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THE ROLE OF LAW IN GLOBAL E-HEALTH: A TOOL FOR DEVELOPMENT AND EQUITY IN A DIGITALLY DIVIDED WORLD

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E-health represents one of the more exciting technological innovations, merging telecommunications, audio/visual technologies and computers in a myriad of ways that range from the provision of medical information to diagnosis and treatment. Like many new information-based technologies, the applications and commensurate ramifications of e-health are only beginning to be appreciated. This Article focuses on e-health in a global context and concerns the application of law to a borderless technology that moves between countries as easily as it moves across state lines. It provides a broad description of the major areas of law that need to be considered in public and private international law as they relate to e-health and takes a twist to consider global privacy law developments which have such a strong bearing on e-health. Admittedly, this cursory review of international public and private laws affecting e-health is less than complete, but hopefully it will afford the health law reader with a framework for further exploration of this subject.

The second area of consideration on which this Article focuses is the topic often referred to as the “digital divide.” This Article explores ways in which the law can be used as a tool to facilitate equitable technology diffusion of e-health, specifically in reference to intellectual property and the availability of capital. The discussion concerning the “digital divide” in e-health in many ways parallels the ongoing controversies surrounding global access to essential medicines and underscores the fact that concern over the diffusion of e-health is a part of the broader issue of access to new health technologies, a theme of growing global importance.

I. E-HEALTH AND PUBLIC INTERNATIONAL LAW

There are no international treaties or global agreements that deal with telemedicine or e-health. Clearly there is a need for a set of principles and standards, which must be developed by the international community to establish a legal framework for electronic medicine. While it seems unlikely that a comprehensive, seamless legal web can be structured that can anticipate

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the demands of providers, patients, vendors and manufacturers in global e-health, a legal structure must be created that can serve as a baseline for the international growth of these technologies. Formulating basic legal principles for international telemedicine and e-health is a task fraught with complexities, and at best will result in only a rather generic agreement. It is unrealistic to expect that a detailed e-health treaty can be crafted governing all aspects of an evolving technology. Even if such a comprehensive document could be devised, striving for specificity at this point may be premature. In this stage of the development of e-health, there is a need for general operating principles which can act as a vehicle to integrate existing, relevant international law and structures into this area. New international e-health legal principles will not be helpful if they are created in a vacuum, divorced from the fact that law in this area is impacted by existing entities such as the World Trade Organization (WTO) and current international agreements that underpin the legal structures and operations of trade, telecommunications and health care delivery sectors.

At this stage, public and private global e-health law is an odd amalgamation of laws affecting trade, telecommunications and, to a more limited extent, health care. At points, there are linkages among the respective areas of law bearing on e-health, but these linkages are largely because telecommunications and trade policies are so interrelated, and not due to any concerted attempt to devise unifying legal principles for e-health technologies. What is presented below is a somewhat eclectic blend of current and evolving factors in public and private international law that are shaping the legal landscape in global e-health.

A. Evolving Principles: Beginning Outside Government

Interestingly enough, our tour of international law concerning e-health begins not with traditional international law-making entities, but rather with non-governmental organizations. It is increasingly common in areas involving new technologies, such as e-health, for general policies and operating procedures to be developed by groups that are closest to the technology. Undoubtedly some of the standard-setting done by private parties who are developers and users of new technology may be self-serving, but there is clearly a need for standards to be formulated by groups that have a firm grasp of the realities of the technology in question. Traditional public law entities such as the WTO and the United Nations increasingly turn to private bodies for assistance in crafting legal policies in areas of technology. For example, the WTO and the United Nations are both working with a private organization, the Global Information Infrastructure Commission (GIIC), to facilitate the development of policies underpinning telecommunications based commerce.¹

1. See Global Information Infrastructure Commission, at <http://www.giic.org> (last visited Oct. 7, 2001).

For purposes of e-health, activities of the World Medical Association (WMA), Health on the Net Foundation and the International Bar Association will be discussed, as the e-health policies of these private groups likely will have a significant impact on the law in this area.

1. World Medical Association

The most detailed set of principles affecting telemedicine that can serve as a helpful reference point are those adopted by the WMA in 1999.² The WMA outlined twenty principles for telemedicine, covering the physician-patient relationship, accountability and responsibility of the physician, the role of the patient, patient consent and confidentiality, quality of care and safety, quality of data and information, authorization and competence in practicing telemedicine, patient records and training in telemedicine.³ It is quite clear from the WMA principles that the Association's goal is to promote the use of telemedicine in ways that will maintain the integrity of the medical treatment process from both a clinical and human rights perspective. For example, in the quality area, the WMA calls for developing evaluation measures which will ensure that the best diagnostic and treatment practices are used, that physicians who practice telemedicine are comfortable with the technology, and that appropriate backup measures be in place should the technology falter.⁴ The WMA is committed to working with medical societies around the world to develop protocols for national and international telemedicine applications, which cover issues such as physician registration, liability and the legal status of electronic medical records.⁵

In addition to the WMA principles, the International Telecommunications Union (ITU) has developed principles to assist with the growth of global telemedicine.⁶ Unlike the WMA, the ITU principles do not focus on the delivery of telemedical services, but rather, are directed toward infrastructure issues. In 1998, under the auspices of the ITU, the World Telecommunications Development Conference in Valetta, Malta, approved ten recommendations to guide infrastructure development in health care and social services, the so-

2. The World Medical Association, Inc., WMA Policy, World Medical Association Statement on Accountability, Responsibilities and Ethical Guidelines in the Practice of Telemedicine (Oct. 1999), available at http://www.wma.net/e/policy/17-36_e.html (last visited Oct. 8, 2001).

3. *Id.*

4. *Id.* See section 22 of the WMA policy for the requirements for authorization and competence in practicing Telemedicine.

5. *Id.* See section 27 of the WMA policy for WMA's recommendations to National Medical Associations.

6. See ITU, SECOND WORLD TELEMEDICINE SYMPOSIUM FOR DEVELOPING COUNTRIES: FINAL REPORT, June 1999 (chapter 3, "Conclusion and Recommendations").

called Valetta Declaration.⁷ The Declaration's recommendations encouraged telecom operators to take an active interest in promoting telemedicine, supporting telemedical projects in the developing world, and encouraging collaboration between the ITU and the World Health Organization (WHO).⁸ The Valetta Declaration led to a 1999 meeting in Buenos Aires at which the ITU called for the creation of incentives to promote global telemedicine, including the reduction of telecom tax rates and service charges and the creation of equity in telecommunications between urban and rural areas.⁹

2. Health on the Net Foundation

A Swiss-based organization, Health on the Net Foundation (HON), has developed an International Code of Conduct for medical and health websites, outlining eight core principles.¹⁰ The HON web principles include authority, medical legitimacy of the site, complementarity in the treatment relationship, confidentiality, attribution, justifiability, transparency of authority, transparency of ownership and honesty in advertising and editorial policy.¹¹ While the HON principles are voluntary, the sponsoring Foundation estimates that the HON Code is endorsed and followed by 3,000 health and medical websites.¹²

3. The IBA Draft Treaty

To date, one model international treaty in e-health has been written, the Draft International Convention on Telemedicine and Telehealth, prepared by the International Bar Association (IBA).¹³ The draft treaty contains eleven articles, including three pivotal articles that outline the general principles binding the agreement together, as well as a section on licensure and

7. The World Telecommunications Development Conference, *Impact of Telecommunications in Health Care and Other Social Services*, Recommendation SG 2/6-98, available at http://www.itu.int/ITU-D/tech/telemedicine/recsg2_6-en.html (last visited Sept. 24, 2000) [hereinafter Recommendation SG 2/6-98].

