Message From The Guest Editor

A few weeks ago, WAML’s President, Professor Thomas Noguchi, honoured me with the task of guest-editing our quarterly newsletter. At first, it seemed something out of range, given the very restricted deadlines, but in spite of the huge amount of work, it turned out being a very enjoyable work. Pleasant indeed, because of the quality of the articles that were diligently and promptly produced by this edition’s collaborators, most of them active WAML members. To these restless friends, I give my public words of gratitude. This is the first issue of 2011. A year that seems very prominent in the history of our association. There are many activities being developed throughout the world, involving WAML members, increasing our participation in educational projects conferences and congresses, and thus, allowing us to fulfill our mission in developing the concepts of Medical Law.

WAML’s cooperation with other entities has become more evident, and this is probably the way we will find to grow in number and quality in the following years. WAML’s session Schedule for next September in the Madeira Islands, during the 19th Triennial Meeting of the International Academy of Forensic Sciences is one good example of that.

Also, the preparation for the next World Congress on Medical Law, in August 2012, in Maceió, Brazil, is developing faster, with new members being added to the Scientific Committee, and events being prepared in order to offer a wide range of discussion topics and provide our members another great opportunity for networking, academic development and integration.

Please visit the congress’ website at www.2012wcml.com and leave your suggestions and ideas.

Eduardo Dantas
WAML’s Vice-President
President of the 2012’s WCML

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The articles presented in this newsletter express the views of the authors and do not necessarily reflect the attitudes or opinions of the WAML
Transplantation of Organs and Tissues in Portugal: A Successful Case

 André D. Pereira
WAML Governor

The first transplant in Portugal – a kidney transplant from a living donor – took place on 20 July 1969 in Coimbra, by Prof. Linhares Furtado. 10 Europeans die per day in the waiting-list for an organ. The drama of a person suffering from a disease that could have a hope of cure through transplantation may lead some people in a desperate situation to unethical paths. A legal system that contributes to lesser availability of organs is contributing to the traffic of human organs. On the contrary, a legal system that provides for more available organs avoids the horrors of traffic of organs. Portuguese law provides a very generous approach to the collection of organs, both from living persons and from deceased bodies. The statistical results are very good in a comparative perspective. Transplantation from living donors has increased substantially in the last 23 years due to a legal change that opened the possibility of donation of non-renewable organs from outside the genetic family. Since 2007, competent adults can exercise the so-called right to bioethical self-determination in case of donation and removal of non-renewable organs or tissues, so one can donate an organ to any other person, including a non-relative. The law does not even require the “existential proximity” as suggested in the Additional Protocol on Transplantation of Organs (Art. 10). A special Entity of Verification and Admissibility of Collection for Transplantation assures that the consent is free and informed. There is a special rule for foreign citizens without legal residence; in this case the consent is valid only after court authorization (art. 6 (6) Law 22/2007). The system is working well and no abuse has been registered. In 2009 there were 65 donations among living persons. 46 would have been possible according to previous legislation, but 19 were only possible since the new law was in force. From these there were 9 donations from wife to husband, 9 from husband to wife and 1 in a de facto union. That represented an increase of 25% in the donation of organs (kidney and liver) among living persons. An impressive number for a start! Portugal with a population of a little more than 10 million inhabitants has achieved a very good post-mortem donation rate. In 2008 there were 283 donors post mortem, that means 26.7 donors per million inhabitants, and in 2009 there were 329 donors post mortem, that is 31 donors per million inhabitants, the second best in Europe, after Spain. Nationally, it is in the Central area where a higher donation rate is reached: 42.7 donors pmp, higher than the Spanish donation rate (34.3 donors pmp), which ranks 1st in this activity worldwide. The reason for this significant increase is the establishment, in May 2008, of the National Network of Collection of Organs, which provides that in all hospitals with an intensive care unit, there is one responsible doctor for the detection of possible donors. The results are: more donors detected; more organs collected, more transplantation of organs and more lives saved! In order to achieve these positive numbers two legal and ethical controversial issues have been decided. Firstly, Portuguese law accepts brain death as the legal criterion of death and, subsequently, the end of the legal person. On the other hand, the opting-out system (or presumed consent) – that is in force in Portugal – contributes to a higher availability of donors and a higher collection of organs. The law presumes that all citizens, stateless persons and aliens legally residing in the territory, are considered to be, post mortem, potential donors, in case they have not expressed the opposite will before the Ministry of Health. The citizen has the right to refuse, but the refusal must be in writing in a formal declaration at the National Registry of Non-Donors (Decree-Law no. 244/94, of 26 September). There is no discrimination for being a Non-Donor; the Non-Donor has all the rights of other citizens and patients, including the right to access to transplantation medicine. However, the success of a opting-out system depends on some conditions: a) the public opinion must trust the doctors and the medical system; b) different teams perform the collection of organs and the transplantation; c) it only takes place in highly regulated facilities and
with professionals with high ethical standards and above the average salaries.

A “legal transplant” is not possible without taking into account the general social and economic system of the country and the concrete implementation of brain death connected with opting-out system.

If public opinion is not absolutely sure of the high ethical and technical standards of the medical teams involved in the whole procedure, there are no good prospects for implementation of such a system.

The same applies for a very liberal system of donation inter vivos: it will only work properly in societies with good social cohesion, and with unquestionable free, not remunerated, and informed consent of the donor.

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**Educative or Punitive Law in Health care Malpractice?**

The aim of this short article is to provoke a discussion about the social benefit of the current structure of malpractice in healthcare activities.

**The question**

Let’s imagine two hospitals. The first hospital (“Class-A-Hospital”) is a very well managed hospital, it has an effective infection commission and a committee for reviewing medical records; it is accredited by the Health Commission and by ONA, and it has strict control of the quality of doctors working in the hospital, requiring expertise and experience of at least 10 years of work; it has an ongoing training program for all the medical and nursing staff, and it always works with the latest equipment on the market, also very well maintained.

The second hospital (“Class-B-Hospital”) is poorly administered. It has neither an active hospital infection commission nor an effective committee for reviewing medical records; it is not accredited by any institution; it does not have its own medical staff so any doctor can use the hospital for his/her practice; it does not take care of preparing its medical or nursing staff and, ultimately, the equipment is outdated and poorly maintained.

If harm was caused to a patient at Class-A-Hospital and at the same time another and similar harm was caused to another patient at the Class-B-Hospital (e.g., an infection caused by a resistant agent; or an instrument left in the patient’s body; or even an allergy due to the interaction of medication), would both Hospitals be treated by the legislation in the same way? If treated as equals, would it be better or worse for society? Would it be better or worse for the consumer?

**In Brazil**

The Class-A-Hospital and the Class-B-Hospital would be treated absolutely in the same way by the law. Both would be subject to the Federal Law nº.8078/90-Consumer Defense Code (CDC), and both would be required to repair all existing damage, present or future, economic or non economic, based on the idea of protecting the victim. The CDC adopted as a rule (articles 12 and 14) the theory of strict liability (e.g. the existence or absence of fault is irrelevant to liability). The only exception to this rule occurs in case of damage caused by a sole professional (e.g., physician, lawyer, engineer and so on). For them the responsibility would still be fault-based - article 14, § 4º, even though the judge could reverse the burden of proof (article 6º, VIII).

Because of this rule the quality of the hospital involved is irrelevant, as is the quality of the professionals involved, or the efforts made by hospital aiming to eliminate the risks of harm.

Such legal structure, coupled with a easy access to the Courts in Brazil, have brought an enormous pressure and some negative consequence. One of them is the development of a negative feeling that quality of care and high competence will never prevent compensation.

**Changing the actual framework**

It becomes clear that: (i) the actual legal framework does not recognize good behavior; (ii) the idea of giving maximum and unlimited protection to one person (to the offender or to the victim) must change in order to achieve the protection of the two parties (the offender and the victim) from the uncertainties of life and also in order to achieve the protection of the collective interest; and (iii) the idea that social peace could be achieved only based on punishment should be rethought. The es-
tablishment of penalties is not the only way to encourage the practice of good behavior. It could also be achieved through the establishment of benefits for compliance with the law. Benefits could be better for stimulating quality of care or preventive measures, especially when considering that the action takes place on the body of a living person (a complex and unpredictable structure), often in great risk and deserving immediate attention.

**From punishment to education**

The sanctions aim, according to ASCENSÃO, as a rule, to force someone to adopt a behavior that he should have previously adopted, or to return to the existent situation before the rule violation, or to compensate someone for damages arising from the non-observance of the rule, or to punish someone for the rule violation or, even, to prevent future breaches (in, ASCENSÃO, José de Oliveira. Introdução à Ciência do Direito. 3ªEd, RJ: Renovar, 2005, p.58). In this framework the behavior of Class-A-Hospital is irrelevant.

Because of that, REALE (in, REALE, Miguel. Lições Preliminares de Direito. 21ªed, SP: Saraiva, 1994, p.75) defends the use of a more refined technique, “not through intimidating sanctions, but through (...) incentives and rewards,” in what is called positive or premial sanctions. This discussion is not new (see, e.g., Jean-Marie Guyau, in Critique de L’idee de Sanction and Norberto Bobbio in Dalla Struttura alla Funzione) but it is so important that ASCENSÃO, even mentions the existence of a Premial Law (ob cit, p. 58). This technique has wide application in the medical field and would reward those who work with clear dedication and strong effort in order to prevent damage in the course of medical practice.

**Conclusion**

The exclusive defense of the offender or the victim does not represent benefits to the society, it simply shifts the risks of social life from one person to another without considering the benefits of a good behavior for the whole society. An example here: for the society would be better to have hospitals with an effective and active infection commission also taking tight control of medical waste than to condemn this hospital to pay alone an unlimited compensation to a patient due to a possible infection caused by a resistant agent. The effects of this simple change in the way of thinking could be even greater if it were associated with (i) the development of a national compulsory insurance to ensure the indemnification of damages resulting from medical and hospital practice, and (ii) the loss of such insurance protection in case of non-compliance with basic standards of conduct (e.g. minimum quality standards) protective of the patient and society.

**Henrique Freire de Oliveira Souza.**

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**Deconstructing the Myth of the Obligation of Results or the Misalignment of a Legal Precedent**

André Nigre

The development of dentistry since early times is well known, since it introduced the conception of the causality of diseases of the oral cavity, constructing the cornerstones of a scientific approach to dentistry and enunciating the founding ethical principles for the clear-cut relationship between dental surgeon and patient, and between dental professionals. Thanks to the technological and scientific changes and developments that have brought about such a rapid development of dentistry, among other benefits, there are now countless types of equipment for treatment and diagnostic tests that provide a level of precision that is inconceivable to even the most optimistic of minds. Added to this, there are new materials and drugs capable of helping in procedures and improving the prognosis of morbidity in patients.

Today, we are also living in times that are marked by values relating to the physical (bodily health and beauty), which establish the dimension of the individual in the context of the social and professional group, a differentiated status for growth and success, and supersede values that were formerly considered fundamental. With this unceasing quest for beauty, for the modern materials to improve the aesthetics and functionality of the oral cavity and also the discovery of anaesthetics, the dental surgeon has come to be seen, somewhat idealis-
tically, as a professional capable of undertaking his/her tasks without disruption and always providing a totally satisfactory result.

Meanwhile, as scientific and technological advances change people’s daily lives, it becomes necessary, if social chaos is to be eschewed, for the legal system to be adapted and transformed to take account of the speed at which certain legal norms become dated, causing an ever wider gap to open between the social and the legal.

Certain more specific areas have emerged within the science of law in response to this growing need, including biolaw, medical law and dental law, which are faced with the Herculean task of fostering contemporary social harmony. In this context, the judiciary must submit to the subjective legal prescription of dental practice and absolutely reject the dichotomy that existed before the passing of Law 8.078/90.

What are known as dental errors or dental malpractice deserve to be analyzed by all legal practitioners from the perspective of the professional act in its axiological nature, the well-conducted treatment, with a view to achieving the greater good, the patient’s well-being, in the understanding that dentistry is by its very nature ruled by laws of biological probability which, despite demonstrating trends, are not exact. Therefore, errors are inevitably a fundamental part of and intrinsic to human nature. According to Edgar Morin, human nature is associated to the order/disorder which results from its complexity and which resides in the human brain. What separates artificial machines, like computers, from natural machines, which are living beings, is the existence in the latter of disorder, interference and error. In the human species, unlike other species, error serves its own genius and allows, by self-correction, for a permanent reorganization that underlies the complexity and aids the progress of the intelligent species.[1]

A distinction must therefore be drawn between the error that is inseparable from the nature of dental practice and the error in which a direct or indirect violation of ethical, contractual or legal norms can be perceived. The latter is unjustifiable.

If health is seen as physical and psychic well-being, it can be understood that in the vast majority of cases, dentistry is of an intrinsically therapeutic nature, as it gives comfort and satisfaction to patients who have suffered from some functional or physical condition that they found unpleasant and which affected their organism and self-esteem.

If one considers that in all its specializations, the core obligation of dentistry remains the same, based on its intrinsically therapeutic nature, then one can clearly perceive the existence of an obligation of means. Therefore, what is required is for dental surgeons to be duly qualified to carry out their profession, and to act with skill, prudence and diligence before, during and after treatment and surgery, while ensuring that patients are garnered with all the information they require.

An analysis of the Brazilian Code of Ethics for Dentistry shows, with sufficient and incontestable clarity, that the responsibility of dentistry is the same across all its specializations and that there is no distinction in the code in question. By its very nature, the professional act practiced by dental surgeons, irrespective of their specialization, restricts the relationship with the patient to an expectation of the best result achievable. However, as this is not an exact science, there is always the likelihood of the result diverging from what was expected, even in the absence of any lack of skill, imprudence or negligence, because of exogenous and endogenous factors of every manner. In comprehending this, it is hoped that legal practitioners will cast off their outdated, preconceived ideas and accept that the law interacts with the canons of dental science, thereby prevailing over the mistaken belief that the dental surgeon’s obligation can be expressed in terms of an outcome.

The view that should serve as a paradigm – for both material law and procedural law – is that whatever the dental surgeon does, their responsibility must always be judged by the proof of guilt and not against a commitment to achieve a given outcome. The repetition of a legal precedent cannot be accepted it if runs counter to the reality of the progress achieved in dental science and legal science.

What one hopes for at the interface of law and dentistry – both, it should be said, living sciences in a process of
systematic change – is that the practitioners of law will bow to the new technical, legal and scientific understanding and absorb this modern source for the accumulation of deeper knowledge.

**André Nigre**

**Medicine Without Borders – new directive on the application of patient rights in cross-border healthcare**

![Image](image_url)

On 19 January 2011 the European Parliament approved a draft directive on the application of patient rights in cross-border healthcare, codifying extensive case law of the EU Court of Justice as regards transborder access to healthcare services in the EU.

Use of medical services provided in another country than the one in which a patient is insured may be a matter of necessity or choice. Health problems encountered while travelling or medical tourism based on quality or price of medical services create various legal implications. On the one hand, there are issues arising in the country of destination relating to access to medical care such as: whether a foreigner may be treated other than in urgent cases, whether he/she may be treated by both public and private providers, whether he/she should wait in the same queue as nationals, whether and how medical documentation should be transferred to patient’s country of origin etc. In addition, there may also be legal problems in the country of origin, such as the use of prescriptions issued in the country where the service was provided. One particular problem concerns coverage of medical services received abroad by the home country national healthcare system. While on the one hand a national healthcare insurer may be interested in reimbursing costs for treatment in low cost countries, it may not necessarily be as willing when it comes to high cost countries. Trying to avoid the gamble, national healthcare systems establish rules to deal with such issues upfront.

The European Union is premised on the idea of a common market with unfettered freedom of movement of goods, services, workers and capital. Travelling in order to receive treatment in another EU country is certainly in line with this concept. On the other hand, since the very outset of the European Union, the healthcare system was treated (and expressly guaranteed in the founding treaty) as an area of exclusive competence of the member states. Even now, in spite of extensive case law of the Court of Justice treating healthcare services – for the sake of freedom of movement as, in principle, any other services, one of the “constitutional” treaties of the EU - the Treaty on the Functioning of the European Union ("TFEU") - allows the EU only a limited competence in this area, the essence of which is for the EU to complement national policies, encourage cooperation among member states, adopt incentive measures – and this only in selected areas. Solely in limited and expressly enumerated fields is the EU empowered to take further reaching actions. As explicitly stated in the TFEU, the EU is obliged to respect the responsibilities of the member states for the definition of their health policy and for the organization and delivery of health services and medical care, including management of health services and allocation of resources.

