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Disclaimer: This March Newsletter contains discussions of various international health matters. The statements made are the opinions of the individual contributors and not of their respective national organizations, WAML, or this Newsletter

Guest Editor's Note



Professor Chunfang Gao

Surgeon professor, chief doctor and president, The 150th Central Hospital of PLA

- President, China Health Law Society
- Professor and Doctoral Supervisor, The Second Military Medical University
- Director, expert, Colorectal Disease Society of PLA

Since 1976 Prof Chunfang has worked as a surgeon in the hospital affiliated to the 2nd Military Medical University of the PLA and deputy chief doctor, chief doctor, deputy president and President of the 150th Central Hospital of the PLA. Since the 1990s, Prof Gao Chunfang has had a unique understanding of the building of the legal system in the field of the medicine and health. He has been in the forefront of guiding the protection

of people's life and health on the country's, medical apparatus, healthy food, clinical trials, products registration and manufacture, and the related issues of medical law in the field of medical institutions. He has participated in legislative probes and discussions on various laws of the country. Prof Gao Chunfang was a Vice President of the organizing committee of the 17th World Congress on Medical Law in 2008. He was elected President of the China Health Law Society at the 4th Deputies Congress in 2013.

Professor Chunfang Gao

Development of the Discipline of Health Law in China

Gao Chunfang

President of China Health Law Society

Early in April 1988, many scholars expressed their interests and support for establishing a civil society of health law. In March 1993, China Health Law Society (CHLS), China's first civil legal

society directly under the administration of the Ministry of Justice, was formerly licensed by the Ministry of Civil Affairs. As a State-level legal society, CHLS has clearly defined tasks and missions in "carrying out academic research and social services targeting the protection of human living and health rights under the light of the legal relationship between the health law and other branches of the law, which are defined in the new Constitution of the People's Republic of China (adopted in 1982)". However, the then leaders of CLS recognized that CHLS might be better acting independently since the legal issues of life and health, in particular those involved in medical practices and public health, were unique in nature. Then, CLS sent its Vice President & Secretary-General to serve as a leader in CLHS, which remarkably promoted the development of CLHS. Under the leadership of the former and thanks to the support of many top scholars, CLHS has made tremendous progress

in the past two decades: carrying out surveys and investigations; capacity building; compiling monographs and textbooks; participating in law establishment and revision; participating in international exchanges to share China's academic thoughts and opinions with the global colleagues; and providing training, consulting, and services to the general public. The number of its members has increased from dozens at the beginning to thousands now and may exceed 10,000 if the number of the group members is also taken into consideration.

It is well known that law is the product of history. The laws established in different historic periods with different relations and modes of production often dramatically differ. Laws are the rules that regulate the games played by different populations living in different levels of society in a specific historic period. These rules are not inherent and will change over time. They are deemed viable only when they can protect the development of production relations and productivity. The laws in the slave society were designed to protect the slave owners' privilege in owning slaves as tools in a "fair" way. The slaves, in contrast, often would fight against the oppression of these slave owners for their own freedom, which promoted

the social development. In the Western capitalist societies, the laws are established to maintain that "the right to property is inviolable and sacred"; their absolute private laws are used to regulate the rules of social games, with their focus on the property and property rights. A society cannot progress stably without recognizing that living and health rights and interests are legal priorities.

After the establishment of the People's Republic of China, the first three decades witnessed the policies and theories such as "Class Struggle is the Key Link" and "Continuing the Revolution under the Proletarian Dictatorship", during which criminal law was the dominant law to regulate social relations. During the second three decades, along with China's reform and opening-up, the State established private laws focusing on civil legal relationships to regulate property relations. The release of the Property Law and the Tort Law represented new milestones in the legal system construction in China.

However, the legal and academic understanding and opinions on the regulations on the protection of living and health rights and interests remain controversial. In fact, the human living and health rights and interests is regulated and protected by the Constitution.

However, it is practically unacceptable if these rights and interests are completely regulated by the civil legal relations that are based on the principles of "equality and exchange of equal value". First, people, rather than objects, are the subjects of the social activities; second, the value of lives cannot be included in the "pure price" system; third, the civil legal relations that are based on the principles of "equality and exchange of equal value" are not suitable for regulating the living and health rights and interests; and fourth, the protection of the living and health rights and interests involves the multiple dimensions of the society and cannot be simply regulated by the relations of administrative counterparts or by the rules of civil legal systems. Therefore, we may consider this issue from the following perspectives: First, it is important to carry out disciplinary development of health law: the legal relationships of the health law should be further clarified; its legal content must be expanded and the new concepts should be included, so that such subjects can be included in the new discipline of health law. Second, it is needed to carry out research on the connotation and denotation of health law: focusing on the protection of living and health rights and interests, the health law may involve

different sectors including agriculture, forestry, animal husbandry, fishery, and related Industries; it may cover different multi-temporal dimensions including atmosphere, environment, lakes and rivers, soils, and drinking water; it may care for the whole life of a person from birth to death; it may relate to other legal systems including administrative, civil, and criminal laws; and it may include ethics, identification, mediation, arbitration, litigation and judicial systems.

Third, it is necessary to establish academic groups to explore the subjects and other details of this discipline.

Fourth, it is useful to be involved in domestic and international academic exchanges to make our voices heard, so as to establish the legal status of this discipline.

Fifth, it is needed to carry out research and capacity building in relevant disciplines including medical ethics and life ethics. Ethics is pervasive everywhere. The ancient Chinese paid particular attention to ethics, and its formal document on ethics was over 100 years earlier than the ancient Greek. In modern times, medical ethics needs to be further standardized in terms of organization, personnel, qualification, standards, content, scope, impact, assessment, and evaluation. Noninterference somehow

equals to connivance, and connivance results in misconduct.

Sixth, the constitution of CHLS needs to be revised to make it more consistent with the global standards. The World Association for Medical Law has included forensic medicine into its work scope, which has been reflected in its newly revised constitution. As a vice-chairman unit of the association, CHLS should follow such a change. For this reason, we should further discuss and explore this work in the “Contact Center”, so as to understand the internal relationship and necessary connections among these new concepts and optimize the design and consideration of the protection of living and health rights and interests.

The past two decades have witnessed the remarkable progress of CHLS. Today, under innovative leadership, CHLS has a large number of members, and most of them are young individuals; the society has its own journals and has published many monographs, textbooks, and series; and notably, an increasing number of colleges are working tirelessly to establish their own health law disciplines.

I firmly believe that health law shall and will be formally established as a branch of law.

Beijing, October 20, 2014

Public Health Regulations from the Perspective of Paternalism



SU Yu-ju,

Associate Professor of Humanities and Social Science Department, Hainan Medical University; Ph.D. Candidate of Tsinghua University School of Law

In public health regulations, it has become a necessity that the government intervene in the individual's behavior based on paternalism, in an attempt to maintain or promote individual health. Paternalism can be either weak or strong: the weak paternalism is a remedy to the “involuntary” (irrational) self-regarding acts performed by the doers, with an attempt to protect those people whose capacity is deficient; the strong paternalism, in contrast, is an intervention of the “voluntary” (rational) self-regarding acts performed by the doers, with an attempt to prevent the risks borne by the individuals.

1 Weak paternalism: protection of people whose capacity is deficient

Weak paternalism applies when the doer can not achieve self-rule, due to the lack of inner capacity, or when restrained by the external conditions:

(1) Individuals with a limited or no capacity (e.g. minors or mentally disordered individuals); (2) Competent individuals whose reasoning and judgment are affected by alcoholism, coma, or misleading/incomplete external information and thus can not truly exercise their capacity. Under such conditions, interventions may be applied on the “involuntary” self-regarding acts based on the weak paternalism, so as to protect the doers from being hurt by “risky choice that can not truly reflect their willingness”. Therefore, the weak paternalism does not block personal self-rule; rather, it protects and increases the personal self-rule.

2 Strong paternalism: prevention of the self-borne risks

The strong paternalism is the intervention into the doer's voluntary self-regarding acts including:

(1) The doer's potential act only affects his/her own interest, but will not affect other people's interests; (2) Such an act may do damage to the doer's own interests; (3) The act is based on the doer's own subjective willingness; (4) The intervention is

intended to maintain or promote the doer's rights or interests.

Among the public health regulations, the mandatory requirements, such as wearing a seat belt while driving and wearing a helmet during motorcycling, are good examples of strong paternalism.

The opponents of strong paternalism believe that individuals can freely do what they think can bring them certain satisfaction, no matter what the risk might be, even if they have realized the existence of risks. They argue that

(1) The strong paternalism restrains the individual's freedom of choice and blocks people's freedom and thus disregards the intrinsic value of individuals; (2) An individual well knows his/her own interests; the government and the law should maintain value neutrality and should not impose the specific “good life” or its related values upon an individual.

The supporters of the strong paternalism believe that, although the individual's self-rule is important, it does not hold supreme power. The individual's self-rule must be balanced with other rights and interests.

(1) Freedom can be both negative and positive. In a wider sense of freedom, if constraining the negative freedom is accompanied by the improvement of

the positive freedom, the overall freedom can be regarded as intact. Thus, it is positive.

(2) While some extreme liberalists believe that every person is the best judge of his/her own interests, the individual's own choice must always be respected, the self decision is always better than the third-party's decision, and the self-rule is the supreme power. The supporters of the strong paternalism find such statements to be unrealistic and cannot gain uniform support;

(3) Self-rule is not an 'all-or-nothing' concept; rather, it is a 'more or less' concept.

Although these controversies continue, the paternalism-based interventions have been widely applied in various legal fields. In particular, public health has witnessed the active roles of paternalism.

3 Conclusion

With the development of society, the government's role has been transformed from negative duties to positive duties. The government is no longer a night watchman only; rather, it has become a provider of all-round, multi-faceted public services. Meanwhile, the border between self-regarding acts and acts related with a third party increasingly has become vague. Due to limitations in inner capability or external conditions, an individual

often has difficulty ensuring that his/her judgment/behavior is rational. Therefore, the "harm principle" in classical liberalism can not meet the demands of the "real world" interventions. Thus, the concept of paternalism has been recognized as another justification for the government's role in intervening in personal freedom.

SU Yu-ju

Ethics of Assisted Reproductive Technology

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Assisted reproductive technology (ART) has changed the traditional way of birth, thus bringing constant impacts on family ethics and new ethical challenges to a previously simple human society. The couple's and the whole family's rights and obligations to their offspring must be reviewed from new perspectives.

Keywords: assisted reproduction; ethics; infertility
Assisted reproductive technology (ART) allows the human society to complete reproduction independent of the human body, thus bringing many new impacts on marriage, sex and ethics.

1. Ethical issues brought by ART

1.1 Sperm shortage is a common problem due to various reasons. Thus, how to help infertile families to smoothly obtain donor sperm has become a big concern.

1.2 Commercialization of ART

1.2.1 The commercialization of ART in some hospitals is based on the infertile families' urgent needs, despite the high costs. Nowadays a large number of profit-seeking assisted reproduction centers have been established.

1.2.2 Commercialization of donor oocytes Over 80 countries have adopted the oocyte donation policy and China is among them. The number of oocyte. Donors are extremely small both in China and abroad, making the oocytes a scarce resource. Driven by the desire for profits, the sale of human oocytes has been found in many places.

1.3 Some reproduction centers, with an attempt to increase the success rate, often implant more than one embryo. Chinese couples also prefer to increase the number of the implanted embryos due to the current family-planning policy in China. As a result, multiple pregnancies have remarkably increased in China, which also increases the pregnancy risk for the mothers.

1.4 The sibship

determines the family relationship in China. The current problem is: do babies born by means of a donor egg or sperm have the right to be informed? Do the legal parents have the obligation to tell the truth?

2 Ethical reflection

2.1 Looser limitations in the use of the donor sperm

In China, each sperm donor can only impregnate five women. According to scientific research, in a 1.3-billion population, after one sperm donor impregnates five women, the probability of the marriage among these kids is extremely low. Since China has a population of 1.3 billion, is it feasible to loosen such a limitation? Some experts have believed that it may waste the sperm resource. Considering the decreasing sperm quality in males and the extremely small number of sperm donors, a less strict stipulation on the number of women who can be impregnated by one donor may help to shorten the patients' waiting time. The interconnection and sharing of data in sperm banks nationwide can avoid the over-use of sperm. Genetically, using sperm in different areas may help to optimize the quality of newborn babies.

2.2 Strengthening the administration to avoid commercialization

There are at least three

possible ways to address the commercialization of ART: a) establishment of strict laws, regulations and access policies; b) strengthening the administrative capacity of health authorities and c) introduction of third party supervision mechanisms.

2.3 Understanding the risk of multiple pregnancies and need to eliminate iatrogenic multiple pregnancies
The risk of birth defects is significantly higher among newborns born by ART than among the naturally conceived infants; meanwhile, the pregnant women bear more risks. Multiple pregnancies are contrary to the no harm principle and also may impair the stability of society as a whole.

2.4 Based on China's specific conditions, in my opinion, the legal parents should not tell their child the sibship-related information, so as to maintain the stability of familial relations and protect the parents' personal privacy.
In summary, the ART-related ethical issues should be seriously considered. As indicated by Prof. Qiao Jie, we must develop relevant laws and regulations to optimize the ART supervision and administration based on the experiences and practices in the developed countries and on China's specific conditions.

The Dream of CHLS



Professor Chongqi Wu
Vice President & Secretary-in-Chief
of China Health Law Society,
Vice President of World Association
for Medical Law

Twenty-two years ago, after five years of preparatory work and upon the approval of the Chinese authority, the China Health Law Society (CHLS) was formally established at the Great Hall of the People on March 5, 1993. Initially, by focusing on the relationship between health law and other branches of law, we made it clear that the legal relationship of health law had an objective existence independent of a human being's will. It would research the human's right to life and health; in other words, it represented a whole law system that regulates the rules from birth to death. It should be an indispensable branch of law that enforces the content of the Constitution. Later, when I was working in the State Law Office under the Legislative Affairs Committee of the National People's Congress (NPC), I was able to face more issues concerning other sectors,

among which I concluded that all these laws were established to protect the life and health of human beings.

Soon I was privileged to be enlisted in the first legal system training class sponsored by the government in the China University of Political Science and Law. I learned 17 law courses, which further encouraged me to launch a health law society. My thought was encouraged by some old leaders in the National People's Congress and endorsed by the then Minister of Health. The then director of the State Council Legislative Affairs Office also personally participated in the China Health Law Society (CHLS) and served as the principal leader.

