In 1997, control of disease continued as a central focus of activity in international public health law. The World Health Organization (WHO) pursued revision of the International Health regulations for adoption by the World Health Assembly (WHA) in May 1999. Linkage between disease and international trade was raised in both judicial and administrative fora. The WHO worked to build support for development of a framework convention on tobacco, following its 1996 international regulatory strategy for global tobacco control. The threat of biological weapons use resulted in the Fall 1997 decision to vaccinate all American military forces against anthrax, and heightened public health concerns continued into 1998, as tensions mounted for possible military action in Iraq. Climate change, such as global warming, is increasingly linked in the literature to the emergence, frequency, and range of infectious disease. The international AIDS pandemic progressed in 1997 despite medical advances in treatment, largely unavailable to AIDS patients in many countries unable to finance such treatments.

Competition in 1997 culminated in the January 1998 WHO Executive Board selection of former Norwegian Prime Minister, Dr. Gro Harlem Brundtland, as the next WHO Director-General, upon WHA approval in May 1998. Dr. Brundtland announced her intentions to urge public health as a top political priority in WHO member countries, to strengthen recognition of public health as essential in economic development, and to link WHO actions with those of the International Monetary Fund and the World Bank.

1. Emerging and Reemerging Infectious Diseases

A. World Health Organization: General

1. WHO Funding

The financial constraints hindering the WHO's pursuit of its mandate to improve global health have long been known and lamented. The WHA noted in May 1997 that problems with unpaid

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assessed contributions from Members States were growing. The WHA stated that "total unpaid contributions in respect of 1996 and prior years exceeded US$169 million." Although the WHA invoked article 7 of the WHO Constitution to suspend voting privileges of Member States in arrears in their contributions, this penalty seems not to have much effect. The WHA expressed its "concern at the increasingly large number of Members that have been in arrears in the payment of their contributions in recent years to an extent which would justify invoking Article 7 of the Constitution and the unprecedented level of contributions owed by them."

2. Expanded Legal Powers for WHO?

The reluctance of the WHO to use its international legal powers under the WHO Constitution is a well-known and increasingly questioned practice of the WHO. A special group empowered by the WHO Executive Board to review the WHO Constitution issued its report in November 1997, which includes recommendations to increase the WHO's regulatory powers under article 21 of the WHO Constitution. The special group proposed adding to the WHA's authority to adopt regulations in article 21 the power to adopt regulations:

1. on "standards with respect to transplantation of tissues and genetic engineering, including cloning"; and
2. "concerning any other health-related matter falling within the functions of the Organization as set forth in Article 2."

The proposal on allowing the WHA to adopt standards on transplantation and genetic engineering expands the WHA's regulatory authority into controversial new areas such as xenotransplantation and cloning. The second proposal essentially broadens the WHA's authority to adopt regulations equaling the authority it has under article 19 to adopt conventions on any matter within the competence of the WHO. If these proposals are adopted by WHO Member States, they will represent a significant increase in WHA regulatory powers. Such an increase does not necessarily imply the WHO altered its preference for non-binding recommendations and guidelines over binding regulations or conventions. In fact, the Director-General restated the traditional WHO position in May 1997: WHO recommendations and guidelines established through consultative meetings of experts "have proved more effective and more flexible than legally binding instruments such as conventions, which require lengthy procedures before they come into force."

B. EMERGING AND REEMERGING INFECTIOUS DISEASES (EXCLUDING HIV/AIDS)

The WHO dedicated World Health Day 1997 to the global problem of emerging and reemerging infectious diseases (EIDs), which demonstrates the continuing prominence of this
problem in global public health policy. In 1996 infectious diseases caused 17,312,000 deaths worldwide, representing 33 percent of all 1996 deaths. Infectious diseases remained important in many diplomatic contexts in 1997, including the attention given to controlling EIDs at the June 1997 summit of the Group of Seven industrialized countries and at the November 1997 Asia Pacific Economic Cooperation summit. The United States continued its bilateral diplomacy on EIDs through the U.S.-Japan Common Agenda, U.S.-European Trans-Atlantic Agenda, the U.S.-Russian Joint Commission on Economic and Technical Cooperation, and the U.S.-South Africa Binational Commission. The United States also signed a new, five-year cooperation agreement with India on EIDs. In addition, Congress allocated an additional $50 million for fiscal year 1998 to the U.S. Agency for International Development specifically to help control infectious diseases in foreign countries. Finally, as 1997 came to a close, infectious diseases captured worldwide media attention in the form of the transmission to humans of an avian influenza virus in Hong Kong.

These sections briefly highlight some 1997 developments relating to infectious diseases, demonstrating that they increasingly pose challenges in many areas of international law.

1. Revision of the International Health Regulations

The WHO's revision of the International Health Regulations (IHR) continued during 1997, with the WHO publishing two progress reports on the IHR revision. In its last progress report, the WHO stated that the revised IHR would contain important changes "involving a new approach to mandatory notification as well as a major alteration in the structure of the IHR." Instead of requiring notification of only three diseases as at present, the revised IHR...
will "require reporting of a number of defined disease syndromes that are of international importance."20 The structural changes planned for the revised IHR involve moving to a framework document containing core provisions and a series of technical annexes detailing specific obligations.21 Field-testing of syndrome reporting was scheduled to begin in October 1997.22 The WHO anticipates submitting the revised IHR to the WHA in 1999.22

2. International Trade

The WHO and national governments registered much concern in 1997 about the spread of food borne pathogens through international trade. Leading international and national public health agencies, including the WHO and the U.S. Centers for Disease Control and Prevention, sponsored a major conference on emerging food borne pathogens in March 1997, the proceedings of which were published in the influential journal Emerging Infectious Diseases.23

