medical safaris," combining vacation with plastic surgery,[18]

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12. *See, e.g.*, Guerrero v. Copper Queen Hosp., 537 P.2d 1329 (Ariz. 1975).

13. *See, e.g.*, Merrill Matthews, Jr., *Americas: On a Bus to Bangor, Canadians Seeking Health Care*, WALL ST. J., July 5, 2002, at A13, *available at* LEXIS.

14. Steven J. Katz et al., *Phantoms in the Snow: Canadians' Use of Health Care Services in the United States*, HEALTH AFF., May-June 2002, at 19, 27, *available at* http://content.healthaffairs.org/cgi/reprint/21/3/19.

15. *Id.*

16. Ramola Talwar Badam, *Foreign Surgeons Attract U.S. Patients*, SEATTLE TIMES, Sept. 25, 2005, at A1, *available at* 2005 WLNR 15132786 (Westlaw) (reporting 2004 figures for foreign patients treated in India (150,000), Singapore (200,000), and Thailand (600,000)).

17. Owain Johnson, *Bogotá Launches Health Tourism Project*, BRIT. MED. J., July 6, 2002, at 10, *available at* http://www.bmj.com/cgi/content/full/325/7354/10/e.

18. *Medical Tourism: Need Surgery, Will Travel*, CBC NEWS ONLINE, June 18, 2004, http://www.cbc.ca/news/background/healthcare/medicaltourism.html [hereinafter *Medical Tourism*].

while Malaysian hospitals propose surgery in a resort setting.[19] Bumrungrad International Hospital[20] in Bangkok, Thailand, attracted 55,000 patients from the United States in 2005, 83 percent for non-cosmetic procedures.[21] Mexico, often vilified in the highly politicized immigration debate as an exporter of undocumented patients, is developing a strong presence in offering low-cost dental services to patients from across its northern border,[22] while, for instance, Irish dental patients are offered cut-price cosmetic surgery[23] in "Hungary[,] the dental capital of the world."[24]

The largest number of press reports focus on medical tourism services provided in India,[25] where the finance minister has urged his country to become a "global health destination,"[26] and the head of one state, Kerala, declared 2006 to be "The Year of Medical Tourism."[27] Analysts have predicted a $2.1 billion annual medical tourism revenue for India by 2012.[28] Apollo Hospitals, the largest private health care group in Asia, has over seven thousand beds in thirty-eight hospitals (located in several countries, including India, Sri Lanka, Bangladesh, Ghana, Nigeria, Qatar, and Kuwait) and ac-

19. Eric Paul Erickson, *Over The Ocean, Under the Knife: Vacationers Are Making the Time to Work a Little Surgery into Exotic Trips*, CHI. SUN-TIMES, Nov. 27, 2005, at 1C, *available at* 2005 WLNR 20723934 (Westlaw) (noting the rise of Penang as center, and the role of intermediary Beautiful Holidays). *See generally* Beautiful Holidays, Welcome to Beautiful Holidays, http://www.beautiful-holidays.com (last visited Mar. 18, 2007).

20. *See generally* Bumrungrad International, Welcome, http://www.bumrungrad.com (last visited Mar. 18, 2007).

21. Unmesh Kher, *Outsourcing Your Heart: Elective Surgery in India? Medical Tourism is Booming, and U.S. Companies Trying to Contain Health-Care Costs Are Starting to Take Notice*, TIME, May 29, 2006, at 44, 44 *available at* http://www.time.com/time/magazine/article/0,9171,1196429,00.html.

22. *Id.*

23. Kreativ Dental Clinic, Kreativ Dental Clinic Tours Ireland, http://www.kreativdent.ie (last visited Mar. 18, 2007).

24. Victoria Colliver, *Dental Work Too Expensive? Go Overseas*, S.F. CHRON., Apr. 5, 2006, at A1, *available at* 2006 WLNR 5689178 (Westlaw).

25. *See, e.g.*, K. V. Prasad, *Gearing Up for More Medical Tourists*, THE HINDU (India-Online Ed.), Jan. 31, 2006, http://www.hindu.com/2006/01/31/stories/2006013111110100.htm; *Americans and Europeans Are Trekking to India for Surgery, According to Bloomberg Markets Magazine; 'Medical Tourism' is a Growing Business in India, Bloomberg Markets Says*, PR NEWSWIRE U.S., Jan. 27, 2005, *available at* LEXIS.

26. Ray Marcelo, *India Fosters Growing 'Medical Tourism' Sector*, FIN. TIMES, July 2, 2003, at 10, *available at* http://yaleglobal.yale.edu/display.article?id=2016.

27. Adrian Lee, *Medical Tourism: A Hot Destination*, DAILY EXPRESS (London), June 6, 2006, *available at* 2006 WLNR 9669509 (Westlaw).

28. Garud, *supra* note 4, at 318-19; Marcelo, *supra* note 26; *see also Want that Cardiac Surgery Done? Go to India!*, INDIA ABROAD (N.Y. Ed.), June 24, 2005, at A40, *available at* 2005 WLNR 12004858 (Westlaw).

tively promotes its "International Patient Services."[29] Apollo[30] and Escorts Heart Institute and Research Centre,[31] another major Indian tourist destination, even facilitate "virtual patient visits" for family members who are unable to physically accompany patients. Apollo reportedly treated 60,000 medical tourists between 2001 and the spring of 2004.[32] This growing industry is supported by a number of U.S.-based intermediaries such as IndUShealth[33] and Planet Hospital[34] that organize tourists' visits to India and other destinations.[35]

B. *Costs and Reimbursement*

The medical procedures offered by providers in India and other tourist destinations are considerably less expensive than in Western countries such as the United States or the United Kingdom. For example, in India, open-heart procedures cost about 10 percent of the average industrialized-country price.[36]

Historically, procedures that attracted medical tourists were those that were out-of-plan or otherwise would not be reimbursed by the patient's insurer or funded by a national health service. Today, there are some limited exceptions to this paradigm. Blue Cross and Blue Shield (U.S.) and BUPA (U.K.) now reimburse for

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29. Apollo Hosps. Group, Overview, http://apollohospitals.com/overview.asp?PgeuId=1066 (last visited Mar, 18, 2007); Apollo Hosps. Group, International Patients, http://www.apollohospitalgroup.com/International.htm (last visited Mar. 18, 2007); *see also* Medilux Healthcare Ltd., The Apollo Hospitals Group, Guide for Patients and their Doctors, *available at* http://www.mediluxhealth.net/pages/mediluxapollo.htm (follow the "Introductory Brochure" hyperlink under the heading "Downloads," at the bottom of the page) (last visited Mar. 18, 2007); Superbrand 2003-2005, Apollo Hosps. Group, http://www.superbrandsindia.com/superbrands2003/apollo-hospitals/index.htm (last visited Mar. 18, 2007) (discussing the history of the Apollo Hospitals Group).

30. Apollo Hosps. Group, Virtual Patient Visit, http://www.apollohospitals.com/VirtualPatient.asp?Pgeuld=1066 (last visited Mar. 18, 2007).

31. *See generally* Escorts Heart Inst. & Research Centre Limited, International Patients, http://www.ehirc.com/international_patients/index.asp (last visited Mar. 18, 2007).

32. *Medical Tourism*, *supra* note 18; *see also* Jay Soloman, *Traveling Cure: India's New Coup in Outsourcing*, WALL STREET J., Apr. 26, 2004, at A1, *available at* LEXIS.

33. IndUShealth, A New World of Care, http://www.indushealth.com (last visited Mar. 18, 2007).

34. Planet Hosp., Medical Tourism World Wide, http://www.planethospital.com (last visited Mar. 18, 2007).

35. Kher, *supra* note 21, at 46-47.

36. *See* Garud, *supra* note 4, at 319. *See generally The Globalization of Health Care: Can Medical Tourism Reduce Health Care Costs?: Hearing Before the S. Spec. Comm. on Aging*, 109th Cong. (June 27, 2006), *available at* http://aging.senate.gov/hearing_detail.cfm?id=270728&.

treatments at some facilities in India.[37] The same is also true of some of the new "mini-medical," low-cost, limited-benefit plans that increasingly attract U.S. consumers unable to afford traditional health insurance.[38]

Medical tourism has even appeared on the radar of government-funded health care as states seek to reduce their health care costs. For example, a bill introduced in the West Virginia House of Delegates in 2006 would have allowed employees covered by the state's Public Employees Insurance Agency to use Joint Commission International (JCI) accredited foreign hospitals, receive travel reimbursement for themselves and a companion, and participate in the savings with a cash rebate.[39]

A different set of financing problems arises when the medical tourist looks to the destination country to fund his or her health care. The U.K. government has acknowledged that it "ha[s] never required the [N]ational [H]ealth [S]ervice to provide statistics on the number or nationality of overseas visitors treated" by the National Health Service,[40] or the costs involved in providing this treatment (with cost estimates ranging from almost negligible sums to £200 million per year).[41] The government has a website devoted to the issue,[42] and has recently tightened its criteria for free care.[43] The first case of health tourism prosecuted by the National Health Service Counter Fraud Service was settled when an Egyptian businessman who had traveled to London specifically to get "free" National Health Service treatment agreed to pay the £30,000 cost.[44]

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37. Marcelo, *supra* note 26.

38. Kher, *supra* note 21, at 46-47. Reducing costs with medical tourism has also been noted by employers. *See* Rick Martinez, *A Passage to India for Surgery*, NEWS & OBSERVER (Raleigh, N.C.), June 21, 2006, at A17, *available at* 2006 WLNR 10683034 (Westlaw).

39. H.B. 4359, 77th Leg., 2d Sess. (W. Va. 2006), *available at* http://www.legis.state.wv.us/Bill_Text_HTML/2006_SESSIONS/RS/Bills/hb4359%20intr.htm.

40. 436 PARL. DEB., H.C. (6th ser.) (2005) 2745W (statement of Jane Kennedy, Sec'y of State for Health), *available at* http://www.publications.parliament.uk/pa/cm200506/cmhansrd/cm050912/text/50912127.htm.

41. *See Are Health Tourists Draining the NHS?*, BBC NEWS, May 14, 2004, http://news.bbc.co.uk/2/hi/health/3356255.stm.

42. *See* The Dep't of Health (U.K.), Overseas Visitors, http://www.dh.gov.uk/PolicyAndGuidance/International/OverseasVisitors/fs/en (last visited Mar. 18, 2007).

43. National Health Service, 2004, S.I. 2004/614, art. 2, ¶¶ 1-3 (U.K.), *available at* http://www.opsi.gov.uk/si/si2004/20040614.htm (amending National Health Service, 1989 S.I. 1989/306, art. 1, ¶ 2 (U.K.)).

44. *Health 'Tourist' Pays NHS £30,000*, BBC NEWS, Apr. 6, 2005, http://news.bbc.co.uk/2/hi/health/4415491.stm.

In the United States, the costs expended on patients who are undocumented aliens have become part of the immigration debate. The Emergency Medical Treatment and Active Labor Act (EMTALA) requires medical screening (effectively requiring free emergency medical care), regardless of immigration or residency status.[45] Some state legislation[46] and common law tort duties[47] have similar effects. Federal legislators recently have engaged on the issue. Thus, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)[48] provides for reimbursement of emergency health services furnished to undocumented aliens, resulting in large federal payments to border states.[49] In contrast to such largesse, as of July 1, 2006, the Deficit Reduction Act of 2005 requires individuals to provide satisfactory evidence of citizenship or nationality when initially applying for Medicaid or upon a recipient's first Medicaid re-determination.[50] Approximately fifty million low-income people are currently on Medicaid. Historically, self-attestation was sufficient. However, the new rules require more stringent documentation.[51] California recently delayed implementation of the new requirement pending final federal guidance, risking the loss of federal funding.[52] Also, the Pov-

45. Emergency Medical Treatment and Active Labor Act, 42 U.S.C. § 1395dd (Supp. 2003).

46. *See, e.g.*, Guerrero v. Copper Queen Hosp., 537 P.2d 1329, 1331-32 (Ariz. 1975).

47. *See, e.g.*, Wilmington Gen. Hosp. v. Manlove, 174 A.2d 135, 139-40 (Del. 1961). *But see, e.g.*, *Guerrero*, 537 P.2d at 1330-40 ("A private hospital has no duty to accept a patient . . . unless a different public policy has been declared by statute or otherwise.").

48. Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. No. 108-173, § 1011, 117 Stat. 2066, 2432 (codified at 42 U.S.C. § 1395dd); *see also* Dep't of Health & Human Servs., Ctrs. for Medicare & Medicaid Servs., Section 101 Provider Payment Determination, *available at* http://www.cms.hhs.gov/CMSforms/downloads/cms10130a.pdf.

49. *See generally* Robert Pear, *Payments to Help Hospitals Care for Illegal Immigrants*, N.Y. TIMES, May 10, 2005, at A11, *available at* 2005 WLNR 7325694 (Westlaw) (reporting payments of $70.8 million to California, $46 million to Texas, and $45 million to Arizona).

50. Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 6036, 120 Stat. 4 (codified at 42 C.F.R. § 435.407(j)).

51. *See* Letter from Dennis G. Smith, Dir., Ctrs. for Medicaid & State Operations, to State Medicaid Directors (June 9, 2006), *available at* http://www.cms.hhs.gov/smdl/downloads/SMD06012.pdf. *See generally* Robert Pear, *Medicaid Rules Get Tougher About Proof of Citizenship*, N.Y. TIMES, June 5, 2006, at A4, *available at* 2006 WLNR 9593565 (Westlaw).

52. Rong-Gong Lin, II, *State to Delay Benefit Rule: U.S. Law Set to Take Effect July 1 Requires Proof of Citizenship for Medi-Cali Coverage, Officials Fear Hasty Action Could Bar Legitimate Enrollees*, L.A. TIMES, June 7, 2006, at B1, *available at* 2006

erty Law Center has filed a class-action lawsuit challenging the new procedures as violating both the Medicaid Act and due process protections.[53]

As countries increase limitations on the provision of health care to nonresidents, medical professionals are placed in ethical jeopardy when a patient in need of care presents. For example, in the United Kingdom, apparent prohibitions to the provision of free medical care to asylum seekers have raised ethical questions.[54] It is unclear the extent to which health care workers are responsible for investigating the immigration status of patients before treating them.[55] Similarly, those who staff emergency rooms in U.S. border-state hospitals increasingly find themselves drawn into the documentation morass as pressure grows to ask the "immigration question."[56]

C. *Interstate Tourism*

With geographically diverse major medical centers, and health care rationed by personal resources or managed care organizations rather than governmental policies, interstate medical tourism has not been a noticeable phenomenon in the United States. Emergencies aside, patients typically seek treatment where they live and only occasionally travel to specialized providers in other states. Although major medical centers do seek to attract patients from outside their own region or networks and routinely offer travel and accommodation services,[57] these initiatives have not raised any sub-

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WLNR 9721607 (Westlaw); *see also* Rong-Gong Lin, II, *Tighter Medicaid Rules Put on Hold: A Federal Law Requires States to Now Verify Applicants' Citizenship, But California and Others Are Taking It Slow*, L.A. TIMES, Nov. 17, 2006, at B1, *available at* 2006 WLNR 19953795 (Westlaw).

53. Press Release, Sargent Shriver Nat'l Ctr. on Poverty Law, Suit Challenges New Law Requiring 50 Million People in Medicaid to Document Citizenship (June 28, 2006) (on file with *Western New England Law Review*). Subsequently, a preliminary ruling was made against the plaintiffs on standing grounds. Bell v. Leavitt, No. 06 CV 3520, 2007 U.S. Dist. LEXIS 11675 (N.D. Ill. Feb. 16, 2006).

54. *See, e.g.*, Edwin Borman, *Health Tourism*, 328 BRIT. MED. J. 60, 60-61 (2004), *available at* http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=314036&blobtype=pdf.

55. *See, e.g.*, Adrian O'Dowd, *Health Tourism: The Dilemma for Nurses*, NURSING TIMES, Nov. 4, 2003, at 32, 32-34, *available at* 2003 WLNR 10951050 (Westlaw).

56. Julia Preston, *Texas Hospitals' Separate Paths Reflect the Debate on Immigration*, N.Y. TIMES, July 18, 2006, at A1, *available at* 2006 WLNR 12327709 (Westlaw) (quoting Leticia Martinez, a patient at Parkland Memorial in Dallas, Texas).