It was at the 17th World Congress on Medical Law, which was held in Beijing in 2008, that the public began to recognize that the health law was a compound law that focused on the protection of the life and health rights and interests, with an attempt to regulate any relevant social relations. Since then, the academic environment of CHLS has become unprecedentedly active. Up to now more than 40 colleges and universities have established the discipline of health law, and centers for health law studies have been established in medical schools, law schools, universities, and social science

academies. Today, almost all the departments of humanities & social sciences in medical colleges (including traditional Chinese medicine colleges) across China offer this course. Notably, research on health law has not been limited only to addressing medical disputes. For example, of over 190 articles presented in the CHLS meeting held in October 2014, less than 5% were still talking about this topic. This does not mean that the medical disputes have been well addressed; rather, experts and scholars now have wider academic ideas and new research approaches. This is also a persuasive answer to the questioning about whether health law can exist or whether it has potential to further develop.

There is still a long way to go during the construction and the establishment of health law as a branch of law. Many of the CHLS founders, including me, are old people now and some of them have passed away. With the development of the society, the protection of the rights to life and health is an inevitable issue.

The CHLS must have its own dream in the coming years. This dream covers from birth till death. During this long period of life, research on health law must target the bottom-line rules,

regulatory rules and supreme rules. The formation of a human being is not just the development of a fertilized egg in the uterus till delivery and cloning is no longer an illusory fancy. The law must investigate both the value of cloning science and its controllability during its development, so as to avoid any potential disaster. Surrogacy involves many legal issues, which must be proactively studied by the Society. In vitro fertilization (IVF) is a useful measure to address infertility; however, for a legal couple who are the receivers of a fertilized egg, if one or both dies, the ownership of the fertilized egg will be a novel legal issue. If the fertilized egg is an object, how to regulate its “ownership”? If somebody else has the right to inherit, how to make the fertilized egg form a person can also be legally problematic. These issues are more complicated than the medical disputes. Some of them involve the bottom line of the rights, which should be regulated from the perspective of law, ethics and sometime arbitration. After the death of a couple who were the owners of the fertilized egg, although law can settle whether the egg should belong to the relatives of the husband or those of the wife, other issues including people, fairness,

reasonability and actual family conditions should also be considered, so as to make the final decision meet the public order and good customs. Thus, the teaching of health law needs to address issues including what to teach, what to learn, how to teach, and how to learn. Teaching of health law remains a problem in China. Actually only law courses are offered in most medical colleges and the real health law programs are still on the way. We still need more research, more textbooks, more teachers and more class hours. I hope our colleagues will be determined to resolve this issue. Ethics is not the ethicists' exclusive domain. Research on the right to life and health always involves ethical issues. Ethical issues involving spouses should never be neglected. The over-emphasis on the autonomy and privacy caused the loosening of the premarital check-up, which results in a sharply increased number of infants with inherited diseases, disability or deformity. Such issues need to be addressed by the CLHS members, and our voices need to be heard by the government and the legislature. Drug trials have far exceeded ethical limits. Driven by economic benefits, some drug companies have broken the bottom line of law;

sadly, no one questions or opposes their malpractices. Also the genetically modified foods (GM foods), some people's claims of “Non-hazardous” are loud in the media, although such claims are never based on solid evidence. These should be the research priorities in the coming years. Disease and its treatment are the most concerning issues throughout life. In the medical field, there are still large gaps between expectation and reality, demand and supply, targets and means, and standards and motives. As a result, numerous social, environmental and cultural conflicts and disputes have undermined the good health care order and medical environments. Currently, the settlement of these conflicts and disputes is mainly dependent on a dual structure including both medical malpractice expertise and judicial expertise. We need to study the confusion remaining after some questionable mediations and trials to assist the government to establish new settlement mechanisms and management methods. These issues shall be the research priorities for the Society members in the future and also reflect the power and value of the Society.

Our other key tasks in the near future may include: First, efforts should be made to establish local or institutional societies. Second, efforts should be made to urge the education authorities to recognize health law as a secondary discipline. Third, research should be enhanced by the current health law research centers. More standardized management of drugs, foods and health care products should be urgently explored. Fourth, it is important to carry out capacity building in serving society. In addition to the legal service centers, the Society shall plan to establish mediation centers, expertise centers and counseling centers. Fifth, and finally, we must pay particular attention to the care of vulnerable populations including disabled people and elderly people. Many other topics including the pollution of air, water, soil and oceans can be investigated in the field of health law. These topics should also be our research priorities, since all of them may do harm to the right to life and health. In the future, our academic exchanges shall be wider, deeper and more specific, so as to fully exert the role and value of CHLS. The Society members should fully utilize this platform in accordance of law. Let's work together to strengthen the discipline

construction of health and finally realize our dream of establishing the health law as a branch of law. I fully believe that this dream shall and will be realized.

Professor Chongqi Wu

Current Publications of the China Health Law Society

1. China Health Law (3rd Edition) by Wu Chong-qi
2. Q&A on the Legal Aspects of Food Safety by Wu Chong-qi and Li Ji-ning
3. A Brief Primer on Law for Health Care Professionals by Wu Chong-qi
4. Health Law (2nd Edition) by Wu Chong-qi and Zhang Jing
5. Practices in the Forensic Identification of Medical Malpractice by Feng Zheng-jun
6. Prevention and Management of Medico-legal Risks by Zhao Min
7. Legal Practice in Medical Procedures by Wang Ping and Deng Hong
8. An Introduction to Health Law by Shi Jun-hua
9. The Law of Healthcare Administration by Pu Chuan and Gu Jin-xian
10. Frontier Health

and Quarantine Law: Theories and Practices by Zhang Ji-wen

From 2009 to 2015, the China Health Law Society has edited 33 Books of Health Law, among which 11 books have been published, 4 books are currently being printed and the other 18 books will be finalized, edited and published in 2015.

When all books are published, we will provide an English list of articles, editors' comments and brief introductions.

In Print

1. General Outline on Hundred Varieties of Medicinal and Edible Foods (I) by Liu Qiu
2. General Outline on Hundred Varieties of Medicinal and Edible Foods (II) by Liu Qiu
3. Health Crimes on Endangering Medicines by Ding Chao-gang
4. General Outline on Pharmacy Law by Tian Kan

Will Be Published in 2015

1. Legal Practices in Community Health by Wang Ping
2. Practices in Health Inspection and Supervision by Yang Shu-juan
3. Health Civil Law by Shi Yue
4. Health Procedural Law by Dai Jin-zeng
5. Go to Court for Justice by Zheng Xue-qian

6. Practices of the Law on Traditional Chinese Medicine by Wang Mei-hong
7. Practices of the Law in Foreign Countries by Deng Hong
8. Practical Guideline for Medical Law Lawyers by Chen Zhi-hua
9. Practical Guideline on Legal Issues for Medical Institutions by Qiu Yong-gui
10. Science of Medical Law by Luo Gang
11. Management of Medical Disputes by Xie Fang
12. A Casebook on Typical Medical Disputes by Xie Fang
13. Practices in Military Medical Law by Xu Qin-geng
14. An Introduction to the People's Mediation for Medical Disputes by Feng Zheng-jun
15. How Far Is It from Hospital to Court: Avoid Medical Disputes in Your Office by Su Jun and Feng Zheng-jun
16. Practices on Sterilization Method by Wang Yi
17. Persistence for Truth: Controversies on Health Law and Medical Reform Policies by Hu Xiao-xiang
18. Selected Cases of Medical Disputes by Cui Gao-ming

We Always Remember Mrs. Noguchi

We felt a little cold during last year's Christmas and even colder when we got the news that the beloved Mrs. Noguchi had passed away.

I first met Prof Noguchi in 2004 when we bid to host the 17th World Congress for Medical Law (WCML). Over 70 years old, Prof Noguchi left me with an unforgettable impression. That meeting, in 2004, began a 10 year friendship from both sides of the Pacific Ocean. In 2007, very old Prof Noguchi and Mrs. Noguchi carried our flier to San Antonio, Texas, and promoted the 17th WCML, in Beijing, at the ACLM Annual Meeting. We had breakfast together in Milwaukee, in October 2013, and talked freely and imagined the bright future, also we agreed that Prof and Mrs. Noguchi would be in Beijing together to attend the International Conference on Health Law and Bioethics in October 2014. We discussed, in June the nursing of Mrs. Noguchi when she would attend the Beijing Conference. Unfortunately, Prof Noguchi came to Beijing alone in October for the conference. On the eve of Christmas we received the sad news, from Prof Noguchi, "I do not feel the same festive mood that we always had this year, because Mrs. Noguchi has passed away".



I could not totally realize the pain of my brother, Prof Noguchi, towards the sad issue and even could not imagine the loneliness when he comes back to the apartment. However, you must keep strong and healthy for the university and building of the WAML ever since your beloved wife has passed away.

Mrs. Noguchi will live forever in the hearts of all colleagues of the China Health Law Society.

Best wishes
Wu Chongqi
2015-01-04

Prof Wu has encapsulated the feeling of all of us in the WAML and our sympathy for Prof Noguchi. I am in debt to Prof Wu for voicing that which we all feel. I add to Prof Wu's condolences with those of all our family within the WAML. It is part of my background at times such as this to wish Tom Noguchi a long life, to publically echo the thoughts of Prof Wu and to thank Prof Wu for teaching me my role

and for opening the door for all of us to express our regrets for his loss and to say that we all feel for our President in his loss and our loss as she was a tough and critical lady who was not shy to express her views and was the power behind the throne.

Roy G Beran
Secretary-General
World Association for
Medical Law

WAML President's Report



Thomas T. Noguchi,
President of WAML

This March issue is devoted to information for the coming WAML World Congress on Medical Law and Ethics. This is the first Congress directly managed by the WAML.

WAML Meeting Manager, Denise McNally will be responsible for running an efficient Meeting. This management is designed to standardize presentations and to be more academic with an emphasis on learning with clear objectives. Instead of accepting papers on all subjects, the program will be focused on the training of the medical and legal professions.

The WAML is engaged in long range planning for the future WAML Congresses, as it is beneficial financially to commit program chairs as well as to convention sites about four years in advance. This will result in more effective and successful Congresses.

This is the first WAML Congress that will offer the Continuation of Medical Education (CME) as well as Continuation of Legal Education (CLE) Credits to appropriate applicants. This requires that we focus on learning without using parallel rooms where attendance would not have the full learning experience. We believe we need to be more effective and reach out to the professions; WAML has been actively developing collaborative agreements with leading national and international associations and societies. It is important we reach out to younger scientists as well as students and trainees. We are eager to develop networking

poster sessions, with authors in front of the poster at the designated time. Breakfast sessions will be again networking sessions. WAML Committee meetings may also be held during the breakfast sessions.

The WAML is taking a financial risk for the first time, it will depend on registration fees as well as benefits from the convention hotel. So, I urge all attendees to support the WAML by staying at the designated hotel. If you stay outside and too few registered members stay in the convention hotel, we will lose benefits and may face a financial loss.

In order to make the Coimbra Conference successful, we need to reduce the unnecessary expenditure, but we will focus on the excellence and success of the scientific program. It will place more emphasis on learning experience rather than entertainment.

We depend on your support, so please urge your colleagues to attend, and bring more members to support continuation of the Congress. Bring your young scientists as well as student or trainee members,

The abstract deadline is coming soon. You have about 2 weeks left to submit your abstract. The final program will be out well before the Congress. Electronic abstract submission enables

prompt acceptance and notification of authors and production of the final program well before the Congress.

Let us make the Coimbra Congress successful! I will be welcoming you at the registration desk in Coimbra.

Thomas T. Noguchi
President, WAML

WAML Secretary General's Report



Prof. Roy Beran,
WAML Secretary General

It's time to prepare another Newsletter and with it another Secretary General's Report. It's hard to believe we are already into the third month of 2015 and only 5 months away from the next World Congress on Medical Law (WCML) to be held in Coimbra, Portugal. I have booked my airfare – have you? It seems only yesterday that Professor Noguchi and I visited our colleagues in Beijing and were the guests of the Chinese Health Law Society. More recently, I met with our Japanese Governor, Professor Mitsuyasu Kurosu to

discuss possibly holding a WCML in Tokyo. I was also honoured to give a talk looking at Legal and Ethical Issues in Clinical Research to the Tokyo Medical University Hospital. Professor Noguchi visited Israel as part of our strengthening ties with the UNESCO Chair in Bioethics and also gave a number of talks while being hosted by the UNESCO Chair and also by our Executive Vice President, Dr Oren Asman.

Life is extremely hectic and the Executive Committee continues to work on your behalf. We share numerous emails on a daily basis and Professor Andre Periera has been enthusiastic and diligent in the preparation for Coimbra. I remind you all that submission of abstracts closes on 1st April 2015 and will then go to the Adjudicating Committee to evaluate. The new format for the WCML will be to adopt a target of only 3 focused themes to concentrate and augment the calibre of the material to be presented. The new approach has been chosen to reduce the breadth of material to be discussed at each WCML, but at the same time to ensure that the intellectual status and scientific quality is enriched by honing down topics to select fewer issues, but to deal with these in greater depth. Each of the 3

topics has a focused plenary session with internationally recognised experts providing invited lecturers from within their area of eminence. The aim is to organise a meeting that satisfies the needs of those who dominate internationally in health law, legal medicine and bioethics while concurrently also providing food for thought for our junior colleagues who are starting out. The goal is to excite the young and nurture their search for knowledge and maybe promote a new enthusiasm to generate enhanced post-graduate research and local and international exchange. We have set our sights extremely high with the hope that the WCML becomes the 'not-to-be-missed' meeting that everyone in our spheres of interest cannot afford to miss, with those who cannot join us genuinely feeling disadvantaged by not being there.

The World Association for Medical Law (WAML) has created Memoranda of Understanding (MOU) with world-leading bodies, such that the WAML and these organizations will have reciprocal benefits. This will allow WAML members to attend the meetings of those organizations and those organisations should also occupy seats on the Council of Presidents. From my personal perspective, the WAML has entered the dialogue

with the Australasian College of Legal Medicine (Oz ACLM), which runs: Expert Witness Training Courses; Basic Law Intensives designed to initiate better understanding of the interface of medicine and law; and Practical Law Intensives to provide more focused education to teach health professionals how to appreciate more accurately the direct impact of the law on their delivery of health care; in addition to the Annual Scientific Meeting. As a result of these MOU, it is envisaged that WAML members will gain member discounts to these courses while reciprocity will ensure Oz ACLM members similar member discounts to the WCML, WAML merchandise and publication.