In spite of this strict principle, the European Court of Justice (now: the Court of Justice) has for a long time treated healthcare services as any other services falling under the scope of freedom of movement. The issue of particular importance was not necessarily whether patients can be treated in other states (usually this is the case, especially in private practices), but rather - whether the costs of such treatment should be covered by domestic healthcare insurance. Needless to say such costs can be particularly high in the case of healthcare services – and hence a refusal of reimbursement could, in practice, cause a most important hindrance to freedom of movement of healthcare services. The issue was not uncontroversial. It is worthwhile to point out that in the European Union, in principle, healthcare insurance is traditionally (and still - predominantly) public, which means that healthcare does not operate according to market mechanisms (an issue reflected e.g. in no valuation of healthcare risks of a patient entering a scheme and no possibility of rejection based on such a risk) and at the same time that healthcare spending has direct implications for the state budget.
In its case law, the Court delineated conditions under which patients from one member state may go to another member state and a national healthcare insurance may not deny reimbursement of costs incurred by a patient. Those conditions were later laid down in the EU legislation – which was then interpreted broadly (and “extended” to the benefit of a patient) by the Court. One could thus conclude that in the field of healthcare it is the EU legislator who constantly tries to “catch up” with the Court. Divergence of case law from regulation has led to a situation in which transborder healthcare is now regulated by two bodies of rules: a regulation on coordination (first, regulation no. 1408/71, now substituted by regulation no. 883/2004) and case law based on freedom to provide services. The Court is much more generous for patients than EU legislators in terms of requirements which have to be met before a patient may go to another member state and, subsequently, ask for reimbursement from his national system. On the other hand, a system based on coordination is more beneficial to patients when it comes to reimbursement. Based on regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems, patients may seek medical treatment in another EU member state and get reimbursement from a national insurer where (i) a case is urgent (a matter of emergency) or (ii) a patient received prior consent from a national insurer. If any of those conditions is met, a patient shall receive 100% reimbursement (all costs he bore in another member state will be covered). Lack of consent will not be an obstacle to receive reimbursement if a treatment may not be provided to a patient in his / her country of origin in time “acceptable in the light of an objective medical assessment”. The Court of Justice “extended” those situations – basing mostly on freedom to provide services (unsurprising considering the strict wording of the regulation). Namely, the Court distinguished hospital and out-of-hospital (ambulatory) care. Only in the case of hospital care is a patient required to obtain prior consent of a national insurer. As regards out-of-hospital care, no prior consent is required – a patient from Poland may simply go to Germany and ask for reimbursement upon coming back. However, in such a case, reimbursement will not cover the entirety of costs, but only the amount which would be covered by a national insurer had a patient remained in his home country. The rest needs to be paid by a patient himself / herself.

Therefore a system created by the Court is partly more favourable to a patient than the one based on a regulation on coordination (when it comes to conditions for reimbursement), partly less (as regards the scope of reimbursement).

Those two systems function separately and in parallel. A new legislative instrument which has just been adopted by the European Parliament – a directive on the application of patient rights in cross-border healthcare – aims to codify the case law of the Court of Justice issued to date based on freedom to provide services. It will not change much as to the substance when it comes to possibility of receiving treatment abroad – the principles have already been provided by the Court. The very process of enactment and implementation will however without a doubt make this issue more widely known and may thus empower the patients. In addition, it shall provide a basis for recognition of prescriptions in the EU and provide a framework for cooperation of national healthcare assessment bodies.

Natalia Lojko

Allocation of Health Care Resources in the UK - Ethical Dimension

It seems to be uncontroversial that the British National Health Service (NHS) is unable to supply all the demand for health care services. The National Health Service was created in order to provide consistent levels of care, available to all citizens according to their needs. Since the beginning, however, the paucity of resources has been the biggest obstacle to achieving the goals outlined above.

This essay aims to discuss John McKie’s statement that ‘[w]e … live in a society where we allow people to die when it costs too much to save them’. Thus, our explanation will focus on the ethical dimension of healthcare resource allocation.
It was part of the conventional wisdom that providing the whole population with free and comprehensive health care would improve the quality of citizens’ health, and as a result, the demand for health care services would gradually decrease. This assumption has, however, proved to be false. In recent years, governments in the UK have increased spending on health at above the rate of inflation, but the NHS continues to face financial difficulties.

In the debates about the allocation of healthcare resources, the principle of justice is often mentioned. Since there are not enough resources available to offer everyone the quality of care they would desire, how do we determine who to treat?

There are three approaches that try to solve this complex issue. The first one would give priority to those patients with the greatest need. The second one is a merit approach: the greater the citizen’s contribution to society, the greater priority he would have in accessing available resources (QALY calculation is a good example as demonstrated below). And the third approach would consider the basis of equality to deal with.

resources allocation matters.

The Relevance of Needs

The problem about considering needs is to build a sort of hierarchy for them. It means that authorities should determine value judgements about what types of needs are more important than others, such as: life-preserving or life-enhancing needs.

It is worth citing the example of a patient suffering an immediate threat to life. Does this patient need the resources more than a patient who needs a hip operation to enhance his life? It is certainly a tough decision for the authorities to take.

Quality Adjusted Life Years (QALY)

QALY is a calculation designed to determine the cost effectiveness of a proposed course of treatment. It is also a rationing strategy to maximize health gains. According to Jackson, QALY measures the amount and quality of extra-life provided by a particular treatment.

The QALY score will be the difference between two factors (life expectancy and quality of life) before and after treatment. A quality of life scale ranges from 0 (death) to 1.0 (full health).

For example, let us consider that without treatment patient A is deemed to have 2 years of life left, and her quality of life is judged to be 0.5. Then we should multiply life expectancy and quality of life score: 2 x 0.5 = 1. So, before treatment, her life contains 1 QALY. Suppose treatment Y would provide her with 6 years with a quality of life of 1.0: 6 x 1 = 6. Thus, post-treatment, her life contains 6 QALYs. The QALY value of treatment Y is therefore 5 (6 – 1=5).

The next step is to calculate the Cost per QALY.

Let us suppose, for instance, that treatment Y costs £10,000. Given that it provides 5 QALYs, the cost per QALY will be £2,000 (10,000 ÷ 5).

There is a public institution named National Institute for Clinical Excellence (NICE), which was designed to establish uniform standards for health care provision and the QALY calculation is its preferred tool to determine which treatments to fund and which patients to treat.

The principal opponent of the QALY calculation is the philosopher John Harris. In his article ‘It’s not NICE to Discriminate’, he comments on the proposal made by NICE to ban the provision of drugs for the patients suffering from dementia on the grounds that such treatment would not be cost effective. He suggests that the true idea is that ‘the patients’ are not cost effective to society, not the drugs.

Is it ethically justifiable to place a value on human life? The QALY system seems to clearly discriminate against the very ill people and also the elderly ones.

On response to Harris’ article, some representatives of NICE soon provided counter arguments. Claxton and Culver commented that NICE very carefully analyses the interventions undertaken or not in the NHS. They argue that NICE carries out a consultation process with all stakeholders with the purpose of identifying investment priorities. They also advocate that a decision to allocate a finite amount of resources to one patient or to one class of patients is made if that course of action will provide the greatest value for money. NICE is not concerned with the identity of those who benefit or lose out as a result of its decisions. Thus, it will be incidental if some decisions prove disadvantageous for the elderly or chronically ill people, for instance.

Equality

Amy Gutmann argues
that equality of access means that everyone with an equivalent health need should have equivalent access to the available resources.

This approach, however, begs a complicated question (as pointed out by Jackson) “Is an alcoholic who needs a liver transplant ‘like’ a non-drinker with a history of liver disease who has a similarly urgent need for a transplant, or does the patient’s alcoholism turn them into ‘unlike’ cases?”

In conclusion, we shall argue that John Mckie’s statement was brutally honest and true. Regarding this issue, we agree with Professor Emily Jackson’s opinion, as follows: “One thing is certain: there will never be sufficient funds devoted to the NHS to eliminate the need to make tough choices about the allocation of scarce resources. The important questions are therefore not whether to ration treatment within the NHS, but how to do this in the fairest way and who should be charged with making these difficult decisions.”

Ivandro Campos

Mentally Ill Patients and the Autonomy of the Will

Mental illness is a transient or permanent disorder affecting the functioning of the brain mechanism within the individual. Disturbances or irregularities may be caused by various brain diseases such as syphilis, acute infections; traumatic psychosis; or intoxication of psychotropic substances. Other noteworthy brain dysfunctions also include schizophrenia, neurosis and manic depression (among others).

Contributors to changes in human behavior also include: (i) organic disorders such as the physiological alteration of the brain (ex. a smaller frontal cortex) which commonly occurs among schizophrenia patients; (ii) genetic - certain genes induce patients to seek for new emotions (ex. drug addicts) and characteristics that also lead to depression, hostility, impulsivity and anxiety (ex. syndromes caused by mutations of chromosomes 11, 17, 18, 22).

Patients under regular medical care may possess a deviated will when submitted to drugs that alter physical-chemical-psychic components of their bodies. Medical drugs may also be a factor which transform discernment and emotions. In some extreme cases, the perception of reality and personality can be transformed.

Among the legal consequences, mentally ill patients are unable to carry out normal acts of civil life, and thus lead us to the major topic of discussion of this article: the influence on the autonomy of the will of patients who are inserted in this context. Would a mentally ill patient carry the proper autonomy of the will and/or sufficient capacity in order to make coherent decisions?

The answer is based solely by the objective analysis of the patient performed by health professionals (psychologists and psychiatrists) coupled with the proper use of scientific techniques. The patient’s opinion of reality, possession of skills and understanding of self-determination are the key elements of measurement based on their judgment and on a decision making process.

The conclusion will depend on the health of each patient in order to provide a value-judgment. This information will facilitate healthcare professionals in the process of assessing whether the patient will be restricted (or not) to practice the norms of civil life (including acts directly related to the autonomy of his/her will). The inherent madness does not necessarily deprive the person of a judgment / decision making process. However, the level of alienation shall be observed in each case. Situations that do not allow patients to distinguish reality from fantasy, falsity from truth, and other issues affecting their cognitive capacity are elements that may not be rejected in order to respect or regard that person as a human being. Providing this type of patient freedom and dignity are situations that cannot be excluded under any circumstance.

The Brazilian legal system, not only in its constitutional field, but also in the infra-constitutional field offers a level protection to patients with mental disorders. Examples of legislation in this realm can be seen in the Civil Code, Law nr. 10.216/01 and Law nr. 10.708/03. These rights are intended to ensure humanity and respect. Furthermore, benefits
such as (i) the maintenance of their health, (ii) recovery, (iii) social rehabilitation, (iv) protection from any form of abuse, (v) right to the presence of a physician, (vi) guarantee of hospitalization, (vii) information about their disease, (viii) assistance for rehabilitation (ix) among many others may be observed. However, when the need for involuntary treatment or opposing manifestation of his/her will, two important criteria converge into the treatment of patients’ afflicted with mental illness: Ethics and Legality. The hospitalization of this person should occur, for example, when extra-hospital resources are insufficient, without discredit to his/her reintegration into society. Behavioral symptoms such as levels of danger, unpredictability or curability are all factors that shall be observed. Involuntary hospitalization seeks to avoid possible crises, abuses of the mentally ill and also prevent the patient from possible oversights or omissions. Respect for human dignity (exalted in the Universal Declaration of Human Rights of 1948 and, also, a principle widely observed in Western legal systems in democratic countries) is noteworthy. The forced isolation and its legal consequences should be focused towards the recovery of the patient or for protection of collective interaction (protection of public order; “prone to suicidal patients” or absence of conditions “for taking care of ones self”). Even the treatment of involuntary isolation may be bounded by the state due to the parens patriae prerogative.

Still, the autonomy of the will should be observed and praised upon the patient’s dignity. If the patient’s dignity is disregarded, changes in their social behavior may be perceived. In the further pursuit of patient dignity, isolation must be submitted to rigorous planning as should all medical services, health care, occupational therapy and recreation. External control of these treatments is fundamental. Supervision by (i) non-governmental bodies and (ii) prosecutors is needed. Periodically, patients with mental diseases should have their cases reviewed by a team of qualified professionals in order to implement a possible reintegration of the individual into society. Failure to assess the condition of the patient’s treatment (especially when there is a lack of willingness to the treatment and deprivation of freedom) may cause irreversible damage to the patient. To this end, tests should be highlighted and should be obligatorily used. The mentally ill, in the course of their treatment, need to be interviewed. Treatments that seek to overwhelm the patient are unacceptable. Even bereft of his/her expressed will, the treatment should always have an objective to seek and overcome the patients difficulties. The treatment should also pursue the welfare and emotional growth of the patient (emotion - a human feeling that does not depend on the autonomy / discernment of the patient). The search for balance in the subject matter regarding the patient’s duty of care, patient’s freedom, patient’s happiness and patient’s emotions are all challenges to be resolved on a case by case basis with emphasis laying heavily on the respect for human dignity.

In sum, we conclude that the treatment provided to the patient is a determining factor for the preservation of the patient’s welfare. This “welfare” factor is linked to patient clinical evolution as it also is directly linked to the preservation and / or expansion of their power of discernment and self-determination.

Washington Fonseca
Attorney-at-law

Special Educational Projects for Law and Medical Students in Israel

Promoting Interdisciplinary Interactions to Widen the Ethical Perspective and Interprofessional Collaboration and Education

Oren Asman, LLM
Calin Shapira, MD
Noga Ben Sasson
Dorit Shaham, MD

In this section, we would like to present two unique educational initiatives that take place in Israel, involving experts of different fields, collaborating in an educational endeavour to promote ethics based thinking and decision making among professionals and students:

1. The Forum for Health, Ethics and Law - “Legal Clinics” for students of the Zefat College School of Law conducted in collaboration with The Ziv Medical Center in Zefat;
2. Program of Medical Humanities - for Medical School students at the Hebrew University-Hadassah Medical Center, conducted in collaboration with experts from the International Center for Health, Law and Ethics, Haifa University.

1. The Forum for Health,
Ethics and Law (Legal Clinics), Directed by Adv. Oren Asman from the Zefat Academic College School of Law, together with Dr. Calin Sasson, Director of the Ziv Medical Center and Mrs. Noga Ben Sasson, Director of the Ziv Special School and a member of the Hospital’s ethics committee, was formed in 2010 as a pilot project, aiming to promote ethical based thinking related to the clinical setting among health care professionals, law students and jurists.

During their 3rd year of Law school, a selected group of students take part in the course “Legal Clinics”. The students meet at the hospital with health care professionals, exposing them to the dilemmas and uncertainties that hospital staff face daily. The Professionals present real live cases post-facto and share the emotional burden that relates to the medical, ethical and medico-legal issues involved.

These presentations are combined with a lively deliberation which seems to provide all the participants with a wider understanding of the complexity of medical law and medical ethics, illustrating how laws and codes can at times supply insufficient or unclear “solutions” to various conflicts and dilemmas. This year, the following topics are covered: Social Services; Child and adolescent psychiatry; Patients near death; In house hospice (outside the hospital); Child development; Adult Psychiatry; gynecology and obstetrics; Hospital management, and ethics committees.

The project is also intended to increase the overall interest in ethics among the hospital staff. Most of the presenters are senior professionals from different departments. The syllabus was constructed in cooperation with the hospital management which encourages this project and takes an active part in the meetings and the discussions.

For pedagogical reasons, each meeting is followed by a short feedback by the students and the presenters, in order to consider future revisions to the program.

Evaluation (grading) of the students in this project will be based on a written assignment. Each student will write a paper about an ethical or medico-legal issue, basing it also on a personal interview with one of the professionals taking part in the project.

This aim of this academic assignment, supervised by the program directors, is to engage both the Law students and the health care professionals in a collaborative work, promoting a shared discussion and hopefully extending the spectrum of ethical and legal thinking of both jurists and health care professionals.

2. The Program on Medical Humanities

Medical Humanities is an integrated, interdisciplinary approach to recording and interpreting human experiences of illness, disability, and medical intervention, encompassing fields within the arts, humanities, and social sciences. Dr. Dorith Shalam of the Hebrew University – Hadassah Medical School established in 1997 a Medical Humanities program addressing three main concepts: (1) moral reasoning and ethical considerations, (2) professionalism, and (3) the social and cultural context of medicine, each of which is revisited during the entire six years of medical studies, each time on a higher level, according to the concept of a “spiral curriculum”. The courses—encompassing topics applicable to medicine in general as well as subjects of special significance to physicians in Israel—are taught in a combination of frontal lectures, small group discussions, and early clinical exposure, where students in their first year visit medical wards and interview patients.

The course on Medicine and Law, directed by Adv. Naama Wietchn, is taught in the third year and introduces the basic concepts of legal thought and the structure of the legal system in Israel, and then concentrates on the legal domains that have a direct bearing on medical practice, including patient rights and the dying patient. It is intended to provide students with practical legal tools to deal with ethical and legal dilemmas. The course is taught as a combination of lectures and small groups of about 20 students, each of which is moderated by a lawyer/ethicist together with a physician, who provides examples from his/her own clinical experience.

We found these meetings to be quite thought provoking, not only to the students, but also to the physicians and the legal and ethical experts. It provided a unique opportunity to challenge the existing interpretations and understating of ethical-legal dilemmas for both the professionals and the students taking part in this program. These 2 educational projects strive to widen the horizons of students engaging in health related matters, by exposing them to the work and
ways of thinking of professionals of fields other than their future field of work. Law students meet health care professionals and learn about “their way of thinking”. Medical students meet ethicists, lawyers, and professionals of various humanistic fields and learn about “their way of thinking”. To some extent, these project are a part of the global attempt, supported by the WHO, to promote interprofessional Collaboration and Education (See : “Interprofessional Collaboration and Education in Health Care – An Ongoing Project” WAML Newsletter Volume 2 Issue 2 (2010)).

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World Association for Medical Law
Secretary General’s Report

This is my first Secretary-General’s report for 2011 and it is salient to note that the special editor for this issue of the newsletter is Professor Dantas, who is a member of the Board of Governors and a Vice President of the World Association for Medical Law (WAML) and is the President of the Organising Committee for the next World Congress of Medical Law (WCML) to be held in Brazil, in 2012. Professor Dantas is a most valuable member of the WAML and a great ambassador for our principles and practices within health law, legal medicine and bioethics.