The link between food borne pathogens and growing volumes of international trade in food and food products implicates international trade law. This link was clearly noticed in early October 1997 when the Clinton Administration launched a new policy initiative to improve the safety of food imported into the United States.24 This policy initiative was provoked by a New York Times article reporting serious problems with U.S. efforts to monitor food imports.25 The United States and the European Union (E.U.) are in the midst of a controversy concerning a plan to ban approximately $4.5 billion in U.S. cosmetics and pharmaceuticals because they contain bovine-derived tallow and gelatin that could act as vectors of bovine spongiform encephalopathy, which can cause a new variant of the fatal human brain disease called Creutzfeldt-Jakob disease.26 In December 1997 the United States blocked the importation of Guatemalan raspberries from March 15, 1998, until August 15, 1998, because of the link between prior imports and outbreaks of disease in the United States caused by the parasite cyclospora.27

Although not a case involving infectious diseases, the WTO panel and Appellate Body28 decisions in the Beef Hormones Case have implications for sanitary and phytosanitary measures of WTO Member States that address human, animal, and plant infectious diseases because these decisions are the first to interpret the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).29 In April 1996 the United States requested

19. Id.
20. Id. at 214.
21. Id.
27. Cyclosporiasis: Guatemalan Raspberries Banned-US (electronic mail communication from ProMED-mail), Dec. 20, 1997.
the establishment of a WTO panel to rule on the compatibility with the GATT and the SPS Agreement of the European Community (EC) ban on imports of meat raised with growth-promotion hormones.\textsuperscript{30} The WTO panel found that the EC ban violated articles 3.1, 3.3, 5.1, and 5.5 of the SPS Agreement.\textsuperscript{31} The core panel holding was that the European Community did not provide a scientific basis or evidence for its import ban.\textsuperscript{32} While the Appellate Body upheld the panel’s conclusion that the European Community did not satisfy the science-based disciplines of the SPS Agreement, and thus was in violation of articles 3.3 and 5.1, it reversed the panel’s rulings that the European Community also violated of articles 3.1 and 5.5 of the SPS Agreement.\textsuperscript{33}

The Appellate Body also reversed the panel’s allocation of the burden of proof by holding that the SPS Agreement requires the complaining member state to make a prima facie case that the SPS Agreement was violated before the burden shifts to the accused member state.\textsuperscript{34} The Appellate Body’s allocation of the burden of proof may make it harder for a member state to challenge the SPS measures of other member states than it would be under the Hormones Panel Report.\textsuperscript{35} In addition, the Appellate Body’s interpretations of articles 3 and 5 emphasized member states’ sovereignty in implementing SPS measures;\textsuperscript{36} such interpretations might make it easier for a member state to provide scientific justifications for its SPS measures than are possible under the Hormones Panel Report.\textsuperscript{37}

At its May 1997 meeting the WHA addressed a number of other issues involving the intersection of international trade and health: (1) the quality of pharmaceutical products moving in international commerce;\textsuperscript{38} and (2) the quality of biological products moving in international commerce.\textsuperscript{39} The WHA also addressed the issue of the cross-border advertising, promotion, and sale of medical products on the Internet and requested the Director-General to convene a WHO ad hoc working group to review the concerns arising in this area.\textsuperscript{40}


\textsuperscript{31} Hormones Appellate Report, supra note 28, ¶ 9.1.


\textsuperscript{33} Hormones Appellate Report, supra note 28, ¶ 235.

\textsuperscript{34} Id. ¶ 253(a).

\textsuperscript{35} WTO Beef Hormones: US and EU Both Claim Victory, Bridges Wkly. Trade News Dig., Jan. 19, 1998 (noting that the shift in the burden of proof to the complaining party might make SPS challenges more difficult).

\textsuperscript{36} Hormones Appellate Report, supra note 28, ¶¶ 104, 172 (interpreting the relationship between Articles 3.1 and 3.3 and ¶¶ 186-87 (interpreting article 5.1’s risk assessment mandate not to require any demonstration of a threshold of risk and to include examination and evaluation of risks not susceptible to investigation by scientific methods).


\textsuperscript{38} Guidelines on the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, World Health Assembly Res. WHA50.3 (May 12, 1997).

\textsuperscript{39} Quality of Biological Products Moving in International Commerce, World Health Assembly Res. WHA50.20 (May 12, 1997). Part of this Resolution requested the Director-General to review the relation between WHO guidelines on the quality of biological products and WTO agreements, particularly the Agreement on Technical Barriers to Trade, the SPS Agreement, and the Agreement on Trade-Related Aspects of Intellectual Property Rights, and to submit a report to the Executive Board in May 1998.

\textsuperscript{40} Cross-Border Advertising, Promotion and Sale of Medical Products Using the Internet, World Health Assembly Res. WHA50.4 (May 12, 1997).
3. Biological Weapons

The threat of biological weapons was a theme in literature on EIDs. The stand-offs between the United Nations and Iraq over inspections of Iraq's nuclear, chemical, and biological weapons facilities in 1997 highlighted a year in which concern for the proliferation of biological weapons was high. In August 1997 the prestigious Journal of the American Medical Association devoted most of an issue to the threat of biological weapons. In Geneva, negotiations continued on drafting a Protocol to the 1972 Biological Weapons Convention that would establish a compliance regime to strengthen the Convention's prohibition on the development, production, and stockpiling of biological weapons. Many important issues remain unresolved in the negotiations on the Protocol, including the scope and intrusiveness of the compliance regime and the protection of national security information and private sector confidential information.

Meanwhile, American concerns about countries using biological weapons factored into: (1) President Clinton's new guidelines for American policy on using nuclear weapons, under which such weapons may be used against an enemy attacking with biological weapons; and (2) the U.S. military's decision to vaccinate all American forces against anthrax.

4. International Environmental Law

Global warming was in the spotlight in 1997 as states met in Berlin and then in Kyoto to negotiate a Protocol to the 1992 Climate Change Convention. Global warming was featured in literature on EIDs because of the prospects that climate change could increase the frequency and geographical range of certain infectious diseases and their insect vectors. While the argument that global warming will increase infectious disease problems is controversial, the very existence of the controversy makes international environmental law and its development at Kyoto relevant to global public health policy.