Some of you may wonder why I specifically identified the ACLM as the Oz ACLM but my reasoning is simple, as there exists our older sister organization the US ACLM with which WAML has also negotiated an MOU with similar reciprocity. I am acutely aware that it is unwise to identify organizations by name because invariably one will be forgotten, thus creating offence and nothing could be further from my intent. The WAML is negotiating MOU with many organizations and I selected the Oz ACLM

as an example because I was a Foundation Fellow and for a decade, its President. To avoid the potential for confusion, I also identified the US ACLM but I do not want to create any animosity by not mentioning all the other organizations with which the WAML has, or will, negotiate MOU and I would hate to see this Secretary General's report be misconstrued as showing favouritism. The purpose is to highlight the added benefit of WAML membership to open the doors of a myriad of other great national and international organizations with discounted rates for meetings and merchandise. Similarly it emphasises the 'open door' approach of the WAML to be inclusive, co-operative and to cross-fertilise with all and any organization, which hold(s) equally ethical and educative values. The above invites members of the organizations, with which the WAML has negotiated an MOU, to ask for their discounted registration for the Coimbra WCML. We sincerely hope to meet with you in Coimbra and I am never averse to discuss matters of interest and even indulge in an ale or two (or in Portugal maybe a sherry, rose or port) should you be so inclined. Knowing Andre Periera, our honorary treasurer,

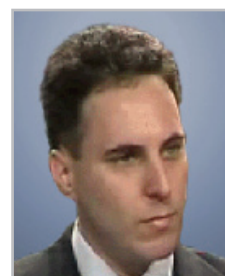
as I think I do – I can assure you that not only does he have his serious and academic qualities but he also seems to enjoy life to the absolute maximum. As President of the Coimbra WCML, I am sure he will ensure that the local atmosphere and capacity of Coimbra to excite and entice will be incorporated into this high powered conference. I invite you all to let your hair down – I would if I still had any! The Coimbra WCML is partnering with a conference exploring Islamic Bioethics. At a time when Islam is shamed by the death cult that is ISIS, I am proud to be part of a conference that emphasises that barbarism, cruelty and inhumanity is not the foundation of Islam but rather a blight on its true religious commitment, which true Muslims should follow. It is so pleasing to attend Board of Governors' meetings that include Muslims, Jews, Christians of differing denominations and Buddhists, to name but a few religions that sit around the table together with atheists and agnostics and yet we meet as brothers and sisters with a single purpose, to foster the ideals and principles of the WAML. We are there to serve your needs as our constituents and all of us consider it a privilege to be allowed to do so. As I write this Secretary

General's report on a Sunday night in beautiful Sydney, I am acutely aware of how small our world is, how different we all are and how much we can learn from each other. There may be only one God, (as is taught in my religion), or there may be many (as believed by others) but it makes not a jot of difference if we follow the basic tenet of all religions to care for others, do good and protect our fellow as we would like to be protected ourselves. It follows that a critical review of Islamic Bioethics is timely and I sincerely look forward to learning more about it. As they say both in Judaism and Islam – 'May peace be with you!' Join us in Coimbra and learn with us in both the WCML and the Review of Islamic Bioethics. I hope that my ramblings have motivated you to become more engaged with the WAML and to join us in Coimbra. If that has been achieved then I will ask for one more commitment, namely to stay at the conference hotel. We are banking on our participants taking advantage of our agreed discounted conference rate for rooms, which also translates to other savings when running the meeting. As I always conclude, the WAML is your organization, though now with added inducement of membership benefits to affiliated organizations

with which WAML has entered MOUs. Should you have suggestions, expectations and requests from your Board of Governors or Executive please feel free to make contact with us. We are here for your benefit – only you can decide if we meet your needs. We definitely cannot do so if you don't let us know where we are not achieving what you expect of us.

Roy G Beran
Secretary-General
World Association for
Medical Law

WAML in The Electronic Age



Oren Asman,
WAML Educational Committee Chair

The WAML has been going through an electronic revolution over the past several years and thus its overall exposure increased significantly.

Our [WAML Facebook page](https://www.facebook.com/the-waml) currently has over seven hundred "Likes" and serves as a platform for sharing information, news, links and online content: ([Link: https://www.facebook.com/the-waml](https://www.facebook.com/the-waml))

Our [WAML YouTube](#)

channel gained over 3500 views. (Link: <https://www.youtube.com/user/TheWAML>)

It now also contains 2 videos that focus on the themes of the 21st World Congress for Medical Law to be held in Coimbra, Portugal on August 2nd-6th 2015.

An interview on **Islamic Bioethics** (Link: <https://www.youtube.com/watch?v=VuRPbc5onHg>)

An interview on **Ageing and Health Law** (Link: <https://www.youtube.com/watch?v=tEUbMXXvQTK>)

Our **WAML Newsletter** is published online for the 6th year now and has become an important vehicle for sharing information and knowledge internationally (Link: <http://wafml.memberlodge.org/page-1155583>)

Our **WAML Journal of Medicine and Law** has “gone green” and is now distributed to the WAML members electronically.

Our members and prospective members are encouraged to use, share and contribute to these online resources and spread the word. We are happy to have technology on our side and would love to further expand its use for the benefit of the members and the society

Dr. Oren Asman
WAML Educational
Committee Chair

The international quarterly journal “Medicine and Law”



Mohammed Saif-Alden Wattad
WAML Editor-in-Chief, International
Journal of Medicine and Law

Nearly five years have passed since I was appointed to serve as the Editor-in-Chief of the International Journal ‘Medicine and Law,’ on August 2010, at the 18th Congress on Medical Law (WCML).

Serving in this position has been a great responsibility. This is in particular due to the high longstanding reputation of the Journal under Prof. Amnon Carmi, who established the Journal in 1978 and served as its Editor-in-Chief till 2010.

During these five years, it has been my intention to enhance the quality of published articles. For this to be achieved, I have taken the following important measures: First, Mr. Yehuda Levy was appointed as a second language editor. Together with Mrs. Dorothy Daboval, Mr. Levy has elaborated on the language editorial work of the published articles, thus putting them in the best linguistic shape. Both editors have suc-

cessfully put the Journal in the highest possible professional level. Second, Ms. Natali Goldring was appointed as the Indexing Editor, thus professionalizing the process of indexing each published issue of the Journal. And third, the review process of submitted articles has been altered to take the form of blinded peer-review, with additional review if required. The Journal has become very selective and competitive, thus accepting the very best articles among all submitted for publication. This has been possible due to the high quality of the review process, through which the reviewers provide authors with very detailed review of their articles. It has been my desire to enlarge the quantity of the published articles, yet preserve the high standard of academic publication. For this to be achieved: First, the Journal has constantly published calls for papers, in particular before or following national and international conferences related to the Journal’s areas of interest. The Journal has accessed the WCMLs serving as a platform for publishing papers otherwise presented at these conferences. Second, the Journal has developed the concept of “Theme Issue,” whereby members of the editorial board served as guest editors for these particular issues. This way, the Journal not only guarantees

the publication of a larger amount of papers but encourages professional papers written by leading experts in the theme issues’ subject-matter. Since 2010, the Journal has invited additional international experts to join the editorial board, thereby guaranteeing its capacity to review a wider range of topics, reinforcing the comparative and international nature of the Journal. More than 20 experts have joined the editorial board and each, in his/her role, has contributed to the Journal’s reputation and its quality. Together with the World Association for Medical Law (WAML) leadership, I have been working on achieving an Impact Factor for the Journal, which shall reflect on the Journal’s high reputation, thus providing the Journal with official recognition of its professionalism. This recognition is of the utmost importance to the Journal, especially given that the Journal has been identified by the renowned Kennedy Institute of Ethics as a “Priority Journal” and remains the ‘flag ship’ of the WAML, making it an integral component of the rights of membership of the WAML.

Dr. Mohammed

* The 2014-2015 Schusterman Fellow, Visiting Assistant Professor, University of California at Irvine, Department of Political Science; Assistant Professor, Zefat

Academic College, School of Law; Editor-in-Chief, the International Journal 'Medicine and Law'; Member of the World Association of Medicine and Law, and Member of the Management Board of the International Center for Health, Law and Ethics.

21st World Congress on Medical Law Coimbra, Portugal August 2-6, 2015



Dr. André Dias Pereira,
Program Chair - 21st WCML
<http://wafml.memberlodge.org/event-703110>
Professor of Law - University of Coimbra - Portugal
Director - Centre for Biomedical Law - University of Coimbra

The University of Coimbra, the uptown



("Alta") and Sofia were classified by UNESCO as World Heritage sites



According to the Rector of the prestigious University of Coimbra, "the decision of UNESCO underlines the universal value of the Portuguese culture and language, as well as the major role played by Portugal in the formation of the world as we know it". Coimbra becomes the 15th UNESCO World Heritage site in Portugal. Situated on a hill overlooking the city, the University of Coimbra with its colleges grew and evolved over more than seven centuries within the old town. Notable university buildings include the 12th century Cathedral of Santa Cruz and a number of 16th century colleges, the Royal Palace of Alcáçova, which has housed the University since 1537, the Joane Library with its rich baroque decor, the 18th century Botanical Garden and University Press, as well as the

large "University City" created during the 1940s. The University's edifices became a reference in the development of other institutions of higher education in the Portuguese-speaking world where it also

exerted a major influence on learning and literature. Coimbra offers an outstanding example of an integrated university city with a specific urban typology as well as its own ceremonial and cultural traditions that have been kept alive through the ages.

Dr. André Dias Pereira

WAML Meeting Planning and Administration



Denise McNally,
WAML Administrative Officer and Meeting Planner

JOIN us at the 21st World Congress on Medical Law (WCML) August 2 – 6, 2015



Important Dates:

Abstract Submission:
April 1, 2015

Notification to Authors:
April 30, 2015

Early Registration: May 15, 2015

Late Registration: July 15, 2015

Abstract Submission
<http://wafml.memberlodge.org/page-1841452>

Early Registration
– <http://wafml.memberlodge.org/event-703110>

Hotel Reservations
Deadline June 1, 2015 – <http://wafml.memberlodge.org/Hotel-Reservations>

Ground Transportation
- Due to lack of interest, bus transportation service from Lisbon Airport to Coimbra has been cancelled August 2, 2015. Please see <http://wafml.memberlodge.org/Ground-Transportation> for additional options.

If you are interested in booking a Pre or Post Congress Tour or arrange private transportation please visit <http://waml2015.admeus.net/>. You may also visit <http://www.portugaltravelholidays.pt/en/our-tours.html> for additional tours.

Preliminary Program
<http://wafml.memberlodge.org/page-1841460>

Scientific Committee
<http://wafml.memberlodge.org/Scientific-Committee>

Islamic Bioethics Session
<http://wafml.memberlodge.org/Islamic-Bioethics>

The Congress will take place at HOTEL VILA

GALE and will commence with a Welcome Reception Sunday evening August 2, 2015. The Welcome Reception is the perfect venue to meet with colleagues. Registration is open and we encourage everyone to attend.

Book your hotel room early as the deadline is June 1, 2015. We recommend staying at the hotel where the program and all functions will be provided. WAML negotiated complimentary meeting space, complimentary internet and breakfast buffet in your room rate of 100.00€ single room per night and 120.00€ for double twin room per night. **IMPORTANT NOTE: If you choose to stay at another hotel the WAML will have to charge an entry fee of \$75 on top of your registration.** So please plan on staying with us at the Hotel Vila Galé Coimbra.

The Congress will conclude Thursday, August 6, 2015 with a Gala Dinner and Awards Ceremony. **Plan to check into the hotel August 2, 2015 or earlier and checking out August 7, 2015 or later to ensure you are able to attend all functions of the organization and have time for tours you may be of interest.**

Your Full Registration Package Includes:

- Admission to the Scientific and Poster Sessions
- Admission to the Sunday Evening Welcome Reception
- Admission to the Civic Reception (Sponsored by Coimbra Mayor at City Hall)
- Admission to the Thursday evening Gala Dinner and Awards Ceremony
- Admission to all coffee breaks

Guest registration will be offered when registering.

André Dias Pereira will be your Program Chairman.

The program will consist of four topics:

- Ageing and Health Law
- Information Technology & Health Law
- Migrations & Health Law
- Islamic Bioethics

Please check the website often for program updates. See you in Portugal!

Save the date for the 22nd World Congress on Medical Law which will be held August 7-11, 2016 in Los Angeles, California (USA).



The Congress will commence with a Welcome Reception, Sunday evening August 7, 2016, followed by the Opening Ceremony the morning of Monday, August 8, 2016 and conclude on August 11, 2016, with a Gala Dinner. We encourage everyone to attend.

WAML has secured the Millennium Biltmore Hotel <http://www.millenniumhotels.com/millenniumbiltmorelosangeles/> as your Congress venue. Congress attendees will receive a special room rate of \$199 USD single or double and complimentary guest room wireless internet. WAML President Thomas Noguchi will be your Program Chairman and we look forward to seeing you in Los Angeles, California (USA).

Membership Dues

The purpose of the World Association for Medical Law (WAML) is to encourage the study and discussion of health law, legal medicine, ethics and forensic medicine, for the benefit of society and the advancement of human rights.

Membership in WAML is Annual and for 2015 your membership dues are \$150. WAML members enjoy many benefits which include access to quarterly E-Newsletters,

discount registration fees to the WAML Congress, notice of upcoming events, active website information and the "Medicine and Law" electronic Journal. You recently received a notice that your 2015 membership dues were owed by January 1, 2015. We encourage you to log into the WAML website www.thewaml.com and pay. You also have the option to pay by check or wire transfer. If you would like to pay by check or wire transfer please contact me at worldassocmedlaw@gmail.com for further information.



<http://www.facebook.com/thewaml>



<http://twitter.com/thewaml>

FUTURE MEETINGS

Of Affiliated National Associations and
Collaborating Organizations

Law & Medicine Down Under: Shared Experiences, Divergent Paths

June 7-13, 2015

Sydney, Australia

Website: <http://www.law.siu.edu/australia-cle.html>

International Council of Nurses

June 19-23, 2015

Seoul, Republic of Korea

Website: www.icn2015.com

21st Annual WAML World Congress

August 2-6, 2015

Coimbra, Portugal

Website: www.thewaml.com

5th International Conference on Advance Care Planning and End of Life Care

September 9 – 12, 2015

Munich, Germany

www.acpel2015.org

49th Annual Meeting of the National Association of Medical Examiners

October 2-6, 2015

Charlotte, NC (USA)

Website: www.thename.org

22nd Annual WAML World Congress

August 7-11, 2016

Los Angeles, CA (USA)

Website: www.thewaml.com

50th Annual Meeting of the National Association of Medical Examiners

September 9-13, 2016

Minneapolis, MN, USA

Website: <http://www.toyo.ac.jp/site/english-about/campuses>

Website: www.thename.org

51st Annual Meeting of the National Association of Medical Examiners

October 13-17, 2017

Scottsdale, AZ, USA

Website: <http://www.toyo.ac.jp/site/english-about/campuses>

Website: www.thename.org

21st

World congress on medical law

Coimbra, Portugal August 2-6, 2015

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Do You Have an Idea, Comment, or Suggestion?

Please contact

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World Association For Medical Law

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June - August 2015

www.thewaml.com

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Legal Doctrine of Medical Due Process as a Fundamental Model of Medical Law



Dean, Professor Dr. Katsunori Kai
Waseda Law School,
Waseda University

The area of life science, medical science and medicine is very dynamic and flexible. Recently, the invention of “induced pluripotent stem cell (= iPS Cell)” by Prof. Shinya Yamanaka (the Nobel Prize winner), of Kyoto University in Japan, in 2007, gives us the possibility to use “regenerative medicine” or “tissue engineering” without the need to break human embryos, as is necessary when using “embryonic stem cell (=ES Cell)”. Now efforts are being made to overcome the risks of cancer using the technique of iPS Cell.

