COMPARATIVE HEALTH SYSTEMS

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PREFACE

Health is the state of well being cherished by people in different parts of the world. It might have been viewed narrowly as mere absence of diseases but has now become increasingly clear that health encompass many other aspects. The definition introduced by the World Health Organization as the state of complete physical, mental and social well-being is now often referred to by health professionals all over the world. For the Thai populace health is the state of being happy. This could be taken to encompass other dimensions beyond the WHO definition. Taking health beyond diseases and medicines has a far reaching implications on the efforts to improve health. First of all it leads us to consider many other sub-systems besides what we have been accustomed to, namely the focus on health services delivery system. We have been used to equating health to health services. We expect to have better health by expanding and upgrading our health services system and we know now that it does not work that way. Good health requires many other inputs beyond health services delivery system. A system that spends more per capita does not necessarily mean better health for her population. Some that may seem to use less resources may even be able to make her people comparatively healthier.

Whether we like it or not, our health services delivery system is the big spender of our available and limited resources. It is important to learn from different countries in order to avoid mistakes and embark on a more cost-effective path. This is not implying that we can take whatever works in other countries and apply it in Thailand. We will have to look at each lesson critically and the only thing that may come out of a study on other countries' health services system is to find out what to be avoided. This may be valuable enough for the real knowledge is to know what we do not know and keep on searching for more.

As much as health services have been at the heart of most health development efforts, health behaviour has become more of an emphasis due to the changing illnesses pattern. The emergence of the diseases of affluence brought about by unhealthy behaviour rather than germs and microbes or due to deficiency of some kind. Many approaches have been introduced to bring about a society in which each member will exert his or her best effort to avoid unhealthy behaviour and adopt healthy life style so that they do not have to depend too much on the health services system. It is a well accepted fact that keeping oneself healthy is far less costly than finding a cure for illness. In this respect many countries make use of legislative measures to help bringing a healthier population and save expense on avoidable illness. Legislation in health serve many other purposes than merely bringing healthy behaviour. It helps to set rules and regulations that are needed for managing our health system rather than leave it to individual discretion. Legislation becomes another crucial tool for effective public health development. It is definitely important to know where it works and where its limitation are.

Professor Milton Roemer and his wife Ruth Roemer are two well recognized public health experts among the international public health community. The Health Systems Research Institute of Thailand has been fortunate to have received their continuous support, technical and spiritual. The articles contained in this publication is the lectures delivered in Bangkok in December 1994 by the two distinguished scholars. With the kind support and permission from both Professor Milton and his wife the Health Systems Research Institute is pleased to share with our colleagues in public health this valuable document. We are certain that the knowledge of health systems of many countries over the world and the critical look at health legislation will benefit policy makers as well as many other who work to bring better health for our people in different parts of this planet earth.

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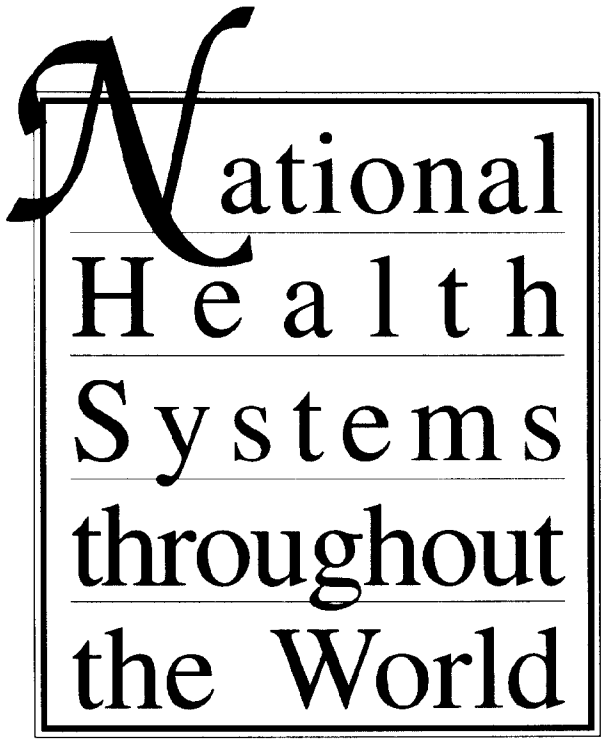
National
Health
Systems
throughout
the World

National Health Systems throughout the World

Milton I. Roemer, M.D.

Every country has a national health system, which reflects its history, its economic development, and its dominant political ideology. Because of these diverse circumstances, there are several **types** of health systems, the highlights of which this lecture will examine in both industrialized and developing countries.

Composition of Health Systems

Any national health system in a country at any stage of economic development may be analyzed according to five principal component parts: (1) resources, (2) organization, (3) management, (4) economic support, and (5) delivery of services.

The **resources** of health system consist of human resources (personnel), facilities (hospitals, health centers, etc.), commodities (drugs, equipment, supplies, etc.), and knowledge. Each of these may be produced or acquired in different ways and to various extents.

Health programs may be **organized** under diverse sponsorships. In virtually all health systems there is one principal authority of government (at several levels), other governmental agencies with health functions, voluntary health agencies, enterprise, and a private health care market. The proportions among these five major forms of organization very greatly in different countries.

The **management** of health systems entails several processes: health planning, administration, regulation, and legislation. The methods of carrying out each managerial process tend to very mainly with a country's dominant political ideology.

The **economic support** of the various parts of a health system usually depends on one or more financial mechanisms. These may be governmental tax revenues (at different levels), social insurance (statutory), voluntary insurance, charity, and personal households. In economically less developed countries, foreign aid may pay a role.

Finally, the four component parts of a health system lead to the crucial fifth part: **the delivery of health services.** These may be analyzed according to: primary health care (preventive and curative), secondary care, and tertiary care. In most health systems, furthermore, there are special modes of delivery of health services to certain populations and for certain disorders.

The combined characteristics of these five component parts permit the designation of each national health system according to certain **types.** While history, economic level, and political ideology determine these types, their attributes may be classified according to the degree of **market intervention by government.** The organization of every health system, it was noted, includes a private health care market. The proportions and characteristics of this market depend on the extent of intervention in the market process--supply, demand, competition, and price--by government.

By such analysis, the national health systems in the world's approximately 165 sovereign countries may be scaled into four main types. Going from the least

market intervention to the most, these **health system types** are: (1) entrepreneurial, (2) welfare-oriented, (3) comprehensive, and (4) socialist. This scaling may be applied, furthermore, to countries at high, middle and low levels of economic development.

Entrepreneurial Health Systems

An entrepreneurial health system in a highly industrialized country is best illustrated by that in the **United States.** Indeed, in 1990 there is probably no other country that belongs in this category, although Australia may have fitted into it 20 years before. Health resources of all sorts are relatively abundant in the United States. Physicians are plentiful (about 220 per 100,000 population), and for each physician there are 15 or 20 associated health personnel--nurses, pharmacists, dentists, technicians, physical therapists, administrators, etc. Within medicine, there is a high degree of specialization, so that only about 15 percent of doctors are generalists. About two-thirds of hospital beds are in non-governmental institutions, and 10 percent of the total are operated for profit.

In the 50 U.S. states and 3,100 counties, there are local public health authorities engaged in environmental sanitation, communicable disease control, preventive service for mothers and infants, and certain other functions. The largest channel for providing health care, however, is the **private market** of thousands of independent medical practitioners, pharmacies, laboratories, and so on.

Economic support for the U.S. health system comes predominantly from private sources--for about 60 percent of the vast expenditures in 1987 of $2200 per capita. Of these health funds spent in the private sector, about half are derived from voluntary insurance, sold by hundreds of commercial or non-profit companies. The public sector of 40 percent is derived partly from social insurance (social security legislation) and partly from federal, state, and local tax revenues. As a share of gross national product (GNP), U.S. health expenditures consume 14 percent--the largest percentage of any country. Still, some 15 percent of the population are without adequate economic protection for health care costs.

The largest governmentally sponsored programs of medical care are "Medicare" for the elderly and totally disabled and "Medicaid" for the poor; under both of these programs doctors and other practitioners are paid by the fee-for-service method, administrated with much elasticity.

In spite of these highly entrepreneurial characteristics, the U.S. health system has been undergoing rapid changes. The long-term trend of economic support has been toward increased financing through collectivized mechanisms. The delivery of health service has also been subjected to various patterns of organization, so that teams of health personnel working in clinics and community health centers, as well as hospitals, are becoming increasingly common. Various legislative strategies are being actively debated to achieve universal population coverage for health services in the United States.

An entrepreneurial type of health systems in a middle-income developing country is that found in the ***Philippines Republic***. Despite the general poverty of the national population (GNP per capita in 1986 was $590), of all health-related expenditures in 1980, 75 percent came from private sources. There are 76 provinces with locally elected governors, but the central Ministry of Health, like other ministries, has its own representatives in each province. The Provincial Health Officers and, below them District Health Officers, theoretically supervise

MoH hospitals, but most of their work concerns conventional preventive public health services.

Major responsibility for financing medical care is vested in the Philippine Medical Care Commission, which is independent of the MoH. It administers a social insurance program, covering in 1980 about 28 percent of the population. Unlike policies in welfare-oriented health systems, these constitute **higher** paid in both pubic and private employment.

The output of physicians and nurses in the Philippines, is quite high, but more than half of the new graduates leave the country. In 1984, therefore, there were in the country only 14.3 physician per 100,00 population; more than half of these were settled in and around the national capital, with 22 percent of the people. There are 23 medical schools training physicians but only three are governmental; the other 20 are small private schools run by private doctors as profit-making enterprises.

Of all Philippines physicians, 59 percent in 1981 were engaged entirely in private practice. Nearly all of the 41 percent in government employment also did private work part-time. Among dentists, 84 percent were wholly private. Hospitals are relatively abundant, with 1.8 beds per 1,000 people in 1981. Of the 1600 facilities, however, 74 percent were private, with 55 percent of the total beds. Only affluent patients and some covered by the social insurance (who can afford the copayments) can use the private hospitals. Even the public hospitals, moreover, make charges for drugs and diagnostic procedures, except to totally indigent patients.

A low-income developing country of Africa, with entrepreneurial health system policies, in ***Kenya***. Its GNP per capita in 1986 was only $324, but its ruling Kenya African National Union (KANU) partly has been committed to a policy of free private enterprise.

The seven provinces and, within these, 41 districts are each headed by a medical officer, who is appointed by the central government. Below the level of the district, planning in 1972 called for 254 "rural health units" (staffed entirely by auxiliary personnel), but by 1984 only 120 of these were in operation. The Kenyan government estimated that primary health care had been brought within reach of only about 30 percent of the rural population.

Loosely linked to the MoH is a National Hospital Insurance Fund, that insures about 12 percent of the population. As in the Philippines, it is the **higher** paid employed or self-employed persons who must pay premiums, and there is no contribution from employers.

There are many non-governmental health agencies in Kenya, the most important of which are **religious missions** from Europe and America. In 1981 these missions controlled about 25 percent of the hospitals beds, while 46 percent were in government facilities and 29 percent were purely private. The mission hospitals got 24 percent of their operating costs from government grants, but 60 percent came from private patient fees.

Kenya's physicians numbered 10.5 per 100,000 population in 1981; of these 53 percent were in the national capital, Nairobi, with 6 percent of the population, and 94 percent of the people had to depend on the remaining 47 percent of doctors. In 1982, at least 70 percent of all Kenya physicians were entirely in private practice, and the 30 percent in government also practiced privately part-time.

The outcome of all these entrepreneurial policies in Kenya is a life expectancy at birth, as of 1986, of only 57 years, compared with 61 years in other countries of comparable income level.

Welfare-Oriented Health Systems

Many heath systems of Western Europe are welfare-oriented. as are the systems of Canada, Japan, and Australia. The heath system of the Federal Republic of ***Germany*** has mobilized economic support, to make heath service available to practically all its people, for the longest period of time, so that it may well serve to illustrate this system type in an industrialized country.

After many years of voluntary health care insurance organizations among low-income workers, Germany enacted mandatory legislation for such insurance in 1883. The kinds of workers covered and the scope of health services provided were gradually broadened. The insurance is now carried by several hundred relatively small "sickness funds," that are regulated by government as to their costs, benefits, and methods of administration. The principal governmental responsibility for this social insurance is the Ministry of Labor and Social Affairs in the central government, and also in each of the nine "lander" or provinces.

The medical staffs of the proprietary hospitals are open to any qualified local physician, but in government and voluntary non-profit facilities there are "closed" medical staffs of salaries physicians.

The payment of non-salaried physicians for their services in Germany is a complex process, resulting from long historical developments. The sickness funds enter into contracts with associations of physicians, which are paid periodic per capital amounts, according to each fund's membership. Then the medical association reviews and pays the fees charged by physicians. If in a quarter year, the fees charged exceed the money available, less than the full amount of each fee may be paid.

The German pharmaceutical industry, largely as an offshoot of the dye industry, is especially robust. Hundreds of new or slightly modified drugs are produced each year and dispensed by private pharmacies. The tragedy of " thalidomide"--causing severely defective babies, when taken by the pregnant woman--occurred in West Germany in the 1960s, and led to more regulatory drug legislation in Germany and many other countries. On the other hand, one must recognize that the principle of chemotherapy originated in 1912 in Germany (Paul Ehrlich and "Salvarsan"), and the sulfonamides were first synthesized by German chemists.

In contrast to the United States, the entire health system in Germany required expenditure of 8.2 percent of the gross domestic product (GAP), as of 1987. Of this amount, 77 percent was derived from programs under government and only 23 percent cam from the private sector. Most of the public sector funds came from the social insurance, administered by the sickness funds. In spite of Germany's period of brutal fascism and the experience of defeat in two world wars (1914 - 18 and 1939-45), the German health system has continued to serve well the great majority of the population to the present time.

The welfare-oriented health systems of ***Australia*** and Canada are more fully under the umbrella of government, without use of intermediary insurance agencies. In Australia, there was no history of worker's insurance funds, so that health insurance is managed by a single national government authority. In ***Canada*** the key

administrative bodies are the provincial governments, with partial funding by grants from federal government. In both countries, funds come mainly from general revenues, rather than earmarked employer/employee contributions. Most of the health services are still provided by private doctors, who are paid by negotiated fee, and hospitals are paid by perspective global budgets. In Australia, most hospitals are sponsored by local governments, and in Canada the majority are controlled by churches or other voluntary bodies.

Among developing countries, there are many with welfare-oriented health systems. At the middle-income level, Thailand would fit; many are in Latin America, were Social Security programs have been widely organized. Peru, with a national population of about 20,000,000 and a GNP per capita of $1153 in 1986, may be taken as illustrative.