In the past, the year between the biennial WCMLs, has been a very quiet time for the WAML. This is not the case in 2011. Already members of the Executive Committee and the Board of Governors have accepted invitations to represent the WAML at a number of co-badged meetings in places such as Kiev, in the Ukraine, and in Portugal. Professor Noguchi, our President, held a meeting in conjunction with the American College of Legal Medicine to espouse the virtues of the WAML. This allows a new level of cross-fertilisation between similar organisations and the WAML that highlights both the similarity and the diversity of the various opinions that are held amongst otherwise like-minded people. The WAML is keen to ensure that we support organisations and meetings which underwrite similar values to those held by the WAML and especially those organised by affiliated bodies.

Over the last few months, I have been in contact with leaders in our fields of legal medicine, encompassing both legal and forensic medicine, health law and bioethics on an almost daily basis. It is very encouraging to see the enthusiasm and breadth of interest that is prevalent amongst colleagues around the world and it is our sincere belief that the WAML has the capacity to draw together such world leaders. We have invited organisations, from around the globe, to become affiliated members of the WAML. To ensure that they can fully experience the rich experience that the WAML has to offer, it was decided, in Zagreb, to have a two-year moratorium on the collecting of organisational fees for affiliated associations. Despite the removal of the need to pay such membership dues, these organisations still will be given the opportunity to nominate a representative to participate in the Council of Presidents, thereby joining other such representatives under the global WAML umbrella to share ideas, experiences and to both gain and give advice. As part of the service provided by the WAML, to assist these affiliated organisations, the WAML has agreed to publicise meetings within the newsletter and to offer a process of cross-fertilisation that benefits all concerned. This is of special benefit to our membership as it highlights meetings around the world that may be of interest and it offers the service of a notice-board to allow further education. It also provides greater access to the expertise within the WAML.

I can advise that our membership is growing, our services are expanding, we are constantly on the lookout for new ways to enhance and enrich that which we offer our members and we welcome any suggestions.
that you, our readers, may offer. I take this belated opportunity to wish all of you a very successful 2011 and to encourage each of you to become more active within the WAML. Should you wish to contribute more, you may contact our administrative officer, Ms Denise McNally, at e-mail address <mcnallyd@cvalley.net>. The aim of the Executive Committee and the Board of Governors is to enhance the inclusive nature of the WAML, for which we need the support and engagement of all of our members.

Roy G. Beran
Secretary General of the World Association for Medical Law

The 18th World Congress on Medical Law

Ksenija Turkovic

The World Association for Medical Law entrusted the Faculty of Law in the University of Zagreb and the Association for Patients’ Rights with the organization of the 18th World Congress on Medical Law and thus recognized their efforts for the development of medical law at home and abroad. The Congress was held from the 8th to 12th August 2010 and included 400 participants from 57 countries from all continents. They debated medicine, law and ethics from the perspective of human rights and the further development of medical law. Besides the Faculty of Law (University of Zagreb), the World Association of Medical Law (WAML) and the Croatian Association for Patients’ Rights, contributions were given to the organization of the Congress by the Medical School (University of Zagreb), the Croatian Ministry of Justice and Croatian Ministry of Health and Social Welfare. The Zagreb Congress was held under the auspices of the Croatian President, Ivo Josipovic, Ph.D., with the wholehearted support of the City of Zagreb.

WAML was founded through the initiative of the Belgian professor, Raphaël Dierkens, in 1967, at the University of Ghent, when the first Congress was held. At the time of its founding, the main objectives of the Association were: stimulation of research and discussion on issues related to medical law; finding possible solutions in a manner consistent with human rights; promotion of the study of consequences of new developments in medicine and allied sciences; detection and response to questions concerning the issue of health rights of the individual; and providing professional and scientific impact on the international level on the basis of choice of professional leadership that will advocate for the development of medical law and related areas. To achieve these objectives, the Association assumed the task of organizing the World Congresses on Medical Law every third year and, since 1994, every second year. The objectives of the Association have expanded since its founding but it still strives towards achieving the health rights of individuals to the fullest extent. Nowadays, the goal of the Association is to encourage the study, and to discuss, issues pertaining to health law, legal and forensic medicine and ethics and their solutions in a way that is beneficial to humanity and human rights. The WAML aim is to promote the study of the legal, ethical and moral dilemmas brought about by rapid development in medicine and health care.

In the past ten years, the number of scientists and experts in the field of health and medical law in Croatia has increased significantly. The number of elective courses covering specific areas of health law has also been growing. In April 2009, the UNESCO Chair in Bioethics Unit and Law was established at the Faculty of Law in Zagreb whose holder is Ksenija Turkovic, Ph.D. The first manual to be used in teaching was published as well. Besides the optional subject «Medicine and Law», which Zvonimir Separovic, Ph.D. first began teaching at the Faculty of Law in Zagreb, the subject «Bioethics and Human Rights», a course in English, will start in the academic year 2011/2012. The holders of the subjects are Ksenija Turkovic, Ph.D. along with teaching assistants Suncana Roksandic Vidlicka and Aleksandar Marsavelski. In addition, a Masters degree in medical law was established at the Faculty of Law, University of Split. The first generation of students enrolled in the academic year 2008/2009. Currently the course for students of the second generation is being held. In practice, Medical Law appears through a system of laws that regulates health care - medical, dental, pharmaceutical, medical biochemistry, nursing, physiotherapy and midwifery activity and other health activities, as well as laws on the provision of health care and health care organization. Representatives of these professions participated...
in this year’s congress in Croatia and are the leading professors and scientists who deal with medical and health law. The 18th World Congress on Medical Law was opened by the Croatian president Ivo Josipovic, Ph.D. in the Crystal Hall of the Westin Hotel. The participants were also welcomed by Milan Bandic, the Mayor of Zagreb, Dr. Ante Zvonimir Golem, Secretary of State for Health in the Ministry of Health and Social Welfare, Zoran Piculjan, MA, State Secretary in the Ministry of Justice; Josip Kregar, Ph.D., the President of the Congress, Zeljko Potočnjak, Ph.D., the Dean of the Faculty of Law in Zagreb, Professor Amnon Carmi, the President of the WAML, Dr. Dula Rusinovic Susnara, MA, Vice President of the WAML; and Ksenija Turkovic, Ph.D., the President of the Scientific Committee of the Congress.

At the opening ceremony, Professor Separovic received a WAML award for the outstanding contribution to the development of medical law at the international level. Professor Separovic founded the subject of medicine and law at the Law Faculty in Zagreb and he has been an active participant in international congresses of medical law at the outset. 436 authors from around the world applied for presentation at the Congress, 400 papers were published in the Book of Proceedings (CD format) and their summaries were published in the Book of Abstracts. Each session or workshop had two leaders, in most cases, one Croatian and one from abroad. Fifty student volunteers from the Faculty of Law and the Faculty of Medicine also played a significant role and contributed to the high quality and the pleasant atmosphere at the Congress. Along with research, the Congress offered a rich social program for participants, which included an introduction to Croatian culture and customs. Mayor Milan Bandic hosted a reception in the Palace of Dverce.

Discussions taking place in the Congress were not only of great importance for scientists and medical experts in law but also a boost for the further development of medical and health law in the Republic of Croatia. Since one of the main themes of the Congress was the organization of health systems in Europe and the world, the meeting was also important for institutions of the health system in Croatia. The main idea of the Zagreb Congress was health as a human right. Topics covered at the Congress were very diverse and their access to treatment was interdisciplinary.

Papers were presented at the plenary sessions (lectures in a large hall with simultaneous translation into four foreign languages), lectures and workshops (workshops). The workshop «Health and asylum seekers - unregistered migrants in Europe» was organized in cooperation with the European Association for Health Law, and a session on mental health with the World Psychiatry Association. At the 18th World Congress on Medical Law, WAML celebrated the 30th Anniversary of the Journal of Law & Medicine in the Aula of the University of Zagreb. Dr. Mohammed Wattad, Ze’fat Academic College in Israel, was elected to be the new Editor-in-Chief. The presentation of the guide of Open Society Institute, New York, was held as well. It was named «Advancing Human Rights in Patient Care, a Guide to Transitional Law in Seven Countries».

During the Congress, numerous meetings of the delegations were conducted. The Israeli delegation was invited to attend a meeting of lawyers, doctors and nurses with representatives of Croatian doctors, lawyers (led by attorney Josip Madaric) and nurses (Ljiljana Lujačic, the legal advisor of the Croatian Chamber of Nurses and Katarina Dugina, President of the Zagreb branch of the Croatian Chamber of Nurses). The meeting was also attended by representatives of the Association of Lawyers in Croatian health care (Snjezana Cerjan, the President, Davor Augustin, the Secretary, and attorney Peter Letica).

A student competition was also held at the Congress. Twenty students from this country and abroad, presented their papers before the jury composed of Anne Marie Duguet, Ph.D., Iris Golder Lang, PhD., Oren Asman and student representative Sergej Vukobratovic. At the end of the competition, the jury awarded three prizes for individual student work and one award for group student work, consisting of a diploma, a cash prize, and one-week and two-week scholarships to any of the seminars, which will be held at the Centre for Advanced Studies (CaaS) in Dubrovnik and the Association de Recherche et de Formation en Droit Médical in Toulouse. A Law student at the University of Toulouse,
Ireh Otihbor Iyioha, won first place for her work, «Public Health, Cultural Norms and Criminal Law: An Inconvenient Union?». Second place went to a student of the Faculty of Philosophy in Zagreb, Vjera Dujic, for her work, «Indicators that Affect in Vitro Fertization in Croatia», and third place went to Helena Peterkova from Charles University in Prague for her work, «Withholding and Withdrawal of Medical Treatment - Czech Medical Law at the Crossroads». Fourth place went to the best group composed of students of the Faculty of Law in Zagreb: Neva Lukin, Andrea Ostric and Vedrana Ravlic, for their work, «Counterfeiting of Medicines».

The organizers of the Congress dedicated special attention to the closing plenary session at which the following spoke: Henriette Roscam Abbing, Ph.D., Faculty of Law, University of Utrecht, Herman Nys, Ph.D., Leuven University, Professor Amnon Carmi, until recently President of the WAML, and Ksenija Turkovic, Ph.D. The theme of the session was «Building and maintaining a health care system that protects human rights» (Building and Maintaining A Human Rights Friendly Health System). The aim of the session was to discuss the necessary conditions for effective protection of human rights in the health care system. The Zagreb Congress will also be remembered for electing a new President of the WAML. Professor Thomas Noguchi succeeded Prof. Amnon Carmi. Professor Noguchi is a prominent forensic expert and teaches at the University of Southern California (USC) and has served as Chief Medical Examiner-Coroner, County of Los Angeles. As the new President of the WAML, Prof. Noguchi was the last speaker at the Congress and spoke in his presentation about the Past and Future of WAML that stated in the coming years he plans to put more emphasis on educational programs in medical law.

At the closing ceremony, the Brazilian delegation announced the 19th World Congress on Medical Law, which will be held from 9th to 13th August 2012 in the city of Maceió. At the meeting of the Board of Governors of the WAML in Zagreb it was decided by vote that the 20th World Congress on Medical Law will be hosted by Indonesia. The Congress was an excellent opportunity for professional and scientific training, the sharing of knowledge, experiences and opinions on a global level for all the participants and it opened the way for new research, as well as more and more intensive international cooperation. We can safely say that the participants of the Zagreb Congress can optimistically anticipate the next World Congress on Medical Law and, in the meantime, transfer knowledge and apply it in their home countries.

References for this article are available from the authors.

Ksenija Turkovic

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**FUTURE MEETINGS**

Of Affiliated National Associations and Collaborating Organizations

**Legal Medicine and Medical Ethics**

Addis Ababa University Faculty of Medicine Auditorium Black Lion (Tikur Anbessa) Hospital Ethiopia

March 24-26, 2011

Contact: James C. Johnston, M.D., J.D., Professor of Neurology
Email: johnstonMDJD@aol.com

**Transplantology: Legal and Ethical Aspects**

April 6, 2011

Azerbaijan

Contact: Dr. Vugar Mammadov
Email: vumammadov@yahoo.com

**Global Perspectives of Ethical Issues in Health System**

May 2-6, 2011

Azerbaijan

Contact: Dr. Vugar Mammadov
Email: vumammadov@yahoo.com

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Celebration – Reception

The 30th Anniversary Publication of the International Journal of Medicine and Law
Vth All-Ukrainian (IVth International) Research and Practice Conference in Medical Law: “Medical Law of Ukraine: Legislative Provision in the Sphere of Health Care (Genesis, International Standards, Development and Improvement Trends)”
May 19 – 21, 2011
Odessa, Ukraine
Contact: Iryna Senyuta prlawlab@ukr.net
Chairman of Organizing Committee, President ANO “Foundation of Medical Law and Bioethics of Ukraine”
Website: www.medicallaw.org.ua

UNESCO Chair in Bioethics
The National/International Meeting of the Chair will be held in Singapore
May 22-30, 2011
Contact: Professor Amnon Carmi
Email: amnoncarmi@gmail.com
Website: www.bioethicsconference2011.com

National Association of Medical Examiners 45th Anniversary Meeting “Controversies in Forensic Pathology” Cruise to Juneau, Sitka, Ketchikan, Hubbard Glacier and British Columbia
August 6 – 13, 2011
Contact: Denise McNally
Email: name@thename.org
Website: www.thename.org

International Association of Forensic Sciences
September 12 – 17, 2011
Madeira, Portugal
Contact: Duarte Nuno Vieira
Email: dnvieira@inml.mj.pt
Website: www.iafs2011.mj.pt

International Symposium on Advances in Legal Medicine (8th ISALM) Combined with the 90th Annual Conference German Society of Legal Medicine.
September – October 1, 2011.
Frankfurt am Main, Germany
Email: isalm2011(at)conventus.de
Website: http://isalm2011.de

Health Care Rationing Conference
December 9 – 10, 2010
Rotterdam, The Netherlands
Contact: Roos van Bemmel
Website: www.erasmusobservatoryonhealthlaw.nl

International Center for Health, Law and Ethics
December 19-20, 2011
Har Haracarmel Hotel, Haifa
Contact: Professor Amnon Carmi
Email: amnoncarmi@gmail.com
ichle@lawmail.haifa.ac.il

WAML Brazil
August 9 -13, 2012
The European Convention on Human Rights and Biomedicine came into force in 1999, almost twenty years after the Council of Europe first called for a pan-European convention on issues in bioethics to harmonize disparate national regulations. The Bioethics Convention is the first such document to have binding force internationally, and is therefore of eminent importance, comparable to the European Convention on Human Rights. The purpose of the Convention is to protect the rights of all human beings in a situation where biomedical technology is developing fast and where possibilities for misconduct are also abundant. Science with its new complexity and its profound effects on all spheres of human life can present either a dark side or a bright side, depending on how it is used. The Convention contains common European standards for the protection of the human person in the context of biomedical sciences. It is expected to fill a lot of the legal vacuum that still surrounds bioethics.

Along with advances of biomedical research, there is a growing awareness and recognition of patients’ rights. What to think about the ambivalent nature of many such advances? Not everything that is now technically possible can be justified on ethical grounds but where to draw the line? For example, as the science of genetics progresses, the protection of privacy takes on a new dimension. The genetic analysis of a simple tissue enables us to discover more and more about the biological make-up of individuals and even of embryos, by providing information on both their current and future health. Protection of those unable to give informed consent is another example. The treatment of mental illnesses has improved considerably but there remains a special responsibility towards these vulnerable patients, as regards the choices to be made between protecting their mental health and respecting their autonomy. The Convention’s starting point is that the interests of human beings must prevail over the interests of science or society. It lays down a series of principles and prohibitions concerning such issues as bioethics, medical research, consent, rights to private life and information, equitable access to health care and professional standards. It deals with different settings, such as emergency situations and clinical research. Special attention is paid to the rights of persons unable to consent. In summary, the content of the Convention is as follows:

All forms of discrimination based on the grounds of a person’s genetic make-up are banned. Predictive genetic tests are allowed only for medical purposes. The treaty allows genetic engineering only for preventive, diagnostic or therapeutic reasons and only where it does not aim to change the genetic make-up of a person’s descendants. The use of
techniques of medically assisted procreation to help choose the sex of a child is prohibited, except where it would avoid a serious hereditary condition.

-The Convention sets out rules related to medical research by including detailed and precise conditions, especially for people who cannot give their consent. The creation of human embryos for research purposes is prohibited.

-The Convention states the principle according to which a person has to give the necessary consent for treatment expressly and in advance, except in emergencies. Such consent may be freely withdrawn at any time. The treatment of persons unable to give their consent, such as children and people with mental illnesses, may be carried out only if it could produce real and direct benefit to his or her health.

-All patients have a right to be informed about their health, including the results of predictive genetic tests. The patient’s right not to know is also recognized.

-The removal of organs and other tissues which cannot be regenerated from people who are not able to give consent is prohibited. The only exception is, under certain conditions, for regenerative tissue (especially bone marrow) between siblings.

-The importance of promoting a public debate and consultation on these questions is recognized. The only restrictions are those prescribed by law and which are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others.

-The European Court of Human Rights may be requested to give advisory opinions on legal questions concerning the interpretation of the Convention. The Convention contains basic provisions, and more detailed provisions are situated in additional protocols that are given on the basis of the Convention. So far, four binding protocols have been given. According to the Protocol on the Prohibition of Cloning Human Beings, all interventions seeking to create a human being genetically identical to another human being are prohibited. The Protocol on Organ and Tissue Transplantation is designed to protect the dignity and identity of everyone and to respect fundamental rights with regard to transplantation of organs and tissues of human origin. The purpose of the Protocol on Biomedical Research is to define and safeguard fundamental rights in biomedical research, in particular of those participating in research. The newest protocol deals with genetic testing.