42. See generally 278 JAMA (1997).
48. See Gary Taubes, Apocalypse Not, 278 SCIENCE 1004, 1004 (1997) (reporting on some infectious disease experts' criticism of the predictions that global warming will increase the prevalence of infectious diseases as the Kyoto summit approached).
49. The connection between global public health policy and international environmental law was also seen in the WHA's resolution supporting protection of marine environment in order to reduce risks to human health from environmental degradation. See Protection of the Marine Environment, World Health Assembly Res. WHA50.14 (May 12, 1997).
5. Antimicrobial Resistance

Another infectious disease concern raised frequently in 1997 was the development of antimicrobial resistance in pathogens. While antimicrobial resistance was long a topic in EID literature, worldwide publicity about the identification in Japan and the United States of strains of Staphylococcus aureus with decreased susceptibility to vancomycin created more public awareness of the problem of antimicrobial resistance. The Institute of Medicine’s Forum on Emerging Infections explored antimicrobial resistance in its July 1997 meeting, including national and international legal issues that antimicrobial resistance creates. The WHO held a meeting in October 1997 in Berlin on the use of antimicrobials in food-animals and the risks such use poses for human health. In its report on this meeting, the WHO recommended that: (1) “governments institute laws and regulations pertaining to anti-microbial licensure, prudent use and compliance”; and (2) “[o]n the international level, agreements are needed to reduce the risk of transmitting [anti-microbial] resistance between countries.” The WHO intends that reporting of antimicrobial resistance will form part of the syndrome notification obligations in the revised IHR.

II. AIDS

Developments in AIDS law reflected an uneasy balance of factors in 1997. The number of people infected continued to expand, despite advances in drug therapies to treat those falling ill. The expense of those therapies threatened to bankrupt national health care systems, even as activists called for increased access. Governmental policies on AIDS reflected compassion in some cases and ignorance in others. Court decisions advanced the rights of persons with AIDS in areas of access to medical drugs, employment law, and travel.

A. HIV Antibody Testing and the Further Spread of AIDS

In a disturbing development, the Hungarian Parliament eliminated anonymous HIV testing. The new law provides that when a person tests positive for HIV, “the person . . . must provide his personal identification data at the request of the provider of medical care. The person . . . shall be informed of this prior to the screening examination.” Although the legislature perhaps believed it could better track persons with HIV, the removal of anonymous testing instead drives HIV underground and furthers its spread.

Infection rates for new cases of HIV continued to climb during 1997. UNAIDS estimated that 5.8 million people were infected in 1997. In some places the rise in the number of new...
cases is simply staggering. In Kaliningrad, Russia, for example, where intravenous drugs and commercial sex are reportedly widely available, the number of AIDS cases jumped from twenty-eight in 1996 to more than 1,850 in 1997.\textsuperscript{6} China reported 7,253 cases of HIV infection, but experts estimate that the true figure is 200,000 cases.\textsuperscript{7} Experts at an AIDS Congress in the Philippines estimated that the number of people in Asia affected by HIV, "already estimated at 7 million, could double by the turn of the century."\textsuperscript{8} The head of the AIDS Commission in Uganda estimated that at least 400,000 Ugandans died from AIDS since 1984 and that 1.5 million of Uganda's 18 million people are infected with HIV.\textsuperscript{9}

The number of cases is significant not only for epidemiological reasons, but because AIDS increases poverty and decreases educational opportunities in the developing world.\textsuperscript{60} The World Bank called on developing countries in 1997 to focus on AIDS prevention programs as part of their development strategies.\textsuperscript{61} Warning that the AIDS pandemic is about to explode in China, India, and Eastern Europe, the World Bank urged developing nations to implement controversial AIDS prevention programs,\textsuperscript{62} including needle exchanges and condom distribution,\textsuperscript{63} and a UNAIDS official urged private companies to join the battle against AIDS.\textsuperscript{64} Preventive education remains the best hope for nations to control the further spread of AIDS.

B. ACCESS TO MEDICAL DRUGS

The newest approach to treating HIV combines a protease inhibitor with two or more nucleoside analogues.\textsuperscript{65} Drug combinations, sometimes called an "AIDS cocktail," can cost $12,000 to $15,000 a year in the United States.\textsuperscript{66} These miracle drugs do not work for everyone, as evidenced by the deaths of many having access to the drugs and following the protocol.

Countries providing access to the new medicines available to treat HIV found that their AIDS death rates dropped significantly in 1997. Brazil, for example, saw its AIDS death rate fall for the first time ever after distributing free AIDS treatment drugs.\textsuperscript{67} Of course, most nations cannot afford to provide free drugs to those needing them. In the United States, a country

\textsuperscript{56.} Michael Specter, \textit{At a Western Outpost of Russia, AIDS Spreads "Like a Forest Fire,"} \textit{N.Y. Times}, Nov. 4, 1997, at A1.

\textsuperscript{57.} \textit{Advocate}, Dec. 23, 1997, at 23.

\textsuperscript{58.} \textit{Advocate}, Dec. 9, 1997, at 20.

\textsuperscript{59.} \textit{Uganda, 96 Current Hist.} 400 (1997).


\textsuperscript{62.} Despite the controversy surrounding some programs, certain nations show strong commitment to preventive education. Brazil, for example, announced in 1997 that its new education program will target children as young as four years old with age-appropriate information. \textit{Advocate}, Feb. 4, 1997, at 21.

\textsuperscript{63.} Altman, \textit{supra} note 60, at A10.