Since 1960, **Peru** has become rapidly urbanized, to 67 percent of its residents in 1984; this has meant a reduced dependence on traditional healer or " curanderos. "

The Peruvian Ministry of Health developed by 1985 a national network of 612 health centers and 1,700 health posts. Scores of charitable "beneficencia" hospitals were taken over by the MoH, so that 55.2 percent of the hospital beds (1.56 per 1,000 people) belong to the MoH. Along with the beds of other public agencies, government controls more than 80 percent of the total beds supply.

The country is divided into 17 health regions, and these into 57 health areas. The medical officers in charge of each jurisdiction are centrally appointed and are supposed to supervise all MoH services within their borders. The ambulatory care facilities give general primary care, including treatment of common ailments, although preventive maternal and child health services are emphasized.

Like nearly all Latin American countries, Peru has a Social Security program providing medical care to 18.6 percent of the population. Unlike the Philippines or Germany, this social insurance program provides care in its own polyclinics and hospitals, staffed by salaried medical and allied personnel.

Physicians in Peru numbered 17,500 in 1985 or 91.5 per 100,000 population. Some 70 percent of these work in government agencies, but practice privately part-time, and 30 percent are wholly in private practice. There are seven medical schools, of which only one is private. Maldistribution of doctors is extreme, with 70 percent in 1985 located in Lima, where 16 percent of the population resides.

The welfare-oriented policies in the Peruvian health system are probably best reflected by overall health expenditures. In 1984, 66.5 percent of these came from government and 33.5 percent from private sources.

India is every low income country with a welfare-oriented health system, having characteristics quite different from those in Peru. This huge country of more than 800,000,000 people had a GNP per capital of only $290 in 1986. Since it won independence from British rule in 1947, India has developed a national health system with thousands of publicly financed and publicly operated health facilities

Continued from colonial times, India has 31 states and union territories, which carry major health service responsibilities. In each of these jurisdictions there is a Ministry of Health and Family Welfare, responsible for personal and environmental health services. Within the states and territories there are 408

districts, each containing an average of 2,000,000 people and headed by a Medical Officer of Health.

In every district of India there is a public hospital and several "primary health centers"--8,000 of them in 1988. These are ideally staffed by one or two physicians plus allied health staff, but there are many medical vacancies. Around the primary health centers are more than 100,000 subcenters, staffed entirely by briefly trained auxiliary personnel. Even peripheral to the subcenters, there are "community health volunteers,": trained for a few weeks to encourage sound health practices in the villages.

Although India is only slightly industrialized, it has a Social Security program covering employees of private firms and their dependents. In 1987, this was 28,000,000 people or 3.5 percent of the population, who were entitled to medical care through specially organized facilities or regular MoHFW resources under contract; in large cities insured persons may be served by private general practitioners, paid by capitation.

Of all modern physicians in India, 41 percent work for government health agencies, 12 percent for non-governmental but organized health programs, and 47 percent are entirely in private practice. Altogether in 1987 there were about 325,000 modern physicians or 41 per 100,000 population. A much greater number of **traditional** doctors, however, were almost entirely in private practice throughout India; this included some 400,000 Ayurvedic practitioners and 150,000 homeopathic doctors. Since the late 1970s, the government of India has stressed the training of multi-purpose auxiliary health personnel.

In the early 1980s, total Indian health expenditures amounted to only 3 percent of the GNP. Of this, a study back in 1970 found 84 percent to come from private sources, and it is likely that the private sector still accounts for two-thirds of the total (as in neighboring Pakistan).

For the fight against certain diseases, the national and state MoHFWs in India conduct special campaigns--previously run vertically from the top but now decentralized. Life expectancy at birth in India has increased from 44 years in 1960 to 59 years in 1987. Even the crude birth rate, contributing to India's hugh population, has declined between these years from 42 to 32 per 1,000 population.

Comprehensive Health Systems

In several countries, national health systems that were welfare-oriented for some years underwent further political development after World War II, and became comprehensive in type. This has meant that 100 percent of the national population has become entitled to complete health service, and the financial support has shifted almost entirely to general tax revenues. Larger proportions of doctors and other health personnel have come to work in organized frameworks on salary. Almost all health facilities have come under the direct control of government.

Great Britain adopted this comprehensive type of health system soon after World War II, pursuant to planning done during the war. The Scandinavian countries did likewise in the 1950s. Italy enacted "national health services" legislation in the 1970s, and somewhat less sweepingly this was done in Greece and Spain.

In Great Britain, limited insurance for general practitioner services and drugs has covered low-wage manual workers since 1911. With the 1946 legislation, this program was expanded to provide all ambulatory treatment services, and to become the first pillar of the NHS. Because of the war, British hospitals had been organized into regional groups, and these, headed by Regional Hospital Boards, became the second organizational pillar. Local public health authorities, along with visiting nurse and ambulance services, became the third pillar. Finally, a special administrative channel was reserved for teaching hospitals, affiliated with medical schools.

In 1974, the British NHS was reorganized to achieve greater administrative integration. After a preliminary period, all health services were placed under unified management in some 200 health districts. At this level, a well-trained specialists in management was supported by a specialist in community medicine (including epidemiology). The Regional Hospital Boards were converted into Regional Health Boards, and became the conduits for money from the central government. At all levels there were "community health councils," made up of leading consumers and providers, for advisory purposes.

Popular opinion in Great Britain has been highly favorable toward the NHS, although there are complaints about long waiting lists for elective (non-emergency) surgery in hospitals. The explanation of these delays is fundamentally that the resources provided by government for this large comprehensive health system are inadequate. In 1987, when the United States was spending 11.2 percent of gross domestic product on health and Sweden was spending 9.0 percent, Great Britain was spending only 6.1 percent of its smaller overall GDP. Of this expenditure, 87 percent came from government and 13 percent from the private sector.

Among developing countries, there are very few that have achieved comprehensive health systems, which has entitled 100 percent of their populations to complete health services. One of middle-income level of ***Costa Rica***, which in 1948 abolished its military establishment and then gradually extended its Social Security coverage for medical care to everyone. Another country, of very low income level (GNP per capita of $400 in 1986), is Sri Lanka, a tropical island south of India.

In 1986, ***Sri Lanka*** had 16,100,000 people, with the same sort of vast disparities in family wealth as most developing countries; the richest 20 percent of households earned 50 percent of the total income, while the poorest 20 percent earned only 6 percent of the income. Yet the government health services made available to all these people are remarkably complete. For governance the country is divided into 25 districts, each headed by a centrally appointed medical officer. Within each district, there are about 10 divisions, averaging 60,000 people, with a medically-staffed "divisional health center." Even more peripherally there are " subdivisional health centers," staffed wholly by auxiliary personnel, including " assistant medical practitioners" with two years of training in primary health care.

The supply of modern physicians in Sri Lanka is quite modest--13.4 per 100,000 in 1981--because many are Tamils, who faced ethnic discrimination and therefore migrated. The stock of Ayurvedic practitioners is three times as great, and these are virtually all in private practice. Government health manpower needs in Sri Lanka are met largely by auxiliary personnel.

Nutrition policy in Sri Lanka has been a major factor contributing to health. Soon after independence in 1947, a weekly ration of rice of provided free to every

family; even when this was altered in the 1970s, it was continued for very poor families, along with free lunches for all school children. General education has also had high priority in Sri Lanka. Nearly all girls as well as boys go to primary school, and in 1985 adult literacy was 91 percent for men and 83 percent for women.

The Sri Lankan Ministry of Health in the mid-1980s estimated that 93 percent of the population were readily accessible to health services.

Because of its closeness to India and its cultural similarities, Sri Lanka's health record has often been compared to India's. In 1985, when India's infant mortality rate was 105 per 1,000 live births, the rate in Sri Lanka was 36 per 1,000. In 1987, life expectancy at birth in India was 59 years, and in Sri Lanka was 71 years.

Socialist Health Systems

In countries that have had a revolution install a socialist economic order, the health systems have become socialist in structure and function. This has meant that practically all physical and human resources have been taken over by government, and health services have theoretically become available to everyone. In 1989 and 1990, certain basic changes were brought about in these socialist economic, but conditions may be described as they were shortly before this.

After the Russian Revolution of 1917, the ***Soviet Union*** became the first country with a socialist health system. The changes into a socialist system did not occur overnight, but were essentially completed by 1937. By then, virtually all doctors, nurses, and other health personnel had become public employees, and all hospitals and other health facilities were taken over by government. The private pharmaceutical industry was nationalized; medical schools were removed from the universities and put under the Ministry of Health as academic institutes. Health science research was carried out in other special institutes, also under the Ministry of Health.

All services were free of charge to every Soviet resident, except drugs which had to be purchased in government pharmacies. To provide accessible ambulatory care, hundreds of polyclinics--staffed by generalists, pediatricians, gynecologists, and others were established in the cities, and hundreds of smaller health centers were constructed in rural areas. The Soviet "feldsher"--trained since the nineteenth century--was one to the world's earliest forms of medical assistant, serving mostly in rural areas where physicians were too few.

The Soviet heath system has turned out enormous numbers of physicians, so that the 1986 there were 430 per 100,000 population. Nurses, midwives, and feldshers were also plentiful, but technicians were relatively less numerous than in other industrialized countries. Certain exceptionally well equipped and staffed hospitals and polyclinics, however, were established to serve high Communist Party officials.

Since about 1960, private out-of-hospital health service has expanded slightly in the Soviet Union, for people who can afford to pay private fees. As a general back-up for all polyclinics and hospitals, all large Soviet cities have well-developed **emergency** services, staffed by physicians and feldshers and equipped with modern ambulances. Calls to a central telephone exchange lead to the dispatch of ambulances from various locations in large metropolitan areas.

The health of the population in the Soviet Union improved markedly after the 1917 Revolution for about 50 years. The infant mortality rate decline and the life expectancy at birth increased significantly. Then in the 1970s, these indices changed and health conditions clearly deteriorated. Various explanations were offered, but most important seemed to be the Cold War and the vast military expenditures it entailed. The funds remaining for health services were seriously inadequate.

Soviet health system expediters in the 1970s and 1980s were less than 4.0 percent of national wealth (as calculated by economists from international agencies). This was much lower than in any western industrialized country and far below the health needs.

Cuba is a middle-income developing country that had a social revolution in 1959, and then introduced a thoroughly socialist type of health system. The Cuban population is 10,100,000 and its GNP per capita in 1986 was just under $2,000. The adult literacy attained by 1984 was 96 percent.

As in other socialist countries, practically all responsibility for health services are under the Ministry of Public Health. After several changes since 1959, the country became divided into 14 health provinces, each headed by centrally appointed medical officers. Within the provinces are 169 urban or rural municipalities, which elect local assemblies, and these appoint municipal medical officers. There is virtually no market for private medical care, either modern or traditional.

Health manpower education was greatly expanded after the Cuban revolution, to compensate for the 33 to 50 percent of former physicians, dentists, and pharmacists who left the country. Schools for nurses, dentists, and technicians were also expanded, but Cuba rejected the idea of the "feldsher" or general medical assistant. Leaders said that a revolutionary health system has no place for "second-class doctors" nor for other types of "community health worker". Cuba has not even trained professional midwives; all childbirths are attended by physicians in hospitals.

Physical facilities were also greatly expanded in Cuba after the revolution. By 1982 there were 5.3 hospital beds per 1,000 people, and their geographic distribution was largely equalized.

The most important physical structures in the Cuban health system are the 425 polyclinics, each serving about 25,000 people for general ambulatory care, preventive and curative. For each 5,000 people there is normally a team of four physicians (internist, pediatrician, obstetrician-gynecologist, and dentist)

Since 1983, Cuba has been placing "family practitioners" at posts around the polyclinic, to provide general primary health care to only 600 - 700 persons. Cuba's attitude on family planning is not aggressive, since it feels a need for more population; contraceptive advice and supplies, however, are freely available on request.

As a result of its overall socio-economic policies, as well as its health system, Cuba has attained the best health record of any country in Latin America, including several of much greater per capita wealth. Life expectancy at birth had been 61.8 years in 1960, and by 1982 it was extended to 73.5 years.

A last socialist country, which had a social revolution in 1949, is the People's Republic of ***China***. With more than 1,100,000,000 people and a very complex social history, it is not easy to summarize China's health system, but the highlights may be given. In spite of its socialist ideology, China's overall income level is so low (GNP of $300 in 1986) that government-financed health services for all have **not** yet been achieved.

Having passed through several major periods of political change since the earlier bourgeois revolution of 1911, by 1986 China had a ratio of 57 modern physicians per 100,000 population. There were also 32 traditional Chinese practitioners per 100,000 and, although official policy called for their integration into the government health services, the great majority were in private practice. In addition, there are thousands of assistant doctors (45 per 100,000 people), trained in "secondary medical schools" for three years--**not** be confused with "barefoot doctors". These secondary medical schools also train nurses, technicians, and pharmacy assistants. The "barefoot doctor" was a peasant trained for only a few months, principally during the period of the Cultural Revolution (1965-1975). At their peak there were 1,800,000 of these auxiliaries and, after the death of Chairman Mao Tse-tung of 1976, they were upgraded to "village doctors", numbering 1,245,000 in 1989.

Hospitals also were vastly expanded in socialist China. By 1985 there were hospitals in all 2300 counties and a ratio of 2.1 beds per 1,000 population. Formerly the countries were organized into 27,000 "communes", for local agricultural and other production, but these have been converted to "townships". Each township, as well as the municipal districts, as health centers for general primary health care.

Through deliberate planning, China has developed 800 pharmaceutical plants, that produce some 3,000 modern drug compounds; in addition, it has 480 plants for manufacture of traditional drugs. These drugs are distributed through some 360 pharmaceutical warehouses in the provinces to hospitals, health centers, and some 20,000 local pharmacies.

The central MoPH establishes general policies, but most responsibility is carried by corresponding agencies in each of the 21 mainland provinces (leaving aside Taiwan), 5 autonomous regions, and 3 centrally administered municipalities. Some 90 percent of financial support must come from within each province. Every county also has a Bureau of Public Health, headed by a modern physician.

To help meet the costs of medical care both in hospitals and health centers, 4 forms of health insurance have been developed in China. According to a World Bank Analysis, in 1987 all these forms of insurance accounted for 50 percent of health system expenditures; overall government revenues at all levels contributed 19 percent and private individuals had to pay fees amounting to 32 percent. In terms of people, health insurance covers about 40 percent of the national population with some protection.

Public Health campaigns against malaria, schistosomiasis, tuberculosis, an other diseases are carried out by the Provincial Ministries of Public Health. Research, education of personnel, construction of facilities, and the management of all hospitals and health centers are all functions of government.

Family planning has been a major part of China's social policy since 1968. By 1987, the crude birth rate was reduced to 20 per 1,000 people, Health achievements have likewise been impressive. Infant mortality was reduced from

150 deaths per 1,000 live births in 1960 to 33 per 1,000 in 1987. Life expectancy at birth over the same period was extended from 47 years to 70 years. Eventhough serious inequities persist in the operation of China's health system, its achievements have won world-wide admiration.