57. *See, e.g.*, Johns Hopkins Medicine, Hopkins USA, For Patients, http://www.hopkinsusa.org/USA/Patients/default.asp (last visited Mar. 18, 2007); Univ. of Tex., M.D. Anderson Cancer Ctr., International Center, http://www.mdanderson.org/

stantial legal or ethical concerns. Such major providers are likely to use a bricks-and-mortar franchising model and thus have a physical referral presence in other states.[58]

Of growing interest, however, are online second-opinion services, such as The Cleveland Clinic's Remote Medical Second Opinion service,[59] which offer Internet-based consultations and potentially will attract out-of-state patients to their bricks-and-mortar services. The Cleveland Clinic's service seeks to abide by state licensure laws and specifically excludes[60] the provision of services in states that have highly restrictive rules as to online consultations.[61] Second-opinion sites lack most of the vices seen in the online medical and prescribing services targeted by professional organizations, regulators, and prosecutors.[62] They do share some of the opportunistic characteristics of so-called "questionnaire" prescribing Internet sites (where a prior relationship with the consulting physician is unlikely)[63] and tend to rely on record review rather than physical examination (a common complaint about online "pill-mills").[64] However, second-opinion "services tend not to get involved in prescribing, and their record review process furthers continuity of care by involving, or at least copying their opinions to, the patient's ex-

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departments/IPC (follow the "Patient Services" hyperlink, then the "Patient Travel Service" hyperlink) (last visited Mar. 18, 2007).

58. Thomas R. McLean, *The Offshoring of American Medicine: Scope, Economic Issues and Legal Liabilities*, 14 ANNALS HEALTH L. 205, 227 n.126 (2005); *see, e.g.*, Mayo Clinic, Facts About Mayo Clinic in Arizona, http://www.mayoclinic.org/about/arizona.html (last visited Mar. 18, 2007) (stating that Mayo Clinic Arizona offers services in at least sixty-five different medical and surgical disciplines); Mayo Clinic, Facts About Mayo Clinic in Jacksonville, Florida, http://www.mayoclinic.org/about/jacksonville.html (last visited Mar. 18, 2007) (stating that Mayo Clinic Jacksonville has over 306 physicians and over 4,378 allied health staff).

59. *See generally* Cleveland Clinic, Welcome to MyConsult, My Consult Services, http://www.eclevelandclinic.org/myConsultHome (last visited Mar. 18, 2007); Partners HealthCare System, Inc., Partners Online Specialty Consultations, https://econsults.partners.org (last visited Mar. 18, 2007).

60. Cleveland Clinic, Remote Medical Second Opinion Frequently Asked Questions, www.eclevelandclinic.org/productHome.jsp?productId=standard (follow the "View Remote Medical Second Opinion Frequently Asked Questions" hyperlink, then the "Is the eCleveland Clinic MyConsult remote second opinion service available in every state?" hyperlink) (last visited Mar. 18, 2007).

61. *See, e.g.*, OR. REV. STAT. ANN. §§ 677.135, 677.137 (West 2006).

62. *See* Nicolas P. Terry, *Prescriptions sans Frontières (or How I Stopped Worrying about Viagra on the Web but Grew Concerned about the Future of Healthcare Delivery)*, 4 YALE J. HEALTH POL'Y L. & ETHICS 183, 258-59 (2004) [hereinafter Terry, *Prescriptions sans Frontières*].

63. *Id.* at 259.

64. *Id.*; *see infra* text accompanying note 194.

isting physician."[65] Arguably, physical examination of "the patient is less important in second opinion consultation cases, where most of the analysis flows from review of blood work, scans, and pathology tests" and focuses on treatment options rather than initial diagnosis.[66]

International travel to avoid legal restrictions on types of health care is relatively rare, although not unknown as, for example, in the case of foreign parents leveraging unregulated embryo gender identification in the United States.[67] However, a number of medical tourists do travel or seek to travel outside their own states to benefit from more favorable socio-medical policies governing death and dying. Recall, for example, the well-known *Busalacchi* case.[68] Christine Busalacchi was an accident victim who had entered a permanent vegetative state. Her father and guardian wished to move her from a Missouri rehabilitation center to a Minnesota facility. Missouri sought to block her transfer in part because of a suspicion that her guardian was attempting to leverage the allegedly less stringent requirements in Minnesota for removal of feeding tubes. The Missouri Court of Appeals remanded the case to the trial court for further evidentiary hearings on the guardian's burden "to provide a reasonable basis for the need to move Christine to another jurisdiction other than a desire to avoid the laws of Missouri."[69] The majority opinion stated, "[W]e will not permit [the] guardian to forum shop in an effort to control whether Christine lives or dies."[70] However, Judge Smith, dissenting, pointed out that, "Minnesota is not a medical or ethical wasteland. . . . There is a parochial arrogance in suggesting, as the State does, that only in Missouri can Christine's medical, physical and legal well being be protected or that only here will her best interests be considered."[71]

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65. Terry, *Prescriptions sans Frontières*, *supra* note 62, at 259; *see, e.g.*, Daniel Costello, *Virtual Second Opinions*, L.A. TIMES, Dec. 30, 2002, at F1, *available at* 2002 WLNR 12412963 (Westlaw).

66. Terry, *Prescriptions sans Frontières*, *supra* note 62, at 259; *see, e.g.*, Tara Parker-Pope, *Virtual Second Opinions: When the Web Can Be Better than Seeing a Local Doc*, WALL ST. J., Aug. 12, 2003, at D1, *available at* LEXIS.

67. Carla K. Johnson, *U.S. Sex-Selection Clinics Attract Foreigners*, SEATTLE TIMES, June 15, 2006, at A18, *available at* 2006 WLNR 10391157 (Westlaw).

68. *In re* Busalacchi, No. 59852, 1991 WL 26851 (Mo. Ct. App. Mar. 5, 1991), *later proceedings at* No. 73677, 1991 Mo. LEXIS 107 (Mo. Oct. 16, 1991).

69. *Id.* at *5.

70. *Id.* at *5, *9-10.

71. *Id.* at *10.

Similar issues intrude into the assisted-suicide debate. Switzerland and the Netherlands have less restrictive laws than other European states or the United States.[72] Swiss law only makes assisting suicide illegal when there is "self-interested motivation."[73] Since 1998, Dignitas,[74] a Swiss non-profit relying on its avowed policy of "altruism," has reportedly provided accommodations and the necessary life-ending barbiturates for more than 450 European sick or elderly "tourists" who have traveled to Switzerland to end their lives.[75] In spite of concerns voiced (and even criminal investigations by police)[76] in the deceased's countries of origin,[77] Swiss legislators have refused to revisit their law.[78]

Oregon's Death with Dignity Act (ODWDA)[79] is the only U.S. analog to these more liberal and potentially tourist-attracting regimes.[80] ODWDA "exempts from civil or criminal liability state-licensed physicians who, in compliance with the specific safeguards in [the statute], dispense or prescribe a lethal dose of drugs upon the request of a terminally ill patient."[81] In *Gonzales v. Oregon*,[82] the United States Supreme Court rebuffed an attempt by the U.S. Attorney General to use an interpretation of the federal Controlled

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72. Switzerland, unlike the Netherlands, is not a member of the European Union. *See* European Union, External Relations, EU's Relations with Switzerland, http://ec.europa.eu/comm/external_relations/switzerland/intro/index.htm (last visited Mar. 18, 2007). However, the "interstate" description used herein is appropriate given the country's close relationship with the Union and the bilateral treaties between the parties that provide for, e.g., freedom of movement of persons. *See generally id.*

73. *Dignitas: Swiss Suicide Helpers—"Live with Dignity, Die with Dignity" Is the Slogan of the Swiss Charity*, BBC NEWS, Apr. 15, 2003, http://news.bbc.co.uk/2/hi/health/2948665.stm [hereinafter *Dignitas: Swiss Suicide Helpers*].

74. Dignitas, http://www.dignitas.ch (last visited Mar. 18, 2007).

75. *See generally Dignitas: Swiss Suicide Helpers*, *supra* note 73; *Dignitas: Swiss Suicide Helpers: Swiss Charity Dignitas Has Gained a Worldwide Reputation for Helping People with Chronic Diseases to End Their Lives*, BBC NEWS, Jan. 24 2006, http://news.bbc.co.uk/2/hi/health/4643196.stm.

76. *See, e.g.*, *Death Quiz For Family*, MIRROR (London), June 3, 2006, at 15, *available at* 2006 WLNR 9510879 (Westlaw).

77. *See, e.g.*, *In re* Z (2004) EWHC 2817, [2005] 1 W.L.R. 959, 2004 WL 2790666 (Fam.) (U.K.) (refusing to order an injunction to restrain a competent person from traveling from England to Switzerland for assisted suicide).

78. Hilary White, *Switzerland Refuses to Alter Assisted Suicide Law to Nix Death Tourism*, LIFESITENEWS.COM, June 2, 2006, http://www.lifesite.net/ldn/2006/jun/06060210.html.

79. OR. REV. STAT. §§ 127.800-127.995 (2005).

80. California recently rejected similar legislation. Greg Lucas, *Bill to Allow Assisted Suicide is Rejected: State Senate Committee Head Casts Key Vote Against Measure*, S.F. CHRON., June 28, 2006, at A1, *available at* 2006 WLNR 11178674 (Westlaw).

81. Gonzales v. Oregon, 126 S. Ct. 904, 911 (2006).

82. *Id.*

Substances Act (CSA)[83] to frustrate ODWDA.[84] Unlike the Swiss assisted-suicide law, ODWDA specifically discourages medical tourism by requiring Oregon residency.[85] Critics argue, however, that in practice, the residency determination is delegated to doctors and that it fails to pose a major barrier to nonresidents.[86]

Any interstate assisted-suicide debate is likely to pale in comparison with the future legal landscape relating to abortion. Notwithstanding the controversies that *Roe v. Wade*[87] and its progeny sparked, these decisions essentially provided a national ceiling on legal disincentives to pregnancy terminations, and as a result, should have reduced abortion-related tourism. However, this state of affairs would change rapidly if the Supreme Court takes the bait offered by a highly restricive state abortion statute[88] and reverses *Roe*, particularly as some states will have passed "trigger laws" banning abortion upon *Roe*'s demise.[89]

Of course, federally guaranteed legal equivalence does not always create access to in-state health care. For example, South Dakota has only one abortion provider, a Planned Parenthood clinic staffed only once a week by doctors who travel from Minnesota.[90] Mississippi and North Dakota have similar restrictive access is-

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83. Controlled Substances Act, 21 U.S.C. §§ 801-904 (2000).

84. *Gonzales*, 126 S. Ct. at 922-26. In contrast, a state ban on physician-assisted suicide has been held by the Court not to violate the Due Process Clause of the Fourteenth Amendment. Washington v. Glucksberg, 521 U.S. 702, 734 (1997).

85. OR. REV. STAT. § 127.805 (2005). A person may establish residency in Oregon in the following ways:

(1) Possession of an Oregon driver license;

(2) Registration to vote in Oregon;

(3) Evidence that the person owns or leases property in Oregon; or

(4) Filing of an Oregon tax return for the most recent tax year.

Id. § 127.860.

86. *See, e.g.*, *The Consequences of Legalized Assisted Suicide and Euthanasia: Hearing Before the Subcomm. on the Constitution, Civil Rights and Property Rights of the S. Comm. on the Judiciary*, 109th Cong. (2006) (testimony of Rita L. Marker, Executive Dir., Int'l Task Force on Euthanasia and Assisted Suicide), *available at* http://judiciary.senate.gov/testimony.cfm?id=1916&wit_id5377.

87. Roe v. Wade, 410 U.S. 113 (1973).

88. This was the apparent intent behind the South Dakota statute, H.B. 1215, 2006 Leg., 81st Sess. (S.D. 2006)—however, the legislation was reversed by referendum. *See, e.g.*, Stephanie Simon, *South Dakota Scraps Abortion Ban*, L.A. TIMES, Nov. 8, 2006, at 16, *available at* 2006 WLNR 19353648 (Westlaw).

89. Judy Peres, *States Set Stage for Bans on Abortion*, CHI. TRIB., June 12, 2006, at 1, *available at* 2006 WLNR 10012408 (Westlaw).

90. Evelyn Nieves, *S.D. Abortion Bill Takes Aim at 'Roe'*, WASH. POST, Feb. 24, 2006, at A1, *available at* 2006 WLNR 3182657 (Westlaw).

sues,[91] suggesting that many patients are, in fact, forced to travel outside their own states for constitutionally protected medical treatment.

Differences already exist between abortion laws across the fifty states. For example, twenty-six states require some form of parental consent or court authorization before a minor can terminate a pregnancy,[92] suggesting an incentive for at-risk minors to travel out of state, and attracting controversial federal proposals to criminalize those who transport such tourists or doctors who circumvent out-of-state barriers.[93] If *Roe* is overturned, the vector between restrictive and unrestrictive states is likely to grow, creating a picture of legal and ethical confusion that will exceed even that in Australia, where diverse state laws,[94] albeit generally liberal ones, create uncertainty for doctors and lawyers.[95]

In a possible post-*Roe* world, the United States could also find itself visiting painful issues reminiscent of those experienced in the Republic of Ireland following its constitutional amendment banning abortions.[96] There the temperature of the debate escalated following successful legal challenges against restrictions on travel by women seeking abortions abroad.[97] *Roe*'s companion case, *Doe v. Bolton*,[98] invalidated residency requirements in a Georgia abortion statute on the basis of the Privileges and Immunities Clause[99] because a "contrary holding would mean that a State could limit to its

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91. *Id.*

92. CTR. FOR REPROD. RTS., THE TEEN ENDANGERMENT ACT (H.R. 748; S.8, 396, 403): HARMING YOUNG WOMEN WHO SEEK ABORTIONS (2006), *available at* http://www.crlp.org/pub_fac_ccpa.html.

93. *See, e.g.*, Child Custody Protection Act, S. 403, 109th Cong. (2006).

94. *See* Natasha Cica, *Abortion Law in Australia*, *in* 1998-99 AUSTRALIAN PARLIAMENTARY LIBRARY 1, *available at* http://www.aph.gov.au/library/pubs/rp/1998-99/99rp01.htm (describing the abortion laws of each Australian state and territory).

95. *See, e.g.*, Lachlan J de Crespigny & Julian Savulescu, *Abortion: Time to Clarify Australia's Confusing Laws*, 181 MED. J. AUSTL. 201, 201-03 (2004), *available at* http://www.mja.com.au/public/issues/181_04_160804/dec10242_fm.pdf.

96. Eighth Amendment of the Constitution Act, 1983 (Amend. No. 8/1983) (Ir.), *available at* http://www.irishstatutebook.ie/front.html (follow the "Acts of the Oreachtas" hyperlink, then the "1983" hyperlink, then the "Amendment No 8/1983—Eighth Amendment of the Constitution Act, 1983" hyperlink) (last visited Mar. 18, 2007).

97. *See, e.g.*, Att'y Gen. v. X [1992] 1 I.R. 1, 11 (Ir.); A. v. E. Health Bd., [1998] 1 I.R. 464, 473 (Ir.), *available at* http://www.bailii.org/ie/cases/IEHC/1997/176.html.

98. Doe v. Bolton, 410 U.S. 179 (1973).

99. U.S. CONST. art. IV, § 2, cl. 1.

own residents the general medical care available within its borders."[100] Justice Douglas famously wrote,

> Freedom of movement across frontiers in either direction, and inside frontiers as well, was a part of our heritage. . . . It may be as close to the heart of the individual as the choice of what he eats, or wears, or reads. Freedom of movement is basic in our scheme of values.[101]

Any state that tries to prevent its own residents from traveling to a more liberal abortion state will have to deal with that sentiment, along with a host of federal constitutional impediments, although C. Steven Bradford has argued that the issue is more nuanced than it might appear at first sight.[102]

Such ethically complex and highly politicized issues aside, most interstate tourism tends to be a function of differing reimbursement rules or related state policies. In this area, European courts have faced some of the most challenging issues. Citizens of member states enjoy extensive freedom of movement within the European Union. For example, Council Directive 2004/58,[103] which became

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100. *Doe*, 410 U.S. at 200.

101. Kent v. Dulles, 357 U.S. 116, 126 (1958). See also *Bigelow v. Virginia*, 421 U.S. 809 (1975), in which the Court held a Virginia statute, which was applied against a publisher who carried an advertisement for lawful abortion services available in New York, infringed his First Amendment rights. The majority opinion, authored by Justice Blackmun, contained the following dicta:

> The Virginia Legislature could not have regulated the advertiser's activity in New York, and obviously could not have proscribed the activity in that State. Neither could Virginia prevent its residents from traveling to New York to obtain those services or, as the State conceded, prosecute them for going there. Virginia possessed no authority to regulate the services provided in New York—the skills and credentials of the New York physicians and of the New York professionals who assisted them, the standards of the New York hospitals and clinics to which patients were referred, or the practices and charges of the New York referral services.

Id. at 822-24 (citations omitted).