-The Convention is accompanied by an explanatory report which takes into account the discussions held in the CDBI (Steering Committee on Bioethics) and its Working Group entrusted with the drafting of the Convention; and the remarks and proposals made by member states of the Council of Europe. The report is not an authoritative interpretation of the Convention. Nevertheless, it covers the main issues of the preparatory work and helps to clarifying the object and purpose of the Convention.

The Convention provides minimum protection. This means that a ratifying country may grant stricter protection for its citizens but it may not override these minimum requirements. When ratifying the Convention, a State may make a reservation in respect of a particular provision of the Convention, in case that national legislation is not in conformity with the provision. For example, if a country allows creation of human embryos for research purposes, it may have a reservation on Article 18 prohibiting such practices. If a country ratifies the Convention without reservations, the article becomes binding and the country cannot later take another stand on embryo research without denouncing the Convention. Reservations can later be withdrawn but they cannot be issued later.

By the end of 2008, 34 States had signed and 22 ratified the Convention. Signing the Convention implies the obligation to put the Convention before the national Parliament within a reasonable period of time with a view to ratification. All Scandinavian countries have signed the Convention and Denmark, Norway, Iceland and Finland have also ratified it. Sweden is still preparing its ratification.

It took a long time for the Scandinavian countries to go from signing the Convention to actually ratifying it. This was not due to indifference, rather on the contrary. By tradition, Scandinavian countries have been very meticulous on issues of rules of law. In order to ratify an international treaty, all its requirements must be met in detail. Law must never be on paper only and therefore, provisions can only be laid down if it’s been ascertained that they are fully enforceable. This Newsletter contains reports of three Scandinavian countries – Finland, Sweden, and Norway- and their reactions to the Convention. The Convention contains an enormous amount of difficult ethical and legal issues and it would have been impossible to include discussion on all of those issues in one article. Therefore, choices had to be made. Instead of focusing on the same issues, it was decided to examine different biomedical issues. As a consequence, each of these country reports dealt with a different aspect of ratifying the Convention.

Terhi Hermanson
WAML Guest Editor
Ministerial counsellor
Ministry of Social Affairs and Health Finland
The Bioethics Convention and Finland

Terhi Hermanson  
WAML Guest Editor

Finland ratified the Bioethics Convention in 2010. Along with it, Protocols on the Prohibition of Cloning and on Organ and Tissue Transplantation also were ratified. Already before ratification, Finnish national legislation was in most parts in line with obligations of the Convention and its Protocols. Finland participated actively in the preparation of the treaty system as a member of the Council of Europe. Furthermore, during that preparation of almost 20 years, biomedical legislation in Finland had been altered in order to correspond to the pan European provisions. The Convention resulted in changes especially on the Act on the Status and Rights of Patients, and the Act of Transplantation of Human Organs and Tissues. For example, reproductive cloning - or attempts to create genetically identical humans - was prohibited by making amendments to acts on medical research and on reproductive treatments. Sanctions on illegal interventions on embryos or to the human genome were updated in the Penal Code. In this manner, Finnish national legislation was being developed along with the evolving articles of the Convention. As a result of this, by the time of ratification, Finland was no longer in need of making any further major legislative changes.

The articles of the Convention become directly binding in case there are no national provisions. Some of the Convention provisions do not have specific national counterparts in the Finnish legislature. For example, according to Article 12, predictive genetic tests may be performed only for health purposes or for scientific research linked to health purposes. Finnish insurance companies had made an informal agreement not to require genetic tests when a person applies for health insurance. Until the ratification, this had not been a binding rule. In the future, Finland will prepare national provisions for situations like the example mentioned above. Instead of having to rely on the general provisions of the Convention it is better to have legislation prepared specifically for conditions and culture of a specific country.

Beginning and end of life

Issues on the beginning and end of life have always been subject to very different views due to different belief systems, religions, and cultures. These issues raised such fundamental questions, among parties to the Council of Europe, that during preparation of the Convention it was often difficult to identify a common approach. It would have been impossible to find a common stand on abortion and euthanasia and, however well-intended, the provisions on living wills and research on embryos (Articles 9 and 18) remain somewhat vague.

When does life begin and what is a human being? Does an embryo have legal rights and if so, what if they are in conflict with the mother’s right to her own body? These issues have fundamental meaning, especially from the Catholic perspective. Being mainly Lutheran, Finland has not yet seen a lot of public debate on embryo research. Instead, conditions for terminating a pregnancy are discussed from time to time, and especially what the upper gestational limit should be.

The Council of Europe set up a working party that first aimed at preparing a binding protocol on the protection of the human embryo and foetus. It soon became clear that this was not yet possible and, therefore, the working group settled on a report that presents briefly and impartially the diverse positions that exist on questions related to the protection of the human embryo in vitro, as well as their underlying arguments.

Article 9 states that “previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account.” This wording was drafted very carefully and the Steering Committee on Bioethics (CDBI) spent a lot of time discussing the significance of previously expressed wishes. The Article did not relate solely to emergency situations but also to other cases where the patient had foreseen the possibility of being unable to express his opinion (such as senile dementia). The Committee wanted it to be made clear that the Article did not cover wishes regarding euthanasia or medically assisted suicide. In Finland, greater strength is given to previously expressed wishes than that granted by Article 9. According to Finnish legislation, the patient must not be treated against wishes that he / she has previously expressed. On the other hand, the application of this provision has been restricted by provisions on emergency treatment. There are plans to amend existing legislation in order to give living wills even more strength.

The Convention sets out two principles concerning embryos. It forbids the use of techniques of medically assisted procreation for the purpose of choosing a future child’s sex (except where serious hereditary sex-related disease is to be avoided, Article 14) and the creation of human embryos for research purposes (Article 18). It also
stipulates that, where the law allows research on embryos, it shall ensure adequate protection of the embryo. When Article 18 was being drafted, Dolly the cloned sheep was not yet born. It was not yet possible to clone an embryo by replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of a person (nuclear transfer). The Convention does not take a stand on scientific research using cell lines created by nuclear transfer. The Council of Europe has paid great attention to stem cell research and cloning techniques, but this has took place after the preparatory work on the Convention had been finished.

The Finnish Act on Medical Research prohibits the creation of embryos for research purposes. However, in this act an embryo is defined as a group of cells created by fertilization. Therefore, according to Finnish legislation an embryo created by nuclear transfer is not regarded as an embryo. Finnish legislation is not in conflict with Article 18 since the article does not contain a definition of an embryo. Because of this, Finland did not have to make a reservation in respect of Article 18. When it comes to the issue of nuclear transfer, Finland is not alone other countries are facing a similar situation.

What does ratifying the Convention mean for Finland? For the very moment, in practical terms it does not mean very much since, at the time of ratification, nothing was instantly changed. However, the meaning of the ratification does not lie in the situation of today but it is much more far-reaching. By ratifying, Finland made an informed decision to guarantee the protection set by the Convention and its Protocols, not only for now but also in the future. Finland is committed to abide by this European treaty system and thus join the growing group of States that believe that important ethical principles need to be enforced by binding rules.

Terhi Hermanson
WAML Guest Editor
Ministerial councilor Ministry of Social Affairs and Health Finland

The Implementation of the Bioethics Convention – Challenges from a Norwegian Perspective

Kari Steig

Based on a Government proposal of 13 March 1997, Norway signed the Bioethics Convention 4 April 1997. Furthermore, Norway has also signed two of the four additional protocols – the Protocol on Prohibition of Cloning Human Beings and the Protocol on Biomedical Research.

In order to ratify the Convention, amendments to the national legislation were required and therefore had to be approved by the Norwegian Parliament pursuant to the Norwegian Constitution. Ratification took place on 13 October 2006, and entered into force on 1 February 2007. The Convention and the principles on which it is based had been an important reference in the legal landscape long before formal ratification. To mention one example: In 1999, several important legal reforms were carried out in Norway in order to secure patients’ rights. One of the greatest achievements in this respect was the approval of the Patients’ Rights Act, which entered into force 1 January 2001. According to this Act, patients are, by law, entitled to health care based on equity and without prejudice to social status, gender, sexual orientation and ethnicity. They have the right to receive information and hence the right to give an informed consent, privacy, patient involvement amongst other privileges. These are principles and rights which the Convention also embraces.

Furthermore, regulations concerning application of biotechnology in human medicine, such as genetic testing, the use of pre-implantation genetic diagnosis (PGD), research on embryos and embryonic stem cell research, and prohibition of human cloning had been in place since 1994 as part of the Biotechnology Act. Norway has, since 1972, had a Transplantation Act. This act has been amended several times. As part of the 2001 revision, the prohibition of financial profit from the removal of human organs, tissues and cells was regulated clearly and directly. Even though Norway had not yet ratified the Convention at the time, it is apparent that Article 21 of the Convention was the basis of this provision.

The same revision of 2001 contained another amendment to the Transplantation Act: the regulation on to whom a minor or person, without the capacity to consent, is allowed to donate regenerative tissue. According to the Convention, only the donor’s siblings can receive such donations. According to Norwegian law, the recipients may also be children, parents or, in exceptional cases, other family members. As a part of the debate, it was considered that the principle of mutual interest between close relatives justified the exemption from the free and voluntary consent given by an adult capable of consenting. At that time it was already clear that Norway would have to retain the right to make a reservation to Article 20, paragraph 2, sub-paragraph ii, when ratifying the Convention.

At the time of ratification, the Norwegian Gover-
ment found that the existing legislation fulfilled the Convention’s requirements for the most part. There were two exceptions: the donation of regenerative tissue from minors, which has been discussed above; and the protection of persons without capacity to consent in matters concerning abortion, sterilization and castration.

In order to ensure the legal rights of persons without the capacity to consent, the issue was whether the Abortion Act and the Sterilization Act were in accordance with the Convention. These Acts regulate the criteria on when to carry out an abortion, sterilization or castration – including cases concerning persons incapable of giving consent.

These two Acts were amended when ratifying the Convention but the changes were a codification of existing practice. In other words the existing practice had to be put into legal provisions. According to Article 6, paragraph 1 and Article 26, paragraph 1 of the Convention, medical interventions must be of direct benefit for the person if he or she is without the capacity to give an informed consent. Exceptions to this rule are allowed only when prescribed by law and are necessary in the interest of public safety, for the protection of public health or for the protection of the rights and freedoms of others. Because of this, Norway had to make statutory amendments to both the Abortion Act and the Sterilization Act.

The main principle of the Abortion Act is that the woman herself shall submit a request for termination of pregnancy. In case the woman does not have the capacity to consent, her legal guardian has the right to make the request on her behalf. In such cases the County Governor has to approve the abortion and the abortion must be in the woman’s direct interest. The amendment was a codification of which objectives the County Governor must take into consideration in its assessment. The considerations include: assessment of whether there is a risk that the child could have a serious illness due to conditions such as an inheritable disease; if the mother will be able to take care of the child or not; if the childbirth will lead to unreasonable strain on the mother and so forth. It is important to emphasize that the mere fact that the person has a mental disorder is not a justification or a legal ground for terminating a pregnancy. It will, however, be one of the elements taken into consideration in the overall individual evaluation of whether a woman should terminate her pregnancy or not.

Two other amendments were made to the Sterilization Act. As for abortion, the principal rule is that the request for sterilization or castration shall be submitted by the person himself or herself. In case he or she is incapable of giving consent, the legal guardian may make a request on his/her behalf. The Sterilization Act regulates situations where sterilization is carried out in the best interest of the person and where this is in the best interest of a future child. The provision was considered to be in breach with the Convention’s Article 26, paragraph 1. This is the provision that provides the rationale for allowing sterilization on the basis of the child’s best interest and not the person concerned.

In Norway, either a regional or a national sterilization committee will decide whether the medical procedure shall be carried out or not. In order to fulfill the Convention’s requirements, Norway had to establish, by law, proportionality requirements that would be taken into account when balancing between the intervention and its consequence. The committee can only give its consent if sterilization is the best alternative to avoiding unwanted pregnancies. It is an individual assessment and if use of contraceptives is a realistic alternative this must be taken into consideration. A person without capacity to consent may be castrated on the basis of a request from either the legal guardian or the police commissioner in case there is reason to believe that he will commit a sexual offence due to abnormal sexual instinct. The National Sterilization Council decides whether this intervention shall be carried out. The council is very restrictive in its practice. According to documents from 2005, such an intervention has not been carried out for several years and there is reason to believe that this is still the case.

Norwegian legislation is, to a large extend, already in accordance with several of the additional protocols – even though none are yet ratified by Norway. One example is the Act on Medical Research which became enforceable on 1 July 2009. Many of the principles and provisions in the Protocol on Biomedical Research can be found in the Act on Medical Research – one could even argue that this Protocol has, in reality, been implemented already, long before any formal ratification.

Personally, I believe that it is only a matter of time before any of the other additional protocols will be either signed or, even better, ratified by Norway.

Kari Steig
Adviser/Lawyer
The Norwegian Directorate of Health
On the Road Toward Ratifying the Convention – The Spotlight is on Biobanks and Stremlined Consent

Lena Jönsson

Sweden has signed – but not yet ratified - the European Convention on Human Rights and Biomedicine. The signature has lead to many changes in existing laws and to new legislation. For example, the Act on Biobanks that entered into force in 2003 is proposed to undergo profound changes. Furthermore, provisions on embryo research have been specified; acts on research ethics and genetic integrity now permit research on stem cells from fertilized eggs surplus from in vitro fertilization. The Act on Transplantation and the Patient Data Act are other examples of provisions that are moving Sweden forward and towards implementing the Convention. Sweden has a Scandinavian approach to the question of ratifying an international treaty; all of its requirements must be met to the detail and provisions can only be laid down if it has been ascertained that they can be fully enforced. For Sweden, this means that requirements related to patient rights (Article 3) and patients’ consent (Articles 5-6) remain to be met in full.

Patient rights
A committee was appointed in March 2011 and given the task of improving provisions on patient rights. The first report is to be published no later than June 2012. It will propose measures that would improve the right to health care on equal terms, increase freedom of choice in health care and enhance exchange of information between patients and health care organizations.

Patients’ right to choose a health care provider must be improved. Public health care in Sweden is financed by taxes and in order to contract private alternatives, public procurement is required by each of the twenty regions. Presently, this is a problem in cross-regional care.– Cross-border care (treatment provided in another country) should be even more difficult to solve.

The most crucial issue that prevents Sweden from ratifying the Convention is the requirement for patient consent from patients unable to do so – according to Article 6 of the Convention Consent for mentally incapacitated adults can be given by a legal representative or legal authority. No such institution exists in Sweden and presently this question is “buried” at the Ministry of Justice. The Patient Data Act that came into force in 2008 created a national patient summary, giving all health care organizations electronic access to patient journals. Patients must be given the opportunity to deny their information being made available to other health care organizations. In other words, Sweden has chosen an opt-out solution, i.e., if the patient does not actively object, his or her patient information will be available and can be accessed at the treatment facility, provided that patient’s informed and explicit consent is given in the actual care situation. The requirement for informed and explicit consent does not take into account adults who are not able to give informed consent; the patient’s record cannot be accessed if the patient is mentally incapacitated and the situation is not an emergency. This means that this care-intensive patient group does not have same access to good quality care as do other patients.

Accurate, detailed and accessible patient information is also vital for patient mobility. It is obvious that if the patient is capable of making informed decisions, patient’s access to his/her own pharmaceutical and patient documentation should be as easy as it is for bank customers to access bank statements. From a technical point of view, patients need tools to trans code, translate and decrypt information in cross-border transfer. Legally, this is not a problem – while cross-border electronic access to patient information for health care organizations is technically possible, changes in law are needed in order to allow electronic access to non-Swedish health care organizations. Both methods for making patient information available in cross-border care exclude patients with diminished capacities, unable to consent and those who have no legal means of appointing a legal representative with a right to consent on the their behalf.

Biobanks and patient consent
Among other issues, Sweden is now working on biobanks. They are connected especially with Articles 5, 6, 10, 15 and 17 on consent issues, privacy protection and scientific research. The current Biobanks Act entered into force in 2003, after long debates on donors’ protection of privacy. Since then, patient consent has been required for storage of all tissue samples, regardless of their intended use. There have been no attempts to obtain patients’ consent for samples that were stored before the Act came into force. Therefore the donors - or their families in cases of deceased patients - are not aware that their samples are being stored. Sometimes, supplementary information from patient journals is needed for research purposes. There is a common misconception that the approval of an ethics committee, regarding personal data, allows health care organizations,
as data controllers to give this supplementary patient information from patient records to research projects. This is not the case. The ethics committee decides about how to deal with personal data already in control of the research project – not whether personal data is to be given to the project or not. This decision is to be made by every health care organization as a data controller. This, in turn, may require patient consent, which can cause considerable practical problems, especially if the patient is deceased or unable to consent.

The present requirement to obtain a patient’s explicit consent prior to sample donation is criticized for causing increased administrative costs for the medical system as well as for the research community. Critics claim that if patients are given an opportunity to consent to their samples being taken, they normally choose to do so. Furthermore, patients unable to consent cannot have their samples stored and therefore it is argued that they may not receive best possible care. A hypothetical consent differs from direct consent. In order for passive, silent consent to be a conclusive act, three conditions must be fulfilled: the patient is given information about the procedure; the patient is able to understand it; and he/she does not object to the procedure.

In order to solve problems described above, a new Biobank Act is now proposed and the plan is to have it in force on 1th of January 2012. The purpose of the Act remains unchanged. The issues that have been analyzed are whether:

- the scope of the Act should be expanded in order to include tissue samples also from outside the medical system
- there should be a distinction between different forms of consent
- it should be allowed to register tissue samples in the national biobank registry, and
- the possibility of using tissue samples in criminal investigations should be abolished.