General Trends

In all four types of national health system in industrialized as well as developing countries, certain general trends have been evident over the last 50 years. The **resources**, both human and physical, have been greatly expanded. As more people have survived to the older age-groups and as educational levels have improved, the demands for personal health care everywhere have risen. Every country has responded by developing larger resources and new kinds of health personnel.

The **organization** of health systems, largely under government, has increased and grown more complex. Agencies, both public and private, have multiplied, and in general the strength and scope of Ministries of Health have been enhanced. Non-governmental voluntary agencies have also grown to promote health efforts regarding certain persons, certain disorders, or certain services.

The **management** of national health systems has become generally more sophisticated. Administrators are trained, record systems are formulated, consumers are given a stronger voice, and decision making has become more democratic process. To limit abuses in the private market, regulatory powers have been extended. More and more aspects of health are being subjected to legislative intervention--from reducing the sale of harmful tobacco products to the mobilization of funds for supporting the costs of prevention and treatment.

As a share of national wealth, the **money** devoted to health systems has increased steadily, except perhaps in the European socialist countries. It has grown both in public and private sectors, although more rapidly in the public sector. Off all the health services, those in hospitals have absorbed the most rapidly expanding proportion. With the objective of meting the health needs of more people, rural and urban, the World Heath Organization has stressed everywhere a higher priority for **primary health care**.

In the **patterns of delivery** of health care, the key concept has become teamwork. The importance of this has long been recognized in hospitals, and it is now appreciated in ambulatory care as well. The socialist countries first demonstrated the value of polyclinics and health centers, to provide integrated preventive-curative services to general population, and all countries with other types of health systems have to some extent acted likewise.

These developments in all components of national heath systems add up to the attainment of greater **health care equity** in the world. In the words of the Constitution of the World Health Organization, it was long been agreed that:

> ***The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being, without distinction of race, religion, political economic or social condition.***

Implementation this ideal may lie in the future, but the developments in national health systems over the last half-century give grounds for confidence about its ultimate achievements for confidence about its ultimate achievement.

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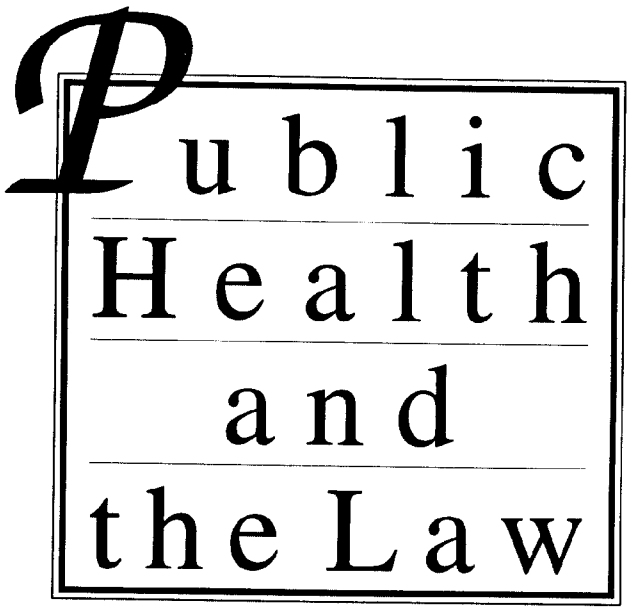
Public
Health
and
the Law

An Overview of Public Health and the Law

Ruth Roemer, J.D.

It is awesome for me to be presenting a talk on an overview of public health and the law in Thailand, a country I have held up as the developing country with the most advanced legislation on tobacco control--more advanced than that of many industrialized countries--and a country whose effective family planning program I have long admired. And now I have learned about the legislative work that your Health Systems Research Institute is doing in other fields. Perhaps my summary will give your cause for pride in your own legislative accomplishments. It may even suggest some ideas for your future work, since I believe that comparative studies of legislation provide useful insights.

Public Health laws, like public health, concerns the health of populations as contrasted with the health of individuals. ThusÁ public health law concerns the legal aspects of providing preventive, curative, and rehabilitative services to populations, although public health law has an important impact on health protection and health care for individuals as well.

As the role of public health has expanded from its early function of preventing the spread of communicable diseases to encompass the development of resources, the organization and financing of the delivery of care, surveillance of the health care system, health promotion, and overall protection of community health, so public health law and legislation have expanded to provide authorization, direction, and regulation of many fields of environmental and personal health services, As Grad has written,

> *The reach of public health law is as broad as the reach of public health itself. Public health and public health law expand to meet the needs of our society.*
>
> *(Grad 1986)*

I should like to begin by setting forth the functions of law and legislation in protecting the public health. Then we may examine several fields of public health law with comments on (1) the general scope of law and legislation, (2) methods of implementing law and policy, (3) selected examples of legislation, and (4) contemporary trends.

Perhaps a caveat or two are in order here. First, it should be noted that law and legislation can play a negative or a positive role with respect to public health. Some laws may be adverse to public health by imposing restrictions on health services based on the knowledge, social conditions, or fiscal constraints obtaining at the time that legislation was adopted. Such negative laws are illustrated by the criminal laws outlawing abortion that are being replaced by legalized abortion in most countries of the world or laws restricting the scope of functions of allied health personnel. Fortunately, laws also pay a constructive role supportive of health by authorizing measures to protect health, to increase access to health services, and to assure that quantity and quality of health care that a society needs.

Second, one should bear in mind that while law performs a technical function of expressing health policy and setting forth procedures for implementing it, the content of the law is determined by the nature and orientation of the political power in the country at any time and place. The element of political will is crucial

to the enactment of health legislation. Legislation can serve as an instrument of change to improve health services and health protection but only if policy makers have the necessary political will.

Functions of health laws

Health laws perform various essential functions in protecting the health of populations.

1. **Laws and legislation prohibit conduct that is injurious to the health of individuals and communities.** Examples of this function are environmental health laws that prohibit the dumping of toxic chemicals in the environment, traditional public health legislation to prevent the spread of disease, laws to control drug abuse (Proter, Arif, and Curren 1986), laws regulating smoking in public places, and laws to regulate the quality of health care.

2. **Health legislation authorizes programs and services the promote the health of individuals and communities.** Many diverse, categorical programs authorized by law provide health services for specific persons (mothers and children, the military, veterans, he mentally ill, the handicapped, the elderly); for specific diseases and conditions (heart disease, cancer, stroke, sexually transmitted diseases, mental illness and retardation, alcoholism and drug abuse, AIDS); and for specific services in various fields (environmental and occupational health, nutrition, mental health, dental health and ambulatory, hospital, and long-term care).

3. **Legislation regulates the production of resources for health care.** Laws authorize or provide financing for the construction of hospitals, health centers, and other health facilities. Legislation provides support for education of the health professions and occupations. Regulation of the production and importation and export of drugs, medical devices, and medical equipment and supplies is carried out under the authority of law. Financial support of research--the production of knowledge--may require legal action.

4. **Legislation provides for the social financing of health care.** This function is carried out by laws establishing systems of national health insurance or a national health service. It is also expressed in government grants for specific health programs, in the imposition of special taxes for health purposes, and in tax exemption for non-profit health facilities.

5. **Legislation authorizes surveillance over the quality of health care.** Examples of this function are licensure laws establishing minimum standards for health personnel and facilities, legislation providing for peer review of the quality of care, and financing programs that regulate the quatity and quality of care. The judicial system, in handing malpractice suits, also carries out this function.

In the process of performing these various functions, health law faces the challenge inherent in all law - that of balancing the interests of the individual and the interests of society. This overriding issue faced by legislators, administrators, and judges is both legal and ethical. To what extent may individual rights be curtailed in order to promote the general welfare? The answer to this question is "it depends." It depends on the degree of risk to the community and the degree of intrusion on individual rights. It depends on the scientific and epidemiological evidence pertaining to the issue being legislated or litigated. It depends on the nature of the legal system and its protection of individual rights.

Environmental health and the law

Environmental health was one of the earliest concerns of public health because of the basic need for a safe water supply and waste disposal in all societies. With the growth of industrialization, modern law to assure a healthful living and working environment has expanded to include control of air and water quality, regulation of domestic waste and industrial and agricultural effluents, management of solid waste disposal, control of marine pollution, regulation of radiation emissions, control of toxic substances in industry and the community, regulation of the use of pesticides in agriculture, and noise abatement. Each of these branches of environmental law is based on the need to protect the public health. In addition, other branches of environmental law, while not directed solely to protecting health, have an important impact on health and the quality of life. These include conservation of natural and environmental resources, land use control and regulations governing housing, and measures to meet population growth and power needs (Grad 1994).

Public health personnel are involved to varying degrees in each of these problems in environmental health. They may be called on to set standards for air and water quality, to treat water to make it potable, to add fluorides to a public water supply to prevent dental caries, to inspect factories for toxic chemicals, to enforce sanitation regulations in markets and restaurants, to develop solid waste disposal systems, and for other tasks. The size and complexity of environmental engineering, management, and control activities have caused principal responsibility for environmental regulation to be placed in non-health agencies with specialized scientific, engineering, and economic expertise in many countries, but public health personnel retain responsibility for managing the health component of environmental control. As they undertake their varied functions, public health environmentalists encounter legislation and regulations designed to control contaminants and prevent harm to the health of the community.

A number of mechanisms are used for environmental control. The most important of these is not a legal mechanism but rather economic considerations that promote compliance with environmental standards. For example, an industry may find it cheaper to clean up its wastes than to pay the penalties for pollution. Or a government may find it advantageous to subsidize practices that will improve environmental quality.

Among the legal remedies used to implement environmental legislation are inspections and citations for violations of established standards of environmental quality; civil penalties for pollution; effluent charges; licensing of businesses and withdrawal of the license in the event of violation of standards; criminal prosecutions to punish violators; injunctions to prevent future harm; and seizure and forfeiture of property in cases of egregious pollution (Grad et al. 1971).

Examples of environmental legislation

Environmental health legislation may be either categorical or comprehensive. Categorical legislation deals with one type of problem, such as air or water quality or solid waste disposal. Comprehensive legislation is designed to provide integrated control of the many and often inter-related insults to the environment having an impact on health.

Choosing examples of categorical environmental legislation at random, we may cited as laws designed to protect health and safety in specific fields the Norwegian legislation on levels of lead compounds and benzene in motor fuel

(Norway 1980), the Australian legislation on limitation of air pollution caused by emissions from stream boiler installation (Australia 1988), and the Israeli law on noise abatement (Israel 1992). Virtually all countries have categorical legislation dealing with various specific aspects of environmental control to promote health.

Both industrialized and developing countries have also enacted comprehensive environmental legislation addressed to multiple aspects of the environment. In the USA, the National Environmental Policy Act of 1969 was designed to create a means for integrating and coordinating the many programs affecting environmental protection (US 1969). The most important provision of the legislation requires the filing of environmental impact statements before major federal projects with significant impact on the environment can be undertaken. The Act required agencies of the federal government to use an interdisciplinary approach in actions to achieve national environmental goals and requires these agencies to consider the environmental consequences of agency action.

Impelled by the increasingly recognized threats to health from environmental pollution, many other countries have enacted comprehensive environmental legislation. An important provision of these laws is the requirement for an environmental assessment in advance of construction of a project to determine its effect on health and on physical and living conditions. The Canadian law establishing an environmental assessment process is designed.

(a) to ensure that the environmental effects of projects receive careful consideration before responsible authorities take actions in connection with them;

(b) to encourage responsible authorities to take actions that promote sustainable development and thereby achieve or maintain a healthy environment and a health economy;

(c) to ensure that projects that are to be carried out in Canada or on federal lands do not cause significant adverse environmental effects outside the jurisdictions in which the projects are carried out; and

(d) to ensure that there be an opportunity for public participation in the environmental assessment process (Canada 1992).

As eastern European countries are making the transition from communism to capitalism, they have recognized that industrialization has been associated with serious degradation of the environment, and have consequently enacted broad environmental protection legislation. In example, Bulgaria's 1991 law provides for monitoring the state of the environment, assessment of environment impacts, and development of environmental policy based on the reduction of hazards to human health and the environment and its relation to damages suffered and benefits lost.

Trends

Although environmental law is not my field, and there are those among you who are much knowledgeable about environmental health than I am, I shall offer some comments on trends in legal aspects of environmental health, derived from the US experience.

First is the trend and, indeed, the need to base law on sound science. Increasingly, policy makers are looking to scientists for risk assessment of particular chemicals and substances. For example, Richard Doll and Richard Peto found that in 1981 30% of US cancer deaths were caused by tobacco and 35% by diet, whereas only approximately 2 percent were caused by pollution (Doll and Peto

1981). Such information certainly suggests priority for tobacco control legislation. It also suggests that, in view of our inability to be precise about the levels of carcinogens that people can tolerate, in the absence of definitive evidence administrative rules and legislation should allow a wide area of discretion to be administrative agencies with expertise (Schwartzbauer and Shindell 1988).

Second, as environmental impact statements are increasingly mandated by legislation, there is a tendency to distinguish between risk assessment and risk management. Risk assessment concerns the adverse impacts on human health of toxic substances. A risk assessment performed on baseline data may yield an estimate of expected carcinogenicity or other health hazard. Risk management reviews the information in light of legal, political, economic, and social factors and determines how to limit exposure. Risk management includes evaluation of the alternatives and various options for dealing with the risk. It is therefore suggested that risk assessment and risk management should be separated and that the assumptions in risk assessment should be clearly stated so as to permit sound review of scientific evidence and adequate presentation of the risks to the public.

Third, as more and more toxic chemicals are introduced into the environment, largely by industry, the response is to enact laws to control hazardous discharges and clean up polluted sites. But as experience is gained with environmental legislation, policy makers are seeking to control hazardous inputs, to prevent use of toxic chemicals, rather than clean up after them. In order to do this, more testing is needed. This is a daunting task, since very little is known about the extent of human and environmental exposure and for 70 percent of 67,000 chemicals in commercial use we have no information on possible health effects (Conservation Foundation, 1984; UN Conference on Environment and Development, Rio de Janeiro, 1992).

Regulation of food and drugs

Laws to prevent the adulteration of food and medicines originated centuries ago (Christoffel, 1982). Today in industrialized countries and to an increasing extent in developing countries people are dependent on commercially produced food and manufactured drugs that they are unable to evaluate themselves. They must rely on governmental regulation of these goods.