102. *See* C. Steven Bradford, *What Happens if* Roe *is Overruled? Extraterritorial Regulation of Abortion by the States*, 35 ARIZ. L. REV. 87, 170 (1993) ("[T]he intuitive reaction against the extraterritorial application of abortion laws is not wholly justified by the case law."); *cf.* Seth F. Kreimer, *The Law of Choice and Choice of Law: Abortion, the Right to Travel, and Extraterritorial Regulation in American Federalism*, 67 N.Y.U. L. REV. 451, 519 (1992) ("The right to travel to more hospitable environs could not, after the fourteenth amendment, be denied to former slaves seeking a better life. Under the same principles, even if *Roe* continues to erode or is ultimately overruled, that right cannot be denied to women seeking to choose their future.").

103. Council Directive 2004/58/EC of 29 Apr. 2004 on the Right of Citizens of the Union and Their Family Members to Move and Reside Freely Within the Territory of the Member States, 2004 O.J. (L 229) 35 (EC), *available at* http://eur-lex.europa.eu/LexUriServ/site/en/oj/2004/l_229/l_22920040629en00350048.pdf; *see also* Council Direc-

effective in April 2006, overhauled the existing patchwork of federal European laws (including the case law of the European Court of Justice)[104] that permitted, for example, freedom of movement of workers and tourists. Under the new Directive, a citizen (and, in most cases, dependents and partners of a citizen) of a Union member state has an almost unfettered right to reside in another member state for three months.[105] Thereafter, the person must be a worker (or self-employed) or have sufficient resources not to become a burden on the social security system of the host state and have comprehensive health insurance.[106] After five years this status converts into a right of permanent residence.[107] Host states have only very limited rights to restrict freedom of movement based on public health grounds.[108] Strong safeguards for equal protection in, for example, access to employment or education, accompany the rights of residency.[109]

The EU treaty severely limits federal control over the health systems of member states.[110] However, the European Court of Justice (ECJ) has taken the position that state health systems cannot act so as to impede federally mandated freedom of movement of persons and services. All EU countries have universal coverage funded either by direct taxation or compulsory social insurance. However, they also have their own cost-containment policies, including forms of rationing. In a series of cases dealing with outpatient care and prescription fulfillment, the ECJ has refused to allow

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tive 2004/38/EC of 29 Apr. 2004 on the Right of Citizens of the Union and Their Family Members to Move and Reside Freely Within the Territory of the Member States, 2004 O.J. (L 158) 77 (EC), *available at* http://www.lex.unict.it/eurolabor/en/documentation/dirapprovate/dir(04)-38en.pdf.

104. *See generally* Juliane Kokott, EU Citizenship—citoyens sans frontières?, Annual European Law Lecture at the Durham European Law Institute (2005) (transcript available at http://www.dur.ac.uk/resources/deli/annuallecture/2005_DELI_Lecture.pdf).

105. Council Directive 2004/58, *supra* note 103, art. 6.

106. *Id.* art. 7.

107. *Id.* arts. 16-20.

108. *Id.* art. 29.

109. *Id.* art. 24.

110. "Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care." EUROPEAN COMM'N, THE INTERNATIONAL MARKET AND HEALTH SERVICES, REPORT OF THE HIGH LEVEL COMMITTEE ON HEALTH 5 (2001), *available at* http://ec.europa.eu/health/ph_overview/Documents/key06_en.pdf.

states to require prior authorization as a condition for reimbursing medical costs incurred in another member state.[111]

The court has been somewhat more circumspect regarding impediments to inpatient care provided elsewhere in the EU, permitting requirements of prior authorization when the member state can provide the care without "undue delay."[112] However, this qualification must now be read subject to the recent *Watts* case.[113] A 75-year-old arthritic patient who had been wait-listed in England for hip replacement surgery, Mrs. Watts applied under the U.K.'s version of the EU's existing medical tourism rules, the so-called E112 scheme,[114] but her application was refused. Subsequently, Mrs. Watts paid £3900 to have the procedure performed in France and then sought reimbursement from the National Health Service, which was refused. The ECJ interpreted EU treaty and legislative provisions regarding freedom of movement of persons and medical services to hold that:

> A refusal to grant prior authorization cannot be based merely on the existence of waiting lists intended to enable the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out in the individual case in question an objective medical assessment of the patient's medical condition, the history and probable course of his illness, the degree of pain he is in and/or the nature of his disability at the time when the request for authorization was made or renewed.[115]

As a result, EU health care systems will be forced to reimburse medical tourists who face "undue delay" in their own countries in light of their individual medical conditions, notwithstanding inter-

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111. *See, e.g.*, Decker v. Caisse de Maladie des Employés Privés, Case C-120/95, 1998 E.C.R. I-01831; Kohll v. Union des Caisses de Maladie, Case C-158/96, 1998 E.C.R. I-01931, 2 C.M.L.R. 879 (1998); Müller-Fauré v. Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen, Case C-385/99, 2003 E.C.R. I-04509; Ludwig Leichtle v. Bundesanstalt für Arbeit, Case C-8/02, 2004 E.C.R. I-02641, *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62002J0008:EN:HTML.

112. *See* Geracrts-Smits v. Stichting Ziekenfonds, Case C-157/99, 2001 E.C.R. I-05473; *Müller-Fauré*, Case C-385/99, 2003 E.C.R. I-04509.

113. Watts v. Bedford Primary Care Trust, Case C-372/04, 2006 E.C.R. I-04325, 3 C.M.L.R. 5.

114. Dep't of Health (U.K.), Going to an EEA Country or Switzerland in Order to Get Treatment, http://www.dh.gov.uk/en/Policyandguidance/Healthadvicefor travellers/index.htm (follow the "Getting medical treatment around the world" hyperlink, then the "Getting treatment in EEA countries and Switzerland" hyperlink) (last visited Mar. 18, 2007).

115. *Watts*, Case C-372/04, 2006 E.C.R. I-04325, 3 C.M.L.R. 5.

nal budgetary considerations. That reimbursement obligation may also include travel costs if the state already pays for travel related to intrastate treatment.[116] Major increases in medical tourism following *Watts* are likely to push EU states further along the road to a pan-European health care system.[117]

D. *Virtual Tourism*

For most Americans, the closest they will ever come to medical tourism is the "virtual" tourism they will experience, often unknowingly, when they visit a foreign website offering medical information or advice. The "medical" content that appears on such sites may be extremely valuable and may come from peer-reviewed sources,[118] but too many sites contain information that is inaccurate,[119] dangerous,[120] or contrary to accepted medical practice.[121]

Other than urging "surfer-beware" and promoting information about high quality sites,[122] there is little to be done to protect American virtual tourists against the harm they might suffer from relying on either domestic or foreign Web content. Formal approaches to assuring Internet content quality assurance are fraught with legal difficulties. "Public law intervention tends to be limited to obviously dangerous health content where government agencies can apply their traditional consumer-protection, drug-regulation, and fraud powers."[123] Attempts at using more robust public regula-

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116. *Id.* ¶¶ 138-43.

117. *See, e.g.*, *EU Chief Supports 'Health Market'*, BBC NEWS, Sept. 5, 2006, http://news.bbc.co.uk/2/hi/health/5315700.stm (reporting EU health Commissioner Markos Kyrianou's argument for single market in health care).

118. *See, e.g.*, WebMD, About WebMD—Editorial Policy, http://www.webmd.com/content/article/60/67018.htm (last visited Mar. 18, 2007).

119. *See, e.g.*, James D. Cooper & Henry M. Feder Jr., *Inaccurate Information About Lyme Disease on the Internet*, 23 PEDIATRIC INFECTIOUS DISEASE J. 1105, 1107 (2004) (noting that, of nineteen websites relating to lyme disease, nine gave inaccurate information concerning two or more topics).

120. *See generally* Claire W. Anderson, *A Call for Internet Pharmacies to Comply with Quality Standards*, 12 QUALITY & SAFETY HEALTH CARE 86 (2003).

121. *See, e.g.*, Robert M. Wolfe et al., *Content and Design Attributes of Antivaccination Web Sites*, 287 JAMA 3245, 3247-48 (2002).

122. *Cf.* HealthRatings.org, Ratings of Health Web Sites, http://www.healthratings.org (last visited Mar. 18, 2007).

123. Terry, *Prescriptions sans Frontières*, *supra* note 62, at 242; *see, e.g.*, Press Release, FTC, FTC Charges Direct Marketers of Ephedra Weight Loss Products with Making Deceptive Efficacy and Safety Claims (July 1, 2003), *available at* http://www.ftc.gov/opa/2003/07/ephedra.htm.

tion or private litigation (even assuming jurisdiction and enforcement) are likely to conflict with guarantees of free speech.[124]

European institutions, including the European Commission,[125] are enamored of self-regulatory ratings systems and codes of conduct[126] often identified by "trustmarks."[127] However, on balance, the "benefits to patients of self-regulatory codes are outweighed by the risks of overconfidence generated by valid trustmarks or outright fraud from the counterfeit ones."[128]

II. OUTSOURCING

Medical tourism (say, a U.S. resident who travels to India for a heart bypass) may be viewed as the complete outsourcing of health care.[129] Traditionally, however, outsourcing has been viewed as the domestic export of non-core (or non-core competency) ancillary tasks.[130] U.S. providers routinely use domestic outsourcing for non-clinical tasks, everything from food service and gift shops to laundry and security. Today, some health care outsourcing is so well established that the service providers are recognized as distinct health care entities; for example, "Pharmacy Benefits Managers" (PBMs) that health plans or employers use to control pharmaceutical costs.[131] By 2005, one hundred U.S. health care providers (representing 6 percent of hospitals and 10 percent of beds) had fully out-

124. *See generally* Nicolas P. Terry, *Cyber-Malpractice: Legal Exposure for Cybermedicine*, 25 AM. J.L. & MED. 327 (1999).

125. *See, e.g.*, Europe's Information Soc'y Thematic Portal, Focusing on Quality, http://europa.eu.int/information_society/activities/health/policy_action_plan/quality_criteria/index_en.htm (last visited Mar. 18, 2007).

126. *See, e.g.*, Internet Healthcare Coalition, eHealth Code of Ethics, http://www.ihealthcoalition.org/ethics/ehcode.html (last visited Mar. 18, 2007); WebMD, Inc., Our Privacy Commitment to You, Health Internet Ethics, http://www.webmd.com/content/pages/8/1761_50193.htm (last visited Mar. 18, 2007).

127. Trustmarks or quality marks are (frequently trademarked) labels or graphical "marks" designed to signify compliance with criteria established by an independent mark holder. *See, e.g.*, Health on the Net Found., HON Code of Conduct (HONcode) for Medical and Health Web Sites, The HONcode in Brief, http://www.hon.ch/HONcode/Conduct.html (last visited Mar. 18, 2007).

128. Terry, *Prescriptions sans Frontières*, note 62, at 243; *see also* Nicolas P. Terry, *A Transatlantic Perspective on Regulating Health Information*, 324 BRIT. MED. J. 602, 602-06 (2002); Nicolas P. Terry, *Rating the "Raters": Legal Exposure of Trustmark Authorities in the Context of Consumer Health Informatics*, 2 J. MED. INTERNET RES. e18 (2000), *available at* http://www.jmir.org/2000/3/e18.

129. *See* Paul Malik, *Insourcing and Outsourcing*, 20 CAN. J. CARDIOLOGY 679, 679 (2004), *available at* http://www.pulsus.com/CARDIOL/20_07/mali_ed.htm.

130. *See, e.g.*, *id.*

131. *See, e.g.*, Milt Freudenheim, *Drugstores Fret as Insurers Demand Pills by Mail*, N.Y. TIMES, Jan. 1, 2005, at A1, *available at* 2005 WLNR 22598 (Westlaw).

sourced their information technologies (IT) functions.[132] Although late to the outsourcing model (compared to, for example, financial services), health care IT (HIT) outsourcing both within the U.S. and offshore is increasing rapidly, and already includes managed care call centers, systems design, and strategic planning.[133]

As documented by Tom McLean, offshoring has a rich, complex socio-political history, and it was only a matter of time before it caught health care services in its web.[134] Non-domestic, offshore outsourcing was first embraced by U.S. IT companies and it has grown exponentially.[135] IT outsourcing has permitted the leveraging of time zones to provide 24-7 support in addition to decreasing labor costs by using highly trained, but less expensive, foreign workers for call centers. Not all foreign outsourcing goes to the Eastern Hemisphere. So-called nearshoring refers to outsourcing to countries that share geographic or cultural proximity with the source country. Increasingly, European countries nearshore to former Eastern bloc countries, while United States companies look to Canada or Ireland.[136]

A. *Offshore Data Processing*

Today, HIT are at the very core of health care. U.S. health care's tardy[137] but rapidly accelerating investment in HIT, including HIPAA-mandated electronic transactions, error-reducing "process-

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132. *The HIT Report from KLAS: Successes and Challenges with Full IT Outsourcing*, 4 ELECTRONICHEALTHCARE 110, 110-16 (2005), *available at* http://www.longwoods.com/product.php?productid=17707&cat=401&page=1 (follow the "Download PDF" hyperlink).

133. *See, e.g.*, Harry Downs, Jr., *Outsourcing and IT: Keeping Innovation In-House*, AHIP COVERAGE, Sept.-Oct. 2004, at 72; Susan Kirkpatrick, *Using Information Networks as a Decision-Making Tool*, J. HEALTHCARE RESOURCE MGMT., Nov. 1995, at 21, 21-24; *see also* Alan Joch, *Wiping the Slate Clean: Why Network Outsourcing is In*, HEALTHCARE INFORMATICS, Jan. 1998, 81, 81-84.

134. *See generally* McLean, *supra* note 58.

135. *See, e.g.*, Saritha Rai, *India Becoming a Crucial Cog in the Machine at I.B.M.*, N.Y. TIMES, June 5, 2006, at C4, *available at* 2006 WLNR 9593509 (Westlaw) (reporting that IBM now has 43,000 employees in India, while continuing to make cuts in its U.S. workforce); *see also* Steve Lohr, *Indian Outsourcer Says Big Profits Will Continue*, N.Y. TIMES, Apr. 15, 2006, at C3, *available at* 2006 WLNR 6337512 (Westlaw) (reporting positive revenue and profits for Indian and U.S. companies' outsourcing operations in India).

136. Geoffrey Nairn, *New Contenders Jostle for Software Crown*, FIN. TIMES (London), Dec. 1, 2004, *available at* 2004 WLNR 12534333 (Westlaw).

137. *See generally* Jeff Goldsmith et al., *Federal Health Information Policy: A Case of Arrested Development*, HEALTH AFF., May-June 2003, at 44.

supporting" technologies, and electronic medical records,[138] has coincided with unprecedented pressure to reduce costs. IT is not a health care industry core competency and has proved itself to be a prime candidate for offshoring. The administrative complexity and costs of U.S. health care are significant contributors to its higher prices relative to other countries.[139] HIPAA's "Administrative Simplification" has not delivered on expected cost-savings;[140] offshoring its mandated electronic transactions processes to lower-cost IT countries might.

In India, data entry costs are less than half of what they are in the United States.[141] In fact, "Already half of the $20 billion U.S. medical transcription industry is outsourced" to other countries.[142] Billing, coding, data-clearing, claims processing, and electronic records data processing and storage follow.

U.S. law extensively regulates the processing and storage of patient data, such as medical records and images, with regard to retention, integrity, confidentiality, and security. Although now supplemented by federal Medicare rules,[143] state statutory rules generally continue to govern the length of time that providers must retain records and images.[144] In addition, the AMA Code of Medical Ethics places an obligation on physicians "to retain patient records which may reasonably be of value to a patient" and urges physicians to take note of state and federal retention rules and applicable medical malpractice statutes of limitation.[145] Similarly, federal regulations,[146] Joint Commission on Accreditation of

138. *See generally* Nicolas P. Terry, *To HIPAA, a Son: Assessing the Technical, Conceptual, and Legal Frameworks for Patient Safety Information*, 12 WIDENER L. REV. 137 (2006) [hereinafter Terry, *To HIPAA, a Son*].

139. Uwe E. Reinhardt et al., *U.S. Health Care Spending in an International Context*, HEALTH AFF., May-June 2004, at 10, 13-15.

140. D'Arcy Guerin Gue with Randa Upham, *The HIPAA Prescription for Healthcare—Why Isn't It Working?*, HEALTH MGMT. TECH., Sept. 2004, at 34, 34, 36.

141. Ed Silverman, *It's a Small World After All: Outsourcing Makes Inroads*, MANAGED CARE, June 2005, at 46, 48.

142. Terry, *To HIPAA, a Son*, *supra* note 138, at 164; *see* David Lazarus, *Looking Offshore: Outsourced UCSF Notes Highlight Privacy Risk, How One Offshore Worker Sent Tremor Through Medical System*, S.F. CHRON., Mar. 28, 2004, at A1 [hereinafter Lazarus, *Looking Offshore*], *available at* 2004 WLNR 7644456 (Westlaw).