\textsuperscript{65.} \textit{AIDS 1997: A Look Back at the Year of Hope}, \textit{Advocate}, Jan. 20, 1998, at 51, 53. The combination therapy, according to a federal task force, "offers a 'high chance' of suppressing replication of the virus." \textit{Id.}


without a nationalized health system, federal spending on these drugs was estimated at $167 million in 1996, $285 million in 1997, and $385 million in 1998.68

As governments grapple with the expenses of these new drugs, they may find themselves being sued by persons needing the drugs for their survival. One surprising and welcome decision resulting from these cases came from the Supreme Court of Costa Rica. On September 23, the court ordered the government health care agency, the Caja Costarricense de Seguro Social, to provide AIDS medications to William Garcia, a man living with AIDS.69 Garcia presented prescriptions for AZT, 3TC, and Crixivan;70 the Caja claimed it could not afford the drugs, which could cost up to $900 per month in Costa Rica.71 Garcia’s attorney offered affidavits showing that the three pharmaceutical companies producing drugs in Costa Rica offer discounts of up to fifty percent to the government if it buys the drugs in large quantities.72 These large discounts are possible in Costa Rica because the health care system is nationalized and “the sole legal source of medication in the country.”73

Although the court initially ruled only on behalf of Garcia, two days later the court also ordered the Caja to provide AIDS medications to three other persons living with AIDS.74 It is unclear how these rulings will affect an estimated 300 other persons in Costa Rica also needing these expensive drugs.75 The ruling in favor of William Garcia came too late for him; he died on October 12, 1997, less than a month after his court victory.76 On the Friday night before his death, he told a friend he was very proud of his decision to go public with his HIV-status and to sue the Costa Rican Government. He told his friend, “I have been very brave.”77

Activists in other countries, such as Patrick Levy and Ricardo Schneider of the Israel AIDS Task Force, followed the Costa Rican litigation closely and used it in arguing that Israel had a duty to continue to supply protease inhibitors to persons living with HIV. Two of Israel’s national healthcare programs had stopped paying for the “cocktail” drug combinations after the Israeli Ministry of Finance refused to pay for these treatments.78 The Ministry reversed its decision, however, when it was presented with the Costa Rica example and other evidence that protease-resistant strains of HIV might develop in Israel if the drugs were not supplied.

C. EMPLOYMENT DISCRIMINATION

A landmark decision from the High Court of Bombay (Mumbai) extended the employment rights of HIV-positive persons in India. The case involved a part-time employee recruited for a full-time position, subject to a medical fitness examination. A medical expert certified that the man was medically fit to perform his job, but that he was HIV-positive. The company fired the man from his casual employment and instituted a new policy requiring HIV testing

68. Pear, supra note 66, at A10.
71. Wright, supra note 69.
72. Id.
73. Id.
74. Id. The case for these three persons and the case filed for William Garcia were filed by Marco Castillo, attorney for a Costa Rican gay civil rights group, Triangulo Rosa. Id. See also Christopher Jones, Activists Open Doors of Third Community Center, WASH. BLADE, Mar. 21, 1997, at 10.
75. Id.
77. Wockner, supra note 70.
as part of pre- and post-recruiting policy. The Lawyers' Collective, a public interest law group in India represented by advocate Anand Grover, filed a petition to challenge the lawfulness of the policy and to reinstate the employee with back pay. Justices Tipnis and Trivedi of the Bombay High Court issued their landmark decision on April 3, 1997, finding it impermissible for the company to condemn an HIV-positive person to "certain economic death." The justices ordered the company to reinstate the employee and to pay his lost wages. Legal observers noted that many HIV-positive persons suffering discrimination in India are afraid to litigate their cases "for fear that their HIV status will become public knowledge." The victorious employee obtained a landmark order, the first of its kind in India, allowing him to suppress his identity and to litigate under a pseudonym to protect his privacy.

D. DEGRADING TREATMENT OR PUNISHMENT

The European Convention on Human Rights prohibits "inhuman or degrading treatment or punishment." In a surprising decision, found that the United Kingdom would violate this provision by deporting a cocaine smuggler with AIDS. The case involved a native of St. Kitts arrested in London for attempting to import cocaine. He was convicted and sentenced to prison, where he was first diagnosed as having HIV. Before he was released from prison, British immigration authorities began procedures to deport the man to St. Kitts. His solicitors asked the Secretary of State to allow him to remain in the United Kingdom "on compassionate grounds since his removal to St. Kitts would entail the loss of the medical treatment he was currently receiving, thereby shortening his life expectancy." At the time of the man's request, his CD4 cell count was below ten and he suffered from "recurrent anemia, bacterial chest infections, malaise, skin rashes, weight loss and periods of extreme fatigue." The High Commission for the Eastern Caribbean States informed the man's doctor that the medical facilities in St. Kitts could not provide the medical treatment he would require. The Antigua and Barbados Red Cross, meanwhile, also confirmed that St. Kitts had "no health care providing for drugs treatment of AIDS." In reviewing the man's claim that deportation to St. Kitts would violate the European Convention on Human Rights, the court took note of various AIDS resolutions, such as one from the U.N. Commission on Human Rights that urged "all States to ensure that their laws, policies and practices introduced in the context of AIDS respect human rights standards."

The court also considered the health care the man would receive in the United Kingdom as compared to the relative lack of care in St. Kitts.