In the post genome era, it may be disadvantageous

for mankind that the law regulates too rigorously scientific and medical activities of this field because it can obstruct the progress of life science or medicine. On the one hand, it is true that the freedom of study and research is guaranteed by Art.23 of the Constitution in Japan. On the other hand, we must carefully examine whether this freedom is unlimited or not. Prof. Koichi Bai, who was the founder of medical law in Japan, had already pointed out some important fundamental perspectives on this aspect in 1974.

- 1) Awareness of the margin of legal intervention into natural facts and progress of natural science,
- 2) The role of law in adjusting conflicts between one interests and another interests, and
- 3) Awareness of positive meaning of legal approach, or guarantee and establishment of fundamental rights (Koichi Bai, *Kagaku to Ho to Seimei to* (Science, Law and Life), in Takamine Matsuo (Ed.), *Seimeikagaku Noto* (in

Japanese) (Life Science Note), 1974, Tokyo University Press, p.197ff. especially pp.200-201.).

These perspectives seem to me to still be very useful today. We must consider the balance between promotion of life science or medical science and protection of human rights in this field. We must rethink how we should regulate illegal misconducts in this field. On this point, Prof. Dr. Albin Eser, who is one of the most famous scholars of medical law in Germany, had also expressed similar opinions in 1984 and recently he proposed a global theory. In his theory, he insists that we should change our paradigm from “Sektorales Medizinrecht” (Sectored Medical Law) into “Integratives Medizinrecht” (Integrative Medical Law including bioethics), in 2006 (Albin Eser, *Perspektiven des Medizin (straf)rechts*. In: Wolfgang Frisch (ed.), *Gegenwartsfragen des Medizinstrafrechts* (in German), 2006, pp. 9-31.). I fundamentally agree

Disclaimer: The articles presented in this newsletter express the views of the authors and do not necessarily reflect the attitudes or opinions of the WAML

with his opinion.

In connection with these perspectives, I have proposed the Legal Doctrine of Medical Due Process as a Fundamental Model of Medical Law, since 2002 (See Katsunori Kai, Hikensha Hogo to Keiho (in Japanese) (Protection of Human Subjects and Criminal Law), 2005, Seibudo, Tokyo, p.7f. and 30ff.). There is a fundamental viewpoint on the way of regulation behind this theory. The ways of regulation are various.

The first is the hard law style (criminal law, administrative law etc.) as in Germany. This system is not suitable for regulation in the medical and scientific fields, because it is too hard to keep up with the everchanging trend of life science.

The second is the soft law style with many official or specialized guidelines in Japan. These guidelines have no legal sanctions, therefore they cannot ensure the prevention of serious abuses. As they are a kind of patch work, we cannot understand the fundamental viewpoint. This model is not suitable in this field even though they are flexible.

The third is the mixture style of hard and soft law, as in UK and Australia. According to this model, we can usually keep up with various new medical and scientific technologies and problems.

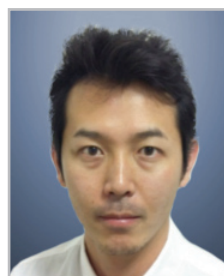
As a result of comparative study, in Japan, we should aim at this mixture of hard law and soft law. And yet, we should consider **“the Legal Doctrine of Medical Due Process”** (See Kai, supra). This is the legal theory which I have advocated for a long time. According to this theory, as a rule, medical innovation/medical research without due process is unlawful. The Medical Due Process system includes (1) informed consent, (2) balancing risks and benefits, (3) due review by an appropriate ethics committee, (4) a system of compensation to human subjects because of the impossibility of foreseeing all potential risks, (5) it contains some legal sanctions against extreme abuses. Following this doctrine, we can build a bridge between law or bioethics and medical and scientific research and practice. I think that we can realize it by enacting the Fundamental Law of Bioethics in Japan.

In my opinion, this theory is meaningful also in the field of useful but disputable new technics for mankind like a neuroscience or nanotechnology (see Katsunori Kai, *Neurolaw in Japan*, in Tade Mattias Spranger(Ed.), *International Neurolaw — A Comparative Analysis*, 2011, Springer Verlag, Heidelberg, pp.215-225 (in English); Katsunori Kai, *Model of Regulation*

on Medical Innovation/ Medical Research from the Perspective of Comparative Law, The Waseda Law Review, Vol.86, No.4, 2011, pp. 253-261 (in English)). We should consider these problems internationally. I think it better that the model of regulation of medical innovation/medical research should be the mixed type of hard law and soft law, namely, four steps which consist of public guideline(=soft law), civil regulation, administrative regulation, and lastly criminal regulation(=hard law). I hope that **“the Legal Doctrine of Medical Due Process”** will become a fundamental model of medical law.

**Dean, Professor
Dr. Katsunori Kai**
Waseda Law School,
Waseda University

Regenerative Medicine Acts in Japan



Tsunakuni IKKA, Ph.D.
Assistant Professor of the Department
of Forensic Medicine in Kyoto
Prefectural University of Medicine

In Japan, there are three acts on Regenerative Medicine (RM). First, the Act on the Promotion

of RM was enacted and enforced in April and May 2013. After Dr. Shinya Yamanaka was awarded the Nobel Prize for Physiology and Medicine in 2012, the Japanese government became keen to build up the system where RM is provided safely in a clinical setting with an intention of making RM a powerful industry. As this is lawmaker-initiated legislation, there are no detailed rules; this Act has only 14 articles. Another two acts were enacted in November 2013 and enforced in November 2014: namely the Act on the Safety of RM (ASRM), Revised Pharmaceuticals Medical Devices and the Therapeutic Products Act respectively (PMDTPA).

From the view point of medical law, healthcare law and bioethics, I am particularly interested in ASRM. Before this Act was implemented, there only existed the Guideline for Somatic Stem Cell Clinical Research, which was drawn up by the Ministry of Health Labor and Welfare (MHLW). Despite that, researchers in general seem to have complied well with the Guideline. On the other hand, there were no rules for privately-practiced cell therapies using somatic stem cells.

In September 2010, a 73-year-old Korean male patient visiting Kyoto city for medical tourism died soon after receiving

somatic stem cell therapy at a local private clinic. The forensic autopsy of the deceased failed to provide the evidence for the cause-effect relationship between the therapy and his death. Upon such verdict, there was no further criminal investigation pursued, and no civil lawsuit brought against the clinic. This case was reported by David Cyranoski, in 468 Nature 465, 25 November 2010. Nonetheless, the physician worked at a new clinic, similar to the one in Kyoto, in Fukuoka city. According to the press, 3,700 persons, including Korean and Japanese, had received similar cell therapies by December 2012. Both the accident in Kyoto and the news concerning the clinic in Fukuoka were so shocking to those researchers who specialized in RM that the Japanese government began to pave the way for action by the legal system with a view to protect clinical research of RM and to monitor and control the private practice of RM.

The most important scheme defined in ASRM is the pre-review process undertaken by a Certified Regenerative Medicine Committee (CRMC) which needs to be recognized by MHLW and may be setup at universities, medical institutions or academic associations.

The act classifies the RM therapy into the following three categories according to the degree of their associated risks to humans:

- Class I (high risk), i.e. using cells such as iPS cells, ES cells and allogeneic cells
- Class II (intermediate risk) i.e. using cells such as autologous somatic stem cells
- Class III (low risk) i.e. using cells such as autologous somatic cells

When a researcher or a physician intends to provide Class I RM, he/she is required to submit a RM provision plan to a Specially Certified Regenerative Medicine Committee (SCRMC) and get approved by MHLW respectively. When a researcher or a physician intends to provide Class II RM, he/she is required to submit a RM provision plan to a SCRMC and to the local regulating body of MHLW. When a researcher or a physician intends to provide Class III RM, he/she is required to submit a RM provision plan to a CRMC and to the local regulating body of MHLW. In sum, the higher the risk of RM is, the more rigorous the pre-reviewing process is.

Next, I would like to show the parties concerned in the typical steps involved in the procedure of obtaining an approval for providing

Class I RM in sequence: (1) a researcher in an RM provider institution submits his/her RM provision plan to the chief at his/her institution. (2) When the chief approves the protocol, he/she proceeds to consult with the SCRMC on the protocol. Before the consultation is initiated, the chief may consult with his/her institutional research ethics committee whether he/she should approve the protocol in its institution, but it is not a legal obligation. (3) SCRMC reviews the RM provision plan under the criteria defined by the act and provides some recommendations, but these recommendations are not legally binding. (4) The chief submits the protocol for the review by MHLW with SCRMC recommendation. MHLW consults the Health Science Council established by MHLW and the Council gives advice. (5) MHLW may approve or disapprove the protocol in question. If necessary, MHLW directs the chief to modify the protocol. It takes at most 90 days in MHLW procedures. (6) Finally, when the chief approves the protocol practice, the applicant's institution can start offering the practice.

ASRM has two important implications for medical and healthcare laws in Japan. Firstly, prior to the introduction of

the Act, the distinction between clinical research and (private) treatment practice was made because the two were under different controls. The Act has put clinical research and (private) treatment practice of RM under the same control. Secondly, as a result, (private) treatment practice of RM must receive prior examination by a CMRC. It means that a physician's clinical discretion has been replaced by the criterion specified by the Act which is the criterion of CMRCs. It was so problematic that before these changes in the afore-mentioned relationship between treatment and research, not enough discussion as to why RM is so special took place.

Both the ASRM and PMDTPA draw a blueprint for applying RM in the clinical settings and RM making pharmaceutical industries. There is a key feature in PMDTPA. In the light of the nature of cell products, a clinical trial conducted just for confirmation of safety and presumption of efficacy is permitted, and the product is released. In that case, within the interim period after the approval and release, the confirmation of efficacy trial must be undertaken for a re-approval. Some serious problems of the new conditional approval system have been raised

in the article by Douglas Sipp in 16(4) Cell Stem Cell 353 (2015).

**Tsunakuni IKKA,
Ph.D.**

Informed Consent and Decision-Making on Behalf of Incapacitated Adults in Japan



Kazuki Chiba, Ph. D.
Professor, Faculty of Law
Hokkai Gakuen University

I would like to discuss informed consent and decision-making on behalf of incapacitated adults for their medical care, not including medical research and terminal care. There has been much discussion about this subject in Japan as in other countries.

Informed Consent

The doctrine of informed consent has been developed over a number of years in Japan by the theories, judgments and the medical community, such as the Japan Medical Association. The Supreme Court decided that there is an obligation by the physician to explain the medical care. The Medical Care Act (No. 205 of July 30, 1948) provides that “In the delivery of medical care, a physician, dentist, pharmacist, nurse

or other medical care professional shall give appropriate explanations and endeavor to foster understanding in the recipients of medical care”. An amendment Act in 1997 (Art. 1-4-2) added an obligation to make an effort.

Informed consent can be divided into two parts. First, the physician shall inform the patient sufficiently before giving medical care. Second, the physician cannot give medical care without valid consent from the patient. If the physician neglects his or her obligations, the physician is liable for damages for the breach of the right of self-determination, regardless of the improvement of the patient’s health condition for the medical care. What is the extent and range of the obligation of the physician? There is much discussion regarding the criteria of the obligation of the physician.

Decision-making on Behalf of Incapacitated Adults

Japan currently has an aging population and is trying to cope with many problems related to medical care. Decision-making, on behalf of incapacitated adults, is one of the most important matters. In medical practice, physicians inform a member of the family about the medical care for the incapacitated adult assuming he or she has a family. A member

of the family consents and decides on the basis of the patient’s advance will, or the presumption of their will, and the best interest for him or her. This practice lacks legal grounds and the family does not have the right to make decisions on behalf of incapacitated adults.

The Ruling for Guardianship

The Japanese Civil Code (Act No. 89 of April 27, 1896) provides for guardianship. With respect to any person who constantly lacks the capacity to discern right and wrong, due to mental disability, the family court may order the commencement of guardianship at the request of the person in question, his or her spouse, any relative within the fourth degree of kinship or a public prosecutor and so forth (Art. 7). “A person who has become subject to the ruling of commencement of guardianship shall be an adult ward, and a guardian of an adult shall be appointed for him or her” (Art. 8). The family court may appoint a guardian of an adult (Art. 843-1) by taking many matters, such as the opinions of the adult ward and all of the conditions of the adult ward into account (Art. 843-4). The guardian of an adult may perform any juristic act, related not only to the administration of property but also to the

personal supervision on behalf of an adult ward, as the statutory agents for considering the opinion of the adult ward and his or her physical and mental situation and life (Art. 858). The guardian can enter into a contract with health care facilities for medical care as the statutory agent. Some law-makers say that the guardian cannot give consent and decide the medical care on behalf of an adult ward. On the other hand, some researchers have the opposite interpretation.

Ruling for Legal Framework for the Mental Health

The Law Related to Mental Health and Welfare of the Person with Mental Disorder (Act No. 123 of May 1, 1950) provides hospitalization for medical care and protection. The amendment Act in 2013 abolished the system about the person responsible for the patient’s protection (usually his or her family), who has many obligations for the person with a mental disorder, and reformed the hospitalization for medical care and protection. In the new law, the administrator of the mental hospital may cause a person to be hospitalized without his/her consent so long as the family and so forth consents to such hospitalization. The person who is judged to

be mentally disordered, based on an examination by a designated physician, needs hospitalization for medical care and protection and so on (Art. 33-1). The definition of family is the spouse, a custodial parent, the person responsible for his or her support, the guardian or the curator (Art. 33-2). There is no priority regarding the family member who gives consent to the hospitalization for medical care and protection.

Conclusion

We need a legal framework for decision-making on behalf of incapacitated adults. I think that the structure and the role of the family have dramatically changed in Japan. There are times when incapacitated adults have no family or cannot rely on his or her family. It is time that we discuss the reform of guardianship and the legislation of the special law regarding decision-making on behalf of incapacitated adults.

Kazuki Chiba, Ph.D.

Proposed Amendment of Data Protection Act



Yuichiro Sato, LLM
Associate Professor of Civil Law
and Medical Law, Tokyo
Gakuei University

The Japanese Data Protection Act (hereinafter “DPA”) was enacted in 2003 and became effective in 2005. It exempts research use of identifiable information, if the use is for research purposes and if the user belongs to an academic institution such as a university (art. 50). As described later, the use of health information for research is controversial and involves difficulties.

Japanese DPA differs from the “European standard” (i.e. Data Protection Directive 95/46/EC) in that: (1) it does not establish a single data protection authority; each ministry has administrative power according to its competence (cf. EU directive art. 28); (2) it does not have a notion of “sensitive personal data” (cf. EU directive art. 8); and (3) it is not clear whether a data subject has a civil right to disclose his/her personal data through court procedure

(A court rejected a claim from a patient saying that DPA does not provide a right of action through civil court procedure (1978 HANREIJIHOU 27 (Tokyo Dist. Ct., 27 Jun. 2007)), cf. EU directive arts.12 and 22). Recently the Cabinet Office proposed an amendment bill of DPA to the Diet, which will solve the above deviations. I welcome the coming amendment generally, but have some fear that (misunderstanding of) the amendment will cause some problems for medical research.