143. *See, e.g.*, Condition of Participation: Medical Record Services, 42 C.F.R. § 482.24(b)(1) (2005) ("Medical records must be retained in their original or legally reproduced form for a period of at least 5 years.").

144. *See, e.g.*, N.M. STAT. ANN. § 14-6-2 (West 2003); LA. REV. STAT. ANN. § 40:2144(F) (2001).

145. CODE OF MEDICAL ETHICS E-7.05 (1994).

146. 42 C.F.R. §§ 482.24(b), (c) (2006).

Healthcare Organizations (JCAHO) accreditation rules,[147] and state licensure laws all impose duties of accuracy, completeness, legibility, and timeliness on the keeping of records.[148] Some state statutes prohibit the alteration of records,[149] and expanding common-law remedies for spoliation penalize their concealment or destruction.[150] There is also authority for the proposition that keeping inadequate records can constitute common-law malpractice.[151] The as yet unanswered question is how effective these domestic-facing regulatory models are in protecting U.S. patient data processed offshore.

Concerns about the confidentiality and security of patient data being processed offshore were highlighted by two events in 2003. First, a medical transcriber in Pakistan, working for a subcontractor for the University of California at San Francisco, e-mailed the hospital and threatened to distribute patient files on the Internet after the contractor allegedly failed to pay her.[152] Just a few weeks later, employees of the Indian office of another U.S. transcription company sent an anonymous e-mail to the company threatening to re-

147. JOINT COMM'N ON ACCREDITATION OF HEALTHCARE ORGS., 2005 CRITICAL ACCESS HOSPITAL STANDARDS, MANAGEMENT OF INFORMATION 14, *available at* http://www.worh.org/pdf_etc/Dec2/standards.pdf ("The medical record contains sufficient information to identify the patient; support the diagnosis/condition; justify the care, treatment, and services; document the course and results of care, treatment, and services; and promote continuity of care among providers.").

148. *See, e.g.*, N.M. STAT. ANN. § 61-6-15(D) (West 2003) ("'Unprofessional or dishonorable conduct' . . . includes . . . (33) improper management of medical records, including failure to maintain timely, accurate, legible and complete medical records."); NEV. REV. STAT. ANN. § 630.3062-1 (LexisNexis 2005); WYO. STAT. ANN. § 33-26-402(a)(xxvii)(G) (2005); Schwarz v. Bd. of Regents, 453 N.Y.S.2d 836 (N.Y. App. Div. 1982); Nieves v. Chassin, 625 N.Y.S.2d 344 (N.Y. App. Div. 1995).

149. *See, e.g.*, NEV. REV. STAT. ANN. § 630.3062-2 (LexisNexis 2005).

150. *See, e.g.*, Keene v. Brigham & Women's Hosp., Inc., 786 N.E.2d 824 (Mass. 2003) (upholding sanction of liability because of missing records); Rosenblit v. Zimmerman, 766 A.2d 749 (N.J. 2000) (canvassing various remedies and adopting independent tort remedy); *cf.* Brown v. Hamid, 856 S.W.2d 51, 57 (Mo. 1993) ("The Missouri cases, statutes, and common law address a physician's duty to let the patient inspect and copy medical records. They do not create an independent duty to *maintain* medical records. To be sure, in another case, failure to maintain medical records may contribute to, or constitute, medical malpractice. . . . There is no need, in this case, to recognize an independent tort of negligent maintenance of medical records.").

151. Thomas v. United States, 660 F. Supp. 216, 218 (D.C. Cir. 1987).

152. David Lazarus, *A Tough Lesson on Medical Privacy, Pakistani Transcriber Threatens UCSF Over Back Pay*, S.F. CHRON., Oct. 22, 2003, at A1, *available at* 2003 WLNR 8302881 (Westlaw); *see also* Lazarus, *Looking Offshore*, *supra* note 142.

lease medical records, but they were apprehended by police at a Bangalore Internet café.[153]

HIPAA privacy (actually, confidentiality)[154] and security applies only to a limited subset of health care entities,[155] "a relatively narrow purview given the range of U.S. and offshore players likely to be involved in [medical data] processing."[156] Notwithstanding, many of the U.S.-based data "extenders," such as outsourced radiology or ICU monitors, likely will be "covered entities." Furthermore, U.S. or offshore data processors of Protected Health Information (PHI)[157] are "business associates"[158] of HIPAA "covered entities."[159] As such, these contractual relationships must incorporate HIPAA limitations on data disclosure.[160]

U.S. records laws and HIPAA confidentiality and security obviously apply to U.S. providers who use offshore data entry and processing.[161] However, questions have been raised as to the extent to which such protections can be enforced against non-U.S. contractors.[162] In 2004, Congressman Edward Markey formally questioned the sufficiency of offshore data protection. Responding, "then HHS Secretary [Tommy] Thompson admitted that his department failed to document the 'nature or content' of the contracts between covered entities and their business associates, or directly regulate

153. David Lazarus, *Extortion Threat to Patients' Records*, S.F. CHRON., Apr. 2, 2004, at A1, *available at* 2004 WLNR 7648210 (Westlaw).

154. *See generally* Nicolas P. Terry & Leslie P. Francis, *Ensuring the Privacy and Confidentiality of Electronic Health Records*, 2007 U. ILL. L. REV. 681 [hereinafter Terry & Francis, *Ensuring the Privacy and Confidentiality of Electronic Health Records*].

155. 45 C.F.R. § 160.103 (2005).

156. Terry, *To HIPAA, a Son*, *supra* note 138, at 164.

157. 45 C.F.R. § 160.103 (defining "protected health information" as "individually identifiable health information," which includes "demographic information collected from an individual, and: (1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (i) That identifies the individual; or (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual").

158. Terry, *To HIPAA, a Son*, *supra* note 138, at 164.

159. *Id.*

160. 45 C.F.R. § 164.504(c) (2005).

161. For a useful survey of the data confidentiality and security issues and detail on legal reform in destination countries, see Barbara Crutchfield George & Deborah Roach Gaut, *Offshore Outsourcing to India by U.S. and E.U. Companies: Legal and Cross-Cultural Issues That Affect Data Privacy Regulation In Business*, 6 U.C. DAVIS BUS. L.J. 13 (2006).

162. *See, e.g.*, David Lazarus, *Medical Charts Not All that Private*, S.F. CHRON., June 8, 2003, at A1, *available at* 2003 WLNR 8241189 (Westlaw).

offshore business associates."[163] Keen to protect their new HIT industries, offshore processing destinations such as India and Pakistan are attempting to reduce the vector between domestic and foreign data-source laws by improving legal protections for outsourced data processed within their borders.[164]

B. *Offshore Medical Services*

Information technologies are obviously highly portable. But other technology that enables portability affects the way clinical services may be provided. Specifically, technology facilitates the disaggregation (e.g., separating an assay from its interpretation)[165] of some heretofore unitary and exclusively professional tasks. Disaggregation of professional tasks already has led to physician extenders, such as nurse practitioners and physician assistants. The technological mediation of health care enables data extenders. Faced with growing shortages in some physician specialties,[166] the health care industry is leveraging this technology to outsource and even offshore some clinical tasks to data extenders. Radiology is already heavily offshored; pathology may soon follow, as may the already outsourced task of ICU monitoring.[167]

The Leapfrog Group, the well-known health safety advocacy organization, has noted that mortality rates are significantly lower in hospital ICUs that are exclusively staffed with board-certified intensivists.[168] ICU demand is increasing dramatically, but at the same time, there is a shortage of both intensivists and pharma-

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163. Terry, *To HIPAA, a Son*, *supra* note 138, at 165 (citing Letter from Tommy G. Thompson, Sec'y, U.S. Dep't of Health & Human Servs., to Edward J. Markey, Congressman, U.S. H. of Reps. 2 (June 14, 2004)).

164. *See, e.g.*, *IT Ministry Unveils Draft of Data Protection Act*, DAILY TIMES (Pakistan), Nov.14, 2004, *available at* http://www.dailytimes.com.pk/default.asp?page=story_14-11-2004_pg7_38.

165. Robert M. Wachter, *The "Dis-location" of U.S. Medicine—The Implications of Medical Outsourcing*, 354 NEW ENG. J. MED. 661, 663 (2006).

166. *See, e.g.*, Raja Mishra, *Radiology Work Shifts To Overnight, Overseas*, BOSTON GLOBE, June 29, 2005, at A1, *available at* 2005 WLNR 10231496 (Westlaw) (noting shortages in Massachusetts of neurosurgery, anesthesiology, gastroenterology, cardiology, orthopedics, and radiology specialists). *See generally* Richard A. Cooper et al., *Economic and Demographic Trends Signal an Impending Physician Shortage*, HEALTH AFF., Jan.-Feb. 2002, at 140, *available at* http://content.healthaffairs.org/cgi/reprint/21/1/140.pdf.

167. Rob Stein, *Hospital Services Performed Overseas*, WASH. POST, Apr. 24, 2005, at A1, *available at* 2005 WLNR 6383494 (Westlaw).

168. THE LEAPFROG GROUP, ICU PHYSICIAN STAFFING 1 (2007), *available at* http://www.leapfroggroup.org/media/file/Leapfrog-ICU_Physician_Staffing_Fact_Sheet.pdf.

cists.[169] As a result, electronic outsourcing of ICU supervision[170] is now common, with more than one hundred U.S. hospitals using remote monitoring for their ICUs.[171] If reimbursement rules change, remote monitoring by home health care agencies likely will follow this trend.[172] There are no obvious practical reasons why such monitoring cannot take place on the other side of the world.

There is a critical shortage of radiologists practicing in the United States, leading to some three hundred U.S. hospitals now outsourcing their imaging.[173] This is possible because of the sophistication of modern Picture Archiving and Communication System networks. Again, outsourcing is possible because of disaggregation and, once disaggregated, there are few barriers to offshore processing. Licensed (frequently dual-licensed), American-trained, and credentialed radiologists in Australia,[174] Israel,[175] and India all provide nighttime coverage for U.S. hospitals. For example, Bangalore-based Teleradiology Solutions uses HIPAA-compliant high-speed connections to provide a "preliminary interpretation" of CT, MRI, conventional, and ultrasound scans within thirty minutes from when the scan takes place in the United States.[176] The term "preliminary interpretation" is used in large part because of the Centers for Medicare and Medicaid Services rule that, some emergency situations aside, Medicare does not reimburse for services furnished outside the United States.[177] As a result, a domestic radiologist will (or should) submit a "final primary report" after subsequently ex-

169. Leo Anthony Celi et al., *The eICU: It's Not Just Telemedicine*, 29 CRITICAL CARE MED. N183, N183-N184 (2001).

170. For a description of the technologies in practice, see Celi, *id.* *See* Carolyn Thompson, *'EICU' Lets Doctors Monitor Many Patients*, eWEEK, Jan. 3, 2005, *available at* 2005 WLNR 1943649 (Westlaw); Timothy J. Mullaney, *The Doctor is (Plugged) In*, BUS. WK., June 26, 2006, at 56, *available at* 2006 WLNR 10780096 (Westlaw).

171. Sarah Lovinger, *Beaming Images Overseas Sparks Controversy at Home*, ACP OBSERVER, May 2006, *available at* http://www.acponline.org/journals/news/may06/outsource.htm.

172. *See, e.g.*, Marilyn J. Field & Jim Grigsby, *Telemedicine and Remote Patient Monitoring*, 288 JAMA 423, 424 (2002), *available at* http://jama.ama-assn.org/cgi/reprint/288/4/423.pdf.

173. Lovinger, *supra* note 171.

174. Greg Gillespie, *Down Under Image Readers Cover U.S. Radiologists*, HEALTH DATA MGMT., July 1, 2005, at 16, *available at* 2005 WLNR 10362694 (Westlaw).

175. Erica Chernofsky, *The View from Here*, JERUSALEM POST (Isr.), Mar. 17, 2006, at 22, *available at* 2006 WLNR 4799982 (Westlaw).

176. *See, e.g.*, Teleradiology Solutions, Interpretive Services, http://www.telradsol.com/services.htm (last visited Mar. 18, 2007).

177. 42 C.F.R. § 411.9(a) (2006). Centers for Medicare & Medicaid Services (CMS) is currently reviewing aspects of this rule. Press Release, CMS, FY 2007 Hospi-

amining the image.[178] However, additional state impediments to such arrangements, such as corporate practice and fee splitting, may not be so simply avoided.[179]

C. *Pharmaceutical Arbitrage*

There are several motives behind patient interest in "outsourcing" access to pharmaceuticals. Worldwide, pharmaceutical companies practice price and distribution discrimination;[180] the limited formularies of state-run health care systems and managed care organizations, or their Pharmacy Benefits Managers (PBMs), bar subsidized access to some drugs, while underinsured patients (those with shallow coverage) increasingly cannot afford the "market price" of drugs prescribed for them.[181] Meanwhile, some outlying "patients" pursue controlled substances or lifestyle drugs that their doctors will not prescribe or that they are too embarrassed to request.[182]

As a general rule, health care consumers or payers in the United States cannot legally acquire prescription drugs outside traditional domestic distribution channels.[183] The FDA, citing the Food, Drug, and Cosmetic Act (FDCA),[184] has taken the position that "gray-market" versions of an approved drug, and even U.S.-

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tal Inpatient Prospective Payment System Proposed Rule (Apr. 12, 2006), *available at* http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1834.

178. Wachter, *supra* note 165, at 662.

179. *See, e.g.*, Nicole Huberfeld, *Be Not Afraid of Change: Time to Eliminate the Corporate Practice of Medicine Doctrine*, 14 HEALTH MATRIX 243, 243-44 (2004).

> The modern version of the corporate practice of medicine doctrine derives from two principles: (1) any person that "practices medicine" must be licensed by the state in which she practices to provide medical services and (2) health care professionals cannot assist unlicensed persons or entities in practicing unlicensed medicine, which prevents the splitting of professional fees with non-professionals.

Id. (citations omitted).

180. *Cf. In re* Canadian Import Antitrust Litigation, 470 F.3d 785, 791 (8th Cir. 2006) ("The absence of competition from Canadian sources in the domestic prescription drug market, therefore, is caused by the federal statutory and regulatory scheme adopted by the United States government, not by the conduct of the defendants. Consequently, the alleged conduct of the defendants did not cause an injury of the type that the antitrust laws were designed to remedy.").

181. *See, e.g.*, Milt Freudenheim, *Drug Prices Up Sharply This Year*, N.Y. TIMES, June 21, 2006, at C1, *available at* 2006 WLNR 10674943 (Westlaw) (discussing an AARP study that noted that the wholesale price of brand-name pharmaceuticals increased 3.9 percent, four times the inflation rate during the first quarter of 2006).

182. *See* Terry, *Prescriptions sans Frontières*, *supra* note 62, at 222, 225.

183. *See generally id.*

184. Food, Drug, & Cosmetic Act, 21 U.S.C. § 355(a) (2000).

sourced reimported drugs, are unapproved because they do not comply with U.S. labeling and packaging requirements[185] and contravene the monopoly on reimportation granted to U.S. manufacturers.[186]

As is the case in most Western countries,[187] an exception exists for those who enter the United States (including returning medical tourists) with personal supplies of prescription drugs. The Controlled Substances Act (CSA)[188] allows individuals to personally import a prescription drug "if: (1) the substance is found in one of the approved 'schedules,' (2) the substance is in its original container, (3) a declaration is made to the United States Customs Service, and (4) use of such substance is permitted by federal and state laws."[189] "There is no personal importation exception in the FDCA. The FDA, however, has issued enforcement guidelines [for customs officers] that create a de facto exemption" where "'the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user.'"[190] The CSA exemption clearly assumes that the drugs are in the possession of a traveler,[191] while the FDA guidance implies the same by excluding commercial and promotional shipments. "The Guidance also states that non-commercial shipments generally include products that are: 'personally carried, shipped by a personal non-commercial representative of a co-signee, or shipped from [a] foreign medical center

185. *See generally* 21 C.F.R. § 314.50 (2006) (listing drug application requirements).

186. 21 U.S.C. § 381(d)(1) ("[N]o drug subject to section 353(b) of this title . . . which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug.").

187. *See, e.g.*, Australian Gov., Therapeutic Goods Admin., Travellers Visiting Australia, Importing Medicines for Personal Use, http://www.tga.gov.au/docs/html/bringmed/intoaust.htm (last visited Mar. 18, 2007).

