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BIOETHICS IN LATIN AMERICA: 1989-1991

I. INTRODUCTION

In our region, bioethics as an academic discipline and a public movement is still in its beginning stages. The historical changes resulting from scientific and technological advances in biomedicine and from the liberal and pluralist character of industrialized countries have barely begun to occur in the developing countries of Latin America, which remain largely "pretechnical" in their orientation. Bioethics as a secular discipline, with its principles of beneficence, autonomy, and justice, and its emphasis on the rational and free agent in the therapeutic relationship, has not yet reached Latin America [5].

Nonetheless, with the dissemination of the new medical technologies (special care, organ transplants, and assisted reproduction) and the advent of democratic governments in the region, public and academic interest in bioethical issues has been stimulated in the 1980s. On the one hand, litigation in medicine has increased, perhaps because of the distance which specialization poses between the professional and the patient; indeed, malpractice and the patient rights movement imitate the "American way" of doing bioethics. On the other hand, there has been an academic resurgence of practical moral and political philosophy which has been applied to medicine according to a pluralistic model of consensus formation, again along the lines of bioethics in the United States [7].

Within this context, it is still too early to expect major developments in bioethics at the governmental and professional levels which this Yearbook surveys. Our region will require a host of legislative and policy responses to the complex realm of today's biomedicine.

This report on major legislation, court rulings, regulatory changes, and policy announcements by governments and professional associations on bioethical topics is based on the search undertaken at our *Centro Nacional de Referencia en Bioetica* for Argentina. Data gathering from other countries of the region posed numerous difficulties, and therefore, unfortunately, the information is fragmentary. Nevertheless, the publications of the Pan-American Health Organization (to which our group has contributed significantly), as well as the regional material gathered in our Center, have been useful for that purpose.

B. Andrew Lustig (Sr. Ed.), Bioethics Yearbook: Volume 2, 83-96.

II. PROFESSIONAL-PATIENT RELATIONSHIP AND HEALTHCARE ETHICS

As with other issues in bioethics, Latin America reveals characteristic tendencies in its approaches to issues of confidentiality, consent to treatment and experimentation, and the notion of a right to health care and its costs. Although it is true that new regulations are appearing both in public policy and in professional guidelines, it is also the case that there is a wide gap between theory and practice in bioethics.

The field of bioethics, born in the United States, has tended to give priority to the principle of autonomy rather than the principle of beneficence. Thus, respect for confidentiality and the requirements of informed consent reflect the priority of autonomy. By contrast, practice in Latin American healthcare and research has tended to emphasize the principle of beneficence.

As a result, relations between medical professionals and patients, as well as health care policies, still exhibit a strongly paternalistic character, despite the ever-growing record of new legislation. If in North America there remains an opposition between theoretical autonomy and practical beneficence, in Latin America there emerges a tension between the priority of beneficence and a principle of justice that theoretically endorses the equal right to health care. Many Latin American societies, because of inadequate social and economic development, are not able to guarantee the right to basic health care.

There is no doubt, however, that recent legislative initiatives, health policy decisions, and updated professional codes are efforts to reduce the distance between beneficent practice and just policies. The paradigm of this transformation has been AIDS, both in its impact on the professional-patient relationship and on health care policy.

Having made these preliminary comments, we will now analyze recent rules concerning the ethical aspects of confidentiality, consent, equal access to health care, and the control of health expenditures.

A. *Confidentiality*

In May 1991 in Argentina, the authorities of La Plata Military District disclosed the results of a blood test among 5,407 adolescents who were to join the Army. One in every 160 persons tested positive for HIV infection. The public disclosure of these results prompted significant public debate. The National Act Number 23.798 on AIDS had been passed in 1990. Article 2 states that the law's provisions are in no case meant to:

> a) affect personal dignity; b) cause discrimination, stigmatization, degradation or humiliation; c) exceed the background of legal exceptions limiting medical secrets....; d) trespass the privacy of any inhabitant of the Argentine Nation; or e) individualize people through cards, records or databases which, for this purpose, [would] be codified [20]

When the above case occurred, this statute was not yet fully in force. Today however, Article Two is viewed as fundamentally safeguarding confidentiality, despite numerous criticisms directed at it.