Legislation related to nutritional quality and food safety regulates the hygienic standards for production and marketing of foods, control of equipment, utensils, and containers, hygiene and health of food handlers, storage and vending places, methods of testing and inspection, requirements for labelling of contents and shelf-life, and advertising of foods. More specialized legislation deals with such matters as food additives, including what additives are allowed, maximum permissible levels, and requirements for package labelling. These regulations include the requirement for iodization of salt to prevent goiter and in some countries labelling foods for salt content to promote uniformity in definitions of low salts content.

Comprehensive drug control legislation, which exists generally in all industrialized countries and in many developing countries, provides authority to control the importation and production of drugs, the licensing of manufacturers, wholesalers, and distributors, drug registration, and the distribution, sale, labelling, advertising and promotion of drugs. A national drug control program regulates the

quality, safety, and efficacy of prescription drugs and over-the-counter drugs and also shares in responsibility for control of narcotic drugs (Chapman 1976).

Enforcement of food and drug laws is carried out through inspections of the manufacturing process, recall or seizure of defective products, civil and criminal penalties for violations of established standards, and injunctions to prevent marketing of food and drug found unsafe or unsanitary. Enforcement relies heavily on rule-making by the food and drug agency and on administrative hearings on violations of standards. Use of administrative law in this field so critical to health hastens the disposition of cases, provides expertise on the technical issues involved, and introduced flexibility in the process of adjudicating cases and designing sanction.

Examples of food and drug legislation

In 1976, Norway became the first country in western Europe to establish a national nutrition and food policy (Norway 1981-2). Its objectives are to encourage healthful dietary habits, develop nutrition and food policy in accord with the recommendations of the World Food Conference, increase production and consumption of Norwegian food products, and improve self-sufficiency in food products. Numerous laws are implemented by various governmental agencies to these ends. The Food Control Coordinating Act of 1978 established a Food Control Board with representation from the various ministries and interests. The Inter-Ministerial Coordinating Committee on Nutrition, composed of leading civil servants in the Ministries of Fisheries, Consumer Affairs and Government Administration, Trade, Industry, Church and Education, Agriculture, the Environment, Health and Social Affairs, and Foreign Affairs, is charged with defining tasks, preparing long-term plans, an implementing policies. The National Nutrition Council is composed of members who represent research and teaching in the fields of nutrition, diet, dietetics, food hygiene and technology, food production, and the food industry. The mandate of the Council is to advise the authorities, industrial organizations, large households, and food producers on nutrition and to disseminate information on diet. Implementation of the national nutrition policy thus depends on permanent inter-ministerial bodies with well-staffed secretariats.

In addition, the national nutrition policy of Norway is elaborated through a health policy on nutrition which includes preventive work and training of personnel; agricultural, fisheries, and price policies that affect production and subsidies of foods; a consumer and school policy to present an appropriate range of foods and develop sound attitudes towards diet and nutrition. The goals of the Norwegian nutrition policy are to motivate individuals to adopt a healthful diet to create a situation in which the individual is able to act favorably (Willumsen 1983).

Illustrative of comprehensive drug control programs is the legislation of Australia, which regulates the manufacture, importation, sale, and distribution of drugs and also establishes a Pharmaceutical Benefits Scheme providing publicly financed prescribed drugs to the entire population (Roemer and Roemer, 1976). About 90 percent of all drugs prescribed in Australia are available on the approved list, and the patient generally pays only a flat $1 co-payment, regardless of the cost of the prescription.

The Foods, Drugs and Devices, and Cosmetics Act of the Philippines provides for a comprehensive food and drug regulatory system governing various aspects of food and drug production and distribution, including standards and quality measures for these products, approval of new drugs, control of adulteration,

labelling requirements, and licensing of manufacture, sale, and import and export of drugs (Philippines 1987).

By contrast with comprehensive food and drug regulatory schemes are the numerous statutes dealing with specific issues in the field. For example, Indonesia requires all government hospitals and health centers to prescribe and use generic drugs for all patients and requires pharmacies to stock essential drugs, including generic drugs (Indonesia 1989). In the USA, voluntary labelling of the contents of foods, long unsatisfactory because of lack of uniformity and difficulty for consumers in interpreting the information, was replaced by mandatory labelling (US 1991). Regulations of the Food and Drug Administration require nutrition labelling on most foods and specify the contents and format for nutrition information (US 1992).

Trend in Food and Drug Control

Control of such essential consumer products as food and drugs requires constant vigilance to monitor the safety and nutritional values of food and the safety, efficacy, and quality of prescription and over-the-counter drugs. Public health agencies, often urged on by consumers, are strengthening surveillance of the production and marketing of both food and drugs and are improving enforcement of labelling and advertising requirements. Provision of information to consumers is becoming a high priority. For example, mandatory labelling of sodium content of foods is a form of consumer education. Warning labels and package inserts in pharmaceuticals are an important part of patient education.

Another trend is to expedite drug approvals and eliminate "drug lag" - trend impelled by the urgent needs of AIDS patients for access to new drugs.

Still another important trend is to encourage the use of generic drugs, which are less costly than brand-name drugs. In the US, this has required repeal of laws banning substitution of generic equivalents for brand-name drugs prescribed by the physician (DeMacro 1975).

Licensure of health personnel

All countries have a governmental system for regulating the qualifications of medical, dental, and a varying number of other health personnel. In some countries licensure may be granted without further examination on completion of an approved educational program. In others a separate examination may be required after completion of the approved educational program. In recent years, recognition of the capacity of licensing laws to do more than specify minimum qualifications for practice - to influence the geographic location of physicians, dentists, and others, to affect the proportions of generalists and specialists, to influence the pattern of practice, and to promote the continued competence of practitioners - has given a new importance to licensing laws for the health professions.

Implementation of licensing laws is carried out by licensing boards composed originally largely of members of the profession to be licensed. In response to the demand for greater public accountability, members of other professions, consumers, and representatives of governmental agencies have been added to the boards in many countries.

The example of nursing licensing laws

To present some insight on the role of licensing laws in regulating the qualifications and functions of health personnel we may take the example of nursing licensure. Nursing practice acts generally provide for personal and educational qualifications of nurses, prescribe the content of nursing curricula, including practical experience, define the scope of nursing practice, specify grounds and procedures for disciplinary action, and provide for renewal of licenses.

As nursing education has been expanded and technology in health care improved, it became clear in the USA and in other countries also that nurses were being underutilized. Although they were equipped by enriched training for new nursing roles, the licensing laws generally barred nurses from undertaking "diagnosis and treatment," which were defined as medical functions. Beginning in 1971 the American states adopted various legislative strategies to authorize an expanded role for nurses (Bullough 1975). These included authorization by the medical and nursing licensing boards of expanded functions, amended definitions of professional nursing to include autonomous functions (New York 1972), adopting standardized procedures and protocols to authorize expanded nursing functions, and allowing individual physicians to delegate the right to diagnose and treat. The legislative changes made in nursing practice acts in state after state expanded the contribution of nurses to patient care and made the profession of nursing more interesting and rewarding.

Legal barriers to extension of the nurse's role in developing countries are particularly grave because the nurse is often the only health professional available in rural areas to provide primary health care. Yet often the medical and pharmacy acts bar the nurse from diagnosing and treating and from prescribing medications. The nursing practice acts restrict not only the scope of nursing practice but also the training that nurses receive (World Health Organization Study Group 1986). In order to alter this negative impact of the law, countries have enacted new statutes to reorient nursing education and to authorize functions for nurses that were formerly the exclusive province of the physician. For example, in 1977 Senegal issues a decree adapting its nursing education to the needs of the country so that nurses will be prepared to serve the rural population (Senegal 1977). In 1982 Dominica authorized its family nurse practitioners to prescribe drugs from the Dominica Nurse Practitioner Formulary (Dominica 1982).

Trends in regulation of personnel

Several trends in regulation of personnel may be noted:

(1) Adapting legislation to provide properly trained personnel for primary health care. This involves modifying the educational system and the clinical or field training to prepare physicians, nurses, and others for primary health care rather than for specialized practice and hospital service.

(2) Expanding the scope of practice of allied and auxiliary personnel so that all personnel are functioning at their maximum level of performance. In the USA the scope of practice of nurses has been greatly expanded.

(3) Requiring service to under-served populations in rural areas and in inner cities. Some countries, such as Norway and Mexico, require a period of service in an underserved area as a condition of licensure.

(4) Enacting laws to provide for the training of mid-level personnel. In the USA, we have authorized the training and functioning of physician's assistants, and other countries have medical assistants, assistant medical practitioners, health technicians, or health assistants.

(5) Requiring continuing education to update the qualifications and skills of physicians, nurses, and other personnel. Although some statutes require continuing education as a conditions of licensure and much voluntary continuing education is provided by professional associations and training institutions, uncertainty exists as to what kind of continuing education is effective and influences practice and performance.

Regulation of health-care facilities

Various mechanisms regulate the quality of the care provided by hospitals, health centers, and long-term care facilities - hospital licensing laws, requirements of the financing system, court decisions, actions of voluntary accrediting bodies, standards of professional associations for specialty training, and rules of the facilities themselves. Legislation sets minimum standards that facilities must meet in order to operate. Legislation also governs the planning, construction, and distribution of facilities.

The cornerstone of this multi-faceted regulatory system is hospital licensure. Hospital licensing laws are important because such a large proportion of care - and care for serious illness - is provided in hospitals and because the costs of hospital and long-term care represent such a large proportion of health care expenditures.

Originally, hospital licensing laws were concerned solely with the physical conditions in the hospital - safety, sanitation, and space. But over the years health facility legislation has expanded to cover many types of health facility and to prescribe requirements to assure not only the safety of the patient but also the quality of her care (Lander 1980). Government sets standards for both public and private institutions. The public purpose of health facilities and the public interest in their use are the basis for public regulation of private institutions. For non-governmental agencies and the private market, legislation may regulate performance to protect public health, may provide support, and may define inter-relationships of private institutes with government.

Implementation of hospital licensing laws is carried out through rule-making by governmental agencies, inspections of facilities, consultations to remedy deficiencies, administrative hearings, injections, denial of reimbursement, license suspension and, if all else fails, through closure of the facility.

Examples of health-care facility regulation

In the USA hospital licensing laws are fairly recent, having been enacted in 1946 following World War II in response to the Hill-Burton Hospital Survey and Construction Act, which required states to specify minimum standards for facilities receiving federal subsidies.

Beginning in 1968 a number of states amended their state hospital licensing laws to enact what were termed comprehensive laws encompassing both physical and patient care standards. For example, the modernized facility licensing law of New York State, enacted in 1969 (New York 1985), contains detailed provisions governing construction, financial reporting, and patient care. The law specifies,

among other matters, requirements for ambulatory care, calls for a comprehensive evaluation of patients on a periodic basis, requires continuity of care when patients are referred outside the hospital, mandates full-time medical staffing in emergency rooms, specifies rules for surgical consultation, and requires general hospitals to admit patients in need of immediate hospitalization without advance inquiry as to their ability to pay. Thus, the provisions of modernized facility licensing laws have moved far beyond bricks and mortar.

Increased emphasis on primary health care in both developing and industrialized countries, frequent provision of care in ambulatory settings, and the performance of surgical procedures, formerly done on an inpatients basis, in outpatient settings are developments that are expanding the scope of regulation to cover new types of facilities. For example, in 1992 the USA provided for regulation of mammography services requiring a certificate to operate a mammography machine, developing standards, procedures for mammography services; and providing federal grant for breast screening services.

Although licensing statutes provide legal mechanisms for enforcement, less onerous strategies are increasingly preferred. Particularly in the field of long-term care, where often the need is to upgrade the quality of care, tying standards of the facility to the financing mechanism is increasingly preferred as an effective sanction.

Even when implemented, the standards specified in a licensing law may be minimal standard rather than the most up-to-date requirements for patients care. To take account of the need to encourage higher standards than those required by the hospital licensing law, a voluntary accreditation system has long been established in the USA. Preparation for JCAH accreditation requires a facility to examine and upgrade its quality.

Control of communicable diseases

Prevention of the spread of communicable diseases was one of the earliest functions of public health. In this effort, two types of law have been employed: laws to assure a sanitary environment (discussed earlier) and laws to regulate human conduct to control the spread of disease.

Turning off the Board Street pump through which cholera was spread was an ideal public health measure because it cut off the source of the disease and benefited the whole population served by that water supply. Such a solution is not always available, however. Therefore, other measures to prevent epidemics have been adopted. Such laws authorize public health officials to ascertain the incidence of communicable disease, to regulate the conduct of those who are infected, and to require measures to prevent its spread. Because these actions involve some restriction of the rights of individuals, the law in this field seeks to balance the need of society for protection against disease and the rights of the individual to privacy and liberty.

Traditional methods of preventing and controlling communicate disease have evoked statutory responses. To assist epidemiological investigation of the incidence of communicable diseases, laws mandating reporting to public health officials of specified communicable diseases by physicians, school authorities, and laboratories have been passed. To prevent and control communicable diseases, the law provides for compulsory examination of individuals who are in a position to spread disease (e.g., food handlers), and of individuals in whom communicable

disease presents special hazards (e.g., school children, applicants for a marriage license, pregnant women). A health officer also generally has power - although it is rarely exercised - to order a person suspected of being infected with a contagious disease to submit to a physical examination (Grad 1990). Similarly, rarely used today is the health officer's power to isolate and quarantine an infected individual, although the power continues on the statute books. The most important legal measure for control of communicable disease is certainly compulsory immunization.

Statutes authorizing these measures for controlling communicable diseases generally provide a civil or criminal penalty for violators, but much preferred are other strategies for implementation of the laws, such as exclusion from school or work. Compliance with a specified immunization schedule may be required for school attendance, as in Ontario, Canada (Ontario, Canada 1982). Compulsory examinations may be required for a marriage license or to obtain a certain job, as in the USA (Grad 1990).

According to WHO, prioritize for most centuries in the field of legislation are laws on communicable diseases on food hygiene.

Example of legislation to control communicable disease

Finland enacted in 1986 a comprehensive ordinance concerned with prevention of communicable diseases through vaccination, distribution of antibody preparations and medicines, the provision of measures related to individuals and their environment that are intended to prevent the development or spread of communicable disease, early diagnosis, screening, and treatment, and medical rehabilitation (Finland 1986).

In 1988, Malaysia amended and consolidated into a single, comprehensive statue its various laws on the prevention and control of infectious diseases. The statue provides for the declaration of an infected areas, examination of vehicles arriving in Malaysia, required notification of infectious diseases to the health authorities, power of health officers to require treatment, immunization, isolation, observation or surveillance, or any other measure necessary to control the disease, obligation of infected persons not to spread the disease, and other matter (Malaysia 1988).

Trends in communicable disease control

Immunization and other measures control communicable diseases are so well accepted today that the principal problems in this field are implementation of immunization programs; the high cost of vaccines, the question of how to compensate those patients who suffer an untoward outcome of immunization; and providing treatment for tuberculosis in developing countries, now that leprosy is being eradicated (Lamb 1994), and in all countries in a time of AIDS (Bayer et al. 1992).