188. Controlled Substances Act, 21 U.S.C. §§ 801-971 (2000).

189. Terry, *Prescriptions sans Frontières*, *supra* note 62, at 205 (citing 21 U.S.C. § 956(a) (2000)). The Controlled Substances Trafficking Prohibition Act of 1998 tightened this exception, stating that a U.S. resident may not enter the United States through an international land border with more than fifty dosage units of a controlled substance unless the individual possesses a valid prescription issued by a practitioner in accordance with federal and state law. *See id.* (citing 21 U.S.C. § 956(a)(2)).

190. Terry, *Prescriptions sans Frontières*, *supra* note 62, at 272 n.129 (quoting FDA, OFF. OF REGULATORY AFF., REGULATORY PROCEDURES MANUAL: CHAPTER 9, SUBCHAPER COVERAGE OF PERSONAL IMPORTATIONS (2006)). Chapter 9 is currently under revision.

191. 21 C.F.R. § 1301.26 (2006) ("Any individual who has in his/her possession a controlled substance . . . may enter or depart the United States . . . .").

where [a] person has undergone treatment.'"[192] Short-term "tourists," frequently retirees on fixed incomes, who take bus rides over the Canadian or Mexican borders to buy their prescription medicines, routinely rely upon the CSA exemption and the FDA guidance.[193]

U.S. patients in increasing numbers have looked to the Internet to acquire "gray-market" drugs. The first generation of online prescribing sites apparently featured licensed doctors who reviewed questionnaire-based histories before writing prescriptions that were then forwarded to associated pharmacy operations for mail-order fulfillment.[194] In reality, most of these prescribing sites used contract ghostwriters of suspect licensure to rubber-stamp the prescriptions.[195] Viewing a fight against online prescribing as part of the "war on drugs," U.S. states amended their physician licensure rules to essentially outlaw this gray market[196] by requiring a "traditional" or "proper" relationship between the prescribing physician and the patient designed to guarantee in-person contact or a "good faith prior examination."[197] At the same time, federal and state authorities have become more rigorous in regulating the activities of online U.S. pharmacies.[198] As a result and not surprisingly, the suppliers have moved offshore. No longer a "gray" area, the

192. Terry, *Prescriptions sans Frontières*, *supra* note 62, at 206-07 (quoting Marvin A. Blumberg, FDA, Information on the Importation of Drugs, Prepared by the Division of Import Operations and Policy, FDA (Apr. 3, 1998), http://www.fda.gov/ora/import/pipinfo.htm); *see also* FDA, OFF. OF REGULATORY AFF., REGULATORY PROCEDURES MANUAL: CHAPTER 9, SUBCHAPER COVERAGE OF PERSONAL IMPORTATIONS (2006), *available at* http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html.

193. *See, e.g.*, Alexander Colhoun, *Get on the Bus: Extreme Answers to Prescription Drug Costs*, CHRISTIAN SCI. MONITOR, Apr. 18, 2000, at 3, *available at* http://www.csmonitor.com/2000/0418/p3s1.html; Randi Hunter Epstein, *Some Retirees Look Abroad for Prescription Drugs*, N.Y. TIMES, Sept. 24, 2002, at F5, *available at* 2002 WLNR 4068017 (Westlaw).

194. *See, e.g.*, State *ex rel.* Stovall v. ConfiMed.com, L.L.C., 38 P.3d 707 (Kan. 2002) (prosecution of questionnaire-prescribing doctor following a state "sting" operation).

195. *See, e.g.*, United States v. Nelson, 72 Fed. App'x 837 (10th Cir. 2003), *aff'd*, 383 F.3d 1227 (10th Cir. 2004).

196. *See* Terry, *Prescriptions sans Frontières*, *supra* note 62, at 204.

197. *See, e.g.*, CAL. BUS. & PROF. CODE § 2242(a) (West 2006); ARIZ. REV. STAT. ANN. § 32-1854 (West 2006).

198. *See, e.g.*, United States v. Rx Depot, Inc., 438 F.3d 1052 (10th Cir. 2006); *see also* Bob Tedeschi, *Pharmacies Endorse Crackdown on Fraud*, N.Y. TIMES, Oct. 24, 2005, at C4, *available at* 2005 WLNR 17161884 (Westlaw) (noting the closing of 4,600 illegal Internet pharmacy sites by federal drug investigators).

issue is now one of practical enforcement.[199] Faced with millions of foreign-sourced drug shipments into the United States each year,[200] law enforcement has tried to slow the traffic with the help of credit card companies,[201] shippers,[202] and even Internet search engines.[203]

The matter might have ended there had it not been for the quite unprecedented entry of several U.S. states into the gray market enterprise. Numerous states and municipalities, concerned about prescription drug costs,[204] have encouraged reimportation and petitioned the FDA for a waiver,[205] or even set up their own reimportation plans.[206] Throughout, the FDA has successfully defended its policy before the federal courts[207] and been resolute in its opposition to state reimportation initiatives. For example, in a 2006 response to a waiver application from the State of Washington, the Agency stated:

> Granting a waiver that permits the importation of prescription drugs from Canada, U.K., Ireland, and other foreign countries will not only result in violations of federal law, but could also put Washington State citizens at risk. FDA approves a drug based on scientific data submitted by the drug sponsor to demonstrate that the drug is safe and effective. We cannot provide adequate assur-

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199. *See generally Prescription Drugs, Preliminary Observations on Efforts to Enforce the Prohibitions on Personal Importation: Hearing Before the S. Permanent Subcomm. on Investigations, Comm. on Governmental Affairs*, 109th Cong. (2004) (statement of Richard M. Stana, Dir., Homeland Security & Justice Issues), *available at* http://www.senate.gov/~govt-aff/_files/072204stana_gao3494.pdf.

200. *See, e.g.*, *A New Source for Discount Prescriptions*, N.Y. TIMES, Dec. 26, 2002, at A36, *available at* 2002 WLNR 4442939 (Westlaw).

201. *See, e.g.*, Gilbert M. Gaul & Mary Pat Flaherty, *Firms Pressed on Internet Drugs; Senate Panel Writes to Credit Card Companies, Shippers*, WASH. POST, Dec. 10, 2003, at A4, *available at* LEXIS.

202. *See, e.g.*, Rick Brooks, *FedEx and UPS Say They Shun Parcels Containing Illicit Drugs*, WALL ST. J., Jan. 9, 2004, at A8, *available at* LEXIS.

203. *See, e.g.*, Gilbert M. Gaul & Mary Pat Flaherty, *Google to Limit Some Drug Ads; Web Giants Asked to Help Discourage Illicit Online Pharmacies*, WASH. POST, Dec. 1, 2003, at A1, *available at* 2003 WLNR 5808635 (Westlaw).

204. For examples of cost savings, see *Cross-border Rx*, CBC NEWS ONLINE, Jan. 17, 2006, http://www.cbc.ca/news/background/drugs.

205. *See, e.g.*, STATE OF VT. AGENCY OF ADMIN., CITIZEN PETITION FOR WAIVER (2003), *available at* http://www.vermontpersonnel.org/employee/pdf/FDAPetition120703.pdf. The FDA subsequently rejected the petition. Letter from William K. Hubbard, Assoc. Comm'r for Pol'y & Planning, FDA, to Michael K. Smith, Sec'y of Admin., State of Vt. (Aug. 4, 2004), *available at* http://www.vermontpersonnel.org/htm/pdf/FDADenial.pdf.

206. *See* Terry, *Prescriptions sans Frontières*, *supra* note 62, at 207-17.

207. *See, e.g.*, Andrews v. U.S. Dep't of Health & Human Servs., No. 04-0307, 2005 U.S. Dist. LEXIS 5710 (D.D.C. Mar. 31, 2005); Vermont v. Leavitt, 405 F. Supp. 2d 466 (D. Vt. 2005).

> ance to your constituents that the drug products delivered to them from foreign countries are the same products approved by FDA.[208]

Undeterred and increasingly irritated with the federal government,[209] several states have persisted and jointly sponsor I-Save RX, a website developed by the governor of Illinois but now also serving residents of Wisconsin, Kansas, Missouri, and Vermont.[210] I-Save RX uses a Canadian PBM as an intermediary,[211] and the PBM sources the drugs from pharmacies and wholesalers in Canada, Ireland, the United Kingdom, New Zealand, and Australia. The I-Save RX program only applies to prescription refills and excludes most controlled substances or drugs that require special handling. Under the program, U.S. prescriptions and medical histories are forwarded to physicians in the supplying countries, apparently rewritten to comply with local laws, and dispensed by local, licensed pharmacists who then ship the medicine to the United States.[212]

Pharmaceutical manufacturers have attempted to cut off foreign pharmacies by more rigorously controlling and policing their wholesale distribution.[213] Not surprisingly, the FDA has targeted shipments into the United States by I-Save RX suppliers[214] and, after lobbying by the United States, Canada's health minister has announced plans to increase regulation of the cross-border trade and to cut off bulk supplies to the United States.[215] Critics have even

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208. Letter from Randall W. Lutter, Assoc. Comm'r for Pol'y & Planning, FDA, to Steven M. Saxe, Dir., Wash. State Bd. of Pharmacy (Mar. 17, 2006), *available at* http://www.fda.gov/oc/opacom/hottopics/importdrugs/saxe031706.html.

209. *See, e.g.*, Vt. Dep't of Human Res., Tackling the Prescription Drug Crisis, http://www.vermontpersonnel.org/htm/prescription.php (last visited Mar. 18, 2007).

210. I-SaveRx, Welcome to I-SaveRx, http://www.i-saverx.net (last visited Mar. 18, 2007).

211. CanaRx, Servs., Inc., CanaRx, http://www.canarx.com (last visited Mar. 18, 2007).

212. I-SaveRx, Frequently Asked Questions: Order Questions, http://www.i-saverx.net/enrollment.htm (last visited Mar. 18, 2007).

213. *See, e.g.*, Mark Heinzl & Tamsin Carlisle, *Canadian Pharmacies vs. Big Drug Makers—Online Retailers Vow to Fight Edict Seeking to Clamp Down on Cheap Exports to the U.S.*, WALL ST. J., Aug. 12, 2003, at D4, *available at* LEXIS; Bernard Simon, *Pfizer Moves To Try To Stop Drugs from Canada*, N.Y. TIMES, Jan. 14, 2004, at W1, *available at* 2004 WLNR 5507399 (Westlaw); *Fearing End to Canada Drugs, States Now Look to Europe*, USA TODAY, Jan. 14, 2005, *available at* http://www.usatoday.com/news/health/2005-01-14-drugs-europe_x.htm.

214. *FDA: Seizes Shipments Imported Through I-Save Rx Program*, AM. HEALTH LINE, Mar. 10, 2005, *available at* LEXIS.

215. Judith Graham, *Canada to Ban Bulk Drug Exports, Allow Internet Sales*, CHI. TRIB., June 30, 2005, at C7, *available at* 2005 WLNR 23487959 (Westlaw); *cf.* Lisa Girion, *Senate Votes to Ease Drug Imports*, L.A. TIMES, July 12, 2006, at C1, *available at*

argued that the I-Save RX program creates confusion among consumers facing enrollment in the new Medicare Part D[216] low-cost drug plans.[217] Notwithstanding, political pressure and consumer complaints have finally led the FDA away from seizing small prescription shipments and to instead concentrate on larger shipments of illegal drugs.[218] However, given adverse changes in the U.S.-Canada exchange rate,[219] and the relatively small number of orders processed by I-Save RX (there are 27 million eligible residents, yet fewer than 20,000 orders were placed in its first two years of operation),[220] it may be that the program now primarily functions as a political symbol.

D. *Clinical Trials*

In 2004, pharmaceutical companies spent nearly $39 billion on research and development. Twenty-one percent of this was spent outside the U.S. The outsourcing of clinical trials is a relatively new drug (and device) research and development (R&D) phenomenon led by the increasing importance of Contract Research Organizations (CROs).[221] The major pharmaceutical companies predict that this outsourcing trend will continue in the near term, with 50-70 percent of clinical trials soon to be performed outside the United States.[222]

2006 WLNR 11980042 (Westlaw) (reporting 2006 House and Senate votes prohibiting customs seizures of prescription drugs imported or carried over the border by individuals).

216. The Medicare Part D program was introduced by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, 2071.

217. Mary Massingale, *State Promotional Effort May Confuse Those Dazed by Medicare Part D*, COPLEY NEWS SERV., Dec. 16, 2005, *available at* Westlaw.

218. *U.S. to Stop Seizing Canadian Drug Imports; New Policy Allows Seniors to Order Cheaper Prescriptions Through the Mail*, MSNBC.COM, Oct. 4, 2006, http://www.msnbc.msn.com/id/15127747.

219. Theresa Agovino, *Savings from Canada Drug Purchasing Falls*, ASSOCIATED PRESS, Jan. 5, 2005 (on file with the author).

220. Richard A. Rettig, *The Industrialization of Clinical Research*, HEALTH AFF., Mar.-Apr. 2000, at 129, 129-46, *available at* http://content.healthaffairs.org/cgi/reprint/19/2/129.pdf; Massingale, *supra* note 217; *see also* Warren Wolfe, *State's Seniors Buy Fewer Canadian Drugs*, STAR TRIB. (Minneapolis-St. Paul), July 12, 2006, at B2, *available at* 2006 WLNR 12097293 (Westlaw) (reporting that sales through the Minnesota RxConnect reimportation program have dropped to an all-time low).

221. Rettig, *supra* note 220, at 129-46.

222. Julie Schmit, *Costs, Regulations Move More Drug Tests Outside USA*, USA TODAY, May 16, 2005, *available at* http://www.usatoday.com/money/industries/health/drugs/2005-05-16-drug-trials-usat_x.htm.

The growth of offshore trials is partly explicable by the opportunities that manufacturers now have for concurrent, rather than sequential (to use the U.S. term), New Drug Applications[223] across several jurisdictions.[224] It is also a function of dramatically lower offshore costs and, according to critics, a way for drug companies to distance themselves from U.S. regulatory scrutiny.[225]

As with medical tourism, and stimulated by increasingly West-friendly intellectual property laws,[226] domestic and U.S.-owned CROs are blossoming in India.[227] Trials are performed in India at 40-60 percent of their cost in Western countries.[228] A large cohort of English-speaking researchers, and a massive patient population with genetically distinct subsets, makes India a particularly attractive location.[229] Offshore medical trials involving human subjects are also increasing in Thailand, Africa, China, and Latin America.

In *The Body Hunters*, a series of articles published in *The Washington Post* in 2000, investigators detailed offshore human experimentation that was marred by inadequate, untranslated, or forged consents, deficient supervision by local ethics committees or FDA investigators, and medical care of participants that met only local, not U.S., standards.[230] One such study investigated was Pfizer

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223. *See* FDA, Ctr. for Drug Evaluation & Research, New Drug Application (NDA) Process, http://www.fda.gov/cder/regulatory/applications/NDA.htm (last visited Mar. 18, 2007).

224. For example, lobbying from international pharmaceutical companies led India to remove the "phase lag" theretofore required by its Drugs and Cosmetics rules. *See* Samiran Nundy & Chandra M. Gulhati, *A New Colonialism?—Conducting Clinical Trials in India*, 352 NEW ENG. J. MED. 1633, 1633 (2005).

225. Schmit, *supra* note 222.

226. Gunjan Sinhu, Outsourcing Drug Work: Pharmaceuticals Ship R&D and Clinical Trials to India, SCI. AM., Aug. 16, 2004, at 24.

227. K. S. Jayaraman, *Outsourcing Clinical Trials to India Rash and Risky, Critics Warn*, 10 NATURE MED. 440 (2004), *available at* http://www.pridco.com/english/media_center/pdf_proxy.php?pdf_id=352.

228. *Id.*; Sinhu, *supra* note 226.

229. Jayaraman, *supra* note 227; *see also* Nundy & Gulhati, *supra* note 224, at 1634.

230. Joe Stevens, *Where Profits and Lives Hang in Balance; Finding an Abundance of Subjects and Lack of Oversight Abroad, Big Drug Companies Test Offshore to Speed Products to Market*, WASH. POST, Dec. 17, 2000, at A1, *available at* LEXIS; Mary Pat Flaherty et al., *Testing Tidal Wave Hits Overseas: On Distant Shores, Drug Firms Avoid Delays—and Scrutiny*, WASH. POST, Dec. 18, 2000, at A1, *available at* LEXIS; Estonia Parnu, *The Dilemma: Submit or Suffer; 'Uninformed Consent' Is Rising Ethic of the Drug Test Boom*, WASH. POST, Dec 19, 2000, at A1, *available at* LEXIS; John Pomfret & Deborah Nelson, *An Isolated Region's Genetic Mother Lode; Harvard-Led Study Mined DNA Riches: Some Donors Say Promises Were Broken*, WASH. POST, Dec. 20, 2000, at A1, *available at* LEXIS; Karen DeYoung & Deborah Nelson, *Latin America Is Ripe for Trials, and Fraud: Frantic Pace Could Overwhelm Controls*, WASH. POST, Dec.