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79. MX v. ZY, 1997 A.I.R. 406 (Bom. High Ct.).
82. Id. at 427.
83. Id. at 428. "The infection appears to have occurred some time before his arrival in the United Kingdom."
84. Id.
85. Id. at 429.
86. Id. at 430.
87. Id.
88. Id. at 433. For more information on these and other international human rights instruments, see Mark E. Wojcik, Global Aspects of AIDS, in David W. Webber, AIDS and the Law (3d ed. 1997).
The court concluded that returning the man to St. Kitts under these circumstances would violate his human rights, despite his illegal status in Great Britain:

It is not disputed that his removal will hasten his death. There is a serious danger that the conditions of adversity which await him in St. Kitts will further reduce his already limited life expectancy and subject him to acute mental and physical suffering. Any medical treatment which he might hope to receive there could not contend with the infections which he may possibly contract on account of his lack of shelter and of a proper diet as well as exposure to the health and sanitation problems which beset the population of St. Kitts. While he may have a cousin in St. Kitts no evidence has been adduced to show whether this person would be willing to or capable of attending to the needs of a terminally ill man. There is no evidence of any other form of moral or social support. Nor has it been shown whether the applicant would be guaranteed a bed in either of the hospitals on the island which, according to the government, care for AIDS patients.9

While cautioning other illegal aliens that they should not expect similar rulings, the court ordered Great Britain to stop deportation proceedings and to provide necessary medical care to this man who entered the country as an attempted cocaine trafficker.90 To deport him would be “inhumane treatment” in violation of the European Convention on Human Rights.91

E. Media Law

One AIDS-related development arose in an advertising campaign by Benetton, a company famous for its controversial advertisements. The company developed a series of posters showing parts of the human body tattooed with the words “HIV Positive.”92 A French court found that the posters were offensive to persons living with HIV and abused the freedom of expression.93 The company was ordered to stop the campaign and to pay damages.94

III. International Tobacco Control

The global tobacco pandemic presents an extraordinary public health challenge.95 Currently, tobacco is responsible for 3.5 million deaths per year, with two-thirds of these deaths occurring in industrialized nations.96 Cigarette smoking, the predominant form of tobacco use, is one of the largest causes of preventable death worldwide and is the leading cause of premature death in developed countries.97 Although the vast majority of those killed thus far by the tobacco epidemic were in industrialized nations, with cigarette sales in industrialized states stagnating, the transnational tobacco industry successfully focused in the last several decades on penetrating

90. Id. at 448-49.
91. Id. at 448.
93. Id.
94. Id.
96. RICHARD PETO ET. AL., Global Tobacco Mortality, Paper Presented at the Tenth World Conference on Tobacco or Health, Beijing, China (1997) (on file with author).
97. WORLD HEALTH ORGANIZATION, FACTS AND FIGURES: WORLD NO TOBACCO DAY (1994). Smoking will be responsible for an estimated 60 million premature deaths in developed states between 1950 and 2000, 37.8 million of the victims being between the ages of 35 and 69. See generally, RICHARD PETO ET. AL., MORTALITY FROM SMOKING IN DEVELOPED COUNTRIES 1950-2000 (1994).
and expanding new markets in Africa, Asia, Latin America, Eastern Europe, and the former states of the Soviet Union, where tobacco regulation is weak or non-existent. The WHO predicts that if current trends persist over the next thirty years, seven million inhabitants of developing nations will die annually from smoking related diseases, accounting for seventy percent of tobacco-related deaths worldwide. Hence, within the next thirty years, smoking will not only be the leading cause of premature mortality in developed states, but also the leading cause of premature death globally.

A. World Health Organization

In order to counter the successful efforts of the transnational tobacco industry to penetrate markets worldwide, the WHO launched an international regulatory strategy for global tobacco control in May 1996. As recommended in the official background report on multilateral regulatory alternatives for tobacco control prepared for the WHO's Executive Board and the WHA, the WHA adopted a resolution calling upon the Director-General of the WHO to: (1) initiate the development of a framework convention on tobacco control in accordance with article 19 of the WHO Constitution; and (2) to include as part of this framework convention a strategy to encourage member nations to move progressively toward the adoption of comprehensive tobacco control polices, and also to deal with aspects of tobacco control transcending national boundaries. In 1997 the WHO endeavored to build support for the development of a framework convention on tobacco, holding its first consultative meeting on member states to the proposed convention in June 1997. In addition, the WHO's international regulatory strategy for tobacco control was officially endorsed by a variety of groups and organizations in 1997, including the American Public Health Association and the 10th World Conference on Tobacco or Health. Further, the United Nation's Conference on Trade and Development, the U.N. focal point on tobacco, established and strengthened contacts with governments, nongovernmental organizations, and over thirty U.N. organizations, particularly in the area of information and exchange of communications among concerned organizations.


103. An International Tobacco Control Policy, Resolution Adopted by the Governing Council of the American Public Health Association, Indianapolis, Indiana (Nov. 12, 1997).

104. Resolutions of the Tenth World Conference on Tobacco or Health, art. 11, Beijing, China (Aug. 24-28, 1997).

B. The United States

On June 27, 1997, a pact was reached between state attorney generals and the American tobacco industry in which the tobacco companies agreed to pay $368.5 billion over the next twenty-five years to compensate states for the costs of treating tobacco-related illness, to finance nationwide anti-smoking programs, and to underwrite health care for millions of uninsured children. The proposed settlement, which must be approved by the President and by Congress, also contains diverse measures designed to restrict advertising and marketing of tobacco to children. Numerous public health authorities, including a Congressional advisory panel headed by former Surgeon General, C. Everett Koop and former FDA Commissioner, David A. Kessler, condemned the proposed settlement, the fate of which is highly uncertain. In addition, a number of public health experts and members of Congress criticized the proposed settlement for failing to address the transnational activities of American tobacco conglomerates.

In response to widespread criticism that U.S. trade policy aggressively promotes American tobacco abroad, at the end of 1997 the U.S. Congress passed a law, introduced by Congressman Lloyd Doggett, that prohibits U.S. Government officials from: (1) promoting tobacco or tobacco products overseas, or (2) opposing tobacco-related laws in another country, provided such laws are applied equally to foreign and domestic products.

C. European Union

In 1997 European health ministers agreed on a sweeping initiative to ban most forms of tobacco advertising by 2006. The European Parliament is expected to approve the agreement next year. The comprehensive advertising ban prohibits most forms of direct and indirect tobacco advertising, sponsorship, and promotion in the name of tobacco products or producers. Most forms of advertising will be banned three years after the Parliament approves the legislation. However, to accommodate some member states, the proposed Directive allows delayed implementation of the tobacco sponsorship ban for major worldwide sporting events, such as Formula One and the world snooker championships.