It is proposed that each county council would be responsible for one regional biobank and health care organizations in each county would have to register. This would improve the usability of biobanks since health care personnel and scientists would easily locate patients’ previous sample donations. This would also improve patients’ right to make changes to their consent.

The present requirement is to have an informed and explicit patient consent prior to all collection and storing of samples. The proposal is to replace it by a right to “opt-out” in those cases where samples are collected for the purpose of care and treatment. An explicit consent would still be required for samples collected for research purposes. This would solve the basic conflict between making tissue samples available for care, treatment and research, while ensuring the privacy of the donor. According to the proposal, there are good reasons to assume that donors, in general, feel positive about allowing samples both for care and treatment as well as for research. However, we cannot presume that all donors would have that attitude.

According to the proposal, a tissue sample may be collected and stored in a biobank even if the donor, due to mental illness, weakened state of health or similar circumstances cannot make an informed decision. As a general rule, such samples may only be used for purposes that do not require explicit consent of the donor. The argument is that those not able to consent must have access to good quality care equally with everyone else. However, it is also proposed that such tissue samples may be stored for future research, since otherwise research on people with dementia-related illnesses, for example, would suffer considerably.

Provisions of the Convention will have to be met. The basic rule of Article 6 is that interventions on people not able to consent may only be carried out for their direct benefit. According to Article 17, research on them is allowed only if strict requirements are met.

It is proposed that in certain circumstances it should be possible to release tissue samples from a biobank for the identification of deceased persons and for investigation into paternity or parenthood. Another proposal is that the Genetic Integrity Act be amended in order to give the same protection of privacy to those who donate sperm, regardless of whether they donate for insemination or for in vitro fertilization. A prohibition is proposed to prevent tissue samples in biobanks from being available for use in criminal investigations.

The national Swedish Biobank Registry

A considerable amount of work has also been carried out on establishing the Swedish Biobank Registry and the system will soon be launched. The proposal for a new Biobank Act has weighed the pros and cons of registering all tissue samples to the Swedish Biobank Registry and the conclusion is that benefits outweigh disadvantages. The registry will facilitate patients’ right to self-determination. If the sample is registered in the Swedish Biobank Registry it will be easier for donors to change their decision on whether the sample may continue to be stored.

The ethics committee argues that the basic assumption is that this is best possible care. A hypothetical consent differs from direct consent. In order for passive, silent consent to be a conclusive act, three conditions must be fulfilled: the patient is given information about the procedure; the patient is able to understand it; and he/she does not object to the procedure.

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This is particularly relevant when a donor has given samples in different circumstances, for example at a private clinic, then at a county hospital and then in a highly specialized hospital of another county council. The donor may also have moved and thus given samples in different parts of the country. It cannot be assumed that a donor remembers all the situations where samples were taken for storage at a biobank.

As stated earlier, Sweden will ratify the Convention when all of its requirements are met to the detail. Therefore, the issue of meeting the requirement for patient consent regarding those with diminished capacities must be solved, as well patients’ right to care on equal terms. It is my belief that the issue of embryo research is well covered in Swedish legislation and presently not subject for debate. I also believe that Sweden is quite prepared for a ratification in these areas.

The issue regarding consent of those with diminished capacities is not even on the present political agenda. That means that without supplementary government assignment to the committee appointed to look into patients’ rights we are looking at a timetable beyond 2014. It remains to be seen whether the committee will offer a legislative solution within its time limits that would solve the conflict between public procurement and the patient’s right to choose health care provider. Hopefully there are also other member states with similar problems, enabling us to join forces. After all, this is what the EU is all about – solving problems together for the common good.

Lena Jönsson
Legal advisor
Landstinget Dalarna
Sweden

World Association for Medical Law Secretary General’s Report

The newsletter was originally designed to be an informal vehicle to encourage the exchange of newsworthy material and enhance a collegial rapport amongst WAML members. Dr. Terhi Hermanson, who has a long career of serving the WAML, both as Chair of the Audit Committee and more recently as the Board of Governor’s representative for Finland, was invited to be the guest editor of this latest newsletter.

For those of you who know Terhi, as I believe I do, she is a person of utmost principle and integrity. This is evident in her selection of topics and articles for this edition of the newsletter. In her unique style she has forced the reader to search his/her own conscience and question approaches to research and adoption of new technology. While it has been a specific goal of the newsletter to avoid the depth of articles that would better lend themselves to papers for our journal, Medicine and Law, Terhi has managed to walk that fine line. She has offered a number of articles, which whet the appetite to discover more and to self-appraise bioethics as it affects one’s day-to-day clinical practice and research endeavours. I commend each of you to read these articles carefully and to consider how their content is relevant to what you do in your daily routine. The aim of the WAML is to foster exchange of ideas but it is equally important to motivate self-reflection and personal challenge. I found the content of the articles in this newsletter did that for me. I hope you, our readers, derive equal value from this edition of the newsletter.

It is worth reiterating that the content of articles reflects the views of their authors and do not, necessarily, reflect the established views of the WAML. Obviously we would refuse to publish newsletter content that was diametrically opposed to the WAML ethos but we offer broad ‘poetic licence’ to encourage debate. Healthy debate is the cornerstone of academic appreciation. It is what separates democracy from autocracy. The WAML has taken this forward in other activities, Oren Asman, our webmaster and treasurer, has initiated a new set forums specifically designed for exchange of ideas. Being in the Autumn of my career, I am not a great user of ‘facebook’, ‘twitter’ and other new and enlightened methods of communication. Conversely, Oren is still in his Spring and has created such vehicles for the WAML. I commend those of you who are not as computer illiterate as am I to visit these forums, make yourself heard, give a voice to your views and strengthen the power of the WAML with rich and vibrant exchange of ideas. Talking about exchange of ideas, a number of the WAML stalwarts joined colleagues in Kyiv, Ukraine for another very successful conference. The WAML co-sponsored the meeting with our affiliated organisation and Radmila Hrevtsova sent us great photos to confirm the success of the Second All-Ukraine Congress on Medical Law, Bioethics and Social Policy. She, her organisation and our WAML members who attended are to be congratulated for their efforts to enhance the ethos that is the basis for the WAML and the bonds of friendship which extend from the Association and the Council of Presidents to our affiliated organisations. If you belong to a national or re-
gional organisation, which has not yet taken advantage of the current moratorium on membership fees, NOW IS THE TIME TO JOIN THE COUNCIL OF PRESIDENTS AS AN AFFILIATED ORGANISATION. The WAML is keen to spread its sponsorship to meetings of affiliated organisations and to offer speakers from it pool as well respected experts. All you need to do is to approach us!

As the northern hemisphere moves into the warmer months, we down-under, are entering winter, especially by the time you receive this newsletter. The Australasian College of Legal Medicine (ACLM) is holding its first Annual Scientific Meeting beyond the Australian borders. The meeting is to be held in the picturesque setting of Queenstown, in the New Zealand ski fields, from 12th to 14th August 2011. Any of our WAML family who wish to attend would be most welcome. It will be combined with a formal Expert Witness Training Course, including didactic lectures and a moot to test the veracity of submitted reports. The faculty will have a real WAML flavour with David Collins, our Executive Vice President, and an Honorary ACLM Fellow, topping the guest list. Wearing my dual hats as WAML Secretary General and ACLM President, I would be thrilled to think that members of the WAML family travelled to New Zealand to join us. Just visit the ACLM (Australasian, not American) webpage to find details. Talking South Island of New Zealand, we in the WAML extend our heartfelt sympathy to the sufferers of the Christchurch earthquakes. We do not stop at New Zealand as we think of the victims of the many floods that affected so many parts of Australia, including Queensland, New South Wales, Victoria and Western Australia. If that was not enough, we need to give special thought to the devastation and nuclear catastrophe that impacted on Japan. The tsunami that washed over so much of Japan, with the subsequent effect on the nuclear power stations, will send its ‘ripples’ across the planet.

In the same way that the WAML is a global organisation, so too is our brotherhood and sisterhood that is humankind. What started in the South Pacific, in New Zealand, enveloped much of Australia and then impacted on Japan, in another hemisphere, will ultimately influence all of us, as far away as Scandinavia, which is the focus of this newsletter. I ask each of you to spare a moment for those who have lost so much in these natural disasters, which have of themselves caused man-made disasters. Think about how fortunate you are, how precious life is, how much each of you have to offer and what you can do to help those less fortunate. As a World Association, let us rhetorically join hands and do our utmost to make this a better place. If you can help those who have lost so much – now is the time for action!!

Roy G. Beran
Secretary General of the World Association for Medical Law

The Beginnings of Medical Ethics and Legal Medicine in Ethiopia

The first Ethiopian conference on Medical Ethics and Legal Medicine was held in Addis Ababa March 24-26, 2011. Professor B. Arda, Professor J. Johnston, Dr. D. Paul and Dr. L. Wallstedt covered a broad range of topics including medical ethics, neuroethics, legal medicine, headache, stroke, epilepsy, pediatric ethical issues and brain death. Ethiopia, arguably the most underdeveloped nation on the planet, has a rapidly growing medical community but remains devoid of any formal ethics or legal medicine education, training, services or guidelines. This conference set the stage for future meetings, training courses and curriculum development, all vital to improving the quality of patient care in this otherwise neglected country. Anyone interested in the 2012 conference should contact Professor John- ston at JohnstonMDJD@aol.com.

Professor B. Arda, Professor J. Johnston, Dr. D. Paul and Dr. L. Wallstedt

Message from the WAML President

I would like to thank my many colleagues who have made contributions to the WAML Newsletters as guest editors and authors. This is the third year and starting this year, it carries a list of coming international and national congresses on medical law and bioethics. Priority has been given to those
meetings sponsored or organized by the WAML governors or members. I would also like to express my appreciation to Dr. Richard S. Wilbur, our Editor-in-Chief of the Newsletter, who reviews and edits every article which appears in the Newsletter and to Denise McNally, our Administrative Officer and Time Keeper, who refers the submitted articles to proof readers. When this is done, Raul Vergara, our graphic designer, sets the articles in the newsletter format. Prof. Roy Beran, WAML Secretary General, writes and edits articles and reviews papers, and then authorizes the Newsletter to be released to members.

My sincere appreciation is also extended to all the guest editors for past issues. This coming June’s guest editor, Dr. Terhi Hermanson of Helsinki, has invited authors to submit articles which provide views on bioethics in Scandinavian countries.

September guest editor will be Adv. Maria Pilar Escobar of Paraguay and December guest editor will be Prof. Andre Pereira of Coimbra University, Portugal. For 2012, the March guest editor will be Dr. Mitsuyasu Kurosu, Tokyo Medical University.

Another development is the WAML Cross Fertilization Program. For this year, we are actively reaching out to other national and international organizations for collaboration on programs. The Second All-Ukrainian Congress, organized by Dr. Radmila Hrevtsova, Academy of Advocacy of Ukraine, Institute of Medical Law, Pharmaceutical Law and Bioethics, was held in April. Since, I could not attend personally, I sent a video message. Our Treasurer, Adv. Oren Asman, was able to attend and set up a WAML Membership Service desk. His effort was very successful and the WAML has now received many requests for collaboration.

Prof. Pereira has also recently arranged to have the WAML Program presented in Coimbra University in July 2011 on “The Convention on Human Rights and Biomedicine – updated or outdated?” The WAML Membership Service Desk will be set up similar to the Ukraine Congress.

Prof. Pereira has arranged a WAML two hour Plenary Session on “Ethics, law and forensic science: Global challenges and dilemmas” at the September International Association of Forensic Sciences (IAFS) Meeting in Madeira, Portugal with Prof. Nuno Duarte Vereira, the IAFS President in September 2011.

This effort will hopefully lead to more collaboration among our affiliated national associations and institutes.

Another development is the WAML Administration now actively assisting the WCML Host Organization Committees by providing more standardized World Congress planning. Denise McNally has been working with Adv. Eduar do Dantas, 2012 Congress President and is also working with Prof. Nasser, the host of the 2014 WCML in Bali, Indonesia.

I am happy to report that the WAML is now operating officially as a Not-for-Profit Membership Organization.

Prof. Thomas T. Noguchi
WAML President

The WAML members contributed to the second all-ukrainian congress on Medical Law, Bioethics and Social Policy

On 14-15 April 2011, the Second All-Ukrainian Congress on Medical Law, Bioethics and Social Policy took place in Kyiv. The first was conducted four years ago – on 14-15 April 2007 – as an initiative of the Ukrainian Medical and Legal Association, the Ukrainian Medical Association and the Academy of Advocacy of Ukraine. This time, the Bioethics Committee, at the National Academy of Sciences of Ukraine and the Information Center on Bioethics, joined the organizers as nowadays medical law cannot be developed without paying regard to bioethics. The event was sup-

IN MEMORIAM

PROFESSOR KOICHI BAI

WAML Medalist, Professor Emeritus Koichi Kai passed away in Tokyo, Japan on January 11, 2011. He was 86 years old. He served on the original 1967 WAML Board of Governors for about 20 years, and founded the Japanese Association of Medical Law in 1969. It was my distinct privilege to know Prof. Bai since 1967 and to have met him on many occasions at professional meetings. Prof. Bai was awarded the WAML Medallion (Dierken’s Medal) in August 2006, which was accepted for him by Professor Hirabayashi, since Prof. Bai was not able to attend.

Prof. Thomas T. Noguchi
WAML President

Dr. Radmila Hrevtsova, Adv.
Dr. Zoryana Chernenko
Adv. Andrey Kershis
ported by the Ministry of Health of Ukraine as well as other state organs and non-governmental organizations.

The Congress gathered about 250 representatives of the medical and legal professions from all regions of Ukraine. Contribution of foreign guests who came from Azerbaijan, Bosnia and Herzegovina, Brazil, Israel, Germany, Poland, Russian Federation, the United States of America, Turkey, and Czech Republic was appreciated.

The video message from the President of the World Association for Medical Law Prof. Thomas Noguchi inspired the Congress participants. Adv. Oren Asman, greeted them on behalf of the Executive Committee. The attendees were also pleased to hear the greetings from the National Association for Medical Law of the Russian Federation that has been a long-term partner of the Ukrainian Medical and Legal Association. The importance of the Congress was pointed out by its Honorary Chairperson Prof. Yuri Kundiev and Prof. Tatyana Varfolomeyeva.

The experience of the International Network of the UNESCO Chair in Bioethics, the Ukrainian Unit of which had been established at the Institute of Medical Law, Pharmaceutical Law and Bioethics of the Academy of Advocacy of Ukraine in December 2010, was a notable moment of the Congress. The objectives and results of the UNESCO Chair in Bioethics activities were outlined by Prof. Amnon Carmi, the Holder of the Chair and Honorary president of the WAML. Heads of Azerbaijan and Israeli Units Prof. Vugar Mammadov and Dr. Samuel Wolfman reported the experience of their respective Units.

The achievements in the development of medical law, between the two congresses, were presented. In 2008, the medico-legal community (the Ukrainian Medical and Legal Association, the Academy of Advocacy of Ukraine and the National Medical University) developed the Concept of Development of Medical Law and Health Care Legislation of Ukraine which has been implemented. Medical law is being more actively included in the curricula of law and medical schools.

In 2009, the Ministry of Health of Ukraine approved the Model Program on medical law for medical higher education (authors: V.Moskalenko, T. Gruzeva, R.Hrevtsova, M.Banchuk). Model programs for law schools have been elaborated. Several books and numerous articles on medical law were published. Scientific schools of medical law are being formed in Kyiv, Lviv, Kharkiv, Donetsk. Legal practice on medical and pharmaceutical law is being developed. Seminars and other events aimed at raising qualification of lawyers and doctors on medical law, primarily on its practical aspects have been conducted. The relevant Model Program, for raising professional qualification of advocates, elaborated at the Academy of Advocacy of Ukraine, was approved by the Highest Qualification Commission of Advocacy at the Cabinet of Ministers of Ukraine.

International contacts are being developed. Special attention was paid to the issues that are currently on the agenda for Ukrainian medical law and bioethics. As pointed out in the introductory speech made by the WAML member Dr. Radmila Hrevtsova, a co-chairperson of the Congress organizing and scientific committees, the most important task which needs to be fulfilled with the use of medical law and bioethics is the legislative support for the reforms of the healthcare system, launched in Ukraine. Members of the associations that organized the Congress have started to actively participate in it.

Another challenge is creating proper legal regulation for new biomedical technologies that should be made after their bioethical evaluation. Improvement is needed for law enforcement practice. Further development of medico-lega l and bioethics education is also required. All of the tasks should be performed with regard to international experience. Such experience in many areas was presented by foreign participants at the Congress, particularly by the WAML members. While discussing the ethical and legal grounds for health care reforms, the speakers paid special attention to the issues of accessibility and quality of health care. Their improvement is a core issue of the reforms. Adv. Ondrej Dostal, a lecturer of the Karlov University (Czech Republic) described the achievements and lessons of Czech health care reforms. Polish experience was defined by Dr. Natalia Lojko (Poland), a Governor of the WAML.

It is important to ensure that people are properly supplied with medicinal products. Dr. Samuel Wolfman, continued the discussion of this topic. He devoted his presentation to regulatory, ethical and legal issues of pharmaceutical marketing.