Legislation on HIV/AIDS (human immunodeficiency virus/acquired immune deficiency syndrome)

As with other communicable diseases, the tragic epidemic of HIV/AIDS presents the classical public health problem of a conflict between the welfare of the community and the right of the individual but with significant differences. Like other sexually transmitted and communicable disease, HIV/AIDS calls for measures to prevent its spread and also for protection of the privacy and other civil rights of persons afflicted with the disease. But HIV/AIDS presents grave and different

problems because as yet there is no cure and no vaccine for prevention and because the incidence of HIV/AIDS is concentrated in the USA and some other countries in certain high-risk individuals - homosexuals and intravenous drug users - who are particularly vulnerable to discrimination.

Legislation has been a significant component of the response to the HIV/AIDS epidemic (World Health Organization 1993; Gostin and Curren 1987). An early response to the epidemic was to require testing of all blood and blood products provided by blood donors and confidential reporting of results. A most effective measure to protect the blood supply was the public health strategy, often adopted without the necessity of legislation, of establishing alternate testing sites (i.e., other than blood collection centers) enabling persons seeking information on their anti-body status to have confidential or entirely anonymous testing without endangering the blood supply.

Most jurisdictions having legislation on HIV/AIDS require reporting of cases of AIDS to a health agency. Some statutes classify AIDS as a sexually transmitted disease, as in the State of Idaho (US), Chile, Guatemala, Iceland, and Sweden. Such an approach permits the testing of prostitutes and tracing of contacts to advise testing and provide counselling. A few jurisdictions require reporting of HIV positively or AIDS Related Complex (ARC). In order to protect the confidentiality of test result, reporting may be anonymous by code, number, or initials.

Protection of the confidentiality of test results has conflicted with the need to protect other members of society. In order to cope with this problem, some laws provide for very limited disclosure to identifying information - for example, to a health care professional engaged in care of an HIV/AIDS patient and to a medical facility that will receive blood, organs, semen, or breast milk from an infected individual. Some jurisdictions authorize a physician to disclose positive HIV antibody status to an individual's spouse or sexual partner when the physician has reason to believe that the individual will not inform the spouse or sexual partner.

A controversial legal issue concerns the recalcitrant patient or seropositive person who does not respond to education, counselling, medical direction, and community pressures to stop infecting others but knowingly exposes others to HIV infection. Legal remedies may exist in the general civil and criminal law. Regulations in the United Kingdom (England and Wales) authorize an order by a justice of the peace to detain the patient if the justice is satisfied that the patient will not take proper precautions to prevent the spread of the disease (UK 1989).

The many statutes on HIV/AIDS are compiles on an on-going basis by the World Health Organization (1993). Here are mentioned several documents illustrating guidelines for action at different levels of government. First, on the international level is the Global Programme on AIDS of the World Health Organization. The goals are to prevent new HIV infection, to provide medical care, support, and counselling to those already infected, and to mobilize all national and international efforts in the struggle against AIDS. The major thrusts of the Programme are (1) to support national AIDS prevention and control programs and (2) to provide global leadership and foster international cooperation (Bulletin of the Pan American Health Organization 1989, pp. 146-151). WHO issues authoritative policy statements, for example, on the safety of blood and blood products (Petricciani et al. 1987); on international travel and the human immunodeficiency virus (HIV) (WHO consultation 1987); and on testing and counselling for HIV infection (WHO consultation 1992).

On a regional level, the Council and Ministers of Health of the European Community have adopted a comprehensive resolution on AIDS covering prevention, use of diagnostic tests, the fight against discrimination, research, international cooperation, monitoring the epidemiological situation, and developing specific measures to combat AIDS (European Community 1990).

On a national level, one may turn to the United States Public Health Service Plan for Prevention and Control of AIDS and the AIDS and the AIDS virus (Institute of Medicine 1988; Report of the Presidential Commission 1988; US Public Health Service 1986). The Plan calls for a strategy to control the disease based on voluntary counselling and testing, conducted with confidentiality and encompassing the following five spheres:

(1) an information base to determine the size of the population at greatest risk, particularly the numbers of homosexuals men, bisexual men, intravenous (IV) drug abusers, and heterosexuals who have multiple partners;

(2) national information and education campaigns on AIDS targeted to the currently uninfected population;

(3) prevention of IV drug abuse transmission;

(4) prevention of sexual transmission through voluntary serological testing and self-referral of sexual and drug abuse contacts, notification and counselling of contacts by health authorities, and targeted education programs; and

(5) prevention of transmissibilities by blood and blood products.

At the local level of government, one may examine the comprehensive New York City Strategic Plan for AIDS (New York City Interagency Task Force on AIDS 1988). The Plan covers the dimensions of the problem faced in New York City and the principles on which the Plan is based, notably inter-governmental cooperation, coordination of the public and private sectors, the crucial role of community-based organizations in providing services, and the need for significantly increased drug treatment resources for intravenous drug users as a way of preventing the spread of AIDS. The Plan outlines in detail new initiatives in the spheres of prevention, clinical and social services (both acute care and long-term care), AIDS care and services in the community, surveillance and research, and, most importantly, protection of human rights to prevent HIV-related discrimination.

Trends in control of the AIDS epidemic

The most controversial issue in the law governing AIDS is the extent to which screening for AIDS--the systematic application of the ELISA test and confirmatory, supplemental tests to specific populations--should be undertaken. While some countries have mandated tests for particular groups, such as prisoners, prostitutes, or immigrants, or even, in some jurisdictions, intravenous drug users or applicants, for a marriage license the overall trend and the weight of authority favor voluntary testing accompanied by counselling for several reasons: (1) it encourages behavior changes and notifications of sexual contacts and persons with whom needles have been shared; (2) if facilitates protection of privacy and therefore does not drive those who believe they may be infected to go "underground"; (3) in a low-prevalence population at test with a high degree of sensitivity and specificity, as the serologic tests for HIV antibodies are, will produce a large proportion of false positive responses, causing great anxiety, providing misleading information, and

requiring confirmatory tests; (4) in any testing system a certain number of false negatives will occur which give a false sense of security and inhibit behavior changes.

Therefore, the WHO Global AIDS strategy strongly favors voluntary testing, counselling, and protection of confidentiality. Mandatory testing without informed consent has no place in an AIDS prevention and control program, WHO states, because it violates the rights and dignity of individuals and is counterproductive to control of the epidemic (WHO consultation on testing and counselling for HIV infection 1992).

Another trend concerns precautions to prevent the transmission of HIV to health-care workers. The increasing prevalence of HIV increases the risk that health-care workers will be exposed to blood from patients infected with HIV. The US Centers for Disease Control has issued an authoritative document emphasizing the need for health-care workers to consider all patients as potentially infected and to adhere rigorously to infection-control precautions. The response to the risk to health-care workers must be universal precautions (US Centers for Disease Control 1987). In 1992, the US Occupational Safety and Health Administration (OSHA) adopted standards mandating universal precautions to protect workers from blood-borne diseases, including the requirement that the employer make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure and follow-up to all employees who have had an exposure incident. These detailed standards provide legal force in the USA to the recommendations of the Centers for Disease Control (US Code of Federal Regulations 1993, sec. 1910.1030).

From the beginning of the AIDS epidemic the issues of privacy, confidentiality, and protection against discrimination have been prominent concerns. But, as Dr.Stephen Joseph, Commissioner of Health of New York City 1986-1990, points out AIDS constitutes a public health emergency which carries within in its extraordinary civil liberties issues; it is not a civil liberties emergency which carries within it extraordinary public health issues (1992). For this reason, the AIDS epidemic raises a double ethical-legal imperative: to prohibit and punish discrimination in employment, housing, health insurance, public accommodations, governmental services, and schooling solely because the person has AIDS or is believed to be seropositive and, at the same time, the expand and intensify the response to the public health emergency created by the epidemic.

Legislation on mental illness

If one were to select a single sector of health services to see the field of health law in microcosm, one should examine health services for the mentally ill. This sector illustrates with particular sharpness the conflict between health needs and legal rights, between protection of the patient and protection of society, and ways to resolve these conflicts.

The scope of legislation affecting the mentally ill is very broad. It includes laws governing admissions to mental hospitals, standards for mental health facilities and care of patients, organization of community mental health programs, legal protection of the person and property of the mentally ill, the doctrines of the right to treatment and right to treatment in the least restrictive alternative setting, legal aspects deinstitutionalization, and mental illness and the criminal defendant (Curran

and Harding 1978). Clearly, we cannot discuss the many legal aspects of mental illness. Here we shall restrict the discussion to mental hospital admission laws.

With the advent of the tranquilizing drugs, the development of the concept of the open hospital and the therapeutic community and with increased awareness of the civil rights of patients, many jurisdictions have amended their centuries-old statutes governing criteria for hospitalization of the mentally ill. In addition to changes in the grounds for admission, the procedures for admission have been modified to assure prompt and non-traumatic admission to mental hospitals when needed, to require periodic review of the need for continued hospitalization, and to assure prompt discharge as soon as the patient is ready.

Example of mental hospital admission law

The first country to enact a modernized mental health law was the United Kingdom, which adopted legislation along lines recommended by the Royal Commission on the Law Relating to Mental Illness and Mental Deficiency in 1957. In the past, in England and Wales involuntary patients were admitted to mental hospitals on an order from a justice of the peace based on one medical certificate from a medical practitioner. This procedure was viewed as providing inadequate safeguards because the magistrate could not form any sound, independent opinion on the patient's mental condition and because the judicial order associated mental hospitalization with the courts and with punishment of crime (Maclay 1960).

The Mental Health Act of 1959, applicable to England and Wales, abolished the judicial order and made compulsory admission, when necessary, a medical matter, requiring two medical opinions, including one from a doctor with special experience (UK 1959). The doctors recommending compulsory detention must specify the grounds for their opinions and state whether alternative methods of dealing with the patient are available and, if so, why they are not appropriate and hospitalization is necessary. The hospital must confirm the need for hospitalization, and on the basis of these three certifications the hospital is authorized to retain the patient for specified time limits. Most importantly, an administrative agency to which patients and their families have access - the Mental Health Review Tribunal - is established in each hospital region, with power to review the appropriateness of hospitalization and to discharge the patient.

Twenty-four years after passage of the Mental Health Act, in 1983, amendments to the law were adopted to strengthen protection of the civil rights of mental patients (UK 1983). These amendments require, among other things, consents to treatment, assurance of patient rights, such as the right to visitors, to pocket money, etc., and establishment of a Board of Visitors to provide surveillance of the quality of care in mental hospitals.

In the climate of opinion created by new methods of treatment of the mentally ill and new public attitudes towards mental illness, New York State revised its mental hospital admission law after an extensive study which found great variations, inequities, and injustices in the involuntary admission of patients to mental hospitals. The measures intended to protect the rights of patients had become a rubber stamp by the judges of the decision of doctors (Association of the Bar of the City of New York 1962).

Accordingly, in 1964 the New York State Legislature unanimously passed a new Mental Hygiene Law (New York 1978). It abolished civil judicial certification of an involuntary patient to a mental hospital and provided that the initial admission of an involuntary patient to a mental hospital is a medical matter, on the application

of a near relative or other interested person and on the recommendations of two physicians, with the concurrence of the admitting hospital. Immediate and periodic legal reviews of the propriety of hospitalization are required. The rights of the patient are protected by an arm of the court, the Mental Health Information Service, which faces towards the patient and his family to inform them of the patient's rights and alternatives and towards the court to inform it of the patient's condition and alternative treatment resources.

A key feature of both the British and the New York laws is the functioning of a protective structure to provide representation of the patients' interests and needs. Both the British Mental Health Review Tribunal and the New York Mental Health Information Service, however, apply only to institutionalized persons.

A deinstitutionalization has increased the numbers of the mentally disabled in the community and many of them have become homeless, recognition has grown of the need for similar protection of noninstitutionalized mentally disabled persons (Association of the Bar of the City of New York 1988). Simon Rosenzweig, who was one of the architects of the New York Mental Hygiene Law of 1964, has proposed establishing an ongoing, continuing legal service for the mentally disabled in the community. Such a service would differ from the service for institutionalized patients in that it would be concerned principally with needs for and entitlements to welfare, housing, treatment, including complaints as to treatment modes, access to ambulatory mental health centers, etc. Rosenzweig envisaged a form of "outpatient commitment' that would assure mental health care in the community and comport with constitutional rights to due process (1990).

Trends in mental hospital admission laws

Modernized mental hospital admission laws reluntary patient to a mental s occurred in the care of mentally ill. But not all problems have been resolved. What standard of proof should be required for involuntary hospitalization? Does the patient have a right to treatment? Does she have right to refuse a particular kind of treatment? What safeguards are afforded for minors deemed in need of mental hospitalization? (Parham v. J.R. et al. 1979). Probably in no field of health law is the conflict between the rights of the individual to liberty and confidential treatment and the right of society to protection from harm so sharp as in the field of mental illness. Resolution of this conflict in various contexts will depend on further advances in psyciatric diagnosis and treatment and on imaginative legal strategies to protect the individual and society.

Legal problems in human reproduction

A priority for public health through the years has been protection of the health of mothers and children. In all countries emphasis has been placed on prenatal and maternity care and on breast feeding, immunization, and well-baby care. A new dimension was added to maternal and child health efforts with the recognition of the importance of birth control and abortion to prevent unwanted pregnancy and assure proper child spacing. Deaths from illegal abortion were the largest single cause of maternal mortality in many countries (and still are in some). Yet laws making abortion crime except when performed to save the life of the woman barred prevention of such tragedies.

To tackle the enormous toll in preventable maternal deaths from dangerous illegal abortion, a number of countries turned in the mid-20th century to legislation action to shift abortion from the illegal to the legal sector of medical practice (Cook

and Dickens 1988). To promote family planning programs laws were enacted removing barriers to access to births control and providing educational and financial support for contraceptive services, for example, France, Germany, Italy, Morocco, and Spain (Isaacs 1981, pp.199-257; Paxman 1980; Mason et al. 1987). Laws also authorized voluntary sterilization, as in Japan, Panama, the Scandinavian countries, and Singapore (Isaacs 1981, pp. 147-148; Stephen et al. 1981). Statues mandating sex education in the schools were adopted (Roemer and Paxman 1985). Also, as another aspect of the woman's choice in reproductive matters, the law has been called on to authorize means to reduce infertility and has addressed alternative or assisted means of reproduction (Andrew 1984; Annas 1984; Annas and Elias 1983; Swiss Institute of Comparative Law 1986; Warnock Committee 1984).