112. Id.
113. Id.
114. Id.
IV. Judicial Decisions by International and Foreign Bodies

A. DECISIONS FROM THE EUROPEAN COURT OF JUSTICE (ECJ or COURT)\textsuperscript{115}

1. \textit{Harry Franzén}\textsuperscript{116}—Swedish Alcohol Monopoly Ruled Legal

On October 23, 1997, the ECJ ruled that Sweden’s state monopoly on the sale of alcohol does not violate article 37 of the EC Treaty because, inter alia, the Alkohollag, the Swedish Law on Alcohol (the Law), is justified on public health grounds.\textsuperscript{117} However, the court held that Sweden’s alcohol licensing system violates articles 30 and 36 of the EC Treaty because: (1) it discriminates against imported products,\textsuperscript{118} and (2) less restrictive alternatives are available to ensure a public health objective.\textsuperscript{119}

The ECJ was asked by a tribunal in the southern Swedish town of Landskrona, where wholesaler Harry Franzén was being prosecuted for selling wine without a license, to rule whether the alcohol monopoly known as Systembolaget Aktiebolag (Systembolaget), a company wholly owned by the Swedish state, contravened the EC Treaty. The Law subjects individuals intentionally or inadvertently selling or producing alcoholic beverages without a license to criminal liability.\textsuperscript{120} Although Franzén had no license to sell alcohol, he argued he could not be convicted under Swedish law because the result would breach EC Treaty provisions on state monopolies and the free movement of goods.\textsuperscript{121}

The court acknowledged that the Law, effective January 1, 1995, properly regulates both production and trade in alcoholic beverages.\textsuperscript{122} The court further recognized that the Law’s objective is aimed particularly at limiting the consumption of beverages having a high alcoholic content in order to reduce the harmful effects their consumption has on human health.\textsuperscript{123}

The Law provides for two types of licenses: production licenses and wholesale licenses.\textsuperscript{124}

\begin{itemize}
  \item \textsuperscript{115} The European Court of Justice (ECJ) is the main judicial institution of the European Community and applies Community law to the cases before it. The ECJ is comprised of fifteen Judges and nine Advocates General. The role of the Advocate General is to present a reasoned and independent opinion of the issues of law in the case.
  \item \textsuperscript{116} Case 189/95, Franzén, CEC (CCH) (1997) [hereinafter Franzén].
  \item \textsuperscript{117} Id. ¶¶ 39, 52. Article 37 of the EC Treaty provides in relevant part: “Member States shall progressively adjust any State monopolies of a commercial character so as to ensure... no discrimination regarding the conditions under which goods are procured and marketed exists between nationals of Member States.” Treaty Establishing the European Economic Community, Mar. 25, 1957, 298 U.N.T.S. 11 [hereinafter EC Treaty].
  \item \textsuperscript{118} Franzén, supra note 116, ¶ 71. Article 30 of the EC Treaty provides: “Quantitative restrictions on imports and all measures having equivalent effect shall, without prejudice to the following provisions, be prohibited between Member States.” EC Treaty, supra note 117, art. 30. Article 36 of the EC Treaty provides in relevant part:
  \begin{quote}
    The provisions of Arts. 30 to 34 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans. . . Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.
  \end{quote}
  \item \textsuperscript{119} Id. art. 36.
  \item \textsuperscript{120} Id. ¶ 19.
  \item \textsuperscript{121} Id. ¶ 32.
  \item \textsuperscript{122} Id. ¶¶ 5, 6, & 33.
  \item \textsuperscript{123} Id. ¶ 3.
  \item \textsuperscript{124} Id. ¶¶ 5, 6, & 70. Under the Law, licenses are issued for a substantial fee by the Alkoholinspektions (Alcohol Inspectorate). Submission of a license application is subject to a fixed charge of SKR 25,000. Additionally, the State requires an annual fee of between SKR 10,000 and 323,750, depending on the type of beverages and quantities produced or marketed. Id.
\end{itemize}
Importation of all wine, strong beer, and spirit drink into Sweden is subject to the possession of a production or wholesale license.\textsuperscript{125} Also, pursuant to the Law, Systembolaget has the exclusive right to sell all wine, strong beer, and spirits in Sweden.\textsuperscript{126} The court observed that the purpose of article 37 of the EC Treaty is to permit Member States to maintain certain commercial monopolies in order to pursue public interest aims with minimal impact on the free movement of goods.\textsuperscript{127} The court additionally noted that “in aiming to protect public health against the harm caused by alcohol, a domestic monopoly on the retail of alcoholic beverages, such as that conferred on Systembolaget, pursues a public interest aim,”\textsuperscript{128} the court found that because “the criteria and selection methods used by Systembolaget do not appear to be either discriminatory or apt to put imported products at a disadvantage . . . .”\textsuperscript{129} It appears that a retail monopoly such as that in question in the main proceedings meets the conditions for being compatible with Article 37 of the Treaty . . . .\textsuperscript{130}

Notwithstanding the foregoing, the court rejected the Swedish Government’s contention that its alcohol licensing scheme is reasonably tailored to achieve public health objectives. The court stated that:

> The licensing system constitutes an obstacle to the importation of alcoholic beverages from other Member States [in] that it imposes additional costs on such beverages, such as intermediary costs, payment of charges and fees for the grant of a license, and costs arising from the obligation to maintain storage capacity in Sweden.\textsuperscript{131}

In this regard, the court determined as follows:

> Although the protection of human health against the harmful effects of alcohol on which the Swedish government relies, is indisputably one of the grounds which may justify derogation from Article 30 of the Treaty, the Swedish Government has not established the licensing system set up by the Law on Alcohol, in particular as regards the condition relating to storage capacity and the high fees and charges which license-holders are required to pay, was proportionate to the public health aim pursued or that this aim could not have been attained by measures less restrictive of intra-Community trade.\textsuperscript{132}

The court thus concluded that the licensing system established by the Law was contrary to article 30 of the EC Treaty.\textsuperscript{133} Interestingly, the court’s decision to uphold Sweden’s alcohol monopoly was contrary to the advisory opinion of the court’s Advocate General,\textsuperscript{134} who proposed that the Swedish monopoly system was prohibited by articles 30 and 37 because Systembolaget controlled which products would be imported into Sweden from other Member States. However, the ECJ agreed with that portion of the Advocate General’s opinion that Sweden’s licensing system could not be justified on grounds of protection of health and life of humans, as provided in article 36, because such protection could be ensured by measures less restrictive of the free movement of goods.