The protection of confidentiality in AIDS cases has lately been the focus of numerous rules in various Latin American countries. Nevertheless, the situation is not uniform throughout the region. In some countries (Ecuador, El Salvador, Guatemala, Honduras, Nicaragua, Paraguay, the Dominican Republic, and Venezuela), a legislative vacuum exists which is likely to be filled by general legislation calling for compulsory reporting of the disease. Brazil, while emphasizing AIDS education, has also insisted on compulsory reporting without specifically attending to issues of confidentiality [24]. Legislation to protect confidentiality in AIDS cases has been passed in Argentina [20], Bolivia [22], Chile [28], Colombia [29], Costa Rica [30], Haiti [31], Mexico [34], Panama ([36];[37]0, Peru [38], and Uruguay [39].

Bolivia and Peru have paid particular attention to the effects on public opinion of breaches of confidentiality in AIDS cases. These countries have discussed adopting criminal sanctions for those who publish sensationalist material. Argentina and Colombia, in turn, rely on legislation in to safeguard patient confidentiality. We have already commented on the Argentine statute. In Colombia, Article 22 of Decree 559 asserts:

> Epidemiologic information related to HIV infection is confidential. Professional secrecy shall not be ...[an impediment] to providing such information in those cases under legal provisions and regulations [29].

Article 33 of that decree states:

> Health suppliers who know or provide health care to an HIV-infected person, either symptomatic or asymptomatic, are compelled to keep confidentiality of consultation, diagnosis and evolution of the disease. This provision shall also be observed in cases of people with risky sexual behavior whose condition is not seropositive [29].

In the broadest sense, professional codes, and those of medical ethics in particular, have traditionally respected the rule of doctor-patient confidentiality. In recent years, declarations have been adapting that rule to modern technological developments. For example, the "Declaration on Ethics in Medicine" of the Latin American Association of Academies of Medicine (Quito,1983) addressed issues of confidentiality raised by the computerization of clinical records. A second example of new rules is the Brazilian "Code of Medical Ethics" [24]. Section Nine of the Code devotes eight articles to confidentiality in general and to particular issues of confidentiality pertaining to minors and workers.

Of special regional significance is the creation of the National Genetic Data bank in Argentina, formed in the wake of the people who disappeared during the military governments of the late 1970s and early 1980s. The purpose of the

Data Bank is to store genetic information belonging to presumptive relatives in order to identify children through genetic engineering techniques. Despite the crucial importance of confidentiality in these cases, the law which created the Data Bank addresses the issue only briefly in the eighth of ten articles: "The records and files of the National Genetic Data Bank shall be kept inviolable and unalterable..." [17]. The Genetic Databank has so far proved essential in identifying fifty missing children. Yet, given the harmful consequences that could follow if such genetic information is used for other questionable purposes, there is need to guarantee confidentiality ([2];[10];[12].

B. *Consent to Treatment and Experimentation*

On his journey to Colombia, Bolivia, Chile, Argentina, and Brazil in 1990 to inform the PAHO on the state of bioethics in Latin America, the American bioethicist James Drane concluded that review committees for scientific research did not function effectively in any country, nor was informed consent generally obtained from patients or research subjects, despite some existing regulations [2]. Drane thus noted the gap between theory and practice to which we have already referred. This situation has not yet been remedied, although non-governmental organizations are making important efforts[1]. To date, only three Latin American countries have passed regulations on informed consent.

1. *Mexico*

The General Health Law and its Regulation on Health Research are the most relevant rules on the subject ([32];[35]). Less important, although more recent, are "Technical Norm Number 313", which regulates the submission of research proposals and technical reports in health care institutions, and "Technical Norm Number 314", which regulates record keeping and data-gathering in health research ([33];[34]).

Article 465 of the General Health Law imposes in prison sentences of one to eight years on those who perform clinical research on human beings without the written consent of the subject or his agent, the latter defined according to Article 100 of that statute. The punishment levied is more severe in cases involving minors, handicapped persons, the elderly, or prisoners. Article 466 sets penalties for those who perform artificial insemination without woman's consent. Article 324 articulates the need for written and expressed consent in order to procure organs and tissues [32].