8. *Id.*

9. Robert M. Frieden & William J. Drake, *The Global Information Infrastructure*, available at <http://www.usinfo.state.gov/products/pubs/archive/telecomm/frieden.htm> (last visited Oct. 7, 2001) [hereinafter Frieden & Drake]. See ITU, *supra* note 6.

10. Health on the Net Foundation, *HON Code of Conduct (Honcode) for medical and health Web sites*, at <http://www.hon.ch/HONcode/Conduct.html> (last modified Jan. 25, 2000).

11. *Id.*

12. Health on the Net Foundation, *FAQ about HONCode*, at http://www.hon.ch/HONcode/FAXs_HONcode.html (last modified May 4, 2001).

13. International Bar Association, Section on Legal Practice Committee 2, *Law and Medicine, Draft International Convention on Telemedicine and Telehealth* (July 22, 1999), available at http://www.mcguirewoods.com/news-resources/publications/products_liability/article493.asp [hereinafter International Bar Association].

confidentiality.¹⁴ The IBA agreement states that health care delivered through electronic means, regardless of the form, should be treated no differently than health care delivered face to face.¹⁵ The model document supports the protection and confidentiality of intellectual property, and the application of requisite national and international treaties in the patent area.¹⁶ At the same time, the treaty also calls for the promotion of telemedicine and telehealth, particularly to the underserved and to the third world, and encourages global partnerships between developed and developing countries.¹⁷ Other treaty principles require signatory governments to commit themselves to telecommunication infrastructure development and passage of legislation that facilitates ethical research practices in telemedicine and prohibits discrimination in the delivery of telemedical services.¹⁸ The IBA lays out an international licensure scheme, applied to physicians and other health care professionals, which affords individual practitioners from a signatory nation the right to be licensed in any nation participating in the treaty as it concerns telemedicine services.¹⁹ While none of the principles noted, those of IBA, WMA or HON, have the authority of law, they are an important part of the evolution of standards affecting e-health and likely will affect the work of official law-making bodies in this area.

B. Trade Law

The evolving body of international trade law must be referenced in matters involving cross border e-health, as established and emerging agreements here will undoubtedly address relevant issues in telemedical relationships concerning professional services and investments. Both global and regional trade agreements impact various aspects of e-health. A detailed consideration of trade law is beyond the scope of this Article, but a general consideration of the impacts of the World Trade Organization and the North American Free Trade Agreement serve to illustrate the complexities and importance of trade law to e-health.

1. The World Trade Organization Agreements

The WTO, through its various treaties, is a significant venue for the development of international legal principles affecting e-health, as it has

14. *Id.* The three pivotal articles include Article 2, which outlines the general principles, Article 3, which provides the regulation of telemedicine and telehealth and authorization to practice and Article 5 covering confidentiality of records.

15. *Id.* (Article 2) (covering general principles).

16. *Id.*

17. *Id.*

18. International Bar Association (Article 2), *supra* note 13 (covering general principles).

19. *Id.* (Article 3) (discussing the regulation of telemedicine and telehealth and the authorization to practice).

become the primary entity for the promotion of orderly global trade.²⁰ The United States has assumed a leading role in persuading the WTO members to include telecommunications, transborder investment and foreign ownership, and intellectual property protections in the organization's mandates.²¹ In its Uruguay round of talks, the WTO created rules that liberalize access to, and use of, telecommunications networks for corporate use.²² In 1997, sixty-eight WTO members, comprising ninety percent of the global communications market, established a pact to allow foreign investment in a member-nation's telecommunications market and provide services to the general public.²³ The hope is that the 1997 pact will increase competition in many world telecom markets, reduce prices and spur infrastructure development.²⁴

A core WTO agreement that impacts telemedicine is the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). In effect since 1995, TRIPS is the most comprehensive multilateral treaty on intellectual property, covering copyright, trademark, geographic indicators, industrial designs, patents and trade secrets.²⁵ TRIPS incorporates the substantive obligations of main conventions on intellectual property, such as those developed by the World Intellectual Property Organization (WIPO), which is particularly relevant in the area of global internet copyright protection.²⁶ TRIPS establishes general principles applicable for the domestic enforcement of IP rights by focusing on procedures and remedies in both civil and criminal contexts.²⁷ In addition, TRIPS provides a mechanism for the WTO to resolve intellectual property disputes which arise among member nations.²⁸ While the WTO, through the TRIPS agreement, dominates global IP, it should be noted that the United Nations is very active in this area through its sponsorship of the United Nations Commission on International Trade Law (UNCITRAL).²⁹

20. Philip M. Nichols, *Realism, Liberalism, Values, and the World Trade Organization*, 17 U. PA. J. INT'L ECON. L. 851 (1996); DEBI BARKER & JERRY MANDER, *INVISIBLE GOVERNMENT – THE WORLD TRADE ORGANIZATION: GLOBAL GOVERNMENT FOR THE NEW MILLENNIUM* (2001), at <http://ifg.org/wto.html> (last visited Jan. 14, 2002).

21. See Frieden & Drake, *supra* note 9.

22. *Id.*

23. *Id.*

24. *Id.*

25. WTO Intellectual Property, *An Overview of the Agreement on Trade Related Aspects of Intellectual Property Rights*, at <http://www.wto.org/intellect/intell2.html> (last visited Oct. 2, 2001).

26. The harmonization of TRIPS and WIPO is a rather complicated and evolving area of International Intellectual Property Law. See Neil W. Netanel, *The Digital Agenda of the World Intellectual Property Organization*, 37 VA. J. INT'L L. 441, 445 (1997).

27. *Id.*

28. *Id.*

29. United Nations Commission on International Trade Law (UNCITRAL), *One World of Commerce: Towards One Commercial Law*, at <http://www.uncitral.org/English/commiss/geninfo.htm> (last visited Oct. 2, 2001).

Another key WTO treaty that impacts e-health arrangements is the General Agreement on Trade in Services (GATS).³⁰ GATS is the first multilateral treaty to establish legally enforceable rights to trade in all services.³¹ The GATS agreement contains three basic principles: all services except those provided in the exercise of government power are covered, there should be no discrimination in favor of national providers (the national treatment principle) and there should be no discrimination between other members of the agreement (the most favored nation principle).³² In 1997, a telecommunications annex was added to the GATS.³³ Under the terms of the annex, each WTO member agreed generally to open public and private telecommunication networks to any service provider of a member state.³⁴ The annex limits conditions applied by members to their telecommunication networks only to those absolutely necessary to maintain the integrity of a nation's telecom system or to promote a country's telecommunications infrastructure.³⁵ A special mandate was included for members to safeguard the confidentiality of cross-border communications.³⁶

2. Regional Trade Agreements: A Consideration of NAFTA

In addition to global trade agreements, e-health will be affected by regional trade agreements such as the North American Free Trade Agreement (NAFTA) or Association of Southeast Asian Nations (ASEAN). Like their global counterparts, regional trade agreements are designed to facilitate the movement of goods and services across borders, but that goal is not easily accomplished. The NAFTA presents an interesting case in point of the barriers which still exist concerning cross border movement of professional services such as e-health.³⁷ In theory, under the investment and professional services chapters of NAFTA, professional services should be able to flow across the borders of the three signatory nations and, thus, would seem to support a regional e-health arrangement.³⁸ While web-based technology can clearly flow among the three

30. General Agreement on Trade in Services, *Services: Rules for Growth & Investment*, at http://www.wto.org/English/thewto_e/whatis_e/tif_e/agrm5_e.htm (last visited Oct. 2, 2001).