\textsuperscript{125} Id.
\textsuperscript{126} Id. \textsuperscript{15, 16.}
\textsuperscript{127} Id. \textsuperscript{39.}
\textsuperscript{128} Id. \textsuperscript{41.}
\textsuperscript{129} Id. \textsuperscript{52.}
\textsuperscript{130} Id. \textsuperscript{66.}
\textsuperscript{131} Id. \textsuperscript{71.}
\textsuperscript{132} Id. \textsuperscript{76.}
\textsuperscript{133} Id. \textsuperscript{75.}
\textsuperscript{134} Advocate General M.B. Elmer delivered his opinion at the sitting of the full court on March 4, 1997.
2. Maria Antonella Garofalo and Others v. Ministero della Sanità—Doctors’ Rights to Practice General Medicine Recognized

On October 16, 1997, the ECJ ruled that an E.U. member state must recognize the right of a doctor to practice medicine in its territory—even if that doctor does not possess a general medical practitioner’s diploma—provided that the doctor acquired the right to practice general medicine under the Member State’s national security scheme prior to January 1, 1995. The ruling was an interpretation of Council Directive 93/16/EEC, April 15, 1993, on the mutual recognition of diplomas, certificates, and other evidence of formal medical qualification. Council Directive 93/16/EEC provides in relevant part:

1. From 1 January 1995, and subject to the acquired rights it has recognized, each Member State shall make the exercise of general medical practice under its national social security scheme conditional on possession of a diploma, certificate or other evidence of formal qualification.
2. Each Member State shall specify the acquired rights that it recognizes. However, it shall recognize the right to exercise the activities of general medical practitioners under its national social security scheme without the diploma, certificate or other evidence of formal qualification . . . as having been acquired by all those doctors who on 31 December 1994 possess such a right . . . and who are established on its territory on that date . . . .

This case originated as a petition by eleven doctors to the Italian Ministry of Health. The petitioners sought to exclude from the list of practitioners under contract with the Palermo Local Health Unit the names of doctors not having diplomas in general practice. Italian law implementing Council Directive 93/16/EEC recognized the rights of all doctors authorized to practice medicine before January 1, 1995, as general practitioners in the public health system. The petitioners claimed Council Directive 93/16/EEC requires doctors to have entered into a service relationship with a member state’s national health system prior to January 1, 1995, in order to practice medicine in that state without a general medical practitioner’s diploma.

The Italian Ministry of Health sought the opinion of the Italian Council of State (Consiglio di Stato). The Council of State, in turn, referred two questions to the court for review: (1) whether Council Directive 93/16/EEC requires a doctor to have entered into an actual service relationship with a Member State’s national health system prior to January 1, 1995, in order to practice medicine in that state without a general medical practitioner’s diploma; and (2) if

136. A preliminary issue was raised as to whether the Italian Council of State was a “court or tribunal” for purposes of petitioning the ECJ. The court recognized the Council of State as such, noting its impartial, adversarial, and independent nature.
138. The Italian Ministry of Health plans, coordinates, and implements actions for the prevention and control of communicable diseases. It is also the WHO counterpart for the Expanded Programme on Immunization and for the surveillance of infectious diseases and Tuberculosis in Italy.
139. Council Directives are addressed to Member States and are binding as to the result, but the Members may choose to modify the form and method of implementing the Directives to adapt to individual national legal systems.
141. Id. ¶ 13.
142. Id. ¶ 14.
so, whether a Member State has the discretion to extend the right to practice medicine to doctors qualified to practice as of January 1, 1995, but who did not enter into a service relationship with the Member State as of that date.\textsuperscript{146}

The ECJ ruled as to the first question that each Member State has discretion to determine the acquired rights of doctors subject to only one condition, namely that each Member State must recognize the acquired rights of those doctors not holding a general medical practitioner's diploma but who, before January 1, 1995, were recognized in that Member State as having a diploma, certificate, or other evidence of formal qualification issued to them in another Member State and who, also before that date, obtained the right to exercise the activities of general medical practitioner under the national social security scheme.\textsuperscript{147} As to the second question, the court determined that the fact that doctors "have not actually entered into a service relationship with the national social security scheme does not prevent doctors who have acquired the right to enter into such a relationship from subsequently establishing one."\textsuperscript{148}

3. *Merck & Co., Inc. (Merck) and Others v. Primecrown Ltd (Primecrown) and Others and Beecham Group plc v. Europharm of Worthing Ltd. (Europharm) Ruling*\textsuperscript{149}—Pharmaceutical Companies May Not Prevent Parallel Importation

On December 5, 1996, the court ruled that parallel importation of patented pharmaceutical products is permissible among Member States.\textsuperscript{150} Merck claimed Primecrown infringed its patents for several drugs marketed in the United Kingdom by carrying out parallel imports of the drugs into the United Kingdom from Spain and Portugal, where patents for the drugs are not recognized, and where generic versions of the drug are available at substantially less cost.\textsuperscript{151} Beecham made a similar complaint against Europharm.\textsuperscript{152}