Inc.'s Nigerian trials of "Trovan,"[231] an antibiotic, on children, resulting in multiple deaths and injuries. A subsequent Nigerian government investigation reportedly concluded that the research was illegal, and, contrary to allegedly altered documentation, the research had not been approved in advance by a Nigerian ethics committee.[232] Lawsuits brought against Pfizer in U.S. federal courts for alleged violations of international law, specifically, the Nuremberg Code and the Declaration of Helsinki, were dismissed for lack of subject matter jurisdiction under, inter alia, the Alien Tort Statute[233] and because of forum non conveniens,[234] notwithstanding evidence of severe deficiencies in parallel legal proceedings in Nigeria.[235] The fictionalized account in *The Constant Gardener* may be the victims' only memorial.[236]

The Common Rule[237] applies to all federally funded research involving human subjects, wherever it takes place.[238] As a result, Institutional Review Boards (IRBs)[239] and other domestic safe-

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21, 2000, at A1, *available at* LEXIS; Mary Pat Flaherty & Doug Struck, *Life by Luck of the Draw; In Third World Drug Tests, Some Subjects Go Untreated*, WASH. POST, Dec. 22, 2000, at A1, *available at* LEXIS.

231. Trovan is the Pfizer brand name for trovafloxacin mesylate.

232. Joe Stevens, *Panel Faults Pfizer in '96 Clinical Trial in Nigeria; Unapproved Drug Tested on Children*, WASH. POST, May 7, 2006, at A1, *available at* LEXIS.

233. 28 U.S.C. § 1350 (2000).

234. Adamu v. Pfizer, Inc., 399 F. Supp. 2d 495, 504-06 (S.D.N.Y. 2005); Abdullahi v. Pfizer, Inc., Nos. 12677, 12678 (WHP), 2005 U.S. Dist. LEXIS 16126, at *54 (S.D.N.Y. Aug. 9, 2005).

235. *Abdullahi*, 2005 U.S. Dist. LEXIS 16126, at *47-52.

236. JOHN LE CARRÉ, THE CONSTANT GARDENER (2000); *see also* Marcia Angell, *The Body Hunters*, N.Y. REV. BOOKS, Oct. 6, 2005, at 23, 23-25 (reviewing THE CONSTANT GARDENER (Universal Pictures 2005) and discussing the overlap of fact and fiction).

237. The Federal Policy for the Protection of Human Subjects, often referred to as the "Common Rule," has been adopted by seventeen federal agencies. It provides for human subject protection by conditioning such research on institutional assurances, institutional review board (IRB) review, and the informed consent of subjects. *See, e.g.*, U.S. Dep't of Health & Human Servs., Off. for Human Research Prot., Policy Guidance, Common Rule, http://www.hhs.gov/ohrp/policy/#common (last visited Mar. 18, 2007).

238. 45 C.F.R. § 46.101 (2005).

239. The FDA describes the role of an IRB as follows:

> Under FDA regulations, an IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research subjects.
>
> The purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of

guards apply.[240] As Alice Page has noted, however, these safeguards are almost exclusively procedural and "provide no guidance to IRBs or researchers about how ethics should be used as a mechanism for protecting human research subjects."[241]

Non-government-funded research (such as that performed by pharmaceutical companies or CROs) is not subject to the Common Rule. However, research leading to a U.S. drug New Drug Application or device Premarket Approval Application must be performed in compliance with generally applicable FDA rules. U.S. clinical studies must be performed under a U.S. Investigational New Drug Application (IND) or an Investigational Device Exemption (IDE). Foreign-based research does not require an IND or IDE, but the research sponsors can choose to apply for one; thereafter, all U.S. safeguards should apply.[242]

If the research is not performed under an IND or IDE, and involves foreign subjects, FDA rules require that the research is conducted in accordance with the ethical principles stated in the *Declaration of Helsinki* or local legal protections, whichever is greater.[243] Federal European standards take a similar approach, incorporating *Helsinki* and other international norms.[244]

In theory, therefore, offshore clinical trials are conditioned on similar qualitative and subject protections as U.S. trials. The difference, however, is in the level of inspection and scrutiny. For example, serious questions have been raised about the adequacy of the medical infrastructure in India to support quality trials, the training

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> humans participating as subjects in the research. To accomplish this purpose, IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research.

FDA, Guidance for Institutional Review Boards and Clinical Investigators, Frequently Asked Questions (1998), http://www.fda.gov/oc/ohrt/irbs/faqs.html.

240. *See, e.g.*, 45 C.F.R. § 46.103. If non-U.S. sites are involved, a Federalwide Assurance of compliance with the U.S. federal regulations is required. *See* U.S. Dep't of Health & Human Servs., Off. for Human Research Prot., Step-by-Step Instructions for Filing a Federalwide Assurance for International (Non-U.S.) Institutions (June 6, 2005), http://www.hhs.gov/ohrp/humansubjects/assurance/ifilasuri.htm.

241. Alice K. Page, *Ethical Issues in International Biomedical Research: An Overview*, 37 J. HEALTH L. 629, 636 (2004).

242. 21 C.F.R. §§ 312.120, 814.15(a) (2006).

243. 21 C.F.R. §§ 312.120(c)(1), 814.15(b). *See generally* FDA, GUIDANCE FOR INDUSTRY: ACCEPTANCE OF FOREIGN CLINICAL STUDIES (2001), *available at* http://www.fda.gov/cder/guidance/fstud.pdf.

244. *See, e.g.*, Commission Directive 2005/28, 2005 O.J. (L 091) 13, *available at* http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:32005L0028:EN:HTML.

of Indian researchers, the quantity and quality of Indian IRBs, and the local ethical standards (including informed-consent deficiencies) applied in dealing with subjects.[245] In a 2001 report, which was triggered by *The Body Hunters* and confirmed the dramatic increase in the number of offshore clinical trials, the U.S. Department of Health and Human Services' Office of Inspector General (OIG) found key differences in the scrutiny of offshore trials.[246] Specifically, the OIG noted deficiencies in the FDA's tracking of non-IND trials, the absence of FDA inspection of foreign IRBs, the lack of any "attestation" requirement for non-IND investigators and a failure to enforce attestation for foreign-based INDs, and generalized staffing, political, and logistical deficiencies that challenged rigorous FDA inspection of foreign research sites.[247]

III. GLOBALIZATION, HEALTH MARKETS, AND REGULATORY DILEMMAS

What can one conclude from this brief survey of medical tourism and outsourcing? Tourists who seek to leverage more favorable socio-medical policies (such as assisted suicide), or outsourcers looking to avoid quality or public-health-related regulation (such as acquiring drugs without prescriptions), may, for now, be dismissed as outliers. Most of the other scenarios described above rotate around international or regional cost vectors. Western tourists travel internationally for cheaper procedures, while Europeans travel regionally to avoid price-related rationing in their states of residence. U.S. hospitals outsource patient and hospital services (such as HIT and imaging) in search of reduced professional labor costs or surplus professionals. Western pharmaceutical companies testing their drugs seek both lower cost subjects (a function of reduced regulatory scrutiny) and less expensive researchers.

These cost-driven transfers are hardly surprising. The United States spends considerably more on health care than any other country, yet is below the Organisation for Economic Co-Operation and Development (OECD) median on service utilization.[248] Ger-

245. Nundy & Gulhati, *supra* note 224, at 1634.

246. U.S. DEP'T OF HEALTH & HUMAN SERVS., OFF. OF INSPECTOR GEN., THE GLOBALIZATION OF CLINICAL TRIALS 15-16 (2001), *available at* http://oig.hhs.gov/oei/reports/oei-01-00-00190.pdf.

247. *Id.* at 6-14; *see also* Jennifer Kahn, *A Nation of Guinea Pigs*, WIRED MAG., Mar. 2006, *available at* http://www.wired.com/wired/archive/14.03/indiadrug.html.

248. *Cf.* MICHAEL F. CANNON & MICHAEL D. TANNER, HEALTHY COMPETITION: WHAT'S HOLDING BACK HEALTH CARE AND HOW TO FREE IT 18-25 (2005) (conceding

ald Anderson and colleagues concluded that the primary difference between the United States and the health care systems of other countries is much higher pricing in the former.[249] They observed that the major reason for disparate pricing across national borders is the variable of "the degree to which [different countries] try to whittle away at the rent earned on the supply side through the creation of market power on the buy (monopsony) side of the market."[250] Thus, medical tourists and outsourcers (a perfect example is a U.S. state reimporting drugs from Canada) are in most cases seeking to leverage the vector between domestic and offshore levels of government intervention on the buy side.

Anderson and colleagues also addressed the question of why the global health care market fails to diminish national differences in buy-side policies (and hence prices).[251] Their explanation was that health care features poorly functioning domestic markets and trade-limiting barriers between domestic markets.[252] Most of the domestic market failures lie outside the scope of this Article.[253] However, the growing traction of "consumer-directed" health care, the latest in a long line of attempts to cure America's runaway health care costs,[254] is worth noting. Consumer Directed Healthcare Plans (CDHPs) have features such as high deductibles and work in tandem with personal Health Savings Accounts (HSAs)—all apparently designed to reduce misaligned incentives inherent in U.S. health care (because of, it is argued, over-reliance on third-

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that there is waste in the system due to, for example, government intervention, but arguing that high levels of spending are partly attributable to high income, elderly populations, beneficial technological advances, and that the United States outperforms other countries with regard to cancer patients and low-birth-weight infants).

249. Gerard F. Anderson et al., *It's the Prices, Stupid: Why the United States is so Different from Other Countries*, HEALTH AFF., May-June 2003, at 89, 89-90, *available at* http://www.medscape.com/viewarticle/452954_1.

250. *Id.* at 102; *see also* Reinhardt et al., *supra* note 139, at 10-25. In the present U.S. market, it takes aggressive pressure on the buy-side to have even minimal effects on pricing. *See* Scott Hensley, *Big Buyers Push for Steep Price Cuts From Drug Makers*, WALL ST. J., June 22, 2006, at B1, *available at* LEXIS.

251. Anderson et al., *supra* note 249.

252. *Id.* at 101-02 ("[N]either the goods and services nor all of the inputs that produce them are perfectly mobile across countries.").

253. *But see generally* CANNON & TANNER, *supra* note 248.

254. For a chronological treatment of attempts to cure health care costs including CDHPS, see Uwe E. Reinhardt, *Churchill's Dictum and the Next New Thing in American Health Care*, 38 BUS. ECON., July 2003, at 3.

party payment and decision-making)[255] and to empower consumers to make "market decisions" about how "their" health care dollars will be spent.[256] However, as related by Edward Larson and Marc Dettmann, preliminary indications are that HSAs "will have little impact on rising health care costs or shrinking health care access."[257] Nevertheless, if consumer-directed health care does prove effective, patients with unfettered access to low-cost foreign health care or heavily outsourced domestic health care may well spend "their" care dollars abroad.[258]

A. *Barriers to Health Care Trading*

At first sight, the number of tradable medical procedures appears to be relatively low. Self-evidently, the patient must be able to travel. But the pool of ambulatory patients has barely been tapped. In fact, the combination of tourism and outsourcing suggests that the number of tradable medical events should increase. Even with an as yet unmet practical ceiling on tourism, the continuing disaggregation of domestic care, coupled with outsourcing of many of its components (for example, offshoring of ICU monitoring or radiology triaging), suggests that physical or practical barriers are not determinative. The question arises, therefore, whether there are other barriers to medical trading that either limit current activity or are likely to cap it in the future.

1. Regulation and Trade Barriers

Policymakers, legislators, and professionals have never shown much enthusiasm for a flat health care world, even within their own borders. For example, in Europe, the Treaty of Rome and its progeny have left health care policy and financing as a matter primarily for the member states.[259] Within the United States, the question of who would regulate physicians was answered as early as 1889, "when the Supreme Court denied a due-process challenge to a West Virginia medical practice act which required state licensure of phy-

255. *See generally* John V. Jacobi, *After Managed Care: Gray Boxes, Tiers and Consumerism*, 47 ST. LOUIS U. L.J. 397 (2003); Greg Scandlen, *Consumer-Driven Health Care: Just a Tweak or a Revolution?*, 24 HEALTH AFF. 1554 (2005).

256. *See* CANNON & TANNER, *supra* note 248, at 66-73.

257. Edward J. Larson & Marc Dettmann, *The Impact of HSAs on Health Care Reform: Preliminary Results After One Year*, 40 WAKE FOREST L. REV. 1087, 1123 (2005).

258. *See* Scandlen, *supra* note 255, at 1554, 1557.

259. *See, e.g.*, Germany v. Parliament, Case C-376/98, 2000 E.C.R. I-08419 (invalidating pan-European tobacco advertising law).

sicians."[260] Only relatively recently, and not universally,[261] have national standards begun to prevail over local ones in malpractice cases.[262] Even HIPAA's "national" standard of health care information confidentiality is undercut by its partial preemption rule that favors "more stringent" state laws.[263]

Somewhat ironically, health care's ignorance that there is a flat world has also been responsible for a relative dearth of legal rules explicitly designed to impede medical trading. Obviously, immigration rules limit the freedom of movement of highly trained medical specialists, creating a supply-side surplus in some less-industrialized countries. As a result, notwithstanding initiatives such as the J-1 Visa Waiver program,[264] developed countries have been unable to satisfy their demand for foreign-trained doctors, and more recently, for nurses.[265] However, providers simply end-run this barrier with

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260. Terry, *Prescriptions sans Frontières*, *supra* note 62, at 190 (citing Dent v. West Virginia, 129 U.S. 114, 122 (1889)).

261. *See, e.g.*, Estate of Hagedorn v. Peterson, 690 N.W.2d 84, 90 (Iowa 2004) (approving jury instruction using a variant of the locality rule).

262. *See, e.g.*, Morrison v. MacNamara, 407 A.2d 555, 565 (D.C. Cir. 1979); Hall v. Hilbun, 466 So.2d 856, 872 (Miss. 1985); Sheeley v. Mem'l Hosp., 710 A.2d 161, 167 (R.I. 1998).

263. 45 C.F.R. § 160.202 (2005); *see, e.g.*, U.S. *ex rel.* Pogue v. Diabetes Treatment Ctrs. of Am., No. 99-3298, 2004 U.S. Dist. LEXIS 21830, at *10 (D.D.C. May 17, 2004); Nat'l Abortion Fed'n v. Ashcroft, No. 03 Civ. 8695 (RCC), 2004 U.S. Dist. LEXIS 4530, at *17 (S.D.N.Y. Mar. 18, 2004).

264. The Rural Initiative—J-1 Visa Waiver program, permits a U.S. Department of Health and Human Services/Immigration and Naturalization Service "waiver[ ] of [the] return-home requirement for foreign physicians who [have] trained in the United States" but who are prepared to stay and work in health professional shortage or medically underserved areas. Press Release, U.S. Dep't of Health & Human Servs., The Rural Initiative—J-1 Visa Waiver (Dec. 17, 2002), *available at* http://www.hhs.gov/ruralinitiative/waiver.html. For information on the effectiveness of the program, see *Foreign Physicians: Preliminary Findings on the Use of J-1 Visa Waivers to Practice in Underserved Areas: Hearing Before the Subcomm. on Immigration, Border Security and Claims of the H. Comm. on the Judiciary*, 109th Cong. (2006) (statement of Leslie G. Aronovitz, Dir., Health Care Issues, U.S. Gen. Accounting Off.), *available at* http://www.gao.gov/new.items/d06773t.pdf.

265. The supply of foreign trained nurses into the United States was robust (with 12,000 to 14,000 annual green cards) until the backlog of 2005. Celia W. Dugger, *U.S. Plan to Lure Nurses May Hurt Poor Nations*, N.Y. TIMES, May 24, 2006, at A1, *available at* 2006 WLNR 8880889 (Westlaw). The Comprehensive Immigration Reform Act of 2006 attempted to remedy this by removing the cap on the immigration of nurses for seven years. Comprehensive Immigration Reform Act of 2006, S. 2611, 109th Cong. (2006); *see* Press Release, Sam Brownback, U.S. Sen., Brownback Comments on Immigration Bill Passage (Mar. 27, 2006), *available at* http://brownback.senate.gov/pressapp/record.cfm?id=253170. However, the overall immigration package was unable to achieve House approval. *See* Adam Nagourney et al., *Bush's Immigration Plan Stalled As House G.O.P. Grew Anxious*, N.Y. TIMES, June 25, 2006, at A1, *available at* 2006 WLNR 10985951 (Westlaw).

outsourcing; immigration may be restricted, but there are minimal barriers to sending disaggregated services (e.g., imaging) offshore to be processed by those same surplus professionals.