Section Two of the Regulation on Health Research discusses "Ethical Aspects of Research on Human Beings". Article 14 of that regulation requires "the written informed consent of the person under research or his proxy". Articles 20-27, in turn, develop at length the concept of and the conditions for informed consent. Articles 29, 36-37, 43, 57-58, and 71, respectively, refer to informed consent for research in communities, for minors or handicapped

persons, for pregnant women, for special populations, and for pharmacological studies [35].

With regard to requirements for the submission of projects and technical research reports in health care institutions, Article 15 of Technical Norm Number 313 emphasizes the need to specify "the way in which ethical precepts will be observed" [33]. Technical Norm Number 324 on record keeping and data gathering in health research sets forth specific requirements for filing information with ethics, research, and biosecurity commissions [34].

2. *Brazil*

The 1988 Code of Medical Ethics forbids physicians to engage in therapeutic experimentation without the consent of the patient or his agent [23]. It also forbids participation in any experiment on human beings for military, political, racial, or eugenic purposes. In addition, Provision Number 1 of the National Health Council discusses the ethical aspects of experimentation by stressing the need for ethics and biosecurity committees and by elaborating the requirements of consent for particular groups [27].

3. *Argentina*

Law number 11044, "The Protection of Persons Involved in Scientific Research", is the first Argentine law to deal broadly with consent [21]. As a provincial statute, it has already encouraged legislative initiatives based on its text, one at a national level and another in the province of Tucuman. According to Article 3, "All research involving study of human beings shall conform to the criteria of respect for their dignity and protection of their rights and welfare". And subsection e of Article 40 states that research involving human subjects requires "the consent of subjects under research or their respective agents through public documents which specifies the risks they face".

The requirement of consent is also emphasized in other articles of the Law. Research subjects are entitled to halt their participation in the research at any time (Article 70). The consent document shall explain "the nature of the procedures the participant will be subject to, eventual risks rising from them, the participant's free choice, and the exclusion of all forms of coercion towards him" (Article 90). In cases involving incompetent persons, consent shall be given "by the agent under authorization of a qualified judge in expeditious lawsuits" (*juicio sumarisimo*) (Article 110). Ethics and research committees are entitled to adjourn any research that may affect the psycho-physical and/or psychosocial well-being of incompetent participants (Article 120). Consent requirements are also specified for pregnant and puerperal women, newborns, fetuses and embryos (Article 140), special populations (Article 220), research where new methods of prevention, diagnosis, treatment, and rehabilitation are studied (Article 240), and pharmacological research (Article 320). Ethics

committees created by this statute (Article 360) shall supervise consent (Article 360).

C. *Equitable Access to Health Care*

The right of equitable access to health care has been proclaimed a human right in Article 25 of the "Universal Declaration of Human Rights", adopted by the United Nations General Assembly on December 10, 1948. In the same year, the Organization of American States (OAS) adopted the "American Declaration of the Rights and Duties of Man", proclaiming (although vaguely) the right to health in Article XI. The "American Convention on Human Rights" (1978), signed by most Latin American countries, promises to gradually achieve full implementation of economic, social and cultural rights, among which there is a right to health, first proclaimed in the "Protocol of Buenos Aires" (OAS, 1967). In this sense, the right of equal access to health care as a "human right" has been elaborated as a matter of international law for more than four decades.

In Latin America, however, the present debate on equitable access to health care exemplifies, once again, the gap between theory and practice. Although different constitutions and statutes in Latin American countries affirm the concept, the conditions necessary to guarantee that the right can be exercised are not always present. Thus, the idea of the "progressive fulfillment" of the right to healthcare relative to the material conditions of each country has developed. In practice, of course, this idea may sometimes be used as an excuse not to fulfill a basic moral obligation. Nonetheless, the statement of norms in the delivery of health care remains fundamental, because norms help to guide the possibilities of effective social transformation. We will now describe various understandings of the right to health care in Latin America.

1. *Argentina*

The Argentine Constitution now in force, which dates from 1853, has no express reference to the right to health care. In Argentine law, the notion of police power presumes that the state has power to limit personal rights in order to protect public health. Policies of various governments, therefore, define the meaning of equal access accordingly. Two national statutes passed in 1989 have set forth a new system of social security and of national health security ([18];[19]).