These legal changes were not achieved without opposition. A minority of the population in a number of countries opposed legalized abortion and even attempted to restrict contraceptive and sex education programs. Despite their efforts, advances in the technology of contraception and changed social attitude concerning sexual behavior and the rights of women have impelled modernization of the laws governing human reproduction.

Legislation on abortion

Abortion at the request of the women or on a wide range of indications has been legalized in the most populous countries of the world - - China, India, Japan, the USA, and the Soviet Union. It is legal in the first three months of pregnancy in Austria, France, Germany, Denmark, and Italy. Abortion is authorized on social or sociomedical grounds in Barbados, Belize, the Scandinavian countries, and the United Kingdom, and it was legal in most of the countries of eastern Europe before the end of the communist regimes. Many countries allow abortion on medical grounds, as in Algeria, Israel, and Switzerland. Abortion is allowed only to save the life of the woman in Colombia, Guatemala, Honduras, Nicaragua, Turkey, and Venezuela. Abortion is prohibited in Chile, the Dominican Republic, Haiti, Panama, Paraguay, the Philippines, and Surinam. The reality in many countries where abortion is illegal or restricted is that it is nevertheless widely practiced, often by physicians, and with acceptance by the public (Cook and Dickens 1988; David 1984; David and Pick de Weiss 1992; Mason et al. 1985).

Trends in abortion laws

Henshaw has analyzed recent trends in abortion laws, from 1988 to 1993, in non-communist industrialized countries, in the formerly communist countries of eastern Europe, and in developing countries (1994). Little change occurred in almost all the non-communist industrialized countries, which had fairly liberal laws. Three of these countries-- Canada, France, and Great Britain--made minor changes liberalizing their laws. Belgium replaced its extremely restrictive law with one allowing women in a state of "distress" to end their pregnancies during the first trimester. In Ireland, a decision of the Supreme Court held that although the law prohibits abortion without exception the procedure is permissible when the pregnant women's life is endangered by physical health conditions or treat of suicide.

Before 1988 most of the formerly communist countries of eastern Europe allowed abortion on request or for social indications. With the end of the communist regimes, three countries that had had severe restrictions on abortion-- Ibania, Mongolia, and Romania-- mmediately authorized abortion on request.

Bulgaria and Hungary liberalized their laws further. But in Poland, the liberal 1956 law was repealed in 1993 by a law allowing abortions only in public hospitals on grounds of threat to life or health of pregnant woman, serious and irremediable malformation of the fetus, and pregnancy resulting from rape or incest (David 1993). On June 30, 1994, the Polish Parliament adopted an amendment that will restore a women's right to terminate her pregnancy on the grounds of "adverse circumstances of life" or "difficult personal circumstances" and will permit terminations in private clinics (International Planned Parenthood Federation 1994). Two other ex-communist countries--the Czech Republic and Serbia--restrict abortions by imposing fairly substantial fees (Henshaw 1994).

Among developing countries, Malaysia replace a restrict law with one modeled on the British statue allowing abortion if continuing a pregnancy involves more risk to the woman's physical or mental health than terminating it. Other developing countries that made minor changes liberalizing their laws are Botswana, Pakistan, Peru and the Sudan (Henshaw 1994). In Indonesia, a family health law of 1992 provides that, in emergency cases, to save the life of a pregnant woman "certain medical procedures" may be performed--a provision, according to the Indonesian Family Planning Association, designed to assure safe services and act as a compromise with those opposed to abortion (David 1993). Developing countries that increased their restrictions on abortion are Argentina, Chile, and Singapore (Henshaw 1994).

Legislative approaches to health promotion

The historical role of public health of preventing disease and disability received a new impetus in 1974 with the publication in Canada of the Lalonde Report, A new Perspective on the Health of Canadians. This report launched a world-wide effort for health promotion, examining and improving the judgments that

> *must be made by individuals in respect of their own living habits, by society in respect of the values it holds, and by governments in respect of both the funds they allocate to the preservation of health and the restrictions they impose on the population for whose well-being they are responsible*
>
> *(Lalonde 1974, p.9).*

How does health promotion differ from the time-honored function of public health, the function of health education? Horowitz defines health education as consisting of any combination of learning experiences designed to facilitate voluntary adaptations of behavior conducive to health. By contrast, health promotion is the process of advocating health to enhance the probability the personal, private, and public support of positive health practices will become a societal norm (Horowitz 1981).

In this effort to establish societal norms that contribute to healthful lifestyles, legislation has proved to be an essential component. This does not denigrate the role of education, which is important to engender the motivation to change behavior. That motivation, however, can be encouraged by societal norms and expectations which, in turn, are promoted by governmental policy expressed in legislation.

Prevention of motor vehicle accidents

The fields in which legislation can be directed to promoting health are many and varied. A high priority has been given to laws to prevent the enormous toll in death and disability from motor vehicle accidents. These include laws setting standards for fitness to drive, mandating the use of child passenger restraint systems, seat belts, and motor cycle crash helmets, and requiring manufacturers of automobiles to install air bags. With the technological innovation of blood alcohol measurement, stringent laws make the presence of a given level of alcohol in the blood a conclusive presumption of drunk driving entailing mandatory fines, jail sentences, license restriction, and rehabilitation programs (California Vehicle Code 1985).

Control of alcohol abuse

Drunk driving laws are but one kind of law to control alcohol abuse. There are two major types of legislation: (1) control of the availability of alcoholic beverages and (2) influencing drinking practices.

In the category of controlling the availability of alcohol are laws to control places of sale, hours of sale, and sales to minors, and to provide controls through taxation and prices (Addiction Research Foundation 1981; Institute of Medicine 1982; Moser 1980). While the evidence on the effectiveness of some of these measures is equivocal, it is generally agreed that decreasing the availability of alcohol is important. The experience of the Province of Ontario, Canada showed that lowering the drinking age increased alcohol related traffic accidents and admissions of teenagers to alcoholism and rehabilitation facilities (Addiction Research Foundation Volume 2, p.151; Single 1984). Increase in price of alcohol relative to income has been associated with a decline in consumption (Moser 1980, p.109).

In the category of regulating drinking practices are control of advertising, punishing public drunkenness, control of drinking and driving, education and information about alcohol, taxation policy, and counselling, treatment, and rehabilitation (Porter et al. 1986). Again, although the evidence on the effectiveness of these measures is conflicting, there are indications that drinking practices can be affected by legislation, combined with education, provided the laws are enforced.

A notable advance in alcohol control policy is the 1985 law in the USA providing for mandatory label information on alcoholic beverages stating that women should not drink alcoholic beverages during pregnancy because of the risk of birth defects and that consumption of alcoholic beverages impairs ability to drive a car or operate machinery, and may cause health problems (US Code of Federal Regulation 1993). Most importantly, the pioneering 1991 law of France bans all advertising of alcoholic beverage (France 1991).

Control of the smoking epidemic

Smoking is the largest, single, avoidable cause of ill health and premature mortality in the world, accounting for an estimated 3 million deaths a year from smoking-related diseases. In response to the world-wide smoking epidemic, governments have intensified their efforts to control smoking by legislation, combined with education and smoking cessation programs.

Two broad categories of laws have been enacted: (1) laws to bring about changes in the production, manufacture, promotion, and sale of tobacco - laws to control the supply (or "production") side, and (2) laws to achieve changes in practices among smokers - laws to control the "demand" (or "consumption") side of tobacco use (Roemer 1993).

In the category of brining about changes in the production, manufacture, promotion, and sale of tobacco are:

1. control of advertising, sales promotion, and sponsorship of tobacco products.
2. requirements for health warnings and statement of tar and nicotine contents on cigarette packages and other tobacco products.
3. control of harmful substances in tobacco--tar, nicotine and additives
4. restrictions on sales to adults
5. economic strategies relating to subsidies, crop substitution, and trade policies.

While all these measures contribute to decline in tobacco consumption, the most important is control of advertising and sponsorship. The tobacco industry spends more than $2 billion a year globally to lure consumers to its products, not counting the cost of indirect advertising through sponsorship of sports and cultural events by tobacco companies. Through advertising the industry conveys the message, especially to young people, that smoking is associated with success, pleasure, relaxation, sports, freedom, beauty in nature, sophistication, virility, and sexuality. Moreover, the substantial revenues received by newspapers and magazines from advertising of tobacco product have a chilling effect on their editorial policies and deter publication of articles of articles on smoking and health.

By 1991, 27 countries in the world had banned all advertising of cigarettes; 77 had enacted partial bans, some limiting the contents of advertisements to facts, barring the depiction of adolescents or children associated with sports, or restricting the amount of space devoted to advertising; and some imposing moderate particle bans prohibiting use of the electronic media for advertising of tobacco products or restricting the hours during which cigarette may be advertised on television. Experience in the Scandinavian countries, particularly Finland and Norway, showed that total bans on advertising combined with strong antismoking policies lowered smoking rates markedly, particularly among young people (World Health Organization 1987). A study of tobacco-promotion policies and consumption trends in 33 countries, commissioned by the New Zealand Toxic Substances Boards, found that when countries were grouped according to the degree of governmental restriction on tobacco promotion the greater the degree of restriction, the greater the average annual fall in tobacco consumption (New Zealand Toxic Substances Board 1989). The alarming uptake in smoking by children and adolescents led Canada, Australia, New Zealand, and France to ban all advertising and promotion of tobacco products (Roemer 1993; Canada 1988; Australia 1989; New Zealand 1990; France 1991).

In the category of legislation to change smoking behavior are:

1. tax and price policies
2. restricting smoking in public places
3. restricting smoking in work place

4. preventing young people from smoking (by prohibiting sales to minors and restricting sales of cigarettes from vending machines)
5. mandating health education

Experience in Canada, Hong Kong, the State of California (USA), and the United Kingdom has shown that raising taxes on tobacco decreases sales (Roemer 1993). An important report from Finland confirms the need for substantial and repeated increases in taxes and prices of tobacco products if consumption is to be significantly reduced (National Board of Health of Finland 1985).

Compelling, scientific evidence on the dangers of environmental tobacco smoke (ETS) led the US Environmental Protection Agency to classify ETS as a Group A human carcinogen, the EPA classification used only when there is sufficient evidence from epidemiologic studies to support a causal association between exposure to the agents and cancer (US Environmental Protection Agency 1993). Because of the EPA's findings on the respiratory health effects of passive smoking, restrictions on smoking in public places and the workplace are of prime importance. Such legislation has been enacted at the national level of government, and it has also been successfully implemented when enacted by states and cities. These laws contribute to the creation of a non-smoking environment and the view that smoking is socially unacceptable. It is generally agreed that social acceptability is the ground on which the battle against the smoking epidemic will be decided.

New impetus was given to tobacco control efforts by revelations in 1994 that the Philip Morris Company knew tobacco was addictive 5 years before the US Surgeon General declared tobacco an addictive substance, that the tobacco industry abruptly terminated research to develop a "safe" cigarette and concealed its findings on the addictiveness of tobacco, and the Brown and Williamson Tobacco Company grew a genetically engineered tobacco in Brazil that more than doubles the amount of nicotine delivered, used it in 5 brands of cigarettes, including 3 brands labeled "light," and has 3 million tons of it in warehouses in the USA (Hilt P.J. April 1, April 20, May 7, June 16, June 17, June 18, June 22, 1994). In February 1994, Dr. David A. Kessler, Commissioner of the US Food and Drug Administration, announced that for the first time the Food and Drug Administration would be willing to regulate the nicotine in cigarettes if it could shown that nicotine is addictive, that the tobacco companies are able to manipulate the amount of nicotine in cigarettes, and that they maintain a certain level of nicotine to assure the addictiveness of their product (Hilts P.J. February 26, 1994). Dr. Kessler has sought the advice of the US Congress on appropriate regulatory measures.

Other health promotion legislation

To promote healthful nutrition, legislation may regulate the quantitative declaration of calories, fats, cholesterol, sodium, sugars, and other nutrients to promote safe and wholesome food, as discussed earlier. Legislation may also establish supplemental feeding programs, such as school lunches and nutritional supplements for low-income pregnant women and infants. An ideal health promotion measure that does not require individual behavior change is fluoridation of public water supplies to prevent dental decay. Community water fluoridation improves the oral health of an entire population regardless of socioeconomic level, education, individual motivation, of the availability of dental personnel (Murrey 1986).

Many of the problems discussed in connection with health promotion are manifestations of stress. Certainly, smoking and alcoholism are largely responses to stress. Stress is also produced by adverse environmental and life situations, such as poor working conditions, poor housing, and unemployment. Stress has so many causes that one needs to address specific problems to ascertain what legislation can do to alleviate them.

The list of health problems associated with stress is long and daunting. It includes drug abuse, depression, suicide, mental illness generally, child abuse, and family violence. Societal responses to these difficult problems lie in social institutions and programs that can be assisted by legislation.

Trends in health promotion legislation

With increasing emphasis on health promotion and disease prevention in many countries, legislation has proved to be a useful tool to established policy, to set standards, to allocate financing for educational programs, and to provide incentives for behavior change through the tax system or allocation of benefits. For example, increasing taxes on cigarettes reduces smoking by young people. Providing free contraceptive services in accessible settings decreases teen-age pregnancy.

Conclusion

Laws can be inspired by a sense of justice and right. We hope that this is generally the case. Law provides the rules that all in society must play by. Health law provides the regulatory system for patients, providers and governments in the sphere of health protection and health services.

While the law may, in some instances, stand as a barrier to innovations in health service, in the main it has proved responsive to new scientific discoveries and to changed social and economic conditions. Where existing policies are inequitable or outmoded, the law has the capacity to serve as an instrument for change. If the outlines for change are uncertain, the law can facilitate the development of mechanisms for defining and achieving solutions.

Working in cooperation with public health experts, the health lawyers can assist and clarify the definition and sound health policy and can promote its implementation for the benefit of individuals and society.

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>
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Critical issues in Health Legislation

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Our topic for today is critical issues in health legislation. I propose to discuss specific problems in the fields that I have reviewed in my earlier lecture, but first I would like to mention some general, cross-cutting issues that affect many types of health legislation.

In my own opinion, the principal issue in health law is the tension between governmental power to protect the public health and fundamental rights of individuals. This tension is apparent in the fields of both environmental health and personnel health services. Regardless of whether the issue is personal freedom or protection of property, the legal entitlements of people and the responsibility of government need to be spelled out clearly. Resolution of this tension depends on several factors: the science base for the regulatory policy, the degree of intrusion on individual rights, and the values of society.

Another general issue concerns the roles of different levels of government, that is, what legislation should be enacted at the national level and what legislation at the sub-national or local level. In some cases, there can be a shared responsibility of different levels of government. With the modern emphasis on decentralization of governmental functions, policy and standards may be defined at the national level and administration of the legislation may be allocated to the regional or local level.