Not surprisingly, some legal rules that impede interstate trade (e.g., licensure) will have the potential to create barriers to international trade. Take, for example, teleradiology. As already noted, the preliminary report made by the non-U.S. radiologist should be followed, upon transmittal back to the United States, by a final report from a domestic radiologist who has examined the image.[266] Domestic providers, possibly aware that local ethical and legal rules can be exploited for protectionist purposes, argue that the U.S. component frequently consists of no more than "ghosting."[267] In May 2006, the American College of Radiology issued a practice statement on this issue, stating that:

> It is unethical and likely fraudulent for a physician who has not personally interpreted the images obtained in a radiologic examination to sign a report or to take attribution of an interpretation of that examination rendered by another physician in a manner that causes the reader of a report to believe that the signing radiologist was the interpreter. This practice, known as ghost reporting, should be strictly prohibited.[268]

The College also called for the outsourced interpreters to possess dual licensure (both in the place where the image was obtained and where interpreted), to be credentialed by the facility where the image was obtained, to have valid malpractice coverage in the state where the image was obtained, and to submit to U.S. jurisdiction.[269]

If tourism continues to increase apace, hospitals may join doctors in looking nervously at the foreign competition. The controversy surrounding domestic, physician-owned specialty hospitals that leverage the "whole hospital" exception to self-referral prohibitions[270] may be predictive. These facilities allegedly cherry-pick "easier" (and hence more profitable) patient referrals and

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266. *See supra* text accompanying notes 177-178.

267. Stein, *supra* note 167 (describing "ghosting" as the practice of "radiology operations . . . staffed with one or two U.S.-certified radiologists who approve reports prepared by less-qualified technicians"); *see infra* note 268 and accompanying text (describing "ghost reporting").

268. Am. Coll. of Radiology, Revised Statement on the Interpretation of Radiology Images Outside the United States (May 2006), *available at* http://www.acr.org/s_acr/doc.asp?CID=541&DID=24137.

269. *Id.*

270. Stark Regulations, 42 C.F.R. §§ 411, 424 (2005).

higher-margin Diagnosis-Related Groups.[271] After extensive lobbying by traditional hospitals, the MMA[272] introduced a since-extended moratorium on such hospitals.[273] High-profit surgical procedures and the government research grants that rotate around them cross-subsidize routine and indigent care. At some point hospitals may view medical-tourism centers as jeopardizing this business model by skimming off their most profitable patients and seek protectionist regulation.

Pharmaceutical companies possess an array of legal mechanisms, national intellectual property laws being the most obvious, to impede pharmaceutical arbitrage. But, to find a public law barrier to the reimportation of drugs from Canada, the FDA had to dig deep into the minutiae of the FDCA and supplement it with a media-friendly "quality" argument.[274] In fact, the FDA's interpretation of the FDCA likely is correct.[275] The problem is that the agency's motives are suspect, determined less by genuine quality concerns and more by a desire to shore up a governmental policy opposed to any intervention in the pharmaceutical market. As Kevin Outterson has observed, either pharmaceutical rents in the United States are supra-optimal, or the pharmaceutical industry has been less than transparent in their counter-arguments.[276] The administration readily accepted the MMA prohibition on buy-side in-

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271. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 507, 117 Stat. 2066, 2295 (amending 42 U.S.C. § 1395nn(d)(3)) (Diagnosis-Related Groups); *see, e.g.*, Am. Hosp. Directory, Medicare Prospective Payment System, http://www.ahd.com/pps.html (last visited Mar. 18, 2007). *See generally* Phillip L. Ronning & Michael Nugent, *Freestanding Heart Hospitals: Is the End Near?*, HEALTHCARE FIN. MGMT., Sept. 2004, at 94.

272. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, § 507.

273. *See generally* Letter from A. Bruce Steinwald, Dir., Health Care, U.S. Gov't Accountability Off., to Charles Grassley, Chairman, and Max Baucus, Ranking Minority Member, S. Comm. on Finance (May 19, 2004), *available at* http://www.gao.gov/new.items/d05647r.pdf (discussing specialty hospitals and potential new facilities).

274. *See supra* note 208 and accompanying text; *see also* U.S. GEN. ACCT. OFF., INTERNET PHARMACIES: SOME POSE SAFETY RISKS FOR CONSUMERS, REPORT TO THE CHAIRMAN, PERMANENT SUBCOMMITTEE ON INVESTIGATIONS, COMMITTEE ON GOVERNMENTAL AFFAIRS, U.S. SENATE 13 (2004), *available at* http://www.gao.gov/new.items/d04820.pdf.

275. *See* Andrews v. U.S. Dep't of Health & Human Servs., No. 04-0307 (JR), 2005 U.S. Dist. LEXIS 5710 (D.D.C. Mar. 31, 2005); Vermont v. Leavitt, 405 F. Supp. 2d 466 (D. Vt. 2005).

276. Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y L. & ETHICS 193, 197 (2005).

tervention[277] and has been equally steadfast in hindering the supply-side pressures that would come with reimportation.

Some domestic regulations applicable to health care are explicitly extraterritorial. For example, the EU data directive extends its reach to offshore medical data processing,[278] a position that created tensions with the United States until the adoption of a safe-harbor model.[279] In contrast, HIPAA appears unaware of any transnational issues. Notwithstanding, outsourcers and their offshore partners will have to be aware of the occasional state regulation, such as California's identity-theft statute, which applies to anyone who "conducts business in California" and imposes a duty to disclose any security breach to affected California residents.[280]

Of course, protectionist legislation is often only one good international "episode" headline away from passage. In 2004, after media coverage of the rogue medical transcriber in Pakistan, Congressman Markey proposed the Personal Data Offshoring Protection Act, which provided for notification to the patient prior to offshore outsourcing and would have required the patient to opt-in before outsourcing to countries with low levels of protection.[281] Similar legislation[282] passed in California but was vetoed by Governor Schwarzenegger.[283]

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277. 42 U.S.C. § 1395w-111(i) (Supp. 2003) ("In order to promote competition . . . and in carrying out this part . . . the Secretary—(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.").

278. Council Directive 95/46 of 24 Oct. 1995 on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data, arts. 25-26, 1995 O.J. (L 281) 31 (EC).

279. U.S. Dep't of Commerce, Welcome to the Safe Harbor, http://www.export.gov/safeharbor/index.html (last visited Mar. 18, 2007). For a survey of different health information protective systems, see generally Nicolas P. Terry, *Privacy and the Health Information Domain: Properties, Models and Unintended Results*, 10 EUR. J. HEALTH L. 223, 228 (2003). *See also EU, U.S. Reach Deal on Sharing Passenger Data from Trans-Atlantic Flights*, USA TODAY, Oct. 6, 2006, *available at* http://www.usatoday.com/travel/news/2006-10-06-eu-us-flier-data_x.htm; Press Release, The Working Party, Press Release on the SWIFT Case, Following the Adoption of the Article 29 Working Party Opinion on the Processing of Personal Data by the Society for Worldwide Interbank Financial Telecommunication (SWIFT) (Nov. 23, 2006), *available at* http://ec.europa.eu/justice_home/fsj/privacy/news/docs/PR_Swift_Affair_23_11_06_en.pdf.

280. CAL. CIV. CODE § 1798.82(a) (West 2006).

281. *See, e.g.*, Personal Data Offshoring Protection Act of 2004, H.R. 4366, 108th Cong. § 3 (2004).

282. S. 1492, 2003-2004 Sess. § 56.32(b) (Cal. 2004).

283. John M. Hubbell & Mark Martin, *Governor Vetoes Bills on Offshoring Jobs: Legislation Bans Foie Gras Starting in 2012*, S.F. CHRON., Sept. 30, 2004, at B1, *available at* 2004 WLNR 7621668 (Westlaw).

2. Limitations on Coverage and the Politics of the Underinsured

In a recent *Health Affairs* article, Aaditya Mattoo and Randeep Rathindran argue that the primary barrier to increased medical tourism from the United States is a lack of coverage under existing health insurance policies.[284] They argue that the United States health care bill could be reduced by up to $2 billion per annum if policies provided a tourism option that included travel expenses.[285] Other than explicit protectionist policies by or impacts on government-funded health care (e.g., Medicare and Medicaid), the authors suggest that tourism coverage is not generally included because of indeterminacies associated with quality and liability exposure, monitoring costs associated with distant providers, and possible oligopolistic behavior by insurers.[286]

As already noted, some Western insurers are making modest entries into overseas fulfillment.[287] With experience, some of these posited barriers may resolve. Near term, Western insurers and policymakers likely will use the threat of overseas fulfillment as a bargaining tool with domestic health care providers. In June 2006, the Senate Special Committee on Aging held hearings on medical tourism.[288] The Committee heard testimony from a family member of a medical tourist, an employer, an insurer, a tourism intermediary, and a U.S. plastic surgeon.[289] Many of the issues discussed herein surfaced in some manner. However, the overall tone of the proceedings had less to do with tourism per se and more to do with the costs of domestic care. For legislators, medical tourism as it currently exists may be an epiphenomenon; like the reimportation of drugs from Canada, it is less of an issue requiring regulatory adjustment and more of a wedge to insert into the debate over health care costs and the plight of the underinsured. That such a wedge can prove effective is illustrated by the contract between the Amish and Mennonite communities and the Lancaster Regional Center in Pennsylvania. Willing to pledge against malpractice claims, pay in

284. Aaditya Mattoo & Randeep Rathindran, *How Health Insurance Inhibits Trade in Health Care*, 25 HEALTH AFF. 358, 360 (2006).

285. *Id.* at 362.

286. *Id.* at 364-66.

287. *See supra* text accompanying note 37.

288. *The Globalization of Health Care: Can Medical Tourism Reduce Health Care Costs? Hearing Before the S. Special Comm. on Aging*, 109th Cong. (2006), *available at* http://aging.senate.gov/hearing_detail.cfm?id=270728&.

289. *Id.*

cash, and contract for a limited number of health care services, the communities negotiated discounted flat-rate payments for the services they required—their negotiations were informed by their experiences with regular travel to Mexico for discounted health care services.[290]

3. Quality and Compensation Costs

Considerable care is needed in assessing whether quality variations between health care systems are creating barriers to tradable procedures or offshore outsourcing. First, "quality" is a far more complex value than the simple absence of error. Second, inherent in framing the quality-barrier question is the danger of stereotyping the medical systems in less developed countries. Third, when providers in industrialized countries raise quality issues, their motives must be examined because of the danger that they may be driven by protectionism rather than concern for patient health.

As to "quality," Uwe Reinhardt and colleagues[291] note that national systems that control costs with rationing frequently do so by implicit or explicit reference to cost-effective outcomes (e.g., choosing not to buy quality-adjusted life years, or QALYs, over a certain cost).[292] Thus, a source country's definition of quality will create potential medical tourists out of those whose treatments fall on the wrong side of a QALY-cost threshold. Equally, a country that sets its QALY cutoff below its available resources will create health surpluses that are then available to treat tourists.

Quality of care issues have been raised by doctors in Germany regarding patients who avoided waiting lists for kidney transplants by visiting commercial transplantation centers in, for example, India or Pakistan. The patients then returned to Germany with problems based on substandard tissue matching practices that lead to higher mortality rates than with "domestic" transplants.[293] Similarly, a survey of Australian plastic surgeons noted complications in patients returning from inexpensive cosmetic surgery in Bangkok. Reported problems included "'hideous scarring' and infections in

290. Joel Millman, *How the Amish Drive Down Medical Costs*, WALL ST. J., Feb. 21, 2006, at B1, *available at* LEXIS.

291. Reinhardt et al., *supra* note 139, at 13-15.

292. Helmut L. Karcher, *German Doctors Protest Against "Organ Tourism"*, 313 BRIT. MED. J. 1282, 1282 (1996). For one critique, see generally John La Puma & Edward F. Lawlor, *Quality-Adjusted Life-Years: Ethical Implications for Physicians and Policymakers*, 263 JAMA 2917 (1990).

293. Karcher, *supra* note 292, at 1282.

breast implants."[294] One surveyed doctor labeled the procedures as "'surgical roulette.'"[295] In June 2006, before a Senate committee, the president of the American Society of Plastic Surgeons testified, "We are all aware of cases, which are reported in the media and which confront some of my colleagues and other physicians, of patients returning to this country with disfigurement and nearly fatal infections associated with unaccredited hospitals and unlicensed providers."[296]

The theoretical quality barrier to medical tourism (and to some lesser extent health care outsourcing) is that the patient may experience poorer health outcomes abroad and, in the event of a medical mishap, reduced legal outcomes (compensation). At this stage, there is simply no data with which to address this "quality" question. For every story about the risks of medical tourism there are countervailing endorsements from satisfied patients[297] or observations that the adverse event rate at the private, tourist-oriented Indian surgery centers is equivalent to the best U.S. facilities.[298]

Certainly, medical tourists who suffer medical mishaps may have to encounter an unfamiliar legal system. For example, the position of the U.K. government, relying on case law that suggests the National Health Service does not have a non-delegable duty to its patients, is that medical tourists who go abroad for treatment under the E112 scheme must rely on remedies, as against the treating provider, offered by the courts of the place of treatment.[299] It may be

294. *Warnings on Plastic Surgery Mistakes*, THE AGE (Austl.), Jan. 17, 2006, *available at* http://www.theage.com.au/news/National/Warnings-on-plastic-surgery-mistakes/2006/01/17/1137466979953.html (quoting Dr. Norm Olbourne); *see also More Australians Heading Overseas for Surgery* (Austl. Broadcasting Corp. television broadcast, July 25, 2005) (transcript available at http://www.abc.net.au/7.30/content/2005/s1422042.htm) (discussing complications following knee surgery on an Australian patient in India).

295. *Warnings on Plastic Surgery Mistakes*, *supra* note 294 (quoting Dr. Norm Olbourne).

296. *The Globalization of Health Care: Can Medical Tourism Reduce Health Care Costs? Hearing Before the S. Special Comm. on Aging*, 109th Cong. (2006) (statement of Bruce Cunningham, Am. Soc'y of Plastic Surgeons), *available at* http://aging.senate.gov/events/hr159bc.pdf.

297. *See, e.g.*, *The Globalization of Health Care: Can Medical Tourism Reduce Health Care Costs? Hearing Before the S. Special Comm. on Aging*, 109th Cong. (2006) (statement of Maggi Ann Grace, patient and patient advocate), *available at* http://aging.senate.gov/events/hr159mg.pdf.

298. John Lancaster, *Surgeries, Side Trips for 'Medical Tourists'; Affordable Care at India's Private Hospitals Draws Growing Number of Foreigners*, WASH. POST, Oct. 21, 2004, at A1, *available at* LEXIS.

299. Cara Guthrie & Hannah Volpé, *Overseas Treatment for NHS Patients*, 2006 J. PERS. INJ. L. 12, 15-16.

the case that the dramatically lower costs of care in, say, India, are a function of that country's lower malpractice recovery[300] and lower malpractice insurance costs,[301] although that canard has been exposed regarding U.S. health care.[302] Injured tourists returning to the United States, or domestic patients who, for some reason, cannot establish liability against the local arm of their offshore provider, undoubtedly will face legal complications, such as jurisdiction and enforcement, in excess of those that would occur in a purely domestic setting.[303]

Currently, the most likely barrier is information costs regarding quality. There are indeterminacies and, hence, substantial information costs relating to the quality of offshore health and legal services.[304] U.S. companies offshoring their HIT and disaggregated services can protect their interests with appropriate contractual, jurisdictional, and choice-of-law provisions, much as they are compelled to protect their patients by "exporting" HIPAA confidentiality and security requirements through "business associate" agreements.[305] After the two reported extortion cases, transcription service agreements now include much stronger controls on subcontracting.[306] Western providers are also likely to face fewer legal problems when they use nearshoring because of the more closely aligned legal cultures and clearer bilateral dispute resolution practices.

Medical tourists, however, face far higher information costs. Here, two scenarios suggest themselves. Either medical tourism will continue unabated with the vast majority of patients encountering no serious medical or legal adverse events, or quality disparities

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300. Garud, *supra* note 4, at 319.

301. Lancaster, *supra* note 298.

302. *See* MICHELLE M. MELLO, ROBERT WOOD JOHNSON FOUND., UNDERSTANDING MEDICAL MALPRACTICE INSURANCE: A PRIMER (2006), *available at* http://www.rwjf.org/publications/synthesis/reports_and_briefs/pdf/no8_primer.pdf.

303. *See, e.g.*, McLean, *supra* note 58, at 247-55; Nathanial H. Hwang, *You've Got Mail—The Concerns of Electronically Outsourcing Radiological Services Overseas*, 25 J. LEG. MED. 469, 477-83 (2004).