Law Number 23.660 regulates social security as an important sector of the Argentine health system. The social security organizations are entities constituted by 6 percent of workers' payments charged to employers, with 3 percent charged to workers (Article 16). The purpose is to devote those resources to health services, although other social benefits should be provided for as well (Article 3). Public or private workers and retired workers (Article

8), as well as families and dependents, are compulsorily included as beneficiaries (Article 9). Social security organizations should devote at least 80 percent of their resources to health care. Those with centralized collection of funds should distribute them again according to a principle of solidarity, in order to assure equitable access to health care (Article 5). The organizations are allowed to devote up to 8 percent of their resources to administrative overhead. Social security organizations, as part of the National System of Social Security, are subject to regulative norms (Article 3).

Decree 358/90, which regulates Law Number 23.660, defines "other social benefits" as those not encompassed by the medical coverage regulated by articles 25, 26, 27, and 28 and those concordants of Law Number 23.661, which we will discuss below [14]. According to Article 3 of Law Number 23.660, social security organizations must guarantee the provision of health services according to norms set by the Health Secretary and the Social Security National Administration.

It is clear that Law Number 23.660 and its accompanying Decree are fundamental to the legal framework that assures equal access to health care in Argentina. Nonetheless, the major instrument for this purpose remains the National System of Social Security.

Law Number 23.661 created the National System of Social Security "with the purpose of assuring the full exercise of health to all inhabitants without social, economic, cultural or geographic discrimination" (Article 10) [19]. Its "fundamental aim is to provide for equitable, integral and humanized health provisions, directed to the promotion, protection, recovery and rehabilitation of health, which shall respond at the highest quality available, and which shall assure the beneficiaries [a uniform] level of services, based on a criterion of distributive justice, without any form of discrimination" (Article 20). These social organizations are agents of health security (Article 20). They must conform to Health Ministry policies aimed at coordinating social security, public health services, and private suppliers (Article 3). Security services are supplied according to national health polices based on a strategy of primary health care, decentralized operation, and freedom of choice of suppliers by beneficiaries (Article 25).

Decree Number 359/90, which regulates Law Number 23.661, broadens the concept of equal access [15]. Article 50 of the Decree states that the population shall be classified into categories according to their income levels in order to assure equity.

In Argentina, the main legal framework for egalitarian access to health care is that provided by Laws Number 23.660 and 23.661 ([18];[19]). It is important to note that the present government has proposed a law which would substantially modify this structure by creating freedom of choice in social security independently of the worker's occupation.

2. *Mexico*

The present Mexican constitution dates from 1917 and asserts the social rights posited by the Mexican Revolution. It did not initially include the concept of a right to health care, but a constitutional and amendment in 1983 added that right to Article four:

> Every person has the right to health protection. The law shall define the ways and means to provide access to health services, and shall establish the participation of the Federation and of federal agencies concerning general health, in accordance with the provisions of Paragraph XVI of Article 73 of this Constitution.

The 1984 General Health Law of Mexico, which we have already quoted, is the legislative document which regulates that constitutional right (Article 1) [32]. The National Health System, which assembles private and public sectors and social services, was created to implement the right to health protection (Article 5). This system aims at providing health services to the population and improving the quality of such services (Article 6). The Ministry of Health is in charge of coordinating the system (Article 7) and of promoting full participation of the private and public sectors as well as of social services (Article 10). Health services are classified as medical care, as public health, or as social welfare (Article 24). Expanding the quality and quantity of health services to vulnerable groups is guaranteed as a priority of the system (Article 25). Primary health care is considered to be basic health service (Article 27). The basic table of health operating costs is established (Article 28), and its permanent existence is assured by the Health Secretary (Article 29).

The Health General Law is the most important legal instrument in Mexico for the regulation of equal access to health care[3]. The essential political instrument, however, is the "National Health Program 1990-1994" of the Ministry of Health, which develops the policies required to enforce the Health General Law.

Although we have only analyzed only two countries in the region with regard to issues of access to health care, Argentina and Mexico reveal two different constitutional bases, and a different legislative development based on civil law rather than on common law (as in Canada, The United States, and the British Caribbean).