Much attention was paid to searching for a fair balance between the rights of patients and health care professionals whose interests may at times seem opposed. Prof. Vugar Mammadov shared the Azerbaij an experience regarding this issue. Dr. Zoryana Chernenko outlined some important aspects of health care professionals' rights protection. Mrs. Valentina Ocheretenko spoke about the challenges of patients' rights protection. She also suggested starting to prepare the Ethical Code for Patients' Rights Movement.
The speech of Dr. Eduardo Dantas, the WAML Vice-President (Brazil), was devoted to acute problems of ensuring the patients’ right for autonomy. Prof. Sanjin Dekovic the WAML Governor (Bosnia and Herzegovina), focused his attention on medico-legal aspects of a physician’s freedom and accountability in selection of treatment methods. Adv. Oren Asman was a moderator of, and a keynote speaker, at the relevant round table exploring psychiatry and the law. The importance of continuing medical law and bioethics education was proved by the seminar „Teaching Bioethics and Medical Law: Methodological Issues“. Prof. Berna Arda a WAML Vice-President, co-moderated the seminar and shared the relevant Turkish experience. Many burning issues were discussed, not only at the plenary sections and six sessions but also during the teleconference bridges Kyiv-Kharkiv and Kyiv-Lviv. A number of initiatives of the Congress organizers and partners were presented at the event. For example, the Ukrainian Unit of the UNESCO Chair in Bioethics at the Academy of Advocacy of Ukraine together with partner organizations plan to launch two projects aimed at medical law and bioethics education – the first for lawyers and other specialists taking part in creating normative acts in the sphere of health care and the second for lawyers providing legal support to clinical trials. The atmosphere of the gathering was work-related but remained creative and friendly at the same time. The event confirmed the usefulness of sharing experiences from different countries that became possible due to the help of the WAML and the importance of international cooperation.

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As we reach the first half of 2011, next year seems more and more close, and the 2012 WCML Organizing Committee is working hard to present a very special congress to WAML’s members and friends. 2012 will represent an opportunity for WAML to grow and expand, as we prepare the 19th World Congress on Medical Law, in Latin America for the first time.

We’re developing a close partnership with the Latin America Medical Law Association, the Brazilian Federal Council of Medicine and other institutions, in order to offer a wide and memorable academic program during the four days of the event, living up to WAML’s tradition, and strengthening networking and cooperation. Besides, the definitive version of the Congress’ web site will be ready soon, with applications to receive early registration and abstract submission. Suggestions on pre and post congress trips will also be available, creating the environment for a whole set of new experiences.

Recently, during another successful meeting in the Ukraine, some members of WAML and of the Scientific Committee gathered and discussed suggestions received through our web site. Right now, we’d like to invite all WAML members to send us their ideas, contributing to the improvement of our meetings. Working together, we can make it better. Brazil is getting ready to welcome you all.

**Eduardo Dantas**
WAML Vice-President
ANNOUNCEMENT

International Association for Education in Ethics (IAEE):
In April 2011 the IAEE was legally established as an association for scholars interested and involved in ethics teaching. The IAEE will function to enhance exchanges of experiences from experts in the field of ethics from different parts of the world. The IAEE will hold international conferences, exchange and analyze experiences with the teaching of ethics in various educational settings, promote the development of knowledge and methods of ethics education and function as a global centre of contact for experts in this field. The first international conference will take place in May 2012 in Pittsburgh, USA. More information: Center for Healthcare Ethics at Duquesne University, Pittsburgh at www.duq.edu/chce/iaee

FUTURE MEETINGS
Of Affiliated National Associations and Collaborating Organizations

WAML International Symposium: Convention on Human Rights and Biomedicine – updated or outdated?
July 11-12, 2011
University of Coimbra, Portugal
Contact: Prof. Andre Pereira
Email: andreper@fd.uc.p

National Association of Medical Examiners 45th Anniversary Meeting “Controversies in Forensic Pathology” Cruise to Juneau, Sitka, Ketchikan, Hubbard Glacier and British Columbia
August 6 – 13, 2011
Contact: Denise McNally
Email: name@thename.org
Website: www.thename.org

International Association of Forensic Sciences ETHICS, LAW AND FORENSIC SCIENCE: GLOBAL CHALLENGES AND DILEMMAS (WAML Scientific session)
September 12 – 17, 2011
Madeira, Portugal
Contact: Duarte Nuno Vieira
Email: dnvieira@inml.mj.pt • Website: www.iafs2011.mj.pt

Using New Technologies in Medicine and Pharmacy: Ethical and Legal Aspects
October 20-21, 2011
Ukraine, the Crimea, Eupathoria
Contact: Radmila Hrevtsova • Email: imedpharmlaw@gmail.com
Email: radmila.hrevtsova@gmail.com, petrovitte@aol.com

Big Pharma: Principles v. Principles
December 8-9, 2011
Rotterdam, Netherlands
Email: info@erasmusobservatoryonhealthlaw.nl
Contact: Mr. Andre den Exter
Website: www.erasmusobservatoryonhealthlaw.nl

Health Care Rationing Conference
December 9 – 10, 2010
Rotterdam, The Netherlands
Contact: Roos van Bemmel
Website: www.erasmusobservatoryonhealthlaw.nl

International Center for Health, Law and Ethics
December 19-20, 2011
Har Hacarmel Hotel, Haifa
Contact: Professor Amnon Carmi
Email: amnoncarmi@gmail.com • Email: iche@lawmail.haifa.ac.il

Do You Have an Idea, Comment, or Suggestion?

Or You Would Like to Submitt Your Article for Future Issues?

Please contact
Denise McNally
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WAML 2011 Issue 2
Message from the Guest Editor

André Pereira
Guest Editor for WAML

The WAML is a worldwide organization with active members in regional organizations! Founded in 1967 by Prof. Dierkens, the WAML has cooperated with the WHO and the UNESCO in several projects. That’s why we should not ask: “what can the WAML do for me, but what can I do for the WAML!”

Its History, prestige and know-how are priceless! In order to fulfill our ethical and professional duties as scholars, lawyers, doctors and humanists engaged in the rule of law and human rights, the WAML is the right Organization to be engaged in!

The more so as the strength of the WAML comes from its influence in regional networks and research projects. That is what one can detect from reading this newsletter, which I had the honor of editing.

The honor became a real pleasure since distinguished Scholars have sent outstanding contributions. The next few pages offer us an outlook into several regional activities: the vibrant activities of the European Association of Health Law; the stimulating debates of the Réseau Universitaire International de Bioéthique/International Academic Network for Bioethics; the ongoing research on Medical error and Liability systems performed at the Centre for Biomedical Law of the University of Coimbra, the intellectually enjoyable experience of the International Symposium Convention on Human Rights and Biomedicine: updated or outdated; as a second part of the prestigious European Summer Course on Health Law and Bioethics at the University of Toulouse III; and the gigantic research activities in the field of medical liability that are going on around Europe and the world and coordinated in Vienna by ECTIL …

We can also read some particular insights into medical liability reforms in Macau, or the thoughts about deontological duties of medical experts, the Private Autologous Cord Blood Banks, and the Portuguese Medico-legal Organization.

Moreover, this newsletter starts with two new columns: “My Hobby”, where we are delighted to begin with our President, Tom Noguchi (read and learn more about his intense life!) and “Notes on History of Medicine”, this issue is dedicated to History of Pharmacy. I hope you will help us to continue these 2 adventures…

One last word to share my happiness… This year the WAML was especially active in Portugal! (1) the WAML co-sponsored the International Symposium “The Convention on Human Rights and Biomedicine” that took place Coimbra; (2) in September, Prof. Noguchi, Adv. Danatas and myself (together with Prof. Fierro) were invited speakers at the International Association on Forensic Sciences meeting in Funchal and the links with the IAFS are now stronger; (3) in November, Adv. Asman, a well-known expert on Mental Health Law, participated in the
Portuguese Congress of Psychiatry in Coimbra. And next year… intense and hot activities will take place in Brazil! Good reading and See you in Maceió!

André Pereira

**Third European Conference on Health Law**

Under the auspices of the European Association for Health Law, the Centre for Biomedical Ethics and Law of the Catholic University of Leuven organized (as part of celebrating its 25th anniversary) the Third European Conference on Health Law on the 6th and 7th of October 2011. The first two of these conferences were organized in Edinburgh, by the team of Professor Graeme Laurie. Thus, for the first time, the European Conference on Health Law was organized on the European continent, in Belgium. The World Association for Medical Law was also founded in Belgium was in 1970.

The central theme of the Conference in Leuven was ‘AN AGEING EUROPE – HEALTH LAW REVISED’. Europe is facing a trend of demographic and social change that is likely to have a significant impact on its health systems in the coming decades. The primary concerns are related to the double challenge of population ageing and population decline. These changes will result in a shrinking workforce to handle the steadily increasing healthcare needs of the very old, who will constitute the fastest growing segment of the population. Adaptation of European health systems, to the new situation, also makes it necessary to revisit familiar and less familiar health law problems.

The Conference was a great success, with more than 160 participants coming from every place in Europe and other parts of the globe. Scientifically speaking, it was most illuminating with presentations and discussions on themes such as: decision making by advance directives, proxis, guardians; end of life decisions; telecare; telemonitoring; the protection of privacy; access to affordable health care; cross border care; medical experiments with elderly subjects; and access to (private) health insurance. The Conference was preceded by a closed workshop for early career researchers, on the 5th of October, which guaranteed an important participation of young scholars. A lot of them subscribed as members of the Association, guaranteeing it a great future.

The prize for the best poster presentation was won by Michiel Verrinden and his colleagues (Access rules stimulating the exchange of biological specimen within biomedical research).

**Herman Nys**
Vice President of WAML

The Convention on Human Rights and Biomedicine was approved by the Council of Europe, in Oviedo, in April 1997. The Convention regulates biomedical law and aims to establish the harmonization of European human rights and principles. The message is clear: science and technology are just a means to serve the human person and not a goal in themselves. Therefore, law and ethics shall regulate the use of technology and not the other way around. The Oviedo Convention has been correctly called the European Constitution of Medical Law and fourteen years after its approval this international document is of paramount importance in the legal debate in medical law, as more countries ratify it. Currently, 28 countries have done so and France is in the process of ratifying it.

Last 11th and 12th July, an international symposium considering this Convention took place at the Faculty of Law of the University of Coimbra (Portugal). This symposium was organized by Dr. André Pereira of the Centre for Biomedical Law and constituted a second part of the European Summer Course on Health Law and Bioethics of the University of Toulouse – III, organized by Prof. Anne-Marie Duguet. The Executive Committee of the WAML has endorsed and co-sponsored this program and several governors and members of the WAML participated in this symposium. Moreover, President Noguchi gave a speech (by video), introducing the role of the WAML.

The issues that were analyzed and discussed match
the chapters of the Convention on Human Rights and Biomedicine: principles; informed consent; private life and right to information; human genome; assisted reproduction technologies; scientific research; organ and tissue removal from living donors for transplantation purposes; prohibition of financial gain from the disposal of a part of the human body; and infringements of the provisions of the convention. (See: http://www.centrodireitobiomedico.org/files/DESDOBRAVEL.pdf)

The success of the symposium was due to the quality of the speakers, of when 19 were women and 8 were men, including the speakers and chairpersons, there were more than 80 participants. There were participants from more than 10 countries (Portugal, Italy, France, Belgium, Germany, Poland, Czech Republic, Ukraine, Brazil, United States and Mauritius).

The audience was highly motivated. This gives us hope for a strong development of medical law with this enthusiastic group and other young colleagues. One should mention the atmosphere of free thinking and fraternal academic debate, which enabled participants to argue conflicting views about sensitive bioethical issues with tolerance for others. That is, in our opinion, the greatest strength of the University and shall remain so.

The Organizing Committee, after debating with the speakers of the symposium, and the members of the Executive Committee of the WAML, reached the following statement: Final Statement:

1. The Convention on Human Rights and Biomedicine has played a major role in the development of medical law in these last 14 years and is becoming a ius commune in most European countries. Therefore, more ratification procedures of the Convention and its Additional Protocols by State Parties should be encouraged and the continuation of the work concerning development and approval of other Protocols should be supported.

2. The principles of human dignity, integrity of the human person; transparency (of medical treatment and medical research); equity in access to health services; and prohibition of financial gains from sale of the human body or its parts are paramount in European bioethics and should be promoted by the Council of Europe and the State Parties.

3. The Symposium contributions proposed new interpretations and demanded a permanent debate about the coherence of the Convention and the community expectations in the field of bioethics, namely in areas like: assisted reproduction technologies; genetic testing; data protection; living wills; end-of-life decisions; and law enforcement.

4. Public debate of the Convention on Human Rights and Biomedicine ought to be encouraged. Notably, graduate students in law, philosophy, bioethics, medicine, nursing, pharmacy, life sciences and other relevant areas should learn and debate the text of the Oviedo Convention and its additional Protocols. Only through education and debate can there be an informed society and a true democratic choice.

5. The prohibition of financial gains or comparable advantage from the human body should be reaffirmed, notably in the field of surrogate motherhood, donation of organs and tissues and in the area of research with human tissues. In order to clarify the balance between the protection of human beings and the advance of science and technology, an additional Protocol concerning prohibition of financial gains from the human body should be enacted. The human genome, as such, is a “Common Good of Humanity” and should remain intellectual property free.

6. The Council of Europe should promote symposia in order to debate each article of the Convention, with a perspective of each State Party and the means of implementation. A report on the evolution of the implementation should be published regularly and the collaboration of academic institutions should be encouraged for this purpose.

André Pereira
Governor of WAML

RESEARCH PROJETS

Academic Research in Bioethics

Brigitte Feuillet
Professor of Law

This could be the new name for the International Academic Network for Bioethics, the network created in 2007 to assess biomedical practices throughout the world. The life sciences and in particular, biomedical science, have considerably progressed over the decades, to offer a multitude of new treatments. Going beyond its initial therapeutic goal,
medical practice offers the unique opportunity to respond to society’s expectations related to individual personal desires. People are able to access techniques which allow them to have children; to assert their social identity; to decide about their end of life...in all, to respond to suffering instead of merely treating disease. Recourse to medical technologies has become, at least in part, a social and cultural phenomenon.

Despite the unquestionable benefits of such progress, it also brings with it risks for fundamental human rights. It can impact upon the structure of families. Faced with increasing demands, we can observe the emergence of a market of ‘well-being’ medicine. The fundamental problem is to find a way to reconcile individual freedom, based on personal autonomy, with the protection of the human being. Legal norms appear to be one of the best tools to address this goal, even if we rely increasingly on ethical norms to regulate the area of biomedicine. Different cultures respond to the challenges of biomedicine in different ways. Biomedical practices deal with issues related to life, to the human body, to sexuality, to reproduction and to death. There is no single understanding of these concepts: it will depend on individuals, on culture or on religion. If one agrees that the law of different countries translates the different social options, it should be analyzed through the prism of other disciplines, such as anthropology, philosophy, sociology, psychoanalysis and psychology...in order to enable an understanding (and respect of the cultural differences) and to reflect upon a possible (universal?) harmonization.

The International Academic Network for Bioethics, created in 2007 by Brigitte Feuillet, a Professor at Rennes Faculty of Law and Member of the French University Institute, aims to address all of these issues. The network, which brings together universities from countries with many diverse cultures, regularly discusses themes linked to biomedical practice. Issues that have already been addressed include: the anonymity of gamete donors in assisted reproduction (Who is my Genetic Parent? Donor Anonymity and Assisted Reproduction: a Cross-Cultural Perspective, Bruylant, 2011); the extent to which an adolescent’s voice should be heard in clinical procedure (Adolescents and Clinical Procedures); the identity of stakeholders providing support to the terminally ill (Loved ones and the terminally ill to be published in 2012); and whether today’s medicine liberates women or turns their body into a mere tool (The Female body and biomedicine to be published in 2012).

This pluridisciplinary and international approach produced workshops and subsequent publications (in French and then in English) in Bruylant’s (Brussels) Collection on “Law, Bioethics, and Society”.

Some of the network’s members (such as B. Feuillet and G Schamps, Professor at Louvain Faculty of Law, and Director of the Centre for Medical law in Belgium...) regularly attend the meetings of the World Association for Medical Law. This body of research, and the connections between the organisations that carry it out, mean that research into biomedical practice can only improve: something of which we should all be proud.

**Brigitte Feuillet**
Professor of Law

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**Malpractice and European Tort Law**

Here at the Institute for European Tort Law in Vienna the subject of medical malpractice is never far from our minds. Indeed, in 2001 the first publication in our long running Tort and Insurance Law series focused on that particular problem area and it is one that we have come to revisit in two recent works: The first (Medical Liability in Europe: A Comparison of Selected Jurisdictions) focused on updating and expanding on the 2001 volume by investigating malpractice in 13 European states. What is immediately clear in the volume is that, while the basic shape of civil liability structures remain similar in many systems—except for the ‘tort only’ approach in England. These play out within a wide range of healthcare, social security and compensation regimens, arguably putting the lie to any degree of utility in looking abroad for better solutions while providing much by way of interesting com-
Some features of the malpractice action in Europe are universal: the difficulties surrounding situations of uncertain causation, which are as obvious in the no-fault regimes of Scandinavia as they are in many others. The desire to focus primarily on a civil remedy, consigns the criminal law to the most flagrantly injurious results of medical treatment. The gap between professional regulation and legal sanction remain in many systems, attesting to the continuing sense of separation between a practitioner’s right to ply his/her trade and a patient’s right not to be negligently injured.

Some features are more specific and it is this specificity that is often the most interesting area of development in a system. Increasingly medical error is co-opted within focused schemes. These are often designed (as in the case of France, Belgium and soon Poland) to provide compensation and remove the stigma of fault from proceedings or (as in the case of Austria and Germany) to provide access to trustworthy, expert arbitration between the parties. Thus they provide, at the very least, a stronger bargaining position with social insurance carriers. Differences in procedure are to be expected, with the various standards (and the burdens) of proof across Europe. This produces a varied set of hurdles for the patient throughout the continent. Perhaps most interesting for the coming decade is the news that some European systems, such as in the Czech Republic, are on the cusp of introducing dedicated provisions regarding the treatment contract in the forthcoming draft code. Similar issues have been raised recently in Germany.