31. *Id.*

32. *Id.*

33. General Agreement on Trade in Services, *Service Agreement Annex on Telecommunications*, at http://www.wto.org/English/tratop_e/serv_e/12-tele.htm (last visited Oct. 2, 2001).

34. *Id.*

35. *Id.*

36. *Id.*

37. John D. Blum, *Telemedicine Poses New Challenges for the Law*, 20 HEALTH L. CAN. 115, 123 (1999).

38. *Id.*

NAFTA countries, cross border physician-patient services may not be so easily arranged under the agreement.

Within the context of NAFTA, signatories are able to opt out of certain provisions and use such exceptions to protect certain industries. The Canadian government exercised its right to opt out of the professional services and investment chapters. To protect health care from NAFTA coverage, an annex to the treaty for social services was created.³⁹ The exemption was clearly a response to a Canadian fear that the agreement would allow for-profit American health care entrepreneurs to do business in Canada.⁴⁰ In 1995, a dispute arose over the interpretation of the social services annex, which resulted in a 1996 letter of agreement explicitly stating that health care services were exempt from NAFTA.⁴¹ On its face it would seem that the 1996 clarification would be a barrier to many types of cross-border e-health arrangements. However, the clarification changes very little in the NAFTA agreement, and while certain types of e-health ventures may be restricted (for instance, having American physicians create telemedicine programs in Canada for provincially covered services), others focusing on non-provincially covered services could be delivered under NAFTA. A more practical barrier to an e-health program involving patient care is the medical licensure restrictions, which both Canadian provinces and American states jealously guard.⁴²

II. INTERNATIONAL LAW-MAKING BODIES: THE CASE OF THE INTERNATIONAL TELECOMMUNICATIONS UNION (ITU)

While telecommunications issues often come within the ambit of trade law, the matter of developing and enforcing global telecom standards is the responsibility of the International Telecommunications Union (ITU).⁴³ The ITU is the world's oldest working international law-making body, created originally by twenty European nations to set standards for the telegraph.⁴⁴ With changes in communication technologies, both the body of the law and the legal infrastructure developed by the ITU have expanded. Today, the International Telecommunications Commission covers all forms of

39. Bryan Schwartz, *NAFTA Reservations in the Areas of Health Care*, 5 HEALTH L.J. 99 (1997).

40. *Id.*

41. *Id.*

42. *Id.*

43. See generally International Telecommunications Union, *ITU's History*, at <http://www.itu.int/aboutitu/history/history.html> (last visited Oct. 2, 2001).

44. George A. Codding, *The International Telecommunications Union: 130 Years of Telecommunications Regulation*, 23 DENV. J. INT'L L. & POL'Y 501, 501 (1995).

telecommunications, and the ITU is the body responsible for virtually all international regulation in the field.⁴⁵

Unlike most modern international organizations, which are based on a permanent charter and subject to special procedural amendments, the ITU Convention—the ITU's primary decision-making body—has to be readopted in part by each ITU Plenipotentiary Conference, the supreme organ of the Union.⁴⁶ The Convention serves the dual purpose of establishing the structure and goals of the ITU, as well as the provisions of technical law.⁴⁷ The rule-making function of the ITU is carried out by the Plenipotentiary Conference, as well as by Administrative Conferences. Administrative Conferences are convened when the need arises to develop or revise administrative regulations, which are then binding on member states as annexes to the Convention.⁴⁸ Technical standard development (focusing on radio frequency, telecommunication networks, equipment and services) is the responsibility of consultative committees.⁴⁹ While the decisions of technical committees are not binding, they tend to be widely followed as consensus is a primary basis of enforcement.⁵⁰ The legal texts adopted by the ITU have been characterized as voluminous and complex, as they include general principles, regulation of technical characteristics and criteria, operational procedures and administrative procedures with reference to the different telecommunication services.⁵¹ Another important part of the ITU mandate is the development of recommendations on the financial organization of cross-border transmissions, which has resulted in the creation of accounting rates that subsidize infrastructure development.⁵²

45. See International Telecommunications Union, *International Telecommunications Union*, at <http://www.itu.int> (last visited Oct. 2, 2001). See also ITU's Constitution and Convention, at <http://www.itu.int/publications/cchtml/> (last visited Nov. 27, 2001), for a sense of the regulatory scope of the body.

46. See Harold M. White & Rita Lauria, *The Impact of New Communications Technologies on International Telecommunications Law and Policy: Cyberspace and the Restructuring of the International Telecommunications Union*, 32 CAL. W. L. REV. 1 (1995). The ITU Plenipotentiary Conference was amended in 1989 in Nice, and the amendment was such that not all of the ITU chapter had to be readopted, but the ITU Convention was split into two parts, separating a permanent statement of purpose and structure from function and procedural sections which needed to be revised in the Plenipotentiary sessions. See Audrey L. Allison, *Meeting the Challenges of Change: The Reform of the International Telecommunications Union*, 45 FED. COMM. L.J. 491 (1993).

47. *Id.*

48. International Telecommunications Convention, Jan. 1, 1975, art. 6, 1975 Austl. T.S. No. 24.

49. *Id.*

50. *Id.*

51. Codding, *supra* note 44, at 508.

52. Friedman & Drake, *supra* note 9.

The ITU is one of the primary bodies focusing on how cyberspace should be regulated globally. Under ITU auspices, there is a growing movement to create uniform international standards of usage for the Internet. For example, in 1999, the ITU approved a universal asynchronous digital subscriber line (ADSL) standard for access to the Internet that will minimize the need for new wiring and facilitate the development of global Internet products and services.⁵³ The ITU's World Telecommunications Standardization Assembly has been actively involved in creating a road map for the future of global telecommunications in areas such as Internet-based networks, Internet mobile telecommunication networks and global multimedia services and systems.⁵⁴ As the organization which sets the baseline for global telecommunications, the ITU standards impacting telemedicine will need to be carefully considered in any international arrangement involving cross-border electronic medicine.

In addition to standard setting, the ITU has been very active in partnering with the private sector to encourage telecommunication system expansions in the developing world.⁵⁵ A primary goal of the ITU is to assist developing countries to plan, build, operate, upgrade, manage and maintain technologies applicable to their respective telecom networks and services.⁵⁶ Beyond national borders, the ITU is concerned with the creation of a global information infrastructure, which, in turn, would have dramatic benefits on individual telecommunications systems.

III. E-HEALTH AND PRIVATE INTERNATIONAL LAW

A. Contracting Principles

While developments in public law will have a profound impact on the future of global e-health, for the present, e-health arrangements are being shaped largely by private law agreements. A great deal could be learned about the uses of e-health globally and the nature of legal concerns which parties have in particular geographic locations through review of private contracts supporting respective e-health arrangements. Unfortunately, there is no public repository for such agreements, and it is only through anecdotal information from drafters that insights can be gleaned. Also, the nature of the contract provisions underpinning e-health ventures is related to the type of technology

53. Ted Stevenson, *ITU Approves Standard for G.lite ADSL*, ISP-Planet (June 23, 1999), at <http://www.isp-planet.com/news/itu-glite.html> (last visited Oct. 3, 2001).

54. Krishna Jayahar, *Globalization and the Legitimacy of International Telecommunications Standard-Setting Organizations*, 5 *IND. J. GLOBAL LEG. STUD.* 711 (1998); see also Tanya L. Yarbrough, *Connecting the World: The Development of the Global Information Infrastructure*, 53 *FED. COMM. L.J.* 315 (March 2001).