III. THE BEGINNING OF LIFE

A. *New Reproductive Technologies*

Although ethical principles have generally been observed in the practice of new reproductive technologies, (NRTs) there is no official legislation on the subject. In Argentina, however, the National Government shows increasing interest in responding to the ethical issues raised by NRTs. In 1989, the National Senate

created an interdisciplinary commission to study NRTs in order to produce appropriate legislation. As a result, artificial insemination and in vitro fertilization (IVF) have recently been regulated [13]. The Penal Code adds an article which sets penalties for married women who are artificially inseminated without the consent of their husbands. In the Province of Buenos Aires, Law 11.044 guides "medical practices such as assisted fertilization of proven efficacy in human beings" [21]. Article 5 explicitly refers to informed consent and reads: "Patients will give their written consent on a pre-printed form where the methods and possible risks the proposed treatment may offer [will be listed]..." This same law requires the formation of a Provincial Ethics Committee whose basic function is to advise the Application Authority on the medical practices it oversees.

The situation in Colombia is very similar to the Argentina. According to Sanchez Torres,

> Despite the medical, legal, social, and ethical implications of these new human reproductive procedures, ... the Government of Colombia has not yet issued any standards to regulate their practice. Therefore, in dealing with related ethical issues, Colombian physicians must rely on guidance issued by the World Medical Association, as set forth in Article 54 of Law 23 (1981)... ([8] p. 511).

Recently, Mexico's General Health Law contemplates penalties for those who perform artificial insemination on adult competent women without their consent, or on those who are under age or incompetent ([35], Article 466).

B. *Abortion*

Abortion remains punishable by law in the countries of the region with two exceptions: (1) the so-called "therapeutic" abortion, when the mother's life is in danger and she consents to the abortion; and (2) cases when pregnancy results from rape. In the latter cases, legal actions – by the victim or her legal representative – should be undertaken prior to the abortion. In the last several years, Argentinian legislation has revealed a variety of attitudes with regard to the range of allowable exceptions [4].

IV. ACTIVE EUTHANASIA

Euthanasia finds no support in the law or in codes of medical ethics. The Brazilian Code of Medical Ethics stipulates that "a physician must use all the diagnostic and treatment resources at his disposal on behalf of the patient"; moreover, he should never employ any "means to shorten the patient's life, even at the request of the patient or whoever is legally responsible for him" ([23], Articles 57 and 66). Naturally, the Brazilian Penal Code penalizes homicide, and euthanasia is deemed homicide because it involves the crime of killing someone.

In Peru, controversy has arisen about whether "compassionate murder", *i.e.* euthanasia, would cause more problems than it would solve. Peruvian legislation also remains reluctant to accept "living wills", by which people can freely express their desire to be allowed to die under certain circumstances. It is feared that scarce medical resources and high costs many unduly influence persons to limit their own care. In addition, there is ongoing discussion about the rights of the family to have the physician withdraw artificial life support in such cases as persistent vegetative state. There is also debate about whether it is humane to prolong life artificially, since resuscitation does not imply brain restoration of brain function. However, the Code of Ethics of the Peruvian Medical Association clearly prohibits helping anyone to commit suicide. Passive forms of euthanasia, such as the interruption of nutrition, have also provoked discussion among Peruvian medical professionals.

Argentina still awaits a frank discussion of euthanasia. Nevertheless, the Penal Code was slightly modified to lessen penalties for those who help others, with their consent, to terminate irreversible physical suffering (Article 73).

V. ORGAN DONATION

A. *Determination of Death*

Argentina passed specific legislation on organ transplantation. Law 21.541, promulgated in 1977, not only legalized the procurement and transplantation of organs and tissues (through cadaveric or *inter vivos* donation), but also created a *National Central Unico Coordinador de Ablació e Implanters* (so called since 1990). The impact of bioethics encouraged the adoption of new standards. Article 11 of the law reads:

> The chiefs of the transplant team (...) must give thorough and clear information, ...in accordance with the sociocultural level of each patient, about the ablation and implant risks, sequels, assumed evolution and postsurgical limitations. Once the donor and the recipient have understood the real meaning of the information, [they can proceed] provided they shall make their decision, freely and at will. The fulfillment of these conditions, and the physician's evaluation of the risks of the practice, will be conveniently documented according to the established norms [16].