European harmonization remains an unlikely possibility in this field, due to the many varied healthcare systems within the Union. In the context of free movement, one must wonder just how well this continued fracturing serves patients, particularly those who choose to go abroad for their treatment.

The second work (Medical Malpractice and Compensation in Global Perspective, forthcoming 2012) was part of collaboration with the Chicago-Kent Law Review. It was drawn from a conference in Vienna, in December 2010. It cast a wider net by putting the problem of malpractice and compensation in a truly global perspective. Among the countries included in this survey (alongside European stalwarts like France, England and Germany) are China, the United States, Japan, and New Zealand. Here, a number of themes emerged:

There are a wide range of legal models applied to the doctor-patient relationship. The traditional, incrementally developed, models, found in many European systems, stand in stark contrast to the codification of the medical relationship within the consumer defence code in Brazil or the explicit emphasis placed on the role of socio-economic rights to medical treatment in South Africa.

A global approach demonstrates the role that improving patient safety and error reporting measures can have in influencing both the frequency and tenor of malpractice actions. Particularly in Japan where, following a spike in the historically low levels of malpractice actions, a programme of peer review and public reporting of error appears to have contributed to lowering litigation rates and improving care successfully over a relatively short period.

Unlike the recent tendency towards compensation schemes, visible in some European states, the same pattern does not seem to be replicated on a global scale. Aside from the scheme in place in New Zealand since the 1970s, which replaced tort law entirely for all accidents, not simply malpractice, there is little evidence of any attempt to take fault out of the liability equation.

Perhaps the most interesting finding of this project has been the recent codification of the rules surrounding the malpractice in China within the context of wider tort reforms. Though not without flaws, this model represents an interesting and modern approach to malpractice that could be useful for other states seeking to codify a separate body of rules in this area.

These studies both remind the reader of the tension between treating malpractice as its own, sui generis form of liability and its place within the general liability systems in a state. Many problems often result from the latter while the former represents a modern, minority approach. The Institute is currently planning a comparative study into liability in situations of financial scarcity. In times of straining healthcare budgets, this area will undoubtedly be the cause of much future litigation and, as such, is ripe for further investigation.

Colm McGrath
Institute for European Tort Law, Vienna.
Private Autologous Cord Blood Banks: Legal and Ethical Issues in Europe

Anne-Marie Duguet
Member of the WAML Audit Committee

In 2004, the European Group on Ethics in sciences and new technologies considered that “the legitimacy of commercial cord blood banks for autologous use should be questioned as they sell a service which presently has no real use regarding therapeutic options”. While some members of the Group consider that this activity should be banned, the majority considers that the activities of these banks should be discouraged but that a strict ban would represent an undue restriction on the freedom of enterprise and the freedom of choice of individuals/couples.

The number of private cord blood banks is increasing. So far, it is estimated that over 200,000 cord blood units are held by the private sector. These companies act as a “biological insurance” for parents. They propose to store a child’s cord blood in return for a fee. When required the banks will provide them with stem cells from the cord blood. Examples of famous people who have accessed private cord blood banks are cited to provide an incentive to families. The argument used is the provision of a “biological insurance” which appears as a “one-in-a-lifetime opportunity”, in case of serious illness of their child.

Being highly advertised, the use of cord blood banks has led to heated debates. The utility of cord blood, as a treatment in serious illnesses, is being spread more and more, such that parents are aware of its potential use. In several countries, different institutions have started to express their concerns about how information is disseminated to avoid exploitation.

A survey on the implementation of the 2004/23/EC Directive on setting standards of quality and safety of human tissues and cells, has been conducted among EU member states, for the European Project POSEIDON, with questions about private autologous cord blood banks being raised.

Autologous cord blood banks have been created in 13 European countries. As some countries do not allow the storage of cord blood for autologous purposes (Cyprus, Denmark, Italy, Portugal, France), families are invited to send the sample elsewhere.

Among the EU member states, the opinion on private cord blood banks differs and the debate is ongoing.

Some countries have clearly expressed their opposition to autologous cord blood banks. Seven national ethics committees have expressed specific opinions on cord blood banks. Cyprus indicated that the services offered by autologous cord blood banks “will most probably not have any realistic use in the foreseeable future”. For French CCNE, the systematic storage of placental blood for exclusively autologous uses, in the present state of medical science, would be illusory,... devoting public resources to these projects would be futile. There is an imputation that dedicated preservation of placental blood (autologous or within a family) is morally reprehensible and thus it should be offered as a possibility, in exceptional circumstances and not routinely. Greece considered that the choice of private use cannot be justified on ethical grounds: the purpose to ensure the widest possible utilisation of these cells, is better served by heterologous transplantation which is ensured by networks of collections and not by autologous transplantation. The Austrian Bioethics commission does not recommend the storage of cord blood stem cells for autologous transplantation. The Irish Council of Bioethics remains unconvinced of the utility of commercial cord blood banking for future personal use. A prohibition of the practice would restrict the personal autonomy of individuals who might wish to avail themselves of such service.

The quality of information given to the parents is of concern. The recommendation is:

- special kinds of advertising should be strictly controlled by the competent authorities.

Clear and transparent information is needed regarding the cost for patients.

- Parents should be informed of the current lack of any scientific or medical justification for systematic collection of cord blood for exclusively autologous purposes.

- Operation of commercial collections must provide comprehensive information to prospective clients and refrain from misleading advertising.

Appropriate public information tools should be developed, including consent forms and information documents for prospective users of already operating companies.

- Specific information material, targeted to parents about the storing of umbilical cord blood, should be developed.

- Accurate and valid information, relating to future therapeutic potential, should be prepared. Misleading advertising should be prohibited.

Regarding the information, the GEE recommends “If commercial cord blood banks are allowed, appropriate information should be given to the consumers willing to use their services, including the fact that: the likelihood that the sample may
be used to treat one’s child is currently negligible; that the future therapeutic possibilities are of a very hypothetical nature; and that up, until now there is no indication that the present research will lead to specific therapeutic application of one’s own cord blood cells. Therefore, information has to be particularly explicit that the auto conservation has little value in the current state of scientific knowledge. This information should be made clear on all media, including internet, and in any contracts linking commercial banks to their customers.”

**Anne-Marie Duguet**
Member of the WAML Audit Committee

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**Medical Liability: From Fault to Alternative Systems**

The Centre for Biomedical Law is carrying out a research project, funded by the Portuguese Foundation for Science and Technology, aiming to study the feasibility of the implementation of a medical responsibility system less aggressive, more effective and aimed at the reduction of medical error.

This study has not yet been performed in Portugal or even in many of the developed countries. It seeks to show how the traditional system of medical responsibility is not reaching its objectives: It does not effectively contribute to the deontological control of the professionals. It does not compensate the damages to those who are victims of malpractice. Nor does it punish damages to the legal assets protected by criminal law.

(Studdert and Brennan - No fault compensation to medical injuries: the prospect for error prevention; JAMA, 286, p.227 a 223).

The project aims to demonstrate that it is not enough to discard the weaknesses of the Portuguese civil liability system by increasing the number of complaints against deficient professionals, by increasing the speed of proceedings for faster convictions or by increasing the sentences and compensation.

One has to consider that the traditional medical responsibility system – based on fault, like that in force in Portugal, has not satisfied any of the purposes for which it was created. In addition, increasing the severity of the system would probably have, contrary to what one might imagine, an adverse effect. Instead of improving results, escalation of the system would bring about an inflated volume of litigation, would impair the level of confidence in the patient/physician relationship and would provoke an increase in “defensive medicine.”

This project commenced with an analysis of the legal and practical framework, regarding professional responsibility. It is anticipated that this will demonstrate that: disciplinary control is frail; actions for compensation of damages are inefficient; and that criminal laws are probably disproportionate, considering the complexity of medical practice.

Should Portuguese law establish a system that does not subject minor negligence to penal responsibility? Since medical practice develops within the framework of a complex system, with uncertain results, violation of the leges artis becomes excessively easy, and probably it also becomes inordinately easy to accuse a professional of negligence, submitting him/her to unrealistic sanctions. Criminal liability – being the most serious and dishonourable – probably should be reserved for the most serious infractions –less for the result than for the high degree of negligence demonstrated by the agent.

Should civil responsibility also abandon the traditional model based on the search for a guilty party? The modern theory of organisation shows that many individual behaviours are induced by the system in which they are integrated. Judicial punishment tends to detract from the improvements that the organisation needs. The judicial punishment of the guilty individual does not help to reduce medical errors within the system. Probably civil responsibility should embark on a transformation towards a no-fault system – a movement that already exists in other countries

Disciplinary responsibility, in its turn, could reinforce its role by exercising control over professional practice and evaluating merit. The advantage is that such actions are executed among peers. This may avoid judicial reviews which cause defensive reactions and delays in the appropriate attribution of compensation.

After demonstrating the disadvantages of the current system, and the advantages of certain transformations, an economic and financial analysis will be required. This is needed to evaluate implications of the proposed changes: on
the activity of the private insurers; on the State budget; on the Health Units; and on the Social Security System.

It is important to note that the current study – and the subsequent economic analysis – is only completely meaningful if, in a third phase, a system of reporting of errors and quasi-errors is set-up. This would allow the-analysis and the issuance of guidelines to reduce such errors in the health care system. In conclusion, this project involves the first part of a wider idea: how to bring about changes in the liability-legal framework so that it could work, as another tool, to improve quality of the health care system, rather than function as a repressive instrument that may cause even more negative results.

Guilherme de Oliveira
Professor - Faculty of Law, University of Coimbra

The Portuguese Medico-Legal Organization and the Portuguese Medico-Legal Council

Duarte Nuno Vieira

The Portuguese medico-legal organization was profoundly restructured, after April 2001 by a structural reform of the Portuguese Ministry of Justice, undertaken at the turn of the millennium. This involved the dissolution of the Institutes of Legal Medicine in Lisbon, Porto and Coimbra, and their unification into a single National Institute of Legal Medicine (NILM). The NILM which is based in Coimbra has three delegations (North, Centre and South, located in Porto, Coimbra and Lisbon respectively), as well as a network of 31 Medico-Legal Offices dispersed throughout the country. Together, these bodies provide medico-legal and forensic coverage for the whole country.

The NILM has the legal status of a public institute, integrated into the indirect administration of the state, (it is overseen by the Ministry of Justice), with autonomy over its own property and administrative and financial matters. Its mission is to provide scientific coordination and training in the area of legal medicine and the other forensic sciences. It also oversees and supervises the activities of its medico-legal departments and of the experts contracted to provide specialist appraisals. It discharges its functions and exercises its remit in collaboration with higher education establishments, particularly medical schools (both public and private), following the celebration of protocols in the area of education, training and scientific research.

The Portuguese model has some innovative aspects (for more details, see www.ecml.org), and is considered by many to be one of the best systems in the world. Indeed, it is often used as a model for study and reference, given the results that have been achieved and the independence and value of the expert appraisals that it provides.

The Medico-Legal Council (MLC) is part of the organizational structure of the NILM and one of the oldest bodies of the Portuguese medico-legal system (operating since 1918). It is thus of great importance for the administration of justice. One of its main functions is to issue expert opinions about technical and scientific matters, whenever a court is hearing a case with medical aspects that are controversial or difficult to interpret (such as cases of medical error, which account for most of its interventions). By law, the technical and scientific appraisals issued by the MLC are not open to review and constitute its definitive opinion on the subject (unless new evidence is produced to justify an amendment). These appraisals thus represent the final word on the matter and the court generally follows them in its final decision. To avoid being inundated with requests from the courts, technical-scientific and ethical consultations of this kind may only be requested by the Ministry of Justice, Supreme Judicial Council, Public Prosecutor or President of the Board of Directors of the NILM.

The MLC is presided over by the president of the board of directors of the NILM. It includes the directors of the three NILM delegations (North, Centre and South), a representative of the disciplinary councils of the three regional sectors of the Portuguese Medical Association, 11 medical professors in various Faculties of Medicine (Clinical Surgery, Clinical Medicine, Obstetrics and Gynaecology, Pathology, Medical Ethics or Law, Orthopaedics and Traumatology, Neurology or Neurosurgery and Psychiatry) and 2 law professors (one from criminal law and the other from civil law) named by the Faculties of Law. Whenever necessary, the MLC may also request the collaboration and presence at meetings of professors from other medical...
areas or higher education establishments and of specialists of recognised merit. This occurs when its permanent members do not have the expertise to assess the matters being reviewed. The secretary of the MLC, is appointed by it, upon the suggestion of the president, and is, preferably, a university lecturer in Legal Medicine. The Medico-Legal Council also has a number of other functions in addition to those mentioned above. These are:

1) To pronounce upon matters of an ethical nature in the context of expert activity and research developed by medico-legal departments in Portugal;
2) To monitor and assess the expert services provided by the INLM, proposing measures deemed to be appropriate for the due fulfilment of its tasks and issuing opinions about any reforms that need to be made to the medico-legal system or its functioning;
3) To issue opinions concerning the cooperation of the medico-legal services with other departments or institutions and to pronounce, of its own initiative or at the request of the president of the board of directors, upon matters relating to the Institute’s functions, drawing up recommendations in the sphere of medico-legal activity.

As already mentioned, the development of legal medicine and the forensic sciences in Portugal has been particularly positive. Since the beginning of the 21st century and the creation of the NILM, there has been an increase in its influence, quality and credibility and it has played a more significant role in education and research. The new organizational model has undoubtedly contributed to this development and is likely to lead to an even brighter future for this area. Its remit is broadened and strengthened in various expert areas of the forensic sciences. It is probable that it will change its name to the National Institute for Legal Medicine and Forensic Sciences. Whatever the development, the Medico-Legal Council will certainly continue to perform an essential role, cooperating with the Courts in the administration of justice and constituting a fundamental national body for expert opinion on legal cases involving medical liability.

Duarte Nuno Vieira
Director of The National institute of Legal Medicine of Portugal

The Medical Expert: Some Deontological Issues

The existence of conflicts between the ethical principles of medicine and the need for expert intervention is common. Sometimes, the medical examiner is called to intervene in a way contrary to his ethical principles. Such judicial requests, supported by criminal investigation laws, often do not consider important medical principles. The expert, before anything else, is a doctor and the activity is a medical act. So the question arises as to what should prevail, namely: ethical duty or compliance with a court order?

The Portuguese Medical Deontological Code states unequivocally that any physician who is called to act as an expert must fulfill that mission, but only while following the precepts of the Code. That is, the Code does not establish any statutory exception that allows the medical expert to ignore the principles contained therein. We must not forget that any doctor may be called upon as an expert. One of the most important precepts, sometimes put in question under judicial orders, is carrying out an examination without the consent, or against the will, of a particular person. Consent to the performance of any medical procedure is one of the fundamental principles of medicine. If there is opposition by the person, in most situations, that medical intervention will not be performed. However, even with opposition by the person to be examined, the doctor may be given the order to carry out an examination.

Among many examples, some time ago, in a region of Portugal, a judicial order was given to a medical expert to conduct a sexual examination in a woman, who had returned from South America and was suspected of carrying intra-vaginal drugs. The woman did not consent to the examination and, therefore, the medical expert refused to use force to compel her to do so. Consequently, the judicial authority started proceedings against the physician for disobeying a court order. It asked an opinion from the National Council of Legal Medicine (an advisory body of the National Institute of Legal Medicine of Portugal) which was favorable to the attitude assumed by the physician, according to the provisions of the Deontological Code. Even if a sexual examination could be performed through the use of force against the wishes of the examined women, it would be difficult to accept the use of medical knowledge for legal purposes.

The woman did not consent to the examination and, therefore, the medical expert refused to use force to compel her to do so. Consequently, the judicial authority started proceedings against the physician for disobeying a court order. It asked an opinion from the National Council of Legal Medicine (an advisory body of the National Institute of Legal Medicine of Portugal) which was favorable to the attitude assumed by the physician, according to the provisions of the Deontological Code. Even if a sexual examination could be performed through the use of force against the wishes of the examined women, it would be difficult to accept the use of medical knowledge for legal purposes.

Article 6 of the Portu-
An endoscopic examina-
tion may involve risks to
the person examined. Is
it legitimate to compel a
person to undergo such an
examination and a doctor
to perform it, when there
is no benefit to that person
and an accident can hap-
pen during the procedure?
If an accident happens,
who will be responsible
for the consequences?
Can the medical expert
decide to carry out such
an examination when
there is no possible ben-
efit to the person being
examined? If so, could a
doctor obey a court order
(as happened in one case
in a Portuguese county)
and give a general anes-
thesia to a teenager who
had been victim of a rape
and was resisting a sexual
examination? A general
anesthesia can create a
danger to health and must
be medically justified.
The positions on this is-
ue may be varied and
diverse. When there may
be a danger to the health
of the person examined, it
can not be acceptable for
a doctor to perform an ex-
ert examination against
the will of the person be-
ing examined, even with
a court order. The situation
is different when there is
no health danger and the
person to be examined
refuses to submit to the
examination only to pro-
tect himself, refusing to
cooperate with justice. It
is now acceptable, in Por-
tugal and in many other
countries, to use force,
for example, to collect a
buccal swab to obtain a
DNA sample from an in-
dividual who has been ac-
cussed of having commit-
ted a crime and refuses to
participate. I do not think
it is correct for a doctor
to collaborate with a refusal
of this nature and, thus,
allow a crime to be cov-
ered up thereby prevent-
ing the course of justice.
The appeal to a superior
court judge decision and
to the Medical Order can
provide mechanisms for
the safeguard of the cor-
rect decisions, when ethi-
cal issues are confronted
with court orders. Ulti-
mately, the conscience of
the medical expert should
always be considered in
the decision.