304. Wachter, *supra* note 165, at 663-64.

305. *See, e.g.*, Sarah E. Hazelwood et al., *Possibilities and Pitfalls of Outsourcing*, HEALTHCARE FIN. MGMT., Oct. 2005, at 44, 45-46, *available at* http://www.findarticles.com/p/articles/mi_m3257/is_10_59/ai_n15777189.

306. Bill Briggs, *Offshore Outsourcing Poses Risks*, HEALTH DATA MGMT., Feb. 2005, at 68, *available at* http://healthdatamanagement.com/html/current/PastIssueStory.cfm?ArticleId=10505&issuedate=2005-02-01. For risk management strategies, see generally Margaret Davino, *Assessing Privacy Risk in Outsourcing*, 75 J. AHIMA 42 (2004), *available at* http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_022546.hcsp?dDocName=bok1_022546.

will become a real or perceived barrier to tradable services. The latter may prove to be the case with U.S. patients who have come to rely on increasingly robust information about the quality of their domestic providers, due to the report cards, outcomes reports, and other data that Kristin Madison usefully describes as the products of "market-facilitating regulation."[307] If this group of potential tourists steps back from foreign medical systems, their health insurers (if involved) or tourism intermediaries will have an incentive to intervene and to demand quality comparability guarantees for their customers. They may refuse to contract with offshore providers that are not accredited by, say, Joint Commission International[308] or may themselves provide insurance packages ensuring coverage for offshore litigation or domestic remedial medical care. A parallel dynamic may emerge in the legal systems of tourist destinations. While some underdeveloped countries may shore up their health quality and compensation systems (as is already occurring in the area of health data protection) to forestall protectionist regulation, others may join a "race to the bottom" to better compete for tourists' hard currencies.

B. *Globalization and Free Trade*

"Globalization" is one of our fledgling century's "magic" words. It is also one that can mean different things to different people, including "economic liberalization" or "global integration."[309] It is used here, and applied to health care, to denote the "increasing interconnectedness of people and places";[310] a connectedness that "undermine[s] the importance of local and even national boundaries in many arenas of human endeavor."[311]

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307. Kristin Madison, *Regulating Health Care Quality in an Information Age*, 40 U.C. DAVIS L. REV. (forthcoming 2007).

308. Joint Comm'n Int'l, About Joint Commission International, http://www.jointcommissioninternational.com/22758 (last visited Mar. 18, 2007); *see also* Mattoo & Rathindran, *supra* note 284, at 366 (urging foreign providers to signal quality by passing U.S. licensing examinations); Lee Hui Chieh, *US Quality Controls for Hospitals in S'pore, Aim Is to Improve Healthcare Quality and Boost Medical Hub Status*, STRAITS TIMES (Sing.), Nov. 2, 2005, *available at* 2005 WLNR 17712514 (Westlaw) (detailing Joint Commission International accreditation of Singapore hospitals).

309. *See, e.g.*, William Scheuerman, *Globalization*, *in* STANFORD ENCYCLOPEDIA OF PHILOSOPHY (2006), http://plato.stanford.edu/entries/globalization; *Globalization*, *in* WIKIPEDIA, http://en.wikipedia.org/wiki/Globalization (last visited Mar. 18, 2007).

310. Roy Smith, *Access to Healthcare via Telehealth: Experiences from the Pacific*, 3 PERSP. ON GLOBAL DEV. & TECH. 197, 198 (2004).

311. Scheuerman, *supra* note 309.

For health care, globalization can have both positive and negative connotations. The positives are obvious. For example, public health improves because improved communications increases access and the speed of access to worldwide research and alarms about health threats.[312] The negative correlate is that the increased personal interconnectedness of people increases the global impact of public health threats, for example the SARS epidemic in 2003 or bioterrorism.[313]

International and regional trade agreements have had little impact on core U.S. health care delivery compared, for example, to impacts on environmental law and policy. In the long term this may change. The General Agreement on Trade in Services (GATS)[314] is likely to increase cross-border trading of services and, as a result, stimulate cross-border recognition of professional licensure. In contrast, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[315] has the potential to negatively affect some cross-border trade such as the reimportation of U.S.-produced pharmaceuticals.[316] Other regional agreements such as the Central America Free Trade Agreement (CAFTA)[317] likely will have similar impacts, both positive and negative.[318]

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312. Laura J. Nosek, *Globalization's Costs to Healthcare: How Can We Pay the Bill?*, NURSING ADMIN. Q., Apr.-June 2004, at 116, 116-17.

313. *Id.* at 117-18; *see also* Nicholas Bakalar, *Speed of the Spread of Flu is Linked to Airline Travel*, N.Y. TIMES, Sept. 12, 2006, at F9, *available at* 2006 WLNR 15784725 (Westlaw). *See generally* Roy L. Simpson, *Global Informing: Impact and Implications of Technology in a Global Marketplace*, NURSING ADMIN. Q., Apr.-June 2004, at 144, 147.

314. *See generally* World Trade Org., General Agreement on Trade in Services (GATS), Annex 1B, 33 I.L.M. 1125, 1167 (1994) [hereinafter "GATS"], *available at* http://www.wto.org/english/docs_e/legal_e/26-gats.pdf.

315. *See generally* World Trade Org., Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Annex 1C, 33 I.L.M. 1197 (1994), *available at* http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

316. *See generally* Ellen R. Shaffer et al., *Global Trade and Public Health*, 95 AM. J. PUB. HEALTH 23 (2005).

317. *See generally* U.S. Dep't of Agric., Foreign Agric. Serv., U.S.-Dominican Republic-Central America Free Trade Agreement (CAFTA-DR), *available at* http://www.fas.usda.gov/itp/CAFTA/cafta.asp (last visited Mar. 16, 2007).

318. For services, see OFF. OF THE U.S. TRADE REPRESENTATIVE, CAFTA IS NOT "ANTI-DENTIST"—STATE LICENSING REQUIREMENTS NOT AFFECTED (2005), *available at* http://www.ustr.gov/assets/Trade_Agreements/Bilateral/CAFTA/Briefing_Book/asset_upload_file876_7881.pdf. For pharmaceuticals, see OFF. OF THE U.S. TRADE REPRESENTATIVE, CAFTA AND ACCESS TO MEDICINES (2005), *available at* http://www.ustr.gov/assets/Trade_Agreements/Bilateral/CAFTA/Briefing_Book/asset_upload_file433_7198.pdf.

The World Bank views globalization as the "[f]reedom and ability of individuals and firms to initiate voluntary economic transactions with residents of other countries."[319] But the implications of agreements like GATS, for example, on national health care systems are still unclear. The agreement is subject to ongoing negotiations and specifically based on commitments and exceptions scheduled by participating nations. In general terms, GATS calls for liberalization in the trade of services.[320] According to Richard D. Smith[321] and Ian S. Mutchnick and colleagues,[322] services[323] likely to be liberalized include telehealth, medical tourism, foreign investment in domestic health care businesses, and the temporary movement across borders by health care workers. Smith suggests that, at this stage in the development of GATS, direct investment creating a foreign "commercial presence" is the "most critical."[324]

So far, examples of U.S. participation in establishing a global health market have tended toward the embarrassing. For example, the United States has taken the position that foreign price controls result in U.S. consumers paying a disproportionate share of pharmaceutical R&D costs.[325] And in recent trade negotiations with Australia, the United States leveraged access to its agricultural market to gain concessions from Australia on its domestic pharmaceutical price controls.[326] For many Western countries, health care "globalization" has been little more than a process for securing access to underdeveloped economies for their capital and health care services, coupled with ensuring worldwide patent protection for their pharmaceutical industries.[327]

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319. BRANKO MILANOVIC, CAN WE DISCERN THE EFFECT OF GLOBALIZATION ON INCOME DISTRIBUTION? EVIDENCE FROM HOUSEHOLD SURVEYS 6 (2004), *available at* http://www.worldbank.org/research/inequality/pdf/GLOBE8.pdf.

320. GATS, *supra* note 314, at 1168 (preamble).

321. Richard D. Smith, *Foreign Direct Investment and Trade in Health Services: A Review of the Literature*, 59 SOC. SCI. & MED. 2313, 2314 (2004).

322. Ian S. Mutchnick et al., *Trading Health Services Across Borders: GATS, Markets, And Caveats*, HEALTH AFF., Jan. 25, 2005, at W5-42, W5-45, W5-47, *available at* http://content.healthaffairs.org/cgi/reprint/hlthaff.w5.42v1.pdf.

323. GATS, *supra* note 314, at 1169 (art. I, 2).

324. Smith, *supra* note 321, at 2318.

325. Reinhardt et al., *supra* note 139, at 17-18.

326. *See generally* Bob Burton, *Australian Drug Pricing Scheme Under Pressure in Free Trade Talks*, 328 BRIT. MED. J. 247 (2004); Bob Burton, *Australia Makes Concessions on Drug Approvals After US Pressure*, 328 BRIT. MED. J. 425 (2004).

327. *See generally* Press Release, Doctors Without Borders/Médecins Sans Frontières, As WHO and UNAIDS Call For Global Treatment Scale-Up, MSF Asks: Where Will the Essential Drugs Come From? (Mar. 28, 2006), *available at* http://www.doctorswithoutborders.org/pr/2006/03-28-2006.cfm.

C. *Non-Market Constraints and Regulatory Dilemmas*

Protectionism aside, today it is difficult to make a case for increased regulation of medical tourism, outsourcing, or arbitrage. In the absence of negative evidence (for example, that medical tourism increases domestic health care costs because of required domestic remedial or follow-up treatments),[328] it is arguable that foreign-sourced, low-cost, high-quality care will stimulate global health care and reduce the market failures seen in Western systems. But the preceding discussion assumes a Western frame—for example, whether offshore clinical trials are a safe basis for U.S. drug approval, or whether U.S. health data processed abroad retains integrity. What has not been discussed is the impact on developing countries of some of this tourist or offshoring activity.[329]

When Atul Gawande spent time in the hospitals of his family's homeland he noted the relative helplessness of Indian health care in the face of rapidly changing demographics—in particular, the rising life expectancy of its patient population. He also was struck by the contrast between poorly resourced and otherwise inadequate public health care facilities and the high-quality private facilities that cater to self-payers and medical tourists.[330] Although India spends 5.1 percent of its GDP on health care, less than 1 percent is spent on public sector health.[331] Meanwhile, many Indian doctors view emigration or, at least, residencies in Western countries, as major and realistic goals,[332] significantly reducing the number of physicians in domestic practice.[333] Not surprisingly, commentators in less-devel-

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328. *See, e.g.*, Amelia Gentleman, *Our Baby Joy, by Test-Tube Tourists who Flew to India: Britons Risked Fury of Health Professionals at Home to Have Banned Multi-Embryo Implant*, OBSERVER (U.K.), Mar. 26, 2006, *available at* 2006 WLNR 5055044 (Westlaw) (reporting objections to foreign IVF procedures counter-indicated in the U.K. on the basis that the National Health Service will bear the cost of potentially difficult multiple births and post-natal care).

329. The issue also has been raised in trade between industrialized countries. For example, some Canadian patient advocacy groups oppose the Canada-U.S. drug trade because of the impact on drug supplies and prices for Canadian patients. *Canadian Groups Ask for Ban on Web Pharmacies*, CTV.CA, Mar. 31 2004, http://www.ctv.ca/servlet/ArticleNews/story/CTVNews/1080740165689_67.

330. Atul Gawande, *Dispatch from India*, 349 NEW ENG. J. MED. 2383, 2383-86 (2003).

331. *Id.* at 2386; Fitzhugh Mullan, *Doctors for the World: Indian Physician Emigration*, 25 HEALTH AFF. 380, 382 (2006).

332. Gawande, *supra* note 330, at 2386.

333. Fitzhugh Mullan, *The Metrics of the Physician Brain Drain*, 353 NEW ENG. J. MED. 1810, 1818 (2005), *available at* http://content.nejm.org/cgi/reprint/353/17/1810.pdf; *see also* Christophe Segouin et al., Editorial, *Globalization in Health Care: Is International Standardization of Quality a Step Toward Outsourcing?*, 17 INT. J. QUALITY

oped countries have questioned the impact of large numbers of medical tourists (in reality a form of medical colonialism) on the waiting lists for treatments for their own citizens.[334]

Similar issues arise with regard to clinical trials. The Western philosophy behind trials involving human subjects is that they are an expression of altruism—a few volunteering now for trials to later benefit the many if the drug proves beneficial. This seems to be a flawed concept when applied to offshore clinical trials. The practical truth is that medically deprived patients in less-developed countries are going to enter such trials in the hope that their personal health future will benefit.[335] Further, medicines tested in less-developed countries often are designed for, or at least initially destined for, industrialized populations. At the very least, the populations that participate in the trials should be guaranteed participation in any benefit and at an affordable price.

The dilemma, of course, is that at a macro level, less-developed countries are looking to health tourists and outsourcing as ways to grow their health care and HIT economies. Their citizens may view apparently beneficent but foreign regulation of activities in their countries as examples of legal colonialism, as no less protectionist than outright legal impediments to travel or offshoring.

CONCLUSION

The health care systems of the United States and other Western countries face physician and nursing shortages; spiraling domestic health care costs; the attraction of pharmaceutical arbitrage; the growing importance of portable, border-agnostic HIT; and possible increases in discretionary patient spending because of consumer-directed health care. These factors suggest that medical tourism and health care outsourcing will expand in the near future. Given concerns about health quality and data protection, it is perhaps surprising that these phenomena are essentially unregulated.

Of the few legal obstructions to tourism that do exist, most are transitional, as regional systems such as the European Union dismantle remaining interstate barriers. Outsourcing is essentially unregulated and is likely to remain that way. While international and

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HEALTH CARE 277, 277-79 (2005). A similar phenomenon applies to domestic nursing populations when developed countries liberalize their immigration policies. *See, e.g.*, Dugger, *supra* note 265.

334. Swati Bhattacharjee, *Noor Fatima and Medical Tourism*, 101 J. INDIAN MED. ASS'N 497, 497 (2003); Garud, *supra* note 4, at 319.

335. *See* Kahn, *supra* note 247.

regional trade agreements have not noticeably accelerated tourism or outsourcing, they will impede outwardly protectionist regulation or legislation proposed in knee-jerk reaction to isolated media reports of adverse events suffered by tourists or offshore data mishaps.

In considering whether these phenomena are sub-optimally regulated, a variety of transnational or potentially transnational health care incidents can be written off as outliers. Thus, we can probably leave for another day the questions about how our regulatory systems should react to a used pacemaker being sold on an online auction site,[336] international robotic surgery,[337] or even online organ matching.[338] Of the areas where more robust patient protections are necessary, the most obvious is in data protection and, specifically, ensuring both that offshore data extenders are covered by U.S. confidentiality and security rules, and that enforcement of those rules is effective. Here, however, the U.S. legal deficiency may be less a function of an offshore location and more of the general inadequacies of the current medical privacy and confidentiality protections.[339] If the political will can be found to revisit medical privacy and confidentiality, then its extraterritorial effect should be made explicit. Other, perhaps less pressing issues, such as real or perceived quality deficiencies, are likely to be met near-term with self-regulatory "patches," such as codes of conduct and accreditation.

Over the long term it is difficult to see a truly global health care market replete with effective transnational patient-protective laws. As a result, there may come a time when domestic legal systems will be forced to address some of the issues raised here. When that time comes, it is imperative that U.S. regulation is sensitive to

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336. *See* Jennifer Ryan, *Pirated Pacemaker Exposes Failings*, E. VALLEY TRIB. (Phoenix), Mar. 20, 2005, *available at* http://www.eastvalleytribune.com/index.php?sty=38232 (noting the sale of stolen pacemakers on eBay, one of which was implanted into a patient in Arizona).

337. McLean, *supra* note 58, at 243-45; *cf.* J. Paul Finn et al., *MR Imaging with Remote Control: Feasibility Study in Cardiovascular Disease*, 241 RADIOLOGY 528, 528-37 (2006).

338. *See, e.g.*, MatchingDonors, http://www.matchingdonors.com (last visited Mar. 18, 2007) (connecting organ donors with patients in need). *See generally* Joyce Howard Price, *Organ Donors Matched Online*, WASH. TIMES, June 11, 2006, at A02, *available at* 2006 WLNR 10051388 (Westlaw); *Pakistan 'Kidney Bazaar' Thrives*, CNN.COM, Nov. 17, 2006 (on file with *Western New England Law Review*).

339. *See generally* Terry & Francis, *Ensuring the Privacy and Confidentiality of Electronic Health Records*, *supra* note 154.

the domestic economies and policies of our trading partners. To avoid accusations of legal colonialism, we need to commence a dialogue as to how best to achieve any future regulation.