55. Recommendation SG 2/6-98, *supra* note 7.

56. *Id.*

and uses in question, as well as to the idiosyncrasies of relevant domestic laws. For example, an agreement to provide international services that involves direct patient care will differ in content from an arrangement to provide advisory services or informational web pages.

Regardless of the nature of the services to be provided, contractual agreements must specify which national law (or laws) will govern and a method for dealing with disputes, if one should arise. While the details of a given arrangement will drive particular contract terms, contracts in this setting should generally cover intellectual property protections, privacy/confidentiality issues and reimbursement and liability questions; similar to what would be seen in a United States-based domestic arrangement. International agreements in e-health have the added complexity of being formulated and enforced in a multi-jurisdictional context where choice of law issues may be quite challenging, as parties have the ability to have agreements governed by laws of nations not privy to a given contract.⁵⁷ Choice of law can even affect an individual user, as some Internet service providers use so-called "click wrap agreements" in which, by agreeing to terms of use, a user also agrees to choice of law and/or forum provisions.⁵⁸

There are emerging international law principles affecting private contractual arrangements, such as the Principles of European Contract Law or the UNIDROIT Principles of International Commercial Contracts.⁵⁹ Such policies illustrate the fact that the lines between private and public international law are murky, as the two areas work interchangeably to mold a body of law. Specific policies, like that of the European Union Directive on the Protection of Consumers in Distance Contracts, also may impact a given e-health agreement.⁶⁰ Under the European Union directive, a United States/European telemedicine arrangement would need to recognize the European Union consumer contract rights provisions in structuring agreements with individuals involving e-mail and the Internet.⁶¹

The European Commission (EC) has put forward a proposal for a Directive to Establish a Legal Framework for the Development of Electronic Commerce

57. Herbert Kronke, *Applicable Law in Torts and Contracts in Cyberspace*, in INTERNET WHICH COURT DECIDES? WHICH LAW APPLIES? 65, 74-84 (Katharina Boele-Woelki & Catherine Kessedjian eds., 1998).

58. Matthew Burnstein, *A Global Network in a Compartmentalized Legal Environment*, in INTERNET WHICH COURT DECIDES? WHICH LAW APPLIES? 23, 31-32 (Katharina Boele-Woelki & Catherine Kessedjian eds., 1998).

59. *Id.* at 29 (using these laws as examples of codified laws that could act as models for unifying substantive Internet law).

60. Directive 97/7/EC of the European Parliament and the Council of 20 May 1997, available at http://www.legalwks.com/conferences/Handouts/ecomlaw/Distance_Selling_Directive.doc (last visited Nov. 27, 2001).

61. *See id.*

within the European Union.⁶² The proposed EC directive contains a number of relevant provisions, such as an agreement that the place of business for an Internet company is where the physical premises are located, as well as the possibility of concluding contracts on-line or the removal of rules requiring that contracts be drawn on paper. Also, the directive adopts the “mere conduit” rule for information intermediaries, which minimizes liability for passing on or storing information unless actual knowledge can be shown.⁶³

B. *The Role of Domestic Laws*

In negotiating an international telemedicine agreement, it will be critical for the parties to be aware of domestic law applicable to all involved parties. Cyberspace exists beyond the borders of any one given nation, and some have even argued that the Internet be viewed as an independent jurisdiction for legal purposes.⁶⁴ The fact is, however, that domestic laws are influencing the Internet, and that individual nations have been able to place their own regulatory spin on cyberspace.⁶⁵ Also, there is a growing movement in international law for nations to enforce the domestic laws of those countries, which are part of common trading blocs, such as the European Union.⁶⁶ It is likely that domestic laws, which impact other areas of e-health beyond the Internet, will also have a significant effect on how arrangements are structured in this area.

By and large, deciphering domestic legal principles in another country that affect telemedicine will be akin to such an exercise in the United States, as the focus will be on identified areas such as intellectual property (IP) and confidentiality. It is unlikely that a search of most country’s relevant domestic laws will uncover a comprehensive framework for e-health. Rather, it is more likely that the relevant domestic laws will be highly scattered and largely applicable to contexts not specific to e-health, as is the case with public

62. Velia M. Leone, *EU Seeks “Free Flow” Legal information Framework for E-Commerce*, Global e-Commerce Law and Business Report (May 1999), available at <http://www.wtexec.com/ec0599.html> (last visited Oct. 3, 2001).

63. *Id.*

64. David R. Johnson & David Post, *Law and Borders—The Rise of Law in Cyberspace*, 48 STAN. L. REV. 1367, 1400-01 (1996) (arguing that since “[g]lobal electronic communications have created new spaces,” a new legal doctrine should be developed applicable only to this sphere).

65. Jos Dumoitier, *Some Legal Issues Related to the Implementation of the European Data Protection Directive in the Belgian Legal System* (paper presented at the 19th International Conference of the Privacy Data Protection Commissioners), at <http://www.dataprotection.gov.uk> (last visited Jan. 14, 2002). Professor Dumoitier presents an interesting discussion of the interrelationship of European domestic law in relationship to Article 189(3) of the Treaty establishing the European Community. This article details the freedom of choice policy of the EC which allows member states leeway in implementing an EC directive.

66. *Id.*

international law. At present, Malaysia is the only country in the world to have enacted a generic telemedicine law, covering licensure, informed consent and telemedicine standard development.⁶⁷ The Malaysian law, enacted in 1997, is quite general and has yet to be implemented, but clearly for arrangements involving that nation, their telemedicine law needs to be factored into any e-health agreement. Over time, more specific domestic legislation and regulations concerning e-health are likely to emerge, further complicating the creation of contracts, as well as posing challenges for the harmonization of e-health with trade law.

IV. PRIVACY: A DOMINANT GLOBAL THEME

Of all the legal issues affecting patients and providers in the global e-health arena, the one issue which has sparked the most universal response on the part of lawmakers worldwide is privacy.⁶⁸ Like the other legal issues discussed, concern for privacy encompasses a broader scope than e-health. But in this situation, it appears that the electronic transfer of medical information, the creation of the electronic medical record and the use of the Internet in health care, all of which are essential aspects of e-health treatment, are critical factors in raising a heightened concern globally about medical privacy. Issues relating to medical privacy in the electronic context have come to the forefront in the United States, with the issuance of complex medical privacy regulations under HIPAA.⁶⁹ While the United States may be somewhat unique in its targeted sectoral focus on medical privacy, other countries have enacted a variety of laws which more typically focus on generic privacy protections in information and communications areas.⁷⁰ A survey of over fifty countries conducted by the London based group, Privacy International, demonstrated that the concerns about privacy are broad based, and that in the past few years, the movement to enact legally based privacy protections has increased.⁷¹

Privacy law and regulation falls into several general categories. One model entails the adoption of a general law that governs the collection, use and

67. Telemedicine Act, No. 564 (1997) (Malay.).

68. 42 U.S.C. § 1320d-1 (1994 & Supp. V). See Mary Beth Johnston & Leighton Roper, *HIPAA Becomes Reality: Compliance with New Privacy, Security, and Electronic Transmission Standards*, 103 W. VA. L. REV. 541 (2001), for a thorough discussion of HIPAA. See Barbara J. Williams, *Virtual Web Wave of the Future: Integration of Healthcare Systems on the Internet*, 76 N. DAKOTA L. REV. 365 (2000).

69. See Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 18, 26, 29 and 42 U.S.C.).

70. ELEC. PRIVACY INFO. CTR. & PRIVACY INT'L, *PRIVACY & HUMAN RIGHTS 2000: AN INTERNATIONAL SURVEY AND DEVELOPMENTS* (Marc Rotenberg, ed., EPIC 2000), available at <http://www.privacyinternational.org/survey/> (last visited Jan. 14, 2002).