Article 21 of the law proposes brain death as a criterion. Actually, a person is considered dead when total and irreversible encephalic activity cessation is verified by a physician [16]. The professionals responsible for this verification are a neurologist or neurosurgeon and a clinician, and neither can be a member of the transplant team.

In Colombia, the increase in organ transplantation prompted the Government to take regulatory measures. In the National Health Code, designated as Law 09 of 1979, Title IX regulates "the donation or transfer of organs, tissues, and organic fluids from cadavers or living persons for transplantation and other therapeutic users". In 1986, the Ministry of Health

issued supplemental Decree 2363, which establishes a definition of "brain death". In 1988, the National Congress passed Law 73, which further regulates the procurement and distribution of solid organs and tissues ([8], p. 511).

The criterion of brain death adopted in Argentina has also been adopted by Bolivia, Chile, Ecuador, Panama, and Peru. In some cases, the criterion of irreversible cardiorespiratory arrest is also mentioned. Costa Rica speaks of "properly tested procedures" and "death certified by methods established by the Health and Welfare Secretary", but without specifications. Similarly, Venezuela sets "procedures appropriate" to determine death legally.

B. *Commercialization of Organs and Tissues*

Not all countries in the region have adopted regulations prohibiting commerce in organs and tissues, despite the likelihood that such trafficking will disproportionately burden those who live in poverty. Moreover, the failure to distinguish commerce in organs from compensation of donors for related costs has created a significant legislative and regulatory vacuum. The absence of a legal basis for donor compensation discourages potential donors, frustrates efforts to inform and educate the public about organ donation, and leaves the matter of compensation to private agreements between donors and recipients ([5], pp. 433-434).

VI. CONCLUSION

Within contemporary medicine, areas such as research with human subjects, organ procurement and distribution, assisted reproduction, the rationing of health care, and the foregoing of life sustaining treatment involve complex ethical choices and require explicit rules and formal decision-making procedures. These rules are increasingly institutionalized in statutes, court opinions, administrative standards, and institutional protocols.

Developments that have transformed medicine in developed countries are now occurring in Latin America. As soon as bioethics is institutionalized in Latin America, the reporting and discussion of major bioethical issues will become more accurate. Toward that end, our Center of Bioethics created two important fora to improve bioethics education and information in the region. The first is the Latin American School of Bioethics (*Escuela Latinoamericana de Bioética, ELABE*). The *ELABE* of the *Fundación Mainetti* is an academic project meant to enhance governmental research on bioethics, bioethics teaching, and health policy studies. Its goal is the qualify individuals to take leadership roles in bioethics, developments in their own countries, and to establish a forum for cultural and scientific exchange throughout the region.

The second forum is the *Federation Latinoamerica de Instituaónes de Bioética* (FELAIBE), an ambitious project of transcultural and international cooperation in bioethics meant to develop a regional philosophy of bioethics

which is complementary to Anglo-American approaches[1].

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NOTES

[1] In 1990, the *Escuela Latinoamericana de Bioètica* (Fundación Mainetti, Argentina) organized its First International Seminar on Ethics Committees. This was the first regional effort to train professionals from Colombia, Uruguay, and Paraguay. The antecedent of this seminar in 1989 was a Course on Health Care Ethics Committees with a national scope. In 1991, the *ELABE* organized its second International Course on Health Care Ethics Committees, taught by Professor Stuart Spicker. Hosted in Gonnet (Argentina), the *Federación Latinoamericana de Instituciones de Bioética* was created last December. One of Dr. Spicker's aims is to foster the development of ethics committees in the Region.

[2] A clear example of this is the case of Hospital Moyano in Argentina. Thirty patients died of cold and malnutrition there in June 1990. Some politicians claimed that the deaths were excused by the national financial crisis.

[3] For a complete and updated version of the law with all its Supplements and Technical Norms, see "Ley General de Salud", 60th edition, 1990, Editorial Porrua, Mexico.

[4] See Fuenzalida-Puelma, Hernan L. *et al.* (eds), 1989, *The Right to Health in the Americas. A Comparative Constitutional Study*, Washington, Pan American Health Organization. This text analyses constitutions of all Latin American countries in connection with the right to health.

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