The court held that articles 30 and 36 of the EC Treaty prohibited holders of a patent for pharmaceutical products from preventing third parties from importing those products from another Member State when the patent holder put the product on the market in that State after its accession to the Community, but before the product could be protected by a patent in that State.\textsuperscript{153} The court reasoned that if a patentee is permitted "[to] prohibit the importation of protected products marketed in another Member State by him or with his consent, he would be able to partition national markets and thereby restrict trade between Member States."\textsuperscript{154}

The ECJ recognized an exception to the foregoing ruling that:

where a patentee is legally bound under either national law or Community law to market his products in a Member State, he cannot be deemed . . . to have given his consent to the marketing of the products concerned . . . [and] is therefore entitled to oppose importation and marketing of those products in the State where they are protected.\textsuperscript{155}

\textsuperscript{144} Id. \textsuperscript{145} Garofalo, supra note 135, \textsuperscript{146} Id. \textsuperscript{147} Cases 267/95-268/95, Merck & Co., Inc. v. Primecrown Ltd.; Beecham Group PLC v. Europharm of Worthing Ltd., CEC (CCH) (1997). \textsuperscript{148} Id. \textsuperscript{149} Id. \textsuperscript{150} Id. \textsuperscript{151} Id. \textsuperscript{152} Id. \textsuperscript{153} Id. \textsuperscript{154} Id. \textsuperscript{155} Id.
However, the court did not recognize such an exception when patentees might be ethically obligated to market their products. 154

Notwithstanding the court's decision in Merck, the debate between pharmaceutical manufacturers and importers continues. The manufacturers argue parallel importation threatens the ability to conduct continuing medical research necessary to develop new drugs. The importers assert that the availability of a cheaper product benefits poor persons and enables a larger segment of the public to enjoy the benefits of the latest pharmaceutical technology.

Health officials and public health authorities took issue with the court's ruling in Merck, stating that the court's decision overlooked the importance of ethical obligations to ensure patient access to medicines in Member States with lower standards of patent protection. Litigation over this topic is destined to erupt in the near future.

B. ADVISORY OPINIONS OF THE ADVOCATES GENERAL OF THE ECJ

1. The National Farmers' Union and Others v. The Ministry of Agriculture, Fisheries and Food, the Commissioners for Customs and Excise155—Opinion Restrictions on Beef Exportation from the United Kingdom

A long-awaited decision is expected in 1998 in connection with the U.K.'s application for the annulment of Decision 96/239156 (the Decision), which established a worldwide ban on beef exportation from the United Kingdom for human consumption. However, if the recent advisory opinion of the ECJ's Advocate General on September 30, 1997, is any indication, the worldwide ban on British beef is likely to remain in effect.

On September 30, 1997, Advocate General G. Tesauro delivered an opinion stating that the Decision, prohibiting the United Kingdom from exporting live cattle, meat, and other products obtained from bovine animals to other Member States or to non-Member countries, is valid. The opinion was rendered in connection with two cases currently pending before the court concerning the containment of bovine spongiform encephalopathy (BSE) or "mad cow disease."

The first case involves a reference from a preliminary ruling from the U.K.'s High Court of Justice, Queen's Bench Division, as a result of proceedings commenced by the British National Farmers' Union (the Union). The Union challenged the measure adopted by British authorities in response to the Directive on three grounds: (1) the Commission was without authority to issue the Decision because its primary purpose is to reassure consumers and not to combat a public health hazard; (2) the Commission lacked power to ban exports to non-Member countries; and (3) less restrictive means are available to accomplish the desired goal.

154. Id. ¶ 53.
   • live bovine animals, their semen, and embryos,
   • meat of bovine animals slaughtered in the United Kingdom,
   • products obtained from bovine animals slaughtered in the United Kingdom which are liable to enter the animal feed or human food chain, and materials destined for use in medicinal products, cosmetics, or pharmaceutical products; and
   • mammalian derived meat and bone-meal.

The decision was modified by Commission Decision 96/362 of June 11, 1996, adding several more restrictions to article 1.
The second case is a direct action by the United Kingdom against the Commission seeking an annulment of the Decision on the same grounds as the Union, and on the additional ground that the Decision unfairly discriminates against the United Kingdom. On July 12, 1996, the ECJ denied the U.K.'s application for interim suspension of the Decision.

The Advocate General opined that Council Directives 90/425\textsuperscript{157} and 89/662\textsuperscript{158} (on veterinary checks and trade in live animals) confer broad latitude upon the Commission to adopt measures necessary to combat serious hazards to the health of both humans and animals. According to the Advocate General, the existence of health hazards justifies appropriate restrictions on the free movement of goods, including exportation to non-Member countries. Restrictions with respect to non-Member countries are necessary to ensure the ban is not thwarted by transit through non-Member countries.

The Advocate General's opinion, though influential, is not binding on the ECJ. The ECJ is expected to hand down a formal judgment in 1998. The Advocate General's opinion followed the release of scientific evidence that comes close to providing a link between BSE and the new variant of Creutzfeldt-Jakob disease in humans.

2. Lisa Jacqueline Grant v. South-West Trains Ltd\textsuperscript{59}—Equal Benefits for Same Sex Couples

On September 30, 1997, Advocate General M. B. Elmer recommended the court hold that an employer's denial of travel concessions to the same sex partner of an employee breached European law guaranteeing equal pay. In this case, the employee commenced a proceeding in an industrial tribunal after being refused concessions that were made available to her male predecessor for his unmarried female partner.

On February 17, 1998, the ECJ rejected the Advocate General's recommendation and held that:

an employer is not required by Community law to treat the situation of a person who has a stable relationship with a partner of the same sex as equivalent to that of a person who is married to or has a stable relationship outside marriage with a partner of the opposite sex.\textsuperscript{160}

The ECJ further held that such treatment does not constitute discrimination prohibited by article 119 of the EC Treaty.


\textsuperscript{160} Id. ¶ 35.