71. *Id.*

dissemination of personal information in the public and private sectors.⁷² This broad law would be enforced by a central agency, which has authority over all privacy matters. The United States follows a sectoral model of privacy regulation, in which laws are focused on broad individual areas, such as finance or health care, and enforcement involves a patchwork of agencies at the state and federal level.⁷³ Self-regulation, another category of privacy regulation, is a popular position with the private sector, as it allows the parties directly involved in a particular telecommunication technology and application to set guidelines which are least burdensome.⁷⁴ In newly emerging areas of technology, self-regulation may be appropriate, as the fluidity of technological innovations and applications make government regulation difficult. However, as privacy has evolved into a fundamental human right, self regulation may face severe political hurdles. The fourth category of privacy protections concerns the use of security technologies, which may be required by a particular government agency, or voluntarily adopted by the field.⁷⁵ Encryption, anonymous remailers, proxy servers, digital cash and smart cards are some of the technologies which have captured the attention of privacy regulators.⁷⁶ Complicating these four general approaches to privacy is the fact that the technologies these regulatory schemes attempt to control are fluid, and the concept of privacy is multifaceted, covering not only information and communications, but also concepts of territorial and bodily integrity. There are also differences in attitudes about privacy from country to country, and the preoccupation with medical privacy rights seen in the West may be viewed as a luxury in the developing world or, at least, not as high of a priority when contrasted with other human needs.

Perhaps the best-known privacy protection guidelines are the Directives on Data Privacy, which were developed by the European Commission and are binding on European Union member nations.⁷⁷ In October of 1998, the European Union Directive on Data Privacy went into effect and became the most comprehensive multinational legal document in the area.⁷⁸ The European Union directive was motivated by the need to develop uniform policies for

72. *Id.* ("Models of Privacy Protection") (describing the four models of privacy protection which are found in national laws).

73. *Id.* (describing sectoral laws).

74. *Id.* (noting that, with respect to self-regulation, such an approach has been followed in the United States, Japan and Singapore).

75. ELEC. PRIVACY INFO. CTR. & PRIVACY INT'L, *PRIVACY & HUMAN RIGHTS 2000: AN INTERNATIONAL SURVEY AND DEVELOPMENTS* (Marc Rotenberg, ed., EPIC 2000), available at <http://www.privacyinternational.org/survey/> (last visited Jan. 14, 2002).

76. *Id.* The technologies noted are also listed in the EPIC/Privacy International Report.

77. 1995 O.J. (L 281) 31.

78. Susan E. Gindin, *As the Cyber-World Turns: The European Union's Data Protection Directive and Trans-Border Flaws of Personal Data*, available at <http://www.info-law.com/cupriv.htm> (last visited Sept. 24, 2001) [hereinafter Gindin].

protection of individual rights in the privacy area, so that there would be no impediment to the flow of data from country to country. The directive provides for basic protections for data subjects (individuals) and places limitations on those who collect, process, use or transmit personal data by manual or automated means. The directive is very broad in its coverage and applies to data in multiple forms. Personal health information is clearly covered in text, sound and image. European Union nations are bound to follow the mandates specified in the directive, but can craft individual forms and methods for enforcing the directive's core content.⁷⁹

Of particular concern are the policies required of European Union members involved in data transfers to non-member third party countries. In the case of the United States, the European Union concluded that the sectoral approach to privacy, which resulted in a regulatory patchwork, did not meet the European standards.⁸⁰ The European Union's finding that American privacy policies were deficient resulted in an agreement between the European Union and the United States Department of Commerce, which created seven safe harbor principles that govern the exchange of personal data from European Union countries to the United States.⁸¹ The seven principles include notice, choice, onward transfer protections, security, data integrity, access and enforcement.⁸² The seven principles are designed to provide certain protections to the European Union citizen whose personal data is being transferred to the United States and mandate that those in control of personally identifiable data follow delineated precautions. The Department of Commerce oversees the implementation of the safe harbors and compiles a list of individuals and companies who subscribe to these principles.⁸³ As part of the safe harbor obligations, participating entities are mandated to engage in dispute resolution mechanisms with sanctioning capacities. In addition, the Federal Trade Commission, under Section 5 of the Federal Trade Commission Act,⁸⁴ which prohibits misrepresentation and deceptive trade practices, may sanction companies who are in violation of safe harbor principles.⁸⁵

79. Jos Dumortier & Diana M. Alonso Blas, *Some Legal Issues Related to the Implementation of the European Data Protection Directive in Belgium*, 11 INT'L REV. L. COMPUTERS & TECH. 221, 221 (1997).

80. See Julia Gladstone, *The U.S. Privacy Balance and the European Privacy Directive: Reflections on the United States Privacy Policy*, 7 WILLAMETTE J. INT'L L. & DISP. RESOL. 10 (2000).

81. Susan H. Nycum, *Safe Harbor*, eCFO (Sept. 2000), at http://www.ecfonet.com/articles/al_safe_harbor.html (last modified Nov. 2000).

82. *Id.*

83. *Id.*

84. Federal Trade Commission Act, 15 U.S.C.A. § 45 (1997).

85. *Safe Harbor Enforcement Overview: Federal and State "Unfair and Deceptive Practices" Authority and Privacy* (July 14, 2001), at <http://www.export.gov/safeharbor/ENFORCEMENTOVERVIEWFINAL.htm> (last visited Sept. 26, 2001).

Like other areas of telemedicine and e-health, workable privacy policies will require broad-based global and regional agreements which will develop a common set of working principles and objectives. Even with such agreements, individual contracts will still play a pivotal role in the protection of individual privacy rights. Most of the European Union member countries have incorporated the European Union directive into their respective national laws, but even with such incorporation, unique features are evident in individual European national privacy laws. For example, in 1998, Portugal adopted the European Union Directive, but in the process of doing so, created its own national data protection commission, imbued with a broad base of oversight and investigatory powers.⁸⁶ Outside of Europe and North America, significant national activity in privacy law is evident, such as the recently enacted Information Technology Act in India that establishes a special tribunal to deal with cyberspace and forge policies in areas such as confidentiality.⁸⁷ Chile is the first Latin American country to enact a national data protection law. The law, which is directed toward government-controlled data banks, represents a first step toward a more comprehensive recognition of personal privacy in Chilean society.⁸⁸ Unquestionably these domestic developments in privacy law will have a profound impact on the development and operation of e-health programs, as these laws were motivated by the core privacy concern, medical privacy.

V. E-HEALTH AND THE DIGITAL DIVIDE

A great deal has been written about the so-called “digital divide,” the line separating the technologically rich West from the developing world.⁸⁹ The disparities in resources among nations have always existed, but with innovations in information and telecommunications technologies (so-called ICT), those disparities have been magnified. Without an equitable global distribution of ICT resources (including e-health), the potential for solidifying a deepening cycle of poverty in many nations throughout the twenty-first

86. Act on the Protection of Personal Data, No. 67198 (transposing into the system directive 951461EC of the European Parliament and of the Council of 24 October 1995 of individuals with regard to the processing of personal data and on the free movement of such), *translated at* http://www.enpd.pt/leis/lei_6798en.html (last visited Oct. 4, 2001).

87. India Cen. Act 21 (2000), Information Technology Act 2000, Ministry of Law, Justice and Company Affairs, New Delhi, 9 June 2000, *translated at* <http://www.mit.gov.in/it-bill.htm> (last visited Sept. 26, 2001).