We have “segment method” in data protection, so DPA binds only persons/bodies in the private sector; central and local governments each have Data Protection Statute/Ordinance (and “arm-length body” such as “National” universities and research institutes are bound by a special statute). In some cases, exemption in research is not provided; in many ordinances of local government, approval of the data protection committee would be needed (in each case) to disclose data to researchers (and I haven’t heard that process used actually).

There are some sets of “ethical” guidelines which the central government, such as Ministry of Health and Ministry of Education, established. These sets

of guidelines generally require research subjects’ consent (depending on the nature of research; for example, opt-out will suffice in many epidemic researches).

In the coming amendment, sensitive personal data DPA calls it “personal data which need special care” is defined as “personal data include race, personal belief, social status, medical history, whether he/she has committed a crime or he/she is a victim of a crime, and other information defined by the cabinet order as to need special care to avoid discrimination, prejudice and other”. Collection of sensitive personal data is strictly restricted it must meet one of 6 requirements provided in art. 17(2) unless data collector has data subject’s consent; cf. other personal data may be collected without consent unless the data collector uses “fraudulent method”, and disclosure to a third party needs similar requirements (cf. other personal data may be disclosed by “opt-out”). Researchers are exempted from data controller’s duties (art. 50), but whether disclosure of personal data (especially sensitive personal data) to researchers is lawful or not is unclear. It is generally said that researchers have had difficulties in collecting data from doctors,

hospitals and local governments after implementation of DPA.

Recently, I was consulted by a researcher planning collection of health data from municipals in a large-scale cohort study. She told me that a data manager said “re-identification” will be prohibited by the art. 38 of the coming amendment. This is based on misunderstanding of the amendment (art. 38 is a prohibition of re-identification by a third party if it gets “de-identified big-data” from the data controller after de-identification; “de-identified big-data” may be sold and bought without data subject’s consent, such as a large number of consumers’ preferences which cannot trace the individual consumer), but I fear that misunderstandings like that will occur in many cases, which will lead to a shrinkage in medical research. I understood the data manager’s hidden message as “Think about recent scandals! Mass media are sensitive and curious about the handling of personal medical history.”

At a governmental committee meeting, Professor Norio Higuchi, Tokyo University, said that DPA actually inhibits medical research, although it exempts researchers from data controller’s duties, and insisted on the need of

specific provisions for medical research using personal information, saying, “We may not fail twice” < http://www.kantei.go.jp/jp/singi/kenkouryou/jisedai_kiban/dai1/siryou8.pdf>. I would partly agree with his opinion; I think a scheme is needed which authorizes the use of (sensitive) personal data without the data subject’s consent. If a committee, or committees, like IRBs in the U.S.A or the Section 251 and the Confidentiality Advisory Group in England is/ are established, situations would be better. It may be an “approval” of research projects by an authority, which should be avoided in terms of freedom of research. But considering the grave chilling effect of the coming amendment, I think it be necessary.

Yuichiro Sato, LLM

WAML President’s Report



Thomas T. Noguchi,
President of WAML

Editor Dr. Wilbur and I express our gratitude to Prof. Katsunori Kai as the Guest Editor for this June

issue.

It is not too late to register to attend the Coimbra World Congress of Medical Law (WCML) August 2 -6, 2015. To register go to <http://wafml.memberlodge.org/>.

I would like to thank the WAML Treasurer, Dr. Andre Pereira, Coimbra University, for taking on the task of being the WCML scientific program chair coordinating with the scientific committee. This is the first time the WAML program chair has completed the final program so far in advance of the beginning of the Congress.

I also express our thanks to WAML Meeting Manager, Denise McNally for her more than a year of dedicated effort in making sure that WAML will have a financially successful Congress.

The WAML Executive Committee has devoted a great deal of effort to collaboration with International and regional organizations. During the last two years, we have worked hard to develop a collaborative affiliation with the American College of Legal Medicine (ACLM), and the leadership of the ACLM has been actively working closely with the WAML. For the 2015 WCML, Continuation of Medical Education (CME) accreditation will be obtained through the ACLM for the many ACLM members who are

also WAML members.

WAML and ICC

Last year, the Prosecutor’s Office of the International Criminal Court (ICC) requested the President of the WAML to attend the Scientific Advisory Board (ICC SAB) in June 2014 in Den Hague, the Netherlands.

For those who don’t know about the ICC, the Wikipedia has this description:

“The **International Criminal Court (ICC or ICt)** is an intergovernmental organization and international tribunal that sits in The Hague in the Netherlands. The ICC has the jurisdiction to prosecute individuals for the international crimes of genocide, crimes against humanity, and war crimes. The ICC is intended to complement existing national judicial systems and it may therefore only exercise its jurisdiction when certain conditions are met, such as when national courts are unwilling or unable to prosecute criminals or when the United Nations Security Council or individual states refer investigations to the Court. The ICC began functioning on 1 July 2002, the date that the Rome Statute entered into force. The Rome Statute is a multilateral treaty which serves as the ICC’s foundational and governing document. States which become

party to the Rome Statute, for example by ratifying it, become member states of the ICC. Currently, there are [123 states](#) which are party to the Rome Statute and therefore members of the ICC.

The ICC has four principal organs: the Presidency, the Judicial Divisions, the Office of the Prosecutor, and the Registry. The President is the most senior judge chosen by his or her peers in the Judicial Division, which hears cases before the Court. The Office of the Prosecutor is headed by the Prosecutor who investigates crimes and initiates proceedings before the Judicial Division. The Registry is headed by the Registrar and is charged with managing all the administrative functions of the ICC, including the headquarters, detention unit, and public defense office.”

Collaboration with the International Academy of Legal Medicine (IALM)

Last year, as President of the WAML, I sent out our request for collaboration with other international organizations. We specifically chose, as the first, collaboration with IALM.

Prof. Santo Devidè FERRARA, President of the IALM, has invited WAML to offer a workshop on medical law and ethics. I have offered the subject of

“The Retention of Tissue and Organs – Health Law and Ethical Issues” at the IALM 2016 symposium which will be in Venice, June 21-24, 2016

Preparation of 2016 World Congress I have been designated as 2016 Program Chair and have chosen the topic of “Hollywood and Medical Law and Ethics”. There will be notable featured speakers from Hollywood. Prepare your schedule to attend this exciting and enjoyable learning experience.

We are meeting in Coimbra, Portugal in less than two months. Meanwhile, I would like to pledge the WAML management will welcome and seriously consider any suggestions from the membership.

Thomas T. Noguchi
President, WAML

WAML Secretary General's Report



Prof. Roy Beran,
WAML Secretary General

This is the last Secretary-General's Report before the World Congress on Medical Law (WCML),

which will be held in Coimbra, Portugal, in the first week of August this year. All the abstracts have been received, reviewed and their authors notified of acceptance, or otherwise. People should have their travel plans in place and yet again I commend all of you, who plan to come to Coimbra, to stay at the conference hotel. This has many advantages, including convenience, will assist in keeping costs of the conference more affordable and ensure ease of networking with better use of time.

Having reviewed my quota of abstracts, I can assure you all that the standard of meeting will be excellent. Knowing Professor Andre Pereira, the Conference Chairperson, as I do, I have no doubt the organization will be seamless and appear effortless, although I know how much work he has put into the job. Appreciating the commitment of all the organising personnel, I am excited that we will all be meeting in less than 3 months and I have no doubt that in 3 month's time we will look back on a very successful and rewarding Congress – see you there!

The World Association for Medical Law (WAML) has been very active in fostering its relations with other like-minded organisations, including

the International Academy of Legal Medicine, which will hold its Scientific Meeting in Italy this year. WAML has been invited to the table as an equal partner. Similarly the Academy has an open invitation to Coimbra.

Closer to home, the Australasian College of Legal Medicine has organised its Annual Scientific Meeting to be held in conjunction with the newly established Association of Forensic Physicians and the local Pathologists' College in September in Queenstown, New Zealand. I have been to Queenstown, on the South Island of New Zealand, on a number of occasions, and it is one of the most beautiful places on the planet. The Australasian College will also host one of its Expert Witness Training Programs in conjunction with this meeting in Queenstown and all WAML members receive preferential membership discounts to participate.

The WAML has been liaising with the Southern Illinois University to assist with its “Summer School” being held in Sydney, in our first weeks of winter. We are particularly involved in the comparative exploration of malpractice. Again, I am looking forward to a very informative and exciting program. I could spend my whole

life travelling between conferences and meetings but unfortunately reality has to set in and somewhere, along the way, I am forced to also earn a living as a simple coalface clinician. While I have to limit my extra curricular activities, this will not stop me catching up with as many of you as is possible, at as many meetings and conferences as are possible, and at as many venues as resources will allow.

The constant expansion of the WAML activities, with its networking and absolute commitment to enhance scientific and intellectual excellence, serves as a tonic to fuel the excitement that attaches to learning and teaching. I am truly looking forward to the next few months, to the WCML in Portugal, together with its concurrent program into Islamic Bioethics. This will be the icing on a cake that offers the opportunity for all of us to grow as individuals and to contribute to fostering an atmosphere of knowledge.

I hope to see you soon in Portugal, if not sooner!! Remember that the WAML is your organisation and you only reap what you sow. I encourage all of you to become more involved, let us know your needs and expectations and help us serve you better.

Roy G Beran
Secretary-General
World Association for
Medical Law

Welcome to Coimbra!



André Dias Pereira
WAML Congress Program Chair

Founded in 1290, the University of Coimbra has been listed as an **UNESCO World Heritage** site since June 2013.

The University of Coimbra shaped the character of the Portuguese Speaking countries, notably Brazil. This historical relationship has nowadays a renewed interest with over 10% of the students coming from the biggest South American country. Coimbra is a University town with a **cosmopolitan flavor**, which attracts students and researchers worldwide, from China to Morocco, from East-Timor to Colombia.

The Faculties of Law and Medicine have a prominent role in the University and in the City. Medical Law has been developing for a long period of time with its roots found

back in the beginning of the 20th Century with the first discipline on Law and Deontology of Pharmacists. Later, in 1988, the Faculty of Law founded the **Centre for Biomedical law**, a European standard research institution in the field. In the last 20 years, the Faculty of Medicine also includes Medical Law, together with Medical Ethics and Deontology, in its curriculum. Coimbra has one of the biggest Hospitals in Portugal, which is very active in clinical research and education at a European level.

Thus, when you come, you will find an intellectual and spiritual environment and background for debating and studying Medical Law.

The best reason to come to Coimbra is to listen and to discuss with almost 200 speakers, coming from over 40 countries, from the 6 Continents, with very high-level presentations concerning the fields of (1) **Ageing & Health Law**; (2) **Information Technologies & Health Law**; (3) **Migrations & Health Law**, as well as very interesting presentation on general topics of Medical Law.

Moreover, we are very happy to accommodate a superb Congress on **Islamic Bioethics**, on August 5th and 6th.

There is also a very

enjoyable social program, with a welcome reception by the pool and feeling the breeze of the **Mondego River**, *Sunday evening*; a terrific night tour to the **World Heritage University**, *Monday evening*; a wonderful town reception in the Cloisters of the Convent where the founder of the Portuguese Nation (D. Afonso Henriques) lies – the **Church of Saint Cross**, *Tuesday evening* and, finally, a nice **Gala Dinner** with Portuguese traditional music - **Fado** – by the pool, illuminated by the moon, in a warm mid-summer night, *Thursday evening*...

Pre and Post Conference tours are very easy to organize, since Portugal is a welcoming country for tourism, with high-quality infrastructure to receive friends and colleagues from all cultures and creeds. Be it sun and sand or history and monuments; or adventure and mountains – all of this can be found near Coimbra, less than 1 or 2 hours away.

I hope to see you on August 2nd evening, by the pool, at Hotel Vila Galé, in Coimbra!

André Dias Pereira
WAML Congress
Program Chair

WAML Meeting Planning and Administration



Denise McNally,
WAML Administrative Officer
and Meeting Planner

**JOIN us at the 21st
World Congress on
Medical Law (WCML)
August 2 – 6, 2015**



You may register at <http://wafml.memberlodge.org/> and if you would prefer to complete a registration form please contact me at worldassoc-medlaw@gmail.com.



If you haven't made your hotel reservations please do so by downloading the form at <http://wafml.memberlodge.org/Hotel-Reservations>. If you need assistance please contact me.

Ground Transportation from Porto and Lisbon airports to Coimbra, Portugal may be found at the following link <http://wafml.memberlodge.org/Ground-Transportation>.

If you are interested in private transportation when you arrive or booking a Pre or Post Congress Tour please visit <http://waml2015.admeus.net/>. You may also visit <http://www.portugaltravelholidays.pt/en/our-tours.html> for additional tours.

Preliminary Program - <http://wafml.memberlodge.org/page-1841460>

Scientific Committee - <http://wafml.memberlodge.org/Scientific-Committee>

Islamic Bioethics Session - <http://wafml.memberlodge.org/Islamic-Bioethics>

All educational sessions will take place at HOTEL VILA GALÉ and will commence with a Wel-

come Reception Sunday evening August 2, 2015. The Welcome Reception is the perfect venue to meet with colleagues. We recommend staying at the hotel where the program and all functions will be provided. Room rates

are 100.00€ single room per night and 120.00€ for double twin room per night. **IMPORTANT NOTE: If you choose to stay at another hotel the WAML will have to charge an entry fee of \$75 on top of your registration which will be collected when you check in at registration.** So please plan on staying with us at the Hotel Vila Galé Coimbra.

The Congress will conclude Thursday, August 6, 2015 with a Gala Dinner and Awards Ceremony. **Plan to check into the hotel August 2, 2015 or earlier and checking out August 7, 2015 or later to ensure you are able to attend all functions of the organization and have time for tours you may be of interest.**

Your Full Registration Package Includes:

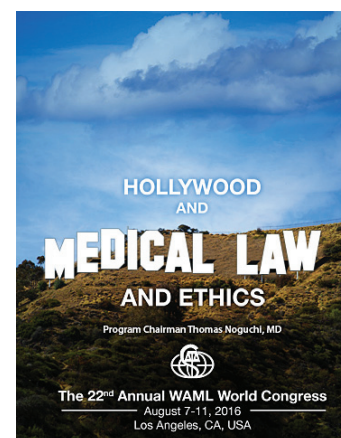
- Admission to the Scientific and Poster Sessions
- Admission to the Sunday Evening Welcome Reception
- Admission to the Civic Reception (Sponsored by Coimbra Mayor at City Hall)
- Admission to the Thursday evening Gala Dinner and Awards Ceremony
- Admission to all coffee breaks

Guest registration will be offered when registering. André Dias Pereira will be your Program Chairman.