Still another general issue concerns the inter-relationship between the public and private sectors of society. The powerful drive for privatization of health services in many countries--notably developing countries and post-communist countries--and the existence of privatization in many industrialized countries, including my own--raise questions as to the role of government in financing, organization of services, quality control, and other aspects.

Still another issue is the concern with costs and quality of care. Can the society afford this legislation? What is its impact on quality of care? What is the appropriate technology, in WHO terms for particular social conditions? What safeguards of access to and quality of care be provided in the face of cost constraints?

A fundamental issue underlying all health legislation is: what is the science base for a proposed public policy? How does one legislate in the face of scientific uncertainty - a question I shall return to.

Finally, what are the mechanisms for enforcement of legislation? The black letter of the law on the statute books is useless if it is not enforced, we all know. The duty of public health professionals is to close the gap between the black letter of the law and its implementation in the real lives of people.

Issues in environmental legislation

Many issues face policy makers and public health administrators in the field of environmental control. Each of these issues merits lengthy analysis, which is not possible here. But even brief mention of the issues shows the magnitude and complexity of the problems in this field.

A priority for all countries, both industrialized and developing, is to balance the interest in the healthful enviroinment and the need for employment and industrial development. This conflict is expressed by Algeria in its law on environmental protection which provides:

> *National development implies the necessary equilibrium between the imperatives of economic growth and those on environmental protection and the preservation of the living conditions of the population.*
>
> *(Algeria 1983).*

The tension between the need for economic growth and the need to protect the quality of the living environment underlies all regulation of environmental population.

Management of environmental problems requires a high degree of scientific knowledge and technical sophistication in various specialized fields. At the same time, the interrelations among the various ambient elements, e.g., the impact of water pollution on land use, requires an inter-sectoral approach involving both health and non-health agencies. These environmental health interfaces and interactions have implications for the geographic jurisdiction of environmental agencies, for the responsibilities of various levels of government, for the functions of environmental health personnel, and for the role of public health personnel in large environmental management agencies (Roemer et al. 1971; Goldsmith 1970).

In the operation of any environmental management system, agencies responsible for regulating substances harmful to health face the difficult question of what limits exist on the agency's regulatory power in light of scientific uncertainty. What are the powers of the agency if there are conflicting scientific opinions or if the evidence is based solely on epidemiological data? (Grad 1994). A case study of the court decision upholding the regulation by the US Environmental Protection Agency restricting the amount of lead additives in gasoline provides important insights on the scope of judicial review and the role of the courts in cases of great technological complexity (Silver 1980).

The issue of how widely accepted a scientific process or theory must be to be admitted in evidence in a lawsuit arose in a case before the US Supreme Court in 1993. The case involved not environmental issues but whether a drug prescribed for nausea during pregnancy caused birth defects. The decision has wide applicability to various kinds of cases involving scientific evidence.

The US Supreme Court, by a vote of 7-2, rejected the test of "general acceptance" of scientific evidence that has been applied in the past and ruled that under modern rules of evidence adopted in the 1970s, particularly Rule 702 of the Federal Rules of Evidence, "general acceptance" is not an absolute prerequisite to admissibility of scientific evidence. The Court's opinion stated that trial judges serve as gatekeepers to ensure that all scientific evidence admitted is not only relevant but reliable. Pertinent evidence based on scientifically valid principles will satisfy these requirements. Although the Court did not set forth the factors that will determine whether the reasoning or methodology of the testimony is scientifically valid, it suggested that whether the theory or technique can be and has been tested may be a factor. While publication in a peer-reviewed journal is not essential for admissibility of evidence, such publication is a relevant, but not a dispositive, factor for a judge to consider in determining whether a method or technique is valid. Also, the known or potential rate of error may be considered.

Justice Blackmum, writing for the majority of Court, recognized that the practice of having the judge determine the admissibility of scientific evidence might, under some circumstances, keep from the jury "authentic insights and innovations," but accepted this risk as the result of Rules of Evidence that are "designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes." Justice Blackmun justified the gatekeeper role by pointing out that there are "important differences between the quest for truth in the courtroom and the quest for truth in the laboratory. Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly."

Since the proceedings I the lower courts had focused almost exclusively on " general acceptance" as a criterion for admission of scientific evidence and excluded other epidemiological, pharmacological, chemical, and laboratory studies, the Court vacated the judgment below and ordered further proceedings consistent with its opinion in this case (Daubert v. Merrell Dow Pharmaceuticals, Inc. 1994).

Finally, an issue that is assuming increasing importance in the field of occupational and environmental health is worker and community involvement in assuring a healthful working and living environment. In a USA worker and community right-to-know laws impose on employers and manufacturers the duty to disclose hazards in the workplace or activities involving toxic exposures (Ashford and Caldart 1985). These laws are not a substitute for enforcement of environmental protection laws, but they are an important aid to better regulation of the environment. The principle is embodied in a international convention, the Convention concerning Occupational Safety and Health and the Working Environment, adopted by the International Labour Organization in 1981. The ILO Convention requires employers and workers and their representatives to cooperate in protecting occupational safety and health. Measures taken by the employer to protect occupational safety and health must be disclosed to workers' representatives, and the workers have a right to know all aspects of occupational safety and health associated with their work. The Convention also requires training of workers and their representatives in occupational safety and health (International Labour Organization 1981).

Issues in Food and Drug Control

Control of such essential consumer products as food and drugs requires constant vigilance to monitor the safety and nutritional values of foods and the safety, efficacy, and quality of prescription and over-the counter drugs. Public heath agencies are concerned with surveillance of the production and marketing of both food and drugs, with labelling and advertising, and with provision of information to the consumers. Mandatory labelling of sodium content of foods is a form of consumer education. Warning labels and package inserts in pharmaceuticals are an important part of patient education.

Drug regulation begins with establishing and implementing protocols for research on and testing of new drugs and proceeds to evaluation of drugs for safety and efficacy. The process of evaluating animal and clinical data and determining health risks from drug trials may be quite drawn out, so that regulatory agencies may be accused of unreasonable delays in approval of new drugs and of "drug lag." In 1992, perhaps partially impelled by the needs of AIDS patients, the US Food and Drug Administration adopted new regulations to accelerate approval of certain new drugs and biological products for serious or life-threatening conditions, with

provisions for any necessary, continued study of drugs' clinical benefits or with restrictions on use, if necessary (US 1992).

Associated with the drug approval process in the determination of national policy governing the import and export of therapeutic drugs. The multiple national standards on acceptability of different drugs affects the availability of drugs in international trade - an increasingly critical problem in a shrinking world (Cook 1987). Fortunately, in 1975 the World Health Organization established a Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce and regularly disseminates information on drugs and drug quality throughout the world. Revised in 1988, the Scheme provides that a pharmaceutical product is certified by the competent authority of the exporting country that the product is authorized for distribution or sale in the exporting country and that the plant at which the product is manufactured is subject to inspection showing that the manufacturer conforms to requirements for goods practice in manufacture and quality control as recommended by WHO (World Health Assembly 1988). Used of international standards is designed to alleviate problems related to variance in standards among countries.

A major problem on which there is great variation in the laws of different jurisdictions is that relating to product liability and compensation for adverse effects of drugs. The tension existing among the interest of the pharmaceutical industry in marketing new drugs, the interest of the consumer in compensation for damages suffered, and the interest of society in promoting development of pharmaceutical products and assuring their availability has led to varying solutions. These have included, to take the example of the USA, decisions holding the manufacturers strictly liable, with damages assessed according to their share of the market where the supplier of the drug could not be identified (Sindell v. Abbott Laboratories 1980) ; decisions holding a manufacturer liable only for failure to follow state-of-the-art manufacturing practices (Brown v. Superior Court 1988); and, in the case of vaccines, development of a no-fault, federally funded compensation system for untoward outcomes of childhood immunizations (US 1986).

Finally, an increasing important issue relates to regulation of drug prices. The high cost of drugs has led to the use of generic drugs and repeal of laws banning substitution of generic equivalents for brand-name drugs prescribed by the physician (DeMarco 1975). Another strategy for controlling drug costs in health care programs is development of a drug formulary or a list of essential drugs for which reimbursement is provided.

Legal issues in personnel licensure

The issues of scope of practice of health personnel recurs periodically as new types of health workers are introduced in a country, such as pharmacy technicians or acupuncturists, and as strengthened preparation of existing categories of personnel warrants expanded functions, as in the case of professional nurses discussed earlier. In fact, an overriding issue in this field is how allied and auxiliary personnel should be credentialed, whether by a governmental mechanism, such as licensure or some form of officially required registration, or by a voluntary mechanism, such as certification by a professional association.

Another concern is to assure equitable and rational geographic and specialty distribution of health professionals. Some countries, such as Norway and Mexico, require physicians to contribute a period of service in an underserved area as a

condition of licensure. Other countries, such as the USA, use governmental funding for medical education as leverage for specialty distribution and as an economic incentive for settlement in rural areas.

The problem of assuring continuing competence has challenged many countries. Various strategies have been adopted, including voluntary and mandatory educational programs, periodic re-examinations, and further clinical training. But no consensus has been reached on the best way to achieve the objective of updated knowledge and skills.

With the introduction of private medical practice in eastern European countries, new legislation specifies the conditions and rules governing private practice. Bulgaria, for example, requires medical specialists wishing to practice privately in their consulting rooms to register with the municipal council. Their scope of practice is limited: private practitioners are not authorized to perform abortions, to administer required immunizations, or to treat communicable diseases, which must be treated in a public health establishment. Private practitioners may not employ unqualified persons or permit them to work under their name (Bulgaria 1991).

Not only licensing laws but various other regulatory mechanisms affect the qualifications and functions of health personnel. These include the educational system, the policies of professional associations, the regulation of work settings, the requirements of payment programs, and judicial decisions in malpractice suits and other legal cases. While the licensing laws impinge directly on the qualifications and functions of health personnel, indirect influences through the methods of providing and paying for care can also shape the health manpower component of a national health system.

Issues in health-care facility regulation

A critical issue in health facility regulation is the authorized supply of beds, whether in public or private facilities and whether subsidized by public funds or not. Since the supply of beds is a major determinant of hospital utilization rates, under conditions of widespread insurance, the control of this supply is extremely important in the overall issue of health care cost containment (Roemer and Shain 1959).

Implementation of requirements for facility licensure is a prominent issue facing governmental agencies responsible for standards in health-care facilities. Frequent inspections and time-consuming consultations require trained staff, often in short supply. Although licensing statutes provide legal mechanisms for enforcement, less onerous strategies are generally preferred. Particularly in the field of long-term care, where often the need is to upgrade the quality of care, tying standards of the facility to the financing mechanism is increasingly preferred as an effective sanction.

Even when implemented, the standards specified in a licensing law may be minimal standards rather than the most up-to-date requirements for patient care. To take account of the need to encourage higher standards than those required by the hospital licensing law, a voluntary accreditation system has long been established in the USA. The Joint Commission on Accreditation of Health Care Organization surveys periodically hospitals and other health care establishments and accredits those that meet its exigent standards.

Licensure of specialized facilities and services - mammography services and radiological equipments; cardiac surgery units; outpatient surgery, etc.

Issues in communicable disease control

Immunization and other measures to control communicable diseases are so well accepted today that the principal problems in this field are spin-offs from effective immunization: the high cost of vaccines; the question of how to compensate those patients who suffer an untoward outcome of immunization; and providing treatment for tuberculosis in developing countries, now that leprosy is being eradicated (Lamb 1994), and in all countries in a time of AIDS (Bayer et al. 1992). These problems are handled in different fashions by the health and legal systems of each country.

Tension between protection of the public health and protection the civil liberties of individuals is a feature of all communicable disease control. This tension was heightened as measures were developed to control the AIDS epidemic (discussed below). Promptly by this tension, a legal scholar in the USA re-examined the balance between collective and individual rights and found current public health laws in the USA inadequate for dealing with the issues. In order to provide health care officials and agencies with the tools to balance individuals rights against public health necessities, Gostin recommended revising US public health legislation to provide clearly stated criteria for defining "public health necessity" to guide public health officials in the exercise of their powers, to assure strong protections of confidentiality in the collection and storage of public health information, and to authorize a graded series of less restrictive measures than currently exist, such as a community health order that can be adjusted to the particular risk to the public health presented by each case (1986).

Legislation on HIV/AIDS (human immunodeficiency virus/acquired immune deficiency syndrome)

Issues in control of AIDS epidemic

As with other communicable diseases, the tragic epidemic of HIV/AIDS presents the classical public health problem of a conflict between the welfare of the community and the rights of the individual but with significant differences. Like other sexually transmitted and communicable diseases, HIV/AIDS calls for measures to prevent its spread and also for protection of the privacy and other civil rights of persons afflicted with the disease. But HIV/AIDS presents grave and different problems because as yet there is no cure and no vaccine for prevention and because the incidence of HIV/AIDS is concentrated in the USA and some other countries in certain high-risk individuals - homosexuals and intravenous drug users - who are particularly vulnerable to discrimination.

The most controversial issue in the law governing AIDS is the extent to which screening for AIDS--the systematic application of the ELISA test and confirmatory, supplemental tests to specific populations--should be undertaken. While some countries have mandated tests for particular groups, such as prisoners, prostitutes, or immigrants, or even, in some jurisdictions, intravenous drug users or applicants, for a marriage license the weight of authority favors voluntary testing accompanied by counselling for several reasons: (1) it encourages behavior changes and notification of sexual contacts and persons with whom needles have been shared; (2) it facilitates protection of privacy and therefore does not drive those who believe they may be infected to go "underground"; (3) in a low-prevalence population a test with a high degree of sensitivity and specificity, as the serologic tests for HIV antibodies are, will produce a large proportion of false positive responses, causing great anxiety, providing misleading information, and requiring confirmatory tests; (4) in any testing system a certain number of false negatives will occur which give a false sense of security and inhibit behavior changes.

Therefore, the WHO Global AIDS strategy strongly favors voluntary testing, counselling, and protection of confidentiality. Mandatory testing without informed consent has no place in an AIDS prevention and control program, WHO states, because it violates the rights and dignity of individuals and is counterproductive to control of the epidemic (WHO consultation on testing and counselling for HIV infection 1992).

Another issue concerns precautions to prevent the transmission of HIV to health-care workers. The increasing prevalence of HIV increases the risk that health-care workers will be exposed to blood from patients infected with HIV. The US Centers for Disease Control has issued an authoritative document emphasizing the need for health-care workers to consider **all** patients as potentially infected and to adhere rigorously to infection-control precautions. The response to the risk to health-care workers must be universal precautions (US Centers for Disease Control 1987). In 1992, the US Occupational Safety and Health Administration (OSHA) adopted standards mandating universal precautions to protect workers from blood-borne diseases, including the requirement that the employer make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure and follow-up to all employees who have had an exposure incident. These detailed standards provide legal force in the USA to the

recommendations of the Centers for Disease Control (US Code of Federal Regulations 1993, sec. 1910.1030).