88. *See generally* Ley Sobre Proteccion de la Vida Privada [Law of the Protection of Private Life Act] 19628.

89. J. M. Spectar, *Bridging the Digital Divide: Frameworks for Access and the World Wireless Web*, 26 N.C. J. INT'L L. & COM. REG. 57, 59 (2000).

century remains a real and troubling prospect.⁹⁰ Amid the chaos of recent protests at international political and trade meetings, there is a unifying concern which has emerged about the need for equity in the diffusion of new, life enhancing technologies around the globe, particularly those in the area of health care.⁹¹

At first blush, the issue of global equitable technology diffusion would appear to be one strictly of an economic nature. A particular country's lack of economic resources to purchase and maintain new technologies may seem to lie at the core of the diffusion problem. While economics is certainly a dominant factor, the multifaceted and complex challenges are sparked by the issues of equitably distributing new life-enhancing technologies and are not strictly financial in nature. The United Nations Digital Opportunity Initiative (DOI) identified five areas on intervention which need to be addressed to facilitate the proliferation of ICT.⁹² The five areas include infrastructure, human capacity, policy, enterprise, content and applications.⁹³ Each of the five areas encompasses multiple elements. For example, infrastructure entails the development of a core information and telecommunications network, achieving relative ubiquity of access, as well as creation of an investment strategy, which supports a country's development priorities.⁹⁴ Law is a key component of infrastructure, as a legal foundation is critical for both the development and maintenance of ICT services of all kinds, including e-health.

The discussion in this Article will focus on two broad aspects of legal infrastructure development: intellectual property and the use of law to facilitate economic resource distribution to finance e-health projects.

A. *Patent Law: Protectionism versus Diffusion*

Few areas have received greater attention in international law of late than intellectual property (IP).⁹⁵ The stunning growth in pharmaceuticals, biotechnology and new medical products has sparked heightened concern on the part of researchers, manufacturers, distributors and others about the

90. See generally United Nations Development Program, *Creating a Development Dynamic* (2001), available at <http://www.opt-init.org/Framework1pages/contents.html> (last visited Sept. 26, 2001) [hereinafter United Nations Development Program].

91. Nick Drager & Robert Beaglehole, *Globalization: Changing the Public Health Landscape*, 79 WHO BULLETIN (2001), available at <http://who.int/bulletin/tableofcontents/2001/vol.79no.9.html> (last visited Oct. 3, 2001).

92. United Nations Development Program, *supra* note 90, at 6-8.

93. *Id.* at 8.

94. *Id.*

95. See, e.g., Samuel K. Murumba, *Globalizing Intellectual Property*, 19 U. PA. J. INT'L ECON. L. 435 (1998).

viability of global patent protections.⁹⁶ The desire to insure workable patent protections in the global marketplace has been countered with a pressure to relax IP protections for life enhancing and life-saving products, particularly pharmaceuticals.⁹⁷ In particular, debates over AIDS drugs can be seen as characterizing the recent tensions in international IP law.⁹⁸ Considerable pressure has been placed on manufacturers to relax patent controls and to allow new AIDS drugs to be sold at lower costs through relaxation in patent law policies that allow for greater flexibility in licensing and importing.⁹⁹

As noted in the first half of this Article, intellectual property in the international context is governed by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, which is administered by the World Trade Organization (WTO).¹⁰⁰ TRIPS contains detailed provisions concerning patent law and supports a legal scheme that recognizes patent holders rights for a twenty-year period.¹⁰¹ TRIPS attempts to balance invention, creativity and protection of intellectual property with social and economic welfare. While the protection of patents for products and processes is central to TRIPS, and in turn to WTO member states, certain exceptions have been created in the treaty.¹⁰² For example, under Article 27 of TRIPS, a government may refuse to grant a patent for inventions which enhance human health or are used for diagnostic, therapeutic or surgical methods.¹⁰³ In addition, patent protections can be waived to allow researchers to use a patented invention to further scientific and technical knowledge, the so-called "Bolar" provision.¹⁰⁴ Of particular significance is Article 31, which permits "other use . . . without authorization of the right holder," for compulsory licensing protections, and permits a national government to authorize the production of a needed, patented product by a party in the country who does not hold the patent.¹⁰⁵ Under TRIPS, compulsory licensure can only occur in

96. Gerold J. Mossinghoff & Vivian S. Kuo, *World Patent System Circa 20XX, A.D.*, 38 IDEA 529 (1998).

97. World Health Organization, *Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement*, DAP Series 7, at 33 (1999).

98. Judy Rein, *International Governance Through Trade Agreement: Patent Protection for Essential Medicine*, 21 NW. J. INT'L. L. & BUS. 379, 380 (2001).

99. *Id.* at 400-02.

100. General Agreement on Tariffs and Trade – Multilateral Trade Negotiations (The Uruguay Round): Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Dec. 15, 1993, 33 I.L.M. 81 [hereinafter TRIPS].

101. MICHAEL BLAKENEY, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A CONCISE GUIDE TO THE TRIPS AGREEMENT 81 (1997).

102. TRIPS, *supra* note 100, at 95 (Article 30).

103. *Id.* at 94 (Article 27).

104. See 35 U.S.C.A. § 271(e)(1) (West 1994 & Supp. V). See also Roche Prods., Inc. v. Bolar Pharm. Co., 572 F. Supp. 255 (E.D.N.Y. 1983).

105. TRIPS, *supra* note 100, at 95 (Article 31).

limited circumstances, such as the existence of a public health emergency, and is restricted by a number of conditions designed to protect the legitimate interests of the patent holder.¹⁰⁶ For example, the party seeking the license must first try to secure the voluntary use of the license, and if a compulsory license is issued, remuneration must still be paid to the patent holder.¹⁰⁷ To date, compulsory licensing has been associated primarily with pharmaceutical products, but clearly it could apply to patents in any field, including e-health.

Parallel, or grey-market imports constitute a loophole in the TRIPS agreement. The concept of parallel imports involves moving products made and marketed by a patent holder in one country into another country at a lower price.¹⁰⁸ Suppose a patent holder produces the same drug in two countries, A and B, but sells the product in country B at a lower price. If the drug sold at the lower price in country B is purchased by an exporter and exported into country C at the lower price without permission of the patent holder, that would constitute a parallel import. The legal principle at work here is referred to as “exhaustion,” the notion that once the patent holder sells its product, the patent is exhausted, and the patent holder no longer retains any rights over what happens to the product.¹⁰⁹ Generally, the TRIPS agreement does not deal directly with the exhaustion of intellectual property rights, with the exception of Article 6 of the agreement.¹¹⁰ Even if a country allows parallel imports to occur under conditions which may be in violation of the TRIPS agreement, such a violation cannot be raised as a WTO dispute unless non-discrimination principles (such as national treatment or most-favored-nation treatment) are violated.¹¹¹

While the TRIPS agreement may allow for a certain level of flexibility in the patent area, the use of compulsory licensure and parallel importing is limited both legally and practically. Compulsory licensure is strictly regulated and is clearly an exception to the usual dictates of patent law. Parallel importing is a way of moving products globally at reduced prices, but it can be severely restricted by the concerted actions of large multinational manufacturers and distributors. A recent dispute concerning AIDS drugs in South Africa provides a vivid example of the ongoing difficulties in the IP area. In 1997, the government of South Africa enacted the Medicines Act, which authorized the country’s health minister to allow parallel imports of

106. *Id.*

107. *Id.*

108. World Trade Organization, *Fact Sheet: TRIPS and Pharmaceutical Patents: Obligations and Exceptions* (April 2001), available at http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm (last visited Sept. 24, 2001).