The program will consist of four topics:

- Ageing and Health Law
- Information Technology & Health Law
- Migrations & Health Law
- Islamic Bioethics

Please check the website often for program updates. See you in Portugal!



Save the date for the 22nd World Congress on Medical Law which will be held August 7-11, 2016 in Los Angeles, California (USA).

The Congress Theme will be Hollywood and Medical Law and Ethics. The Congress will commence with a Welcome Reception, Sunday evening August 7, 2016, followed by the Opening Ceremony the morning of Monday, August 8, 2016 and conclude on August 11, 2016, with a Gala Dinner. We encourage everyone to attend.

WAML has secured the Millennium Biltmore Hotel <http://www.millenniumhotels.com/millenn>

[niumbiltmorelosangeles/](#) as your Congress venue. Congress attendees will receive a special room rate of \$199 USD single or double and complimentary guest room wireless internet.

WAML President Thomas Noguchi will be your Program Chairman and we look forward to seeing you in Los Angeles, California (USA).

Membership Dues

The purpose of the World Association for Medical Law (WAML) is to encourage the study and discussion of health law, legal medicine, ethics and forensic medicine, for the benefit of society and the advancement of human rights.

Membership in WAML is Annual and for 2015 your membership dues are \$150. WAML members enjoy many benefits which include access to quarterly E-Newsletters, discount registration fees to the WAML Congress, notice of upcoming events, active website information and the "Medicine and Law" electronic Journal. You recently received a notice that your 2015 membership dues were owed by January 1, 2015. We encourage you to log into the WAML website www.thewaml.com and pay. You also have the option to pay by check or wire transfer. If you would like to pay by check or wire transfer please contact me

at worldassocmedlaw@gmail.com for further information.

**Do You
Have an Idea,
Comment, or
Suggestion?**

Please contact
Denise McNally
mcnallyd@cvalley.net



<http://www.facebook.com/thewaml>



<http://twitter.com/thewaml>

21st

World congress on medical law

Coimbra, Portugal
August 2-6, 2015

FUTURE MEETINGS

Of Affiliated National Associations and
Collaborating Organizations

Law & Medicine Down Under: Shared Experiences, Divergent Paths

June 7-13, 2015

Sydney, Australia

Website: <http://www.law.siu.edu/australia-cle.html>

International Council of Nurses

June 19-23, 2015

Seoul, Republic of Korea

Website: www.icn2015.com

21st Annual WAML World Congress

August 2-6, 2015

Coimbra, Portugal

Website: www.thewaml.com

5th International Conference on Advance Care Planning and End of Life Care

September 9 – 12, 2015

Munich, Germany

Website: www.acpel2015.org

Australasian College of Legal Medicine (ACLM) Expert Witness Course

September 17 – 18, 2015

Queenstown, New Zealand

www.legalmedicine.com.au/courses

Australasian College of Legal Medicine (ACLM) Annual Scientific Meeting

September 18 - 20, 2015

Queenstown, New Zealand

Website: www.legalmedicine.com.au/courses

49th Annual Meeting of the National Association of Medical Examiners

October 2-6, 2015

Charlotte, NC (USA)

Website: www.thename.org

2nd International Arab Forensic Science and Forensic Medicine Conference

November 8-10, 2015

Riyadh, Kingdom of Saudi Arabia

Website: <http://nauss.edu.sa/asfsfm2015/theArab.htm>

23rd International Academy of Legal Medicine

June 21 – 24, 2016

Venice, Italy

Website: www.ialm.info

22nd Annual WAML World Congress

August 7-11, 2016

Los Angeles, CA (USA)

Website: www.thewaml.com

50th Annual Meeting of the National Association of Medical Examiners

September 9-13, 2016

Minneapolis, MN, USA

Website: www.thename.org

51st Annual Meeting of the National Association of Medical Examiners

October 13-17, 2017

Scottsdale, AZ, USA

Website: www.thename.org



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World Association For Medical Law

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Disclaimer: The articles presented in this newsletter express the views of the authors and do not necessarily reflect the attitudes or opinions of the WAML

Report of the 21ST World Congress on Medical Law



André Dias Pereira
WAML Congress Program Chair

The **21st World Congress on Medical Law** took place in Coimbra, Portugal, from 2 to 6 August 2015. Founded in 1290, the University of Coimbra is listed as **UNESCO World Heritage** site, since June 2013. **The University of Coimbra is celebrating its 725th Anniversary;** It is the oldest University in Portugal and one of the oldest in the world. The Faculty of Law and the Faculty of Medicine have a prominent role in the University and in the City. Therefore,



Medical Law has been developing for a long period of time. Its roots can be found back in the beginning of the 20th Century with the first discipline on Law and Deontology of Pharmacists.



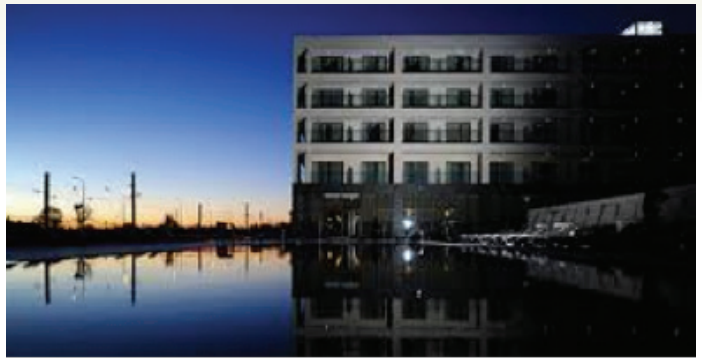
The Rector the University of Coimbra – Prof. Dr. João Gabriel Silva during the Opening Ceremony

Later on, in 1988, the Faculty of Law founded the **Centre for Biomedical law**, a European-standard research institution in the field. In the last 20 years, the Faculty of Medicine also includes Medical law, together with Medical Ethics and Deontology in its curriculum. Moreover, Coimbra has one of the biggest Hospitals in Portugal, which ranks as very active on clinical research and education.

220 abstracts were received and reviewed by the selection committee and there are almost 200 participants from all over the World, coming from over 40 countries, from the 5 Continents, with high-level presentations concerning the fields of (1) Ageing & Health Law, (2) Information Technologies & Health Law, (3) Migrations & Health Law, as well as very interesting presentation on general topics of Medical law.

Moreover, we were very happy to accommodate a superb Congress on Islamic Bioethics, on August 5th and 6th.

The Spanish speaking sessions that lasted two full days had a stunning scientific level and a very friendly atmosphere.



During the first days of August 2015, all participants have enjoyed a nice social program:

The welcome reception by the pool of Hotel Vila Galé, feeling the breeze of the Mondego River, *Sunday evening;*



An amazing Night Tour to the World Heritage University, *Monday evening;*



José Antonio Seonae; Stefania Negri; André Pereira and Federico Montalvo



The **Mayor's reception** took place in the Ceremony Hall of the Town Hall and in the Cloisters of the Convent, Tuesday evening;



Finally, a nice **Gala Dinner** with Portuguese traditional music - Fado – at Hotel Vila Galé, *Thursday evening*.



I would like to gratefully acknowledge all who provided so much input and effort into the planning and implementation of the meeting.

I sincerely thank our invited speakers for their contributions to the program.

The World Congress on Medical Law started a long time ago, with the labor done through internet and email by several committees who have been strengthening ties and developing scientific canons all over the world.



This organization has been a very rewarding experience: to work with so many and so qualified colleagues, who have done so much for the high scientific standards of the Congress.

I am referring to the colleagues of the following committees: **SCIENTIFIC COMMITTEE, Abstract Selection Committee, Early Career Award Committee**



Virgílio Rodriguez-Vazquez, Anne-Marie Duguet Chair of the Committee, Berna Arda and Ken Berger



Miguel Vieito Villar receiving the Young Researcher award

Poster's Award Committee



Ana Elisabete Ferreira receiving the Best Poster's presentation

Moreover, the organization of the Congress that has been done with the leadership and efficiency of the **Meeting Manager of the 21st WCML, Mrs. Denise McNally** with the very important support of my collaborator **Adv. Carla Barbosa**.



Furthermore, we all appreciated the effort and work of our **Volunteer's Team**: coordinated by Carla Barbosa, they were: Ana Elisabete Ferreira, Ana Lopes Chaves, Ana Luísa Santos, Andreia Andrade, Arthur Kullok, Beatriz Naufél, Flávio Tribuna, Gabriela Lacerda Assunção, Rui Claro and Sara Madeira.



One last word of gratitude to **Prof. Thomas Noguchi**: he had the vision and the courage to enroll WAML in a direct organization of the Congress, ensuring a very strong scientific commitment and providing all means to achieve a great goal: many of our conferences and seminars were credited by well known and recognized scientific authority – the American College of Legal Medicine and our Congress offers Continuing Medical Education (CME) credits.



Board of Governor's lunch – Sunday, August 2nd



Tom Noguchi with Roy Beran (left) and André Pereira (right) - Photo by Oren Asman. The Executive Committee working as a team.

André Dias Pereira

Program Chair of the 21st World Congress on Medical Law

Ageing & Health Law



Guilherme de Oliveira

1. The elderly person's fundamental right to health care is less respected and fulfilled than the same right when applied to younger persons, due to **ageism** – the prejudice shown towards ageing and the aged, which may assume various forms “including the absence of services for older adults; age based decision making in health and age rationing; (...) paternalism; forced decisions; (...)” (Law Commission of Ontario, 2009).

All legal instruments must be used to fight against ageism – International Law, Domestic Law, Soft Law.

There are some doubts on the use of a Convention, but in the end of the day an international instrument seems convenient.

Soft law is often more accepted by health professionals than ordinary health law.

2. Health Law has to pay attention to **full respect** for elderly patients, in order to achieve

- a) *Protection and promotion of personal autonomy and informed consent practice; adequate information;*

slowness and time to understand and to decide.

In fact, there is evidence that: the European public perception of the elderly is that of a person of low competence; the elderly are expected to tolerate and accept physical discomfort and pain; they are not properly informed of the reasons why medical tests are carried out; they are not consulted about major decisions regarding their health or life; there is an abusive practice of the presumption of incapacity to understand and believe, followed by a systematic referral of decision to the family, at best; the content of “advanced directives” is used even when the patient is still able to understand and decide; screening instruments for domestic violence and abuse are used, without information and consent of the elderly person.

b) Effective legal representation

It can be said that the means of representation that we inherited from twentieth-century laws no longer meet the needs of protecting people – they were delayed in their enforcement, entailed public statements about the fragilities of the protected citizen, and generated excessive incapacity which extended to all areas of life.

New forms of protection have appeared – more agile, more discreet and more effective: Sachwalterschaft/Betreuung/Sauvegarde de justice/Mandat de protection future/Amministrazione di sostegno/Autotutela/Advanced directives.

c) Quick schemes for damage compensation

In most countries, traditional regimes are too slow and poorly cost-effective.

The *no-fault system* apparently would be better, but it's not easy to accept it for being more expensive and for somehow taking responsibility away from doctors. At least, it could be of use when the patients are elderly, or it should be given priority to judicial cases that involve the elderly (Brazil).

d) “Ageing in place”

Health Law should contribute to maintaining links with places, family and peers, for that staying home or within a community environment is a friendlier way to deliver care, although supported by professionals or trained family/neighbor members.

3. Health Law must be focused on **access** and on **appropriate medical techniques**, to assure

a) Access; quality of care; trained professionals

Several unsuitable practices have been reported around the world:

“one problem per visit”; fewer referrals of the elderly to other specialists; overmedication rather than counseling or other more time-consuming therapies; disregarding relevant symptoms due to the prejudiced view that they are inevitably age-related; deliberation of “low priority” for surgery based merely on age; inclusion or exclusion of therapies based on age and not on the evolution of the disease; pure and simple access denial; lack of preparation of health professionals in gerontology and subsequent substandard care.

b) Long-term care instead of acute care

The priority of health systems has been in “acute care”; but elderly patients often don't need acute care. Systems are lacking equipment and professionals dedicated to “long term care”.

c) Friendly modes of administration of medicines; Friendly medical devices

There is a huge development of this field, coming from “human factors” and ergonomics. But there is always room for health law to intervene in pointing better practices and avoiding errors due to being unable to open the blister pack, taking the wrong doses or giving up on understanding how appliances work.

d) Using information technology

But the planned expansion in the use of information technology calls for special caution: manufacturers must take in account changes in visual acuity, auditory capacity, decreased memory capacity, decreased attentional control, and difficulty in goal maintenance.

Plus, monitoring patients raises problems relating to loss of privacy, depending on the level of intrusion; and there are also problems of security, because widespread use of electronic devices can generate a false sense of security that leaves elderly patients more vulnerable to fraud.

e) Medical research / Clinical trials

The inclusion of the elderly in trial cohorts makes research more difficult and also more expensive (difficulty of understanding, comorbidity, ethical concerns). This leads to the systematic underrepresentation of the elderly in clinical trials for medicines they are eventually going to take. As a consequence, these medicines are not as appropriate or safe as they should be.

An appropriate representation of the geriatric population should be enrolled in clinical trials; after all, this would only be an expression of the “evidence based medicine”

4. Health Law must take part on the **sustainability** of health care systems

a) Promoting one's health through *healthy lifestyles*

Every citizen assumes an active role in 'the creation of health'.

A broader notion of "public health" is coming up, beyond that of contagion and epidemics: illness arising from individual behaviors, free and self-regarding.

The self-regarding nature of the unhealthy behavior chosen by citizens makes much more difficult any coercive state intervention: imperative regulations conflict with autonomy and with free consent.

Relying on information and education to foster voluntary collaboration from the population may be insufficient. Is there a place for some compression of freedom, for the sake of solidarity and sustainability?

b) *Discussing the rationing of care*

An age-based criterion for health care rationing has been proposed since a long time ago. But it's too rough a criterion, for various reasons.

Simply rationalizing will be sufficient? Most people think it will.

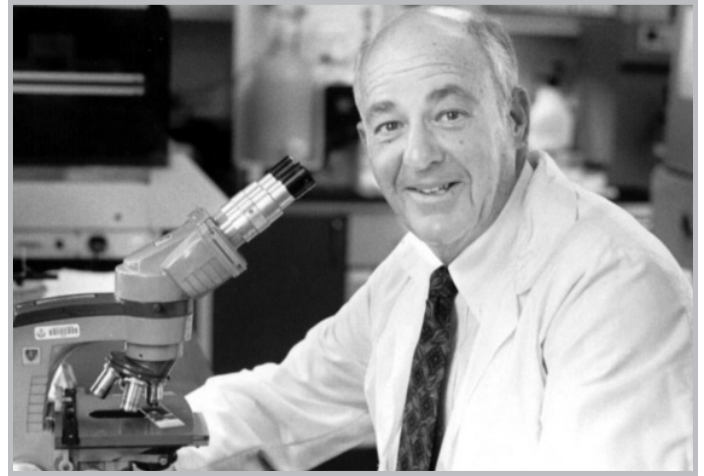
5. Conclusions

Ageism is the underlying bias to fight against. All instruments of law must be used – international law, domestic law and soft law. Huge improvements are being made to give better, more respectful, more comfortable, and less expensive care for elderly persons.