Best regards
Francisco Corte Real

Liability for Medical
Malpractice in Macau,
China. Winds of
Change?

Rui Cascão

Macau, a Portuguese over-
seas possession until 1999,
is nowadays a Special Ad-
ministrative Region of the
People’s Republic of China.
Under the “one country,
two systems” principle,
Macau, as neighbouring
Hong Kong, is allowed
broad autonomy, main-
taining its own independ-
ent political, economical
and legal systems, as well
as its own currency and
borders. The region has
544,600 inhabitants and an
area of roughly 30 square
kilometres, a GDP exceed-
ing US$60,000 (PPP) and
a very high human devel-
opment index (0.944). Its
residents enjoy the highest
life expectancy in the world
(84.37 years) and infant
mortality is low at 4.35
per thousand inhabitants.
The public healthcare
system-shaped after the
Beveridge model-provides
good quality healthcare to
the citizens.
The legal regime of medi-
cal malpractice varies ac-
cording to the private or
Public nature of the entity
providing medical treat-
ent. In the private health-
care sector, the general
principles of the Civil Code
of 1999 apply to cases re-
lated to injury or death re-
sulting from medical treat-
ent and a lawsuit can be
framed in tort and/or in
contract. Injuries, caused
by substandard medical
treatment, are eligible for
compensation. The tort
system of the Civil Code
also applies, with some
significant adaptations, to
malpractice cases where
medical treatment is pro-
vided by the public Health-
care Service. Considering
that the Macau Healthcare
Service is a public law legal
entity, Decree-Law 28/91/
M, concerning the liability
of public entities, is appli-
The application of this statute entails two significant modifications to the general tort law system: 1) the Administrative Court exercises exclusive jurisdiction over the matter; and 2) only the Healthcare System has standing to be sued, rather than the individual healthcare practitioner(s) involved in the adverse event (except if they acted with intention or ultra vires). If the healthcare professionals have acted with intention or gross negligence, the Healthcare Service can take action in order to seek partial or full redress from them.

In 2005, the Healthcare Service brought forward a white book on the reform of medical malpractice law for public consultation. This was heavily influenced by the no-fault compensation systems of New Zealand and that of the Nordic countries. The trend of the reform was obstructed and in 2006 the Healthcare Service initiated public consultation of a draft bill on medical malpractice, which was influenced significantly by the Regulations for Handling Medical Malpractice Cases (2002) of Mainland China. This draft suggested that individual healthcare professionals be held liable, jointly and severally, with the Healthcare Service for medical malpractice. After consultation, the bill was frozen, as healthcare professionals were dissatisfied with the potential consequences and the financial costs of the reform, the lack of clear political backing, and an initial hesitation by health insurers.

In September 2011 the debate about the frozen 2006 draft was rekindled, as some directly elected MP's filed a motion for the issue to be discussed in Parliament. The MP's echoed the lack of satisfaction of the public regarding the difficulties in accessing compensation (since 1999 only 22 malpractice lawsuits have been filed, out of which 11 were heard; and in only 4 cases did plaintiffs receive compensation). This underlined the need for specific legislation on medical malpractice. Healthcare professionals were worried about the costs of insurance and local legal experts disagreed whether special legislation needed to be passed.

Considering the recent developments in the approach to medical adverse events (root cause analysis, learning from error, pro-active prevention of adverse events clinical governance and institutional liability), which have produced a significant impact in healthcare systems and healthcare law, it does appear that passing a statute, reinforcing individual fault and allowing for a blaming culture, is tantamount to rowing against the tides of time and maybe counter-productive. In order to enhance the access of aggrieved patients to compensation for medical adverse events, it is may be more efficient if the Healthcare System of Macau simply changes its adverse event prevention and compensation policy in such a way that it becomes more receptive to non-litigious settlement of claims. It should strive, if patient satisfaction is the objective, to offer of its own volition, fair compensation where this is justified instead of its current policy of initial refusal of any transaction or ADR instance, and litigating all claims, all the way up to the last instance, to the disadvantage of the weaker party-the patient. It could follow the Nordic route, the public budget of the tiny dragon has enough resources for that.

Rui Cascão, LL.B (Coimbra), Ph.D. (Tilburg)

**History of Pharmacy**

In 1902, there was a reform of studies of the three Schools of Pharmacy in Portugal during which there was first established a course in “Ethics and Pharmaceutical Law.” The “Pharmaceutical Ethics and Law” course was optional, not mandatory for all students of Pharmacy.

In 1911, after the establishment of the Republic, education reform determined that the teaching of deontology and pharmaceutical legislation was obligatory.

The question that follows is: “Why did the need to study this subject arise in the transition from the nineteenth to the twentieth century? We believe that this relates to some very profound questions that altered the understanding of pharmacy and medicine. Consider some of these issues in the Portuguese case. In the late nineteenth and early twentieth century the pharmaceutical industry began to gain strength and to consolidate. The traditional prescription pharmacy-made pills no longer had exclusivity. Manufactured drugs, were increasing. New drugs and methods of administration emerged in the world pharmaceutical industry as, for example, tablets and capsules. Advertising of drugs increased in a way never before seen. Portugal was not a country with strong economic resources and a strong tradition of research in chemistry. That lack of tradition and ‘know-how’ was felt strongly in the industrialization of medicine. In Portugal, many pharmaceutical compa-
ties began as small pharmacies, that is, the small lab near a pharmacy often became a pharmaceutical company. This tradition is prevalent in Southern Europe. In the North of Europe the situation was somewhat different with a different mode of emergence of industries. Portugal was caught ‘off guard’ by the industrialization of medicine. The gradual increase in manufactured drugs came at a critical period in Portugal’s pharmaceutical business. Many questions arose around the industrialization of the manufacture of medicines, as can be observed from analysis of Portuguese professional journals and the journal of the Pharmaceutical Society “Lusitana”, a body defending the interests of pharmacists. One of the salient issues was the quality of manufactured drugs. Were there any problems with the administration of medications? It was often acknowledged that, in industrialized medicine, one does not know who produced, or was responsible for, the manufacture of such medications. There was also a problem of ‘counterfeiting’. There are several texts which recognize the ease with which one can ‘fake’ a drug, because of a lack of controls over the process of industrialization and manufacture. The effectiveness of manufactured drugs was also often questioned. When the local pharmacist compounded a medication he/she knew what was in it and what it was intended to do. With the industrialized manufacture of drugs that did not happen. Many of these issues relate to quality control. It also raises questions regarding the independence of the prescriber and the pharmacist as a producer. How does one separate the two functions as they apply to professional liability? In the early twentieth Century, in Portugal and many other countries, there was a total absence of regulations to address these issues. The first laws that were designed to regulate the industrialization of medicine in Portugal originated in the 1930s. It was not until the 1940’s that the first regulatory agency was created: Regulatory Commission Chemicals and Pharmaceuticals - CRPQF.

At the First National Congress of Pharmacy of Lisbon, in 1927, one of the topics covered by many of the presentations was that of the role of the profession. to exercise jurisdiction in accordance with the laws with considerable attention to a high sense of responsibility. The speakers constantly focused attention on the law. They appealed to professional ethics. It is therefore not surprising that this encouraged education in ethics and professional responsibility in Portuguese Schools of Pharmacy.

In Portugal, the first Code of Ethics for Pharmacists was established in 1968 as a result of the fundamental laws of professional practice and the industrialization of medicine as was promulgated in the 1950’s and the 60’s. More recently, Portugal’s accession to the European Union led to the repeal of many of these legal standards - in particular those that pertain to the medicine and the pharmaceutical profession.

**João Rui Pita**
Professor, School of Pharmacy
University of Coimbra

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**My Hobbies**

Thomas T. Noguchi, President of WAML
I feel tremendously pressured but I also feel very rewarded by the resulting accomplishments. I have found that the key to accomplishment is effective time management, balancing work and relaxing moments.

Thomas T. Noguchi
WAML President

Presidential Message for December Newsletter

As 2011 is ending, I look back on our accomplishments over the past one and a half years since I was elected President in Zagreb, Croatia in August 2010. There has been much progress in the WAML organization. We have strengthened the supportive administrative structure and now offer better and more efficient service to our members. I would like to go over the steps I have taken to restructure this Association to provide more active service to the international community.

First, we established a legal entity by registration as a not-for-profit organization. This allows us to expand membership support services, such as providing publications for continuing education, collaborating with other professional organizations and educational institutions and increasing opportunities to seek funds and grants for research and development.

We are interested in open and collaborative decision-making and continue to work toward more transparency to members. I would like to expand communications to, and among, the leadership and all members. The Board Meetings should be open to the members, so members can plan to attend the 2012 Board Meeting at the World Congress in Brazil. Instead of the face-to-face Board Meetings once every other year, now we have more frequent Online Board Meetings and are planning for a lengthy Face-to-Face Board meeting at the WCML. We are establishing a central filing system for all official correspondence, such as the minutes of the Board meetings and have established written policies and procedures under the supervision of our Administrative Officer, Denise McNally.

The WAML should be a more visible and much more activity oriented membership organization. The Executive Committee supports collaboration with other International and National associations to jointly support educational programs.

Some examples include: 1) Adv. Radmyla Hrevtsova of Ukraine hosted the All Ukraine Meeting and WAML collaborated on the program with several of our governors as speakers, 2) Prof. Andre Pereira organized the International Symposium on Medicine and Ethics, supported by the University of Coimbra, 3) The Triennial International Association of Forensic Sciences Meeting (IAFS) is a large meeting with over 1500 delegates from all over the World. Prof. Pereira arranged with the President of the IAFS to have a joint two-hour IAFS-WAML Special Session on Ethics, Law and Forensic Sciences. The Congress took place in Madeira, Portugal. Four speakers at this combined WAML meeting were Prof. Pereira, Adv. Eduardo Dantas, Prof. Marcella Fierro and myself. The American Academy of Forensic Sciences (AAFS) organized an international educational tour in Portugal after the Congress and I was able to visit with Prof. Jose Pinto da Costa, Honorary Governor, and Retired Gover-
Secretary General’s Report

Roy Beran,
Secretary General of WAML

This will be the last newsletter from the World Association for Medical Law (WAML) for this year, 2011, and my last Secretary General’s (SG’s) message was not distributed due to some technical problems with our last newsletter, which have since been rectified. This allows me to communicate with you all and to wish you all “Season’s Greetings”, irrespective of what ‘season’ you may be celebrating or if you are indeed celebrating any particular season at all.

I have a very good Armenian friend who gets the best out of the celebrations in that he celebrates the usual Christmas, on 25th December, and also the Armenian Orthodox Christmas, on 6th January. To avoid any possibility of offending him we wish him a Happy Christmas from the beginning of December through to the middle of January and still feel we probably missed something. This highlights the ethos of the WAML, namely that it is a truly international Association and respects everyone’s opinions, attitudes and beliefs. We, down under, refer to this period as the “Silly Season” when people act differently and we encourage this if it results in a better understanding amongst our fellows. We, in the Executive of the WAML, likewise encourage a broader understanding and appreciation of our colleagues and our friends around the world. The “Arab Spring” has been a central theme for 2011, as have financial woes, and both of these should highlight the need to re-evaluate what is happening around us and how we should modify our behaviour into the future.

When I prepared my previously aborted SG’s Report I wondered what sort of a message I should send. At the time, we, down under, just completed our Annual General Meeting of the Australasian College of Legal Medicine. At that meeting one of our key speakers was Margaret Stark, the founding academic dean of the Faculty of Forensic and Legal Medicine of the Royal College of Physicians in London. Margaret shared with us her unique experiences from the United Kingdom. Margaret is now a Police Surgeon in Sydney, thereby demonstrating what a small
community the world has become. Those of you interested in the UK experience are referred to Stark MM and Norfolk GA J Forens Legal Med 18, 264 – 275, 2011. Our World Association for Medical Law (WAML) is also going through a real period of evolution with many lessons to be learned. It reminds me of the saying, “…The world will step aside for he who knows where he is going!…”

Tom Noguchi, our President, knows where he is travelling and the WAML is being sucked into the vortex left in his wake. Tom has an absolutely clear idea of where he wants to take the WAML and is determined to see this happen. He organised a virtual Board of Governors meeting in July at which his plan for the future was endorsed. He is revolutionising the way the WAML functions and has placed his personal stamp on this modus operandi. One of Tom’s mandates is for transparency and to encourage inclusivity, which brings all the constituents for the Association to the table. He has determined that every member of the WAML should have the opportunity to contribute to the organisation, whether or not that member is on the Board of Governors, or not. One such example is Dick Wilbur, the chair of the finance committee. The fact that Tom hails from the United States means that no other representative from the US can serve on the Board of Governors and yet Dick, as editor-in-chief of the newsletter and chair of the Financial Committee, has just so much to offer. Let me say that working with Dick has been an absolute pleasure. He is a breath of fresh air. He never complains when asked to contribute and shows a depth of wisdom that I have found most enticing. He teaches in such a way that the student feels like he/she is the actual teacher. This is a very special skill and I thank Dick for his contribution and assistance along the way.

I make these comments about Dick because I do not want to have anyone misinterpret what is to follow. Over the last year the WAML has moved very much into an American model, which is both good and not so good. Tom has organised to have the WAML accredited as a ‘not for profit’ organisation in the US. This has translated into the US becoming the de facto home of the WAML with the legal firm, responsible for the ‘not for profit’ registration of the WAML, being given official WAML recognition. Concurrently, the WAML now has an American administrative officer; US chair of the Audit Committee; US financial advisor; US conference organiser; and so it goes. It must be understood that there is nothing wrong with having the US so involved with the administration and each person identified above has made a very positive contribution, in much the same way as has Dick. The WAML is going from strength to strength but I make my comments as a salutary message that if one is not prepared to step up to the plate then others will do so.

The WAML is a world organisation and I personally feel that it must remain as such. This will only remain so if all the membership follow the American example and become equally involved, equally vocal, equally committed and equally prepared to work tirelessly for the good of the WAML. I feel it is imperative that the membership, which is truly representative of a global organisation, becomes committed to expanding the Association on a global level. Together the organisation will continue to grow and will expand its international soul but only if everyone becomes involved.

I make this report as a call to arms. If you want to contribute, then make your willingness known. If you have something to offer, make it your commitment to ensure that the Executive Committee is aware of what you have to offer. Remember, “…The world will step aside for he who knows where he is going!” It is time to consider if you want to host a World Congress of Medical Law on behalf of the WAML. To be eligible the application must arrive at the SG’s office with plenty of time to be considered and appropriately managed. Already we have had expressions of interest for the subsequent meeting in 2016, acknowledging that 2012 is in Latin America and 2014 will be in Indonesia. If you want to play your part and want to become intimately involved in your Association, now is the time to step forward and make your feeling known.

I conclude with my repetition of my Season’s Greetings to you all, recognising that I once thought about becoming an atheist but soon realised that I would then miss out on some wonderful celebrations and holidays. This led me to adopt the alternative approach and worship everything and everyone which translates into many more holidays and happy occasions. May we only meet on Happy Occasions and Celebrations and may the New Year (for those who fol-
low the solar, rather than the lunar calendar) be one of good health, prosperity and productivity. For the others, whose New Year started some time ago, may your year continue to be positive and bring you much joy.

Roy G Beran
Secretary-General
World Association for Medical Law

A Brief Report About the 19th WAML

Eduardo Dantas, Vice-President of WAML

As we approach 2012, the next WCML meeting is coming closer, and the countdown is gaining momentum. The Organizing Committee is working hard to offer to all WAML members and attendees an unforgettable experience. We are collaborating with other associations, among them, the Brazilian Association for Health Law, the European Association for Health Law, the Latin American Association for Medical Law, the Spanish Association for Sanitary Law and the Brazilian Federal Council of Medicine – to develop a scientific program of the highest quality, providing those who join us, in the city of Maceió, more than 400 presentations and conferences and the opportunity to meet and interact with more than 2000 professors, investigators and specialists in the various fields of Health Law, Legal Medicine and Bioethics.

The congress’ website (www.2012wcml.com) is fully operational, and the registration features are already working. So is the call for papers, where those interested can submit their contributions. In a few days, all information about flights, hotels and pre- and post-congress activities also will be available, in order to provide those who wish to be with us all the necessary information for a great conference and a memorable visit.

As part of the WAML, you have an important role to play in the preparation of this meeting. Send us suggestions, ideas and criticisms, so that we can try to achieve higher standards. We count on your active participation, not only in being there but also bringing your contribution to the discussions, presenting papers and helping to spread the word about it. We hope that you will send information to your own contacts, inviting them to be there and help the WAML to reach our academic goals.

Please visit the website, and send us your contribution. Maceió is waiting for YOU!!!!

Eduardo Dantas
WAML Vice-President

Do You Have an Idea, Comment, or Suggestion?
Or You Would Like to Submit Your Article for Future Issues?

Please Contact
Denise McNally
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FUTURE MEETINGS
Of Affiliated National Associations and Collaborating Organizations

International Center for Health, Law and Ethics
December 19-20, 2011
Har Hacarmel Hotel, Haifa
Contact: Professor Amnon Carmi
Email: amnoncarmi@gmail.com • Email: ichle@lawmail.haifa.ac.il