109. *Id.*

110. *Id.*

111. *Id.*

AIDS medicines, as well as compulsory licensure to protect public health.¹¹² Thirty-nine pharmaceutical firms challenged the South African law, but the challenge was subsequently dropped after an agreement was reached which allowed the drug firms to participate in a working group concerning the implementation of the Medicine Act.¹¹³ The South African dispute is indicative of the fact that pharmaceutical companies view the exceptions to patent rights narrowly, and that developing countries will interpret TRIPS exceptions in public health quite broadly.

It is very clear that the questions of global patent protection in reference to pharmaceuticals are very compelling, but how compelling the IP issues are in reference to e-health is not quite as clear. A study conducted by the United Nations Conference on Trade and Development concluded that there was little evidence that intellectual property rights are constraining access to biotechnology in developing countries.¹¹⁴ The United Nations study found that the main challenge for developing countries in accessing biotechnology was tapping into the vast pool of information, which is already freely available. Indeed, e-health which affords global users the opportunity to access extensive health information would appear to fit into the category of available data that needs to be appreciated and judiciously used. E-health, however, involves not just the delivery of health information, but also entails diagnostic and treatment services which will only expand in the future. It is in the area of diagnostics and treatment that IP interests in e-health are most likely to rear their head and, like pharmaceutical products, pose challenges to the diffusion of these existing and developing applications. It is likely that e-health patent holders (hardware and software alike) will be reluctant to offer services to parties who will not honor their patent rights. The ongoing controversies in international IP law are harbingers of the kinds of disputes that may characterize the attempts to maximize e-health technologies in the developing world. In particular, parties who have a stake in commercial e-health ventures will be vigorous defenders of IP protections. While changes in international IP law can be proposed to facilitate e-health diffusion, to be viable, such proposals must be made in conjunction with financing issues.

112. Medicines and Related Substances Control Act of 1965, No. 101 § 15(c) (amended 1997) (S. Afr.).

113. See Treatment Action Campaign Statement, *An Explanation of the Medicine Act and the Implications of the Court Victory* (April 24, 2001), available at <http://www.tac.org.za/ns010424.txt> (last visited Sept. 24, 2001).

114. *UN Report Finds Little Evidence That IP Constrains Biotechnology*, WORLD INTELL. PROP. REP., July 2001, at 21.

B. *Public Law and E-health Financing*

As previously noted, financing alone is not the sole barrier to the diffusion of new technology in the developing world. Certainly, in the case of e-health, an adequate telecommunications infrastructure, availability of supporting technology, health system planning and development and adequate human resources and training are all critical elements in creating and maintaining a viable e-health program. The fact is, however, that in order to create a successful e-health program in the developing world, there is a critical need for financing to support the requisite programmatic elements. For the spread of global e-health, financing must be secured from both public and private sources. In the private commercial context, e-health will only grow and prosper in developing countries if economic models can be created that generate profits for those developing and supplying these services. In the public arena, governments and international organizations need to adopt strategies that will facilitate adequate and ongoing funding. Mechanisms need to be created and supported by individual nations, groups of nations and international organizations to promote investment in e-health technologies. This Article will consider financing of global e-health only in the public context, but with the recognition that for e-health to be widely available, viable commercial models must be developed as well.

1. *Differential Pricing*

Perhaps the most recognized mechanism for global financing of new technologies in low and middle-income countries is differential pricing. On its face, the concept of differential pricing appears straightforward, as it is the adaptation of prices charged by the seller to the purchasing power of governments and households in different countries.¹¹⁵

The producers of e-health technology, under a scheme of differential pricing, would relate prices to each market under the assumption that the price will be what the market or government can bear, and that each national market can be separated.¹¹⁶ In a joint report by the WHO and the WTO, it was pointed out that several conditions need to exist to support a viable differential pricing scheme.¹¹⁷ Some of the conditions noted include stable or fixed costs of production, adequate market power and mechanisms to prevent market leakage

115. World Health Organization and World Trade Organization Secretariats, Norwegian Foreign Affairs Ministry, Global Health Council, *Report of the Workshop on Differential Pricing and Financing of Essential Drug 3* (April 2001), available at http://www.who.int/medicines/library/edm_general/who-wto-hosbjor/who-wto-hosbjor.html (last visited Jan. 25, 2002) [hereinafter Report on Differential Pricing].

116. *See generally id.*

117. *Id.* at 3.

from low to high cost markets.¹¹⁸ There is also a concept in differential pricing referred to as “Ramsey pricing,” which recognizes that patented products having a strong public and social benefit (meaning health enhancing) be either discounted or specially priced in developing countries.¹¹⁹

The complexities of differential pricing are far beyond the framework of this Article, but the decision to pursue differential pricing is quickly followed by a consideration of how such a process ought to be supported. It is here where the public law linkage is forged. The various approaches taken to differential pricing must be grounded in a legal foundation that allows such practices to occur. One mechanism to apply differential pricing is strictly market based, namely, allowing prices to be determined by what sellers can realistically charge in a given market. The difficulty with a market-only approach is that it is dependent on free and open markets, and such a condition is not always present in developing nations. Another approach to facilitating differential pricing includes bilateral negotiated discounts in which the supplying company determines the discount in a given country based on the supplier’s knowledge of product mix, profitability and costs. Additional approaches include regional and global bulk purchasing, voluntary licenses, compulsory licenses and public/private partnerships in which prices are country specific and patent rights are recognized in certain markets and relaxed in others.¹²⁰

With the exception of market based differential pricing, the other pricing/distribution approaches all rest on a necessary public law foundation. While some of the mechanisms noted, such as voluntary and compulsory licensure, do have a current basis in international law, there is not yet an adequate legal foundation to support diverse approaches to differential pricing globally.¹²¹ It is likely that no one approach to differential pricing will emerge as the dominant one, but the diffusion of new technologies such as e-health will require varied pricing policies and further legal infrastructure development to support them adequately.¹²²

The economic and legal issues which must be appreciated and addressed in reference to differential pricing all occur in a highly politicized context. Proposals which alter the rights of sellers to set prices as they wish will likely be vigorously opposed by developers and suppliers of products. Differential pricing undoubtedly will be characterized as a form of price fixing. The ongoing controversy concerning the United Nations global AIDS fund is

118. *Id.* at 4, 13-14.

119. *Id.* at 12.

120. *See generally* Report on Differential Pricing, *supra* note 115.

121. *See generally id.*

122. *See generally id.*

illustrative of the politics of global drug pricing.¹²³ The Bush administration opposes tiered pricing (differential pricing) for AIDS drugs, as well as the creation of a global pricing database, raising concerns about the accuracy of pricing information in such a database as well as potential antitrust problems.¹²⁴ The Europeans, on the other hand, support a centralized global purchasing scheme for necessary medicines that would be administered by an international agency and would allow for differential pricing mechanisms. It is not clear that the stakes over e-health are as high as those in global pharmaceutical pricing, but with the proliferation of e-health products the viability of financing will be an issue caught in the cross winds of politics. If the financial stakes are lower in e-health than in pharmaceuticals, manufacturers and governments may be more willing to liberalize the law to allow for differential pricing for these technologies. However, if such liberalization has a spillover effect into other areas, it may be wishful thinking to believe such practices will not be opposed.