Health Law will be part of this move.

Medicolegal Aspects of Right to Die:

Societal and Ethical concerns



Cyril H. Wecht, M.D., J.D.

The legal history of cases concerned with the right to refuse medical care and the right to die goes back more than 100 years in the United States. The first statement in U.S. law regarding the ethical principle of autonomy was set forth in the famous case of *Schloendorff v. The Society of the New York Hospital* (1914). Judge Benjamin Cardozo (later to become one of the most respected U.S. Supreme Court Justices in our country) stated that "Every human being of adult years and sound mind has the right to determine what shall be done with his own body". For the most part, subsequent litigation in various states has essentially adhered to the same basic principle, namely, that patients have a right to determine whether they wish to continue with life-sustaining treatment. Courts have required "clear and convincing evidence" of an incompetent patient's wishes, i.e., evidence that those were the thoughts clearly and consciously expressed by that patient prior to the onset of an incompetent medical status.

It should be noted that the U.S. Supreme Court in reviewing lower court decisions has determined that under the Due Process Clause of the 14th Amendment to the U.S. Constitution, there is no constitutional right for physician-assisted suicide.

Despite highly regrettable politicization of health care reform measures that encouraged physicians to discuss with Medicare patients the kinds of treatments they would want as they neared the end of life, advanced planning for end-of-life decisions has been

**Do You Have an Idea,
Comment, or Suggestion?**

Please contact
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receiving more and more attention with each passing year. Many people are signing living wills that specify the care they want as death nears, and powers of attorney that authorize relatives or surrogates to make decisions are being implemented with increasing frequency.

These advanced directives early on were sometimes too vague to cover many different, unexpected medical situations. Now a growing number of states are promoting a specific program to help guide physicians in ethically implementing a patient's specific instructions. These programs are known as "Physician Orders for Life-Sustaining Treatment" or "POLST". About eighteen states have enacted laws or regulations that authorize use of these forms, and similar legislative efforts are being considered in more than two dozen other states. These laws generally allow medical institutions to decide whether to offer the POLST forms and to always permit patients and families to decide voluntarily whether to use them. These programs also call for the training of health care providers to teach them how to discuss end-of-life treatment choices with patients suffering with terminal illness, or anyone else wishing to define their health care preferences.

In a recent national survey in the United States, it was determined that more than 80% of patients believe it is important to have their end-of-life wishes set forth in writing, although less than one fourth of them actually accomplished that planning. The survey showed that 70% of respondents did not have written advanced directives. About 40% stated that they had discussed with a close relation what medical treatments they would want at the end of life, but had not followed through to set those wishes down in writing. About 25% said they did not want to talk about death or dying, although only 3% said that they had not thought about the subject at all. Interestingly, only 8% of the patients in that survey had ever been asked about end-of-life treatment wishes by their physician.

Advanced directives allow patients to make their end-of-life wishes known in the event they are unable to communicate. Typical advanced directives include the following: a living will, which addresses such issues as cardiopulmonary resuscitation (CPR); Do Not Resuscitate (DNR) order; Do Not Intubate (DNI) order; and artificial nutrition and hydration. These also include medical power of attorney and physician orders for life-sustaining treatment (POLST).

Physician-Assisted Suicide

Since Ancient Greece, physicians have been tempted

to help desperate patients kill themselves. However, from that time to the present, physician-assisted suicides have been rejected by most physicians as being antithetical to the basic rule of the Hippocratic Oath.

It is fascinating to reflect upon the history of physician-assisted suicide, thinking back in the United States to Dr. Jack Kevorkian who developed his "suicide machine" in 1991.

Three states (Oregon, Washington and Montana) allow for physician-assisted suicide under very strict parameters. In 2011, the Supreme Court of India laid out guidelines for the use of euthanasia in extreme situations involving terminally ill patients. However, the Court did not go so far as to allow for "Active Euthanasia", in which the patient is given life-ending drugs or other lethal intervention. The Court outlined what it considered to be "passive euthanasia", such as ending antibiotics, turning off a heart-lung machine, not proceeding with surgical interventive measures, etc. A handful of other countries, including Belgium, Luxemburg, the Netherlands, and Switzerland allow some form of euthanasia.

In February of this year, the Canadian Supreme Court unanimously overturned the 1993 ban on physician-assisted suicide on the grounds that it impinged on citizens' rights. How much this ruling will affect individuals wishing to die in Canada remains to be determined in the years ahead.

Sociopolitical concern reached such quasi-hysterical proportions in the United States by some groups about "death panels", alleging that a seemingly innocuous bipartisan proposal for Medicare to pay doctors for their time if the patients want to discuss end-of-life issues (e.g., whether they wanted to be kept alive at all costs if there were no chance they would ever leave the hospital), as to result in the deletion of this provision from the final legislative enactment.

As painful as these decisions may be, they are only the beginning of future excruciating reckoning between the soaring costs of medical care and increasingly strained resources. One-fifth of American deaths take place in intensive care, where ten days of most likely futile efforts can cost as much as one-third of a million dollars.

The results of highly troubling surveys resulted in approval by the American Board of Medical Specialties for subspecialty certification in "hospices and palliative medicine". An American living with cancer today has roughly one in four chance of dying in a

hospital and a similar chance of spending a portion of his or her last month in intensive care. Chances are higher with patients who suffer from chronic lung or heart disease. An American with Alzheimer's Disease will very likely spend most of his or her last months in a nursing home. Yet many long-term care facilities are woefully understaffed and ill-equipped to care for demented people. Less than 45% of dying Americans receive hospice care at home, and nearly half of those are referred to hospice within just two weeks of death. Fortunately, over the past two decades, the fields of geriatrics, hospice and palliative medicine have demonstrated that much better care is both feasible and affordable. Some groups have suggested the development of a "Safe Dying Act", which would require medical schools to adequately train medical students to access and treat pain, listen to patients' concerns, collaborate with patients and families in making treatment decisions, etc.

Conclusion:

It is undeniably true and extremely disturbing that despite all the brilliant technological, highly sophisticated advances in medicine that we have experienced in the past few decades, serious problems still exist pertaining to treatment of patients with terminal illnesses. Economics, politics, personal and religious beliefs, and a failure to understand basic medical concepts will continue to present many obstacles in finding ethical, moral and legal ways in which to deal with these problems. Medical educators, ethicists, attorneys, economists, and many other groups must work together to deal with these medical-legal, societal, and ethical concerns regarding end-of-life treatment and the right to die.

National and international professional organizations such as WAML can contribute significantly to the development and promulgation of rational, scientifically sound policies and procedures to deal with this extremely formidable challenge.

Cyril H. Wecht, M.D., J.D.

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Past President, American Academy of Forensic Science
Clinical Professor, Department of Pathology, University of Pittsburgh, School of Medicine
Adjunct Professor of Law, Duquesne University, School of Law, School of Health Science, and School of Pharmacy
Distinguished Professor of Pathology, Carlow University

Information Technologies & Health Law

Telemedicine, Health Law and Ethics



Richard Wilbur

The 21st Century has seen an explosion in the use of information technology worldwide. Not all parts of the globe have progressed as rapidly as others, but all have seen impressive changes in the speed and breadth of the dissemination of knowledge. Health Care is likewise changing briskly. In many areas these two swiftly changing areas overlap and complement each other leading to better care. However, this confluence also raises some legal and ethical issues.

One area of particular interest is that of telemedicine. The ability to have a health professional treat a patient, offer a consultation or teach an improved method of diagnosis or treatment without the need for either party to travel is an obvious improvement in the ease of delivering health care. The patient saves both time and money by eliminating travel and waiting room time. (S)he also is able to have laboratory results, radiological images and physical findings checked by more than one physician without having to go to multiple offices.

All of this is especially valuable for patients who have difficulty getting to a doctor's office because of distance, physical handicap, lack of transport, weather, etc. It is also enhanced when coupled with an electronic health record which eases the problem of moving relevant data from one health delivery site to another.

However, inevitably, problems arise. Some come with the initial cost of setting up such a system, loss of personal touch and danger of loss of privacy from hacking. From the legal liability side there are problems from a number of potential technical breakdowns, medical licensure if the transaction

crosses legal borders and diagnostic or treatment error because of limitations in examination at a distance. In countries such as the USA with defined physician payment networks, the distant patient and the doctor may be in different payment systems even if they are in the same geographic jurisdiction and this would often be true everywhere if political borders are crossed by the telemedicine interaction. Defining responsibility for remuneration of the health care provider could require arbitration or litigation.

Both legally and ethically there are problems as to the establishment of the doctor-patient relationship if it had not existed previously. After a single long distance examination, has a legal responsibility for follow up care been established? If so, how is it carried out? Also, an important part of a professional liability trial is the establishment of “the standard of care”. What is it for telemedicine? Does it differ in the jurisdiction where the patient is located from that one where the doctor is located?

There is the issue of “informed consent” if there is any treatment when the doctor and patient have not actually met. This issue is particularly acute in telesurgery either direct or under surgical telementoring. In Telesurgical Mentoring, an academic surgeon skilled in a particular new procedure and/or instrument is guiding a distant surgeon through his/her first operation in that surgeon’s own hospital which the expert has never visited. How much information about this arrangement does the patient need to know in order to give truly informed consent? It is the community surgeon’s first operation using this procedure, but the telementor’s two hundredth.

Telemedicine offers a multitude of opportunities to advance health care, but also raises a host of new legal and ethical questions yet to be settled.

22nd World congress on medical law

Los Angeles, California
August 2-6, 2015

worldassocmedlaw@gmail.com

Migrations & Health Law

Immigration and Health Care in the United States



Thomas Noguchi

Islamic Bioethics

A Report on the 4th International Islam and Bioethics August 5-6 2015



Vardit Rispler-Chaim

Oren Asman

History

The 1st International Conference on Medical Ethics and Medical Law in Islam was organised at The University of Haifa, Israel in March 2001. Papers presented at the conference were published in the WAML international journal of Medicine and Law vol.21 no.2, 2002. More than fifty scholars, from various disciplines, including law, medicine, theology, sociology, history, Islamic studies, etc., attended the sessions. This attested to the interdisciplinary nature of the issues being considered.

The 2nd International Conference on Medical Ethics

and Medical Law in Islam was held in College Park, Pennsylvania. It attracted approximately 30 papers and an audience of about 100 people from various disciplines. Papers presented in that conference were published in several periodicals, and as a collection of papers.

The 3rd conference of “Islam and Bioethics” was held in Antalya, Turkey, April 14-16, 2010, and 35 participants, representing a variety of academic disciplines, presented papers together with an additional ten posters being presented., Papers presented at the conference were published in a volume entitled “Islam and Bioethics”, ISBN: 978-975-482-930-3, Ankara, 2011. In 2012 the book was also published as an electronic version.

Rational

All three conferences ended with the call from the participants to continue the series of international conferences on Islamic Bioethics. All felt that there is so much more to discuss yet there are very few forums in the world that host scholars dealing with various aspects of Islamic bioethics. Part of the aim was also to be inclusive and bring together participants from Muslim and non-Muslim countries and faiths alike.

Since the Muslim population in Europe and the West is growing, and with it the ethical dilemmas connected to multiculturalism, the demand for Islamic bioethical solutions is both natural and urgent. The subject of multicultural concerns in bioethics was raised in previous conferences but was even more emphasized in the 4th International Islam and Bioethics conference.

The 4th International conference on Islam and Bioethics

The 4th International Islam and Bioethics Conference was assigned two days as a concurrent program within the first of the Annual Scientific Meetings of World Association for Medical Law (WAML) in Coimbra, Portugal, and took place between August 5-6, 2015. The University of Haifa sponsored the Islam and Bioethics Conference which allowed the attendees of the WAML meeting to gain greater exposure to Islamic doctrines and helped foster a better understanding between the different cultures.

The program included 25 active participants who presented papers relevant to Islamic Bioethics, together with posters on the topics, and an audience of about 30-50, including scholars of medical law, legal medicine and bioethics, who otherwise would not

have had the opportunity to expand their appreciation of these topics. Those presenting their works came from Europe, Asia, Africa, and North America with the keynote plenary address delivered by Prof. Farhat Moazam, a world famous scholar in bioethics and a physician from Karachi, Pakistan.

Resolutions and plans for the future

At the end of the conference, the last session was dedicated to reflections on the content of the conference and the following were some of the resolutions that were reached:

According to participants' preference, the 5th Islam and Bioethics International Conference will preferably be held in two or three years.

Papers presented at the 4th Islam and Bioethics Conference will be offered to the International Journal, **Medicine and Law**, for peer review and consideration for publication.

The organisers wish to thank the WAML and its leaders, especially the President, Prof. Thomas Noguchi, and the Program Chair of the 21st World Congress on Medical Law, Prof. André Dias Pereira, for all their support and are looking forward to further cooperation with the WAML in the future. Special thanks go to Ms. Denise McNally for her administrative assistance to make this conference the success that it was.

Vardit Rispler-Chaim and Oren Asman

President's message



Thomas T. Noguchi
WAML President

This 2015 World Congress of the WAML is our first World Congress planned and managed by WAML centrally and the Executive Committee together with the WAML Meeting Manager, Denise McNally, worked hard to make sure the meeting will be successful

This 2015 World Congress's success will guide future meeting planning and management. Many attendees expressed satisfaction with a great scientific program with three themes to concentrate discussion and control our expenditure. The conjoint Islamic ethics program surely added to our success.

I would like to thank so many persons who made the WAML World Congress successful. Thanks to the daily support of the Executive Committee, and members of the Board of Governors, I would like to specially thank the scientific program chairman, Andre Pereira. Meeting manager and planner, Denise McNally, the program committee, paper and poster judges, and the enriched program support by the Coimbra University.

Future World Congress:

The Board of Governors approved the following sites and program chairs.

2017 Vugar Mammadov, Governor, Baku, Azerbaijan

2018 Oren Asman, Executive Vice President, exact site will be determined by the Executive Committee

2019 Katsunori Kai, Secretary General of the Japanese Association of Medical Law, Tokyo, Japan

2020 Kenneth Berger, MD JD, Governor, Canada

There will be a benefit to WAML, it will have greater chance to select the best convention hotel, we will have chance to coordinate themes, so the WAML Meeting Manager and planner will have a much easier time preparing the world congresses.

We have learned a great deal about the value of central management of the WAML Congress. In the future they will have much higher academic caliber programs, and a standardized procedure with theme orientated congresses. Further since it is annual, we can reach out to many areas where we have not had meeting. The aim of the WAML is to reach out to every corner of the globe to collaborate in future advancement.