From the beginning of the AIDS epidemic the issues of privacy, confidentiality, and protection against discrimination have been prominent concerns. But, as Dr. Stephen Joseph, Commissioner of Health of New York City 1986-1990, points out, AIDS constitutes a public health emergency which carries within it extraordinary civil liberties issues; it is not a civil liberties emergency which carries within it extraordinary public health issues (1992). For this reason, the AIDS epidemic raises a double ethical-legal imperative: to prohibit and punish discrimination in employment, housing, health insurance, public accommodations, government services, and schooling solely because the person has AIDS or is believed to be seropositive and, at the same time, to expand and intensify the response to the public health emergency created by the epidemic.

Privacy and confidentiality in relation to various kinds of health-related data are a very current concern in the United States. State laws differ on protection of privacy and confidentiality with respect to different kinds of data. These include HIV-related information, immunization-related data, public health data, and health care information. Different provisions may govern reporting requirements disclosure regulation, access to records, and penalties for violation of laws and regulations.

Legislation on mental illness

If one were to select a single sector of health services to see the field of health law in microcosm, one should examine health services for the mentally ill. This sector illustrates with particular sharpness the conflict between health needs and legal rights, between protection of the patient and protection of society, and ways to resolve these conflicts.

Interestingly, Israel has enacted a law providing for an order for compulsory ambulatory treatment as an alternative to hospitalization or as a follow-up hospitalization for patients meeting the requirements for involuntary hospitalization. The statute provides a right of appeal from an order for ambulatory treatment just as a right of appeal exists from an order for hospitalization (Israel 1990).

Issues in mental hospital admission laws

The scope of legislation affecting the mentally ill is very broad. It includes laws governing admissions to mental hospitals, standards for mental health facilities and care of patients, organization of community mental health programs, legal protection of the person and property of the mentally ill, the doctrines of the right to treatment and right to treatment in the least restrictive alternative setting, legal aspects of deinstitutionalization, and mental illness and the criminal defendant (Currand and Harding 1978). Clearly, we cannot discuss the many legal aspects of mental illness. Here we shall restrict the discussion to mental hospital admission laws.

With the advent of the tranquilizing drugs, the development of the concept of the open hospital and the therapeutic community and with increased awareness of the civil rights of patients, many jurisdictions have amended their centuries-old statutes governing criteria for hospitalization of the mentally ill. Definitions of who is mentally ill have moved away from vague standards, such as "in need of care and treatment" to more precise standards, such as "dangerous to others," " dangerous to self," and "gravely disabled." In addition to changes in the grounds for

admission, the procedures for admission have been modified to assure prompt and non-traumatic admission to mental hospitals when needed, to require periodic review of the need for continued hospitalization, and to assure prompt discharge as soon as patient is ready.

Many of the old commitment laws, as they were called, resemble criminal proceedings. They required a petition to the court, notice of hearing, representation by counsel, a hearing before a judge, often with a jury trial, testimony by witness, and even sometimes a written opinion by the judge as to the necessity for hospitalization. These laws, it was found, provided only the illusion of due process and actually were adverse to the health needs of patients in many cases for prompt and non-traumatic hospitalization (Association of the Bar of the City of New York 1962). Modern statutes have replaced this legalistic procedure with new administrative mechanisms for protecting both the health needs and the legal rights of mental patients. At the same time, an individual's liberty is at stake in an involuntary admission to a mental hospital, the role of the courts in overseeing the propriety of retaining an individual in a hospital has been strengthened.

The Mental Health Act of 1959, applicable to England and Wales, abolished the judicial order and made compulsory admission, when necessary, a medical matter, requiring two medical opinions, including one from a doctor with special experience (UK 1959). The doctors recommending compulsory detention must specify the grounds for their opinions and state whether alternative methods of dealing with the patient are available and, if so, why they are not appropriate and hospitalization is necessary. The hospital must confirm the need for hospitalization, and on the basis of these three certifications the hospital is authorized to retain the patient for specified time limits. Most importantly, an administrative agency to which the patients and their families have access - the Mental Health Review Tribunal - is established in each hospital region, with power to review the appropriateness of hospitalization and to discharge the patient.

Twenty-four years after passage of the Mental Health Act, in 1983, amendments to the law were adopted to strengthen protection of the civil rights of mental patients (UK 1983). These amendments require, among other things, consent to treatment, assurance of patient rights, such as the right to visitors, to pocket money, etc., and establishment of a Board of Visitors to provide surveillance of the quality of care in mental hospitals.

In the climate of opinion created by new methods of treatment of the mentally ill and new public attitudes towards mental illness, New York State revised its mental hospital admission law after an extensive study which found great variations, inequities, and injustices in the involuntary admission of patients to mental hospitals. The measures intended to protect the rights of patients had become a rubber stamp by the judges of the decisions of doctors (Association of the Bar of the City of New York 1962).

Accordingly, in 1964 the New York State Legislature unanimously passed a new Mental Hygiene Law (New York 1978). It abolished civil judicial certification of an involuntary patient to a mental hospital and provided that the initial admission of an involuntary patient to a mental hospital is a medial matter, on the application of a near relative or other interested person and on the recommendations of two physicians, with the concurrence of the admitting hospital. Immediate and periodic legal reviews of the propriety of hospitalization are required. The rights of the patient are protected by an arm of the court, the Mental Health Information Service, which faces towards the patient and his family to inform them of the

patient's right and alternatives and towards the court to inform it of the patient's condition and alternative treatment resources.

A key feature of both the British and the New York laws is the functioning of a protective structure to provide representation of the patient's interests and needs. Both the British Mental health Review Tribunal and the New York Mental Health Information Service, however, apply only to institutionalized persons.

As deinstitutionalization has increased the numbers of the mentally disabled in the community and many of them have become homeless, recognition has grown of the need for similar protection of noninstitutionalized mentally disabled persons (Association of the Bar of the City of New York 1988). Simon Rosenzweig, who was one of the architects of the New York Mental Hygiene Law of 1964, has proposed establishing an ongoing, continuing legal service for the mentally disabled in the community. Such a service would differ from the service for institutionalized patients in that it would be concered principally with needs for and entitlements to welfare, housing, treatment, including complaints as to treatment modes, access to ambulatory mental health centers, etc. Rosenzweig envisaged a form of "outpatient commitment" that would assure mental health care in the community and comport with constitutional rights to due process (1990).

Modernized mental hospital admission laws reflect the revolution that has occurred in the care of the mentally ill. But not all problems have been resolved. What standard of proof should be required for involuntary hospitalization? Does the patient are a right to treatment? Does she have a right to refuse a particular kind of treatment? What safeguards are afforded for minors deemed in need of mental hospitalization? (Parham v. J.R. et al. 1979). Probably in no field of health law is the conflict between the rights of the individual to liberty and confidential treatment and the right of society to protection from harm so sharp as in the field of mental illness. Resolution of this conflict in various contexts will depend on further advances in psychiatric diagnosis and treatment and on imaginative legal strategies to protect the individual and society.

Issues in laws affecting human reproduction

The turnabout in the law governing birth control and abortion that has occurred in the last two decades all over the world has brought significant public health benefits to women and their families. Deaths from illegal abortion of desperate women faced with unwanted pregnancies have been prevented. Infant mortality and morbidity have been combatted by improved spacing of pregnancies (Maine and McNamara 1985). Many adolescents have been able to defer child-bearing to a time more appropriate for parenting (Paxman and Zuckerman 1987; Roemer 1985).

Still, many problems remain. In many countries where abortion is still illegal or restricted, desperate women faced with unwanted pregnancies are driven to illegal, unsafe abortions. Geographic access to family planning and abortion services is uneven. Financial access is a serious problem where universal financing of health services is not available. The shortage of abortion providers is a barrier to access to service. Required third-party authorization by a spouse or a parent blocks or delay services. Further work is needed to prevent teenage pregnancy by improved sex education in the schools and improved access to contraceptive services and abortion. Constant vigilance is necessary to prevent restrictions in law or practice on the right of women to choose to terminate unwanted pregnancies.

Finally, an unknown element in this field is the impact of the tragic epidemic of AIDS on the use of condoms and on the option of abortion for seropositive women.

Issues in health portions legislation

A number of general issues or recurring questions plague the field of legislation for health promotion. Here are some of them:

1. How should the interest in social control and individual liberty be reconciled?
2. What types of legislative control are acceptable and effective?
3. How do various legislative approaches affect different socioeconomic groups, and are they consistent with our notions of equity?
4. What legislative measures are effective in motivating individuals to change their behavoir? And how do we evaluate them?
5. Who should bear the costs of risk-taking behavior?
6. Are environmental measures available that lessen or eliminate the need for behavioral change?
7. What strategies for implementation of legislation are useful?
8. What is the responsibility of government for the people's health vis a vis powerful commercial interests?
9. How should one legislate in the face of scientific uncertainty?

Ethical issues in public health law

Let us begin this brief discussion of the profound and ever-expanding topic of ethical issues in public health law with some definitions. Ethics is a set of philosophical beliefs and practices concerned with questions of justice, fairness, equity, rights, allocation of resources, and costs. Law is a system of principles and rules devised by organized society for the purpose of controlling human conduct. Law may be described as vital process or group of processes by which people living together in a society meet their common problems and solve them to promote the common good (Christoffel, 1982, p.3; Wing 1985, p.1). Law and ethics converge because both are concerned with rights and duties.

Public health is concerned with ethics because, as Beauchamp points out, (1) public health is concerned not only with explaining the occurrence of disease but also with ameliorating it, and (2) public health is concerned with integrative goals expressing the commitment of the whole people to face the threat of death and disease (1985).

A well-known ethicist in the field of health in the United States, Daniel Callahan, has pointed out that the most significant development in the field of bioethics in the decade from 1970 to 1980 was the development of a closer interface between ethics and regulation (Callahan 1980). Formerly, ethics was discussed in terms of individual choice and personal morality. But we have come to examine ethical issues in terms of their legislative, regulatory, and judicial implications.

For example, Peter Barton Hutt, an eminent US expert in the field of food and drug regulation, has stated that all regulation of food and drugs and of the

environment as a whole has emerged from our collective sense of societal ethic. He specifies the following five moral imperatives of government for its regulatory process (Hutt 1980):

1. to protect the public from harm
2. to preserve maximum individual choice
3. to guarantee meaningful public participation in the decision-making process
4. to promote consistent and dependable rules applicable to everyone
5. to provide prompt decisions on all issues that arise in a regulatory context.

While ethical issues pervade much of governmental regulation of health services, in a few fields ethical issues predominate. These may be described as:

(1) clinical decision-making on life and death issues involving providing medical treatment to severely disabled neonates and continuing life-support measures for terminally ill and comatose patients;

(2) regulation of clinical experimentation;

(3) equitable allocation of all resources for health care, including scarce resources, such as equipment for kidney dialysis or organ transplants;

(4) control of non-coital methods of human reproduction, such as *in vitro* fertilization and surrogate motherhood.

A voluminous literature is available on each of these topics and on many others involving ethical issues (Annas 1984; Annas and Elias 1983; Andrews 1984; Bankowski and Bryant 1985; Bankowski et al. 1989; Capron 1983, 1984; Ladimer and Newman 1963; Reich 1978; Walters 1975; Warnock Committee 1984). It is not possible here to do justice to the complexities involved in any one of these issues. Sensitive and difficult questions are involved, such as the best interests of the child and the family, the length of life and the quality of life, assuring individual integrity and autonomy, protecting confidentiality, equitable distribution of resources, competition for scarce resources, and societal values in individual choice and collective conduct.

Virtually all aspects of the provision of health services, both environmental and personal, have ethical aspects. While in the past there has been tension between the goals of environmentalists and the need for employment, some current thinking in the USA envisages environmental policies that take into account the aspirations of the disadvantages and the need for economic growth. In the 1990s it is possible to adopt industrial processes and agricultural methods, they say, that will provide jobs and assure equity for disadvantages populations. Therefore, environmental protection must proceed simultaneously with occupational health protection (Paehlke and Rosenau 1993).

To see the wide impact of ethical issues on personal health services, one may examine ethical issues in the various components of the health system, as defined Milton Roemer:

In the development of resources, ethical issues are involved in decisions on (1) the numbers and kinds of facilities, (2) the kinds of personnel required and their distribution, (3) the type of research undertaken and financed.

With respect to economic support, the principal ethical issue is the imperative of population coverage--economic access, geographic access, and cultural access. The principle of social insurance and the concept of social solidarity should protect the total population.

With respect to organization of services, the basic ethical issue is the organization and distribution of services in relation to need. Ethical issues in management of health services affect planning, administration, and legislation and regulation. All present ethical choices.

Ethical issues in delivery of care concern allocation of resources and rationing in the face of economic constraints; conflict of interest by providers; and evaluating the quality of care according to principles of equity.

The development of law governing ethical issues has provided guidelines to physicians and has narrowed their sphere for making ethical judgments (Grad 1978). In fact, one of the most significant contributions of the law to this field is its capacity to create procedures and processes to resolve ethical questions in medicine and public health. Ethics committees of hospitals, ombudsmen to resolve disputes, patient advocates, review tribunals to monitor involuntary admissions to mental hospitals, protocols to govern care of the terminally ill, and manuals of procedures developed by the medical and nursing professions are all feasible mechanisms promoted and assisted by the law for resolving ethical issues in health care.

For the "Number One" public health problem in the world - the threat of nuclear war - international law is all-important. No better illustration of law in solving ethical problems can be found than our efforts to achieve international agreements to stop the production and deployment of nuclear armaments and eventually to reduce conventional weapons of war. If we can secure the peace of the world through international law, we can surely solve the other ethical problems in public health.

Conclusion

In conclusion, the basic critical issues in health legislation concern access to health care, financing of care, and quality of care. These issues must be resolved within the legal structure and social and economic system of each country. But much can be gained from examination of the legislation of other counties and comparative legal analysis. In this effort, the resource of the *International Digest of Health Legislation* is invaluable, and on specific questions the office of Health Legislation, headed by Mr. S.S. Fluss, is extreamly helpful and informative.

While the development of health legislation involves many technical and scientific questions, at the end of the day it is a question of political will. Thailand's enactment of very advanced and effective tobacco control legislation is an excellent example of the exercise of political will.

Much as we want effective legislation, we must recognized that legislation is not all-powerful. It is important because it expresses the policy of the government; and often provides resources for health programs. Most importantly, legislation provides leverage for launching and carrying out effective programs of health promotion, disease prevention, environmental protection, and provision of health services.

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In 1993 the Los Angeles County Department of Health Services presented on of the two ***Lester Breslow Awards*** for Distinguished Achievement in Public Health to Ruth Roemer.