2. Grants and Donations

In the public sector, e-health development in poor countries can be financed through a scheme of grants and donations from individual governments and international organizations. There is a long-standing global tradition of voluntary resource allocation, foreign aid, for a variety of development purposes.¹²⁵ The United Nations AIDS fund previously noted is an example of a recent global effort to address public health needs on a voluntary basis.¹²⁶ Certainly in e-health, as noted, a number of projects in the developing world are being supported by organizations like the International Telecommunications Union. Individual governments have also committed large sums of money to general and specific humanitarian and public health aid efforts. While funding developments like e-health through charity is helpful, there are many competing interests for such funds, and sustaining charitable funding over long periods of time can be problematic.

VI. A GLOBAL DEVELOPMENT AUTHORITY AND A GLOBAL TAX

A possible approach to regularizing voluntary contributions for development purposes such as e-health is the creation of some type of global development authority. In the late 1950s a proposal was made to amend the United Nations Charter to create a World Development Council that would

123. *The UN Looks at AIDS*, N.Y. TIMES, Jun. 24, 2001, at 12.

124. Donald G. McNeil, *U.S. at Odds With Europe Over Rules on World Drug Pricing*, N.Y. TIMES, July 20, 2001, at A8.

125. Myron J. Frankman, *International Taxation: The Trajectory of an Idea from Lorimer to Brandt*, 24 WORLD DEVELOPMENT 807, 810 (2000).

126. See generally McNeil, *supra* note 124.

provide grants-in-aid or interest free loans for development projects that otherwise could not be funded adequately.¹²⁷ Indeed, e-health projects would present compelling cases for the use of such a global development fund. The difficulty with creating such a fund is that the pressures on the fund from multiple sectors would undoubtedly tax the available resources. Even more problematic would be the international politics that would surround such an organization that would permeate all operational issues from fund development to financial allocation decisions.

Still, even in the face of financial and political challenges, some sort of global fund, if supported by a large international entity like the United Nations or WTO, could provide a valuable source of public financing for health care and other development needs. In the proposal to create a World Development Council noted above, it was suggested that the project be funded by United Nations member country import/export taxes, up to 2.5% of each member's GNP.¹²⁸ Over the years there have been occasional suggestions that some type of global income tax be developed to facilitate funding for broad based resource diffusion.¹²⁹ In 1974, the United Nations passed a resolution calling for a New International Economic Order (NIEO), which was followed by a suggestion that member nations dedicate 0.7% of their annual GNPs to global aid.¹³⁰ In 1980, the Brandt Commission Report on Global Cooperation consolidated a number of earlier proposals dealing with global equity and made a case for the development of an international taxation scheme to achieve parity in global development.¹³¹ A worldwide tax scheme could provide a base for funding vital sectors like health, and as such, aid in the proliferation of technologies like e-health, which will have widespread population benefit. Any tax scheme will face daunting logistical and political issues such as determining the appropriate party to administer such a scheme, establishing rates, and harmonizing the scheme with domestic tax laws.¹³² Still, even a very modest global taxing scheme would yield great benefits, producing a more dependable source of ongoing financing for technology developments and assisting in the proliferation of e-health and other health care delivery programs.

VII. FORMULATING AN APPROACH

The potential of e-health is only beginning to be realized both domestically and internationally. As the technologies develop, e-health may be used to

127. Frankman, *supra* note 125, at 812.

128. *Id.*

129. *Id.* at 812.

130. *Id.* at 813.

131. *Id.* at 814.

132. Frankman, *supra* note 125, at 815.

provide not only information and services, but may become a tool that can be used as a building block in future national health delivery systems. For these potentials to be reached, access to e-health must become a global priority and necessary changes must be made to insure the equitable diffusion of health ICT to all nations, not just those in the developed world. Undoubtedly, plans to diffuse e-health globally will face serious and complex considerations of IP law as manufacturers and suppliers will continue to voice legitimate concerns about product protection, integrity and profits. There is no magic bullet that can balance all the competing interests in a way in which those on the extremes of the issues presented in the diffusion debate will be satisfied. Rather, what are needed are proposals that will allow for modest progress and protect legitimate economic interests, but also guarantee that at least some of the more helpful new e-health technologies can be accessed globally.

To achieve progress in the diffusion of e-health, two things need to happen. First, international patent laws must be liberalized so that developing countries may gain more routine access to life saving technologies, without having to invoke arcane and highly technical exception provisions. Agreements like TRIPS need to reopen in the patent area and special provisions for routine access to new health care technologies must be made. The changes in the law must balance the need for a viable global patent system, and thus nations which seek to use access provisions circumventing established patent laws must demonstrate a case for doing so, and must face a limitation in the frequency a given nation can invoke such patent exceptions.

The second area of reform concerns financing, as a source of consistent and ongoing funding must be developed to provide the necessary funds for developing nations, and in some cases middle income nations, to access e-health and other new technologies. Financing needs to be based on more than charitable largesse. As the evolving global trading system lies at the focal point of the diffusion issues, it would seem reasonable that the WTO assumes a leadership role in devising a funding scheme for underwriting the diffusion of new technologies globally. Clearly the WTO is the new guardian of international patent law, and changes in this area must be made through that organization. But beyond that, WTO's mission to promote global economic development through trade carries with it a mandate to demonstrate that free trade is an important and viable tool for human development. The WTO could begin to address some of its critics' concerns about its seeming indifference to the world's poor by taking the leadership role in devising a funding scheme to diffuse new technologies to developing countries.

One possible approach, which could be launched by WTO to facilitate e-health diffusion, would combine patent law changes with financing. Under WTO auspices, a special development fund should be created to provide grants and loans to developing countries to support e-health and other new technology developments. The fund would be created from contributions of member

states that would be required, as a condition of membership, to contribute a percentage of their GNP into the fund. Each member state would, in turn, raise revenue for the WTO fund in a variety of ways, including the use of taxing schemes directed toward corporate income derived from international trade. Affected corporations that granted compulsory or voluntary licenses for e-health technologies (as well as other qualifying technologies) would, in turn, be eligible for tax credits, based on the number of licenses they issued.

It would be WTO's responsibility to not only collect revenue for the fund from member nations, but also to oversee the awarding of grants and loans to developing and middle income countries for e-health projects, and to monitor the ongoing progress of the respective projects. To receive e-health funding, nations would need to demonstrate how the funds would be used and prove that adequate infrastructure planning had occurred to maximize the benefits of the funds, including amending restrictive national laws and policies. While the goal is to provide consistent and ongoing funding, recipients would be monitored by the WTO to insure that the e-health projects were being properly managed, and that funding could be terminated for failing to meet the conditions of a given award. Undoubtedly, other proposals for diffusing e-health and other medical technologies can and should be devised and all will be fraught with multiple complexities, but there is a genuine and urgent need for boldness and creativity in this area.

VIII. CONCLUDING THOUGHTS

International law in reference to e-health is complex and disjointed, as it is composed of pockets of law that are only linked together by these technologies and applications. There is a great need for mechanisms to link together all of the respective pieces which make up e-health law globally. This will occur eventually through one or more broad based international agreements in the area. It is important to recognize that the law in e-health will always be heavily influenced by domestic laws. No matter what develops in international law, individual nations in crafting their own laws must not be co-opted by provincial interests, but must recognize that local law should be written with a realization of the need for harmonization of law in this area.

On the diffusion side, the potential of e-health must not be restricted to the West, but must be made available to nations around the world. In this regard, e-health is part of a larger need to insure equity of access to new life saving and enhancing technologies worldwide, and for this to happen IP laws must be liberalized. In addition, creative approaches to funding must be found. The law needs to perform a dual role of providing a workable and responsive structure for e-health, as well as facilitating global equity and universal access, a delicate balance, but a critical one for global public health.