2016 Program Chair message

Thomas T. Noguchi
WAML 2016 Program Chair

I am honored to serve as Program Chair for the 2016 World Congress of Medical Law. This role is

to concentrate the scientific program. The World Congress is managed and directed by the WAML Executive Committee along with meeting specialist, Denise McNally and her staff who guarantee hotel rooms, speaking facilities and social programs.

The Congress Theme is Hollywood and Medical Law and Ethics with three subthemes:

Theme #1 Patient centered innovative health care including emphasis on patient safety, patient satisfaction, clinical ethical consultation, graduate training, medical malpractice and resolution,

Theme #2 BioGenetics: – discussion will be Patent conflict, current and future advances, in medical law and ethics, including food safety.

Theme #3 Advances in Legal Medicine especially its contribution to society including prevention.

Please start thinking about your presentation and start preparing your abstract. We will call for abstracts soon and will have the final program by June 1, 2016.

The Program chair will send out monthly information about the progress of the 2016 scientific program and useful information, such as where to go for helpful information. Including where to eat, where to visit and what you and your family can do while in Los Angeles.

Summer in Los Angeles is a famous vacation land, so bring your family and enjoy.

World Congress site in 2016;

The World Congress will be held at the Millennium Biltmore Hotel in downtown Los Angeles. In the last 10 years every thing has been happening there. Top restaurants are opening up, and the most active entertainment center is being developed, which is called "LA Live". It is an entertainment center complex including sports, all sorts of restaurants and shops and all is within walking distance from the Convention hotel. During lunch time, attendees may just walk out and sample food service. And in the evening can make reservations for a fine dining experience. Now top class restaurants are opening monthly in an area which is safe to walk in during the evening. Even those of us who live in Los Angeles are surprised with the fast beautification and varied activities of downtown LA.

Program at a glance: Welcome Reception Sunday, August 7, 2016. The first day of scientific session will begin Monday, August 8, 2016, and conclude in three days. The Gala dinner will be on Wednesday, August 10, 2016. This will give attendees enough time to try out the lunch and dinner opportunities.

WAML Secretary General's Report



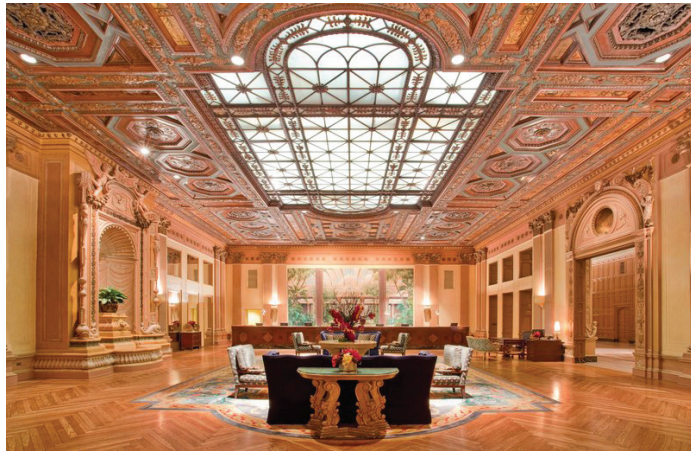
Prof. Roy Beran,
WAML Secretary General

Coimbra was the first World Congress on Medical Law (WCML) for which the World Association for Medical Law (WAML) took absolute responsibility, both for content and for local administration, thereby also assuming the financial risk. This experiment has proven positive and I have no doubt that those who attended were suitably impressed, allowing for the fact that no conference can ever escape total criticisms but these lessons will be taken on board for future WCMLs.

Particularly memorable for me was the close camaraderie that developed amongst participants and the warmth generated. The setting was perfect and attention to detail by our Program Chair, Professor Andre Pereira, was inspiring. He has left our next Program Chair a difficult task but I am sure our President, Professor Thomas Noguchi, is up to the challenge to equal the success of Portugal and add a touch of magic in the home of Walt Disney.

For me, the inclusion of the Islamic Bioethics conference was especially impressive. It allowed better understanding of a faith for which most publicity is often not flattering. It permitted discussion in an open and inclusive fashion without fear or favour. There was the chance to interact with scholars who could explain some of the customs and beliefs in a fashion not usually available to non-Muslims.

I am a strong believer in the concept that any organization is only as strong as its members allow. The enthusiasm of the participants in Coimbra provided a great springboard to enhance the momentum in Los Angeles. WAML is actively fostering interaction and exchange with like-minded organisations and through that, extending its goal of education within our areas of interest in health law, legal medicine and bioethics. The WAML has adopted a very inclusive policy to ensure that all who foster similar beliefs and aspirations can benefit from a wider forum. The WAML has been invited to actively



Millenium Biltmore Hotel in downtown Los Angeles is 2016 WAML congress site.



<http://www.facebook.com/thewaml>

participate in congresses of other organisations, such as the International Academy of Legal Medicine, and to provide focused sessions that allow WAML to both sell its message to a wider audience while gaining additional knowledge and experience from those bodies. This offers a level of symbiosis that must benefit all concerned with the resultant outcome being greater dissemination of knowledge into the wider community.

The executive of the WAML and the Board of Governors continue to work for everyone's benefit. We aspire to an horizon beyond the immediate membership with the goal being to strengthen not only the future of the WAML but also that of health law, legal medicine and bioethics beyond the lifetime of the current incumbents. There has been a gradual changing of the guard with new faces appearing and some of the old faces no longer able to travel the long distances necessary to attend our WCML's. To those who could not join us in Coimbra, I personally wish every happiness and pleasure and sincerely hope that our paths cross in the not-too-distant future. Those to whom I address these comments, know who you are and know I am thinking of you. I have purposefully not mentioned names as Invariably one forgets an important name thereby creating unnecessary umbrage, which I hope to avoid.

For those about to enjoy the Jewish High Holidays, the WAML wishes you a fantastic New Year and wellbeing over the fast. For the rest of you we also wish every success and happiness. As always I invite each and everyone of you to become more active in your organisation.

Roy G Beran
Secretary-General
World Association for Medical Law



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THEWAML](http://twitter.com/THEWAML)

22nd World congress on medical law

Los Angeles, California
August 2-6, 2015

FUTURE MEETINGS

Of Affiliated National Associations and
Collaborating Organizations

Australasian College of Legal Medicine (ACLM)

Expert Witness Course

September 17 – 18, 2015

Queenstown, New Zealand

Website: www.legalmedicine.com.au/courses

Australasian College of Legal Medicine (ACLM)

Annual Scientific Meeting

September 18 - 20, 2015

Queenstown, New Zealand

Website: www.legalmedicine.com.au/courses

5th International Conference on Advance

Care Planning and End of Life Care

September 9 – 12, 2015

Munich, Germany

Website: www.acpel2015.org

49th Annual Meeting of the National Association of Medical Examiners

October 2-6, 2015

Charlotte, NC (USA)

Website: www.thename.org

2nd International Arab Forensic Science and Forensic Medicine Conference

November 8-10, 2015

Riyadh, Kingdom of Saudi Arabia

Website: <http://nauss.edu.sa/asfsfm2015/the arab.htm>

Euthanasia 2016

May 11 – 14, 2016

Website: www.euthanasia2016.com

23rd International Academy of Legal Medicine

June 21 – 24, 2016

Venice, Italy

Website: www.ialm.info

22nd Annual WAML World Congress

August 7-11, 2016

Los Angeles, CA (USA)

Website: www.thewaml.com

50th Annual Meeting of the National Association of Medical Examiners

September 9-13, 2016

Minneapolis, MN, USA

Website: www.thename.org



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Disclaimer: The articles presented in this newsletter express the views of the authors and do not necessarily reflect the attitudes or opinions of the WAML

Guest Editor's Note

Unforgettable Coimbra Hosts the 21st World Congress on Medical Law



**Olaolu A. Osanyin
BL, LL.M, CHP**

Member American College
of Legal Medicine.

Member, Board of Governors of the
World Association for Medical Law.

President, Resource Center for
Medical Law Research
and Development.

The University Town of Coimbra, a UNESCO World Heritage Site, played host to "the Olympics" of the Medical Law Profession from every corner of the Earth from the 2nd to the 6th of August 2015.

This Congress hosted in this breathtaking town was an historic Congress by virtue of the several innovations introduced by the association. Innovations such as the 2015 Congress being the first congress to be

held annually, the first to feature Islamic Bio Ethics as part of the WAML Congress and the first WAML meeting to receive CME accreditation by the American College of Legal Medicine. The meeting also for the first time introduced E-Poster presentation sessions during the Congress. It is very evident that participants had a lot to look forward to.

WAML Congresses afford attendees a rare international forum for discussions and cross fertilization of ideas on a broad range of medical legal issues. The themes for this particular meeting were centered on ageing and health law, information technology and health law, migration and the law, Islamic bioethics and other related topics with a total of 220 abstracts reviewed by the selection committee.

The Hotel Vila Gale served as home away from home for most participants during the Congress with its grandeur furnishing, top notch meals, beverages and services. The hotel is located in the historical

center of Coimbra, with the stunning view of the Mondego River. The proximity of the hotel to historic centers of the town allowed very easy access to major cultural interest areas such as the long staircase Quebra-costas, the ancient Cathedral, the Church of Santa Cruz, the prestigious University of Coimbra and its majestic and breathtaking Library and other places of interests.

The Congress Chair, Professor Andre Dias Pereira, and his team of volunteers were impeccable hosts as they ensured that the comfort of participants and the functionality of the programs were paramount. Professor Pereira was most frequently seen multi-tasking his role on a daily basis as program chair, session moderator, presenter and tour guide. His effort in ensuring a well-organized and flawless Congress deserves huge commendations. The Congress included several interesting and contemporary presentations such

as Prof. Cyril Wecht's Medicolegal Aspects to Right to Die: Societal and Ethical Concerns, Anne Marie Duguet's presentation titled; Access to care in France for Elderly Immigrants from North Africa: Influence of Socio-Cultural Factors: The MATC Survey. Guilherme de Oliveira presented an interesting paper on Health Law and the Elderly, while Joaquim Cerejeira/ Oren Asman and Andre Pereira debated on Ageing, Psychiatry and Law. Richard S. Wilbur's discussion on Tele-mentoring: Legal and Ethical Issues was very thought provoking. Olaolu Osanyin delivered his paper centered on the Ebola Patient Migration: The Nigerian Medicolegal Perspective, while Dr. Farhat Moozam discussed the Challenge of "Doing" Bioethics in the Islamic State Pakistan. Prof Abdul Fadl Mohsin Ebrahim presented his paper on Methods and Sources of Justification in Islamic Medical Ethics. Dr. William Hinnant's expository paper titled "Granny Goes to Jail": How to Avoid Medicaid Elder Care Liability in the United States alongside other presentations by participants from all over the Globe truly made the Congress a highly informative and educative platform. A special and optional Expert Witness Workshop was also organized with Prof. Roy Beran, Prof.

Francisco Corte-Real Goncalves and Prof. Andre Pereira as speakers for interested attendees at a discounted fee. The meeting also successfully reintroduced the Early Career Best Paper Awards which had several entries and presentations from young, up and coming, medical law Scholars and Practitioners. For instance, Sandra Collin's presentation titled; The Simulated Facebook Pages: High Fidelity Teaching on Professional Use of Social Media, received commendations from attendees for her resourcefulness and articulation. Nilay Tarhan's paper, focused on Early Aging and Health Assurance, provoked a lot of discussions and questions. The winner for the 2015 WAML Early Career Best Paper Award was presented to Miguel Vieito Villar for his exhilarating paper titled: A Legal Approach to E-Health and Elderly People: Indirect Discrimination vs. Health Efficiency. He also contributed one of the articles in this Newsletter. The introduction of E-Poster presentations into the WAML program was very commendable as attendees had the opportunity of listening to fascinating E posters presentations such as Richard Kelly's presentation on Attending Physician Fatigue: An Undiagnosed Problem, other presenters such

as Margarida Silvestre/ Duarte Nuno Vieira discussed the "Do not Resuscitate Order-Ethical and Legal Aspects of a Life Decision", amongst several other presentations. The Award for the best 2015 WAML E-Poster Award was presented to Ana Elisabete Ferreira who spoke on "Philosophy of Neurolaw". It is also worthy of note that the General Assembly of the 2015 WAML Congress elected Barrister Olaolu Osanyin from Nigeria as a member of the Board of Governors. It is imperative to state that with this appointment, the World Association for Medical Law has appointed the first African onto the Board of Governors, consequently it is expected that an African country should be able to host the World Congress on Medical Law. It is without any doubt that the 21st World Congress was a huge success, being a smooth blend of high quality medical law presentations and discussions with unforgettable networking potentials for participants hosted in such a beautiful and historic town. The delicious cuisine, warmth and hospitality of the beautiful people of the richly cultural town of Coimbra definitely ensured that attendees departed reluctantly. With the new format of an annual World Congress, the 22nd World Congress scheduled from the 7th-11 August 2016 in Los

Angeles, California will no doubt be highly promising as it will be hosted in Hollywood and all hands are on deck to ensure a successful outing. The Program Chair for the 2016 World Congress is non-other than the WAML President Prof. Thomas Noguchi who will be ably supported by WAML Administrator Denise McNally. All members are implored to mark this upcoming Congress on their calendars and submit abstracts as there will be three subthemes namely; Patient centered innovative health care, Biogenetics with patent conflict, most cutting edge scientific advances including food safety and issues of medical law and ethics and Legal medicine. Interested attendees can review the WAML website at www.thewaml.com for further details. **See you all in Hollywood!!!!**

No Decision About the Elderly...Without the Elderly



Miguel Vieito Villar
Member American College
of Legal Medicine.

University of Santiago de Compostela

Winner of the 2015 WAML Early
Career Best Paper Award.

One of the main
concerns of World

Health Organization in this Century is the progressive increase in number of the ageing population (currently, a specific document is under development in this Organization: the “Global Strategy and Action Plan on Ageing and Health”), coming from the extraordinary development of health techniques and procedures to prolong our final moment. This is even a bigger concern for Countries like Japan, Italy, Germany or Finland with the highest rates of people over the age of 65. Although the rate in Spain is not as high as the rate in other European Countries, the rates in some Autonomous Communities are among the highest in the whole world, being 24.27% for 2014 in Galicia (an Autonomous Community in the Northwestern Spain).

In this context, some Health Administrations are trying to fight these circumstances by applying some new measures to control and monitor chronic diseases, long-term patients and social care. Some of these new regulations and programs go through electronic Health Administration (e-Health), using new technologies such as smartphones, tablet-pc’s and laptops, and integrating them into traditional medical care. Although these may seem

quite useful and efficient measures to implement, they have an important defect of perspective: they have not been designed for the benefit of older people, but from an economic approach.

Looking through some data regarding the use of new technologies by elder persons in the Spanish context (these data can be extrapolated to some other European Countries), we discover some important facts to bear in mind: more than 50% do not have a personal computer, 3 out of 4 have never used the Internet and almost 70% do prefer a face-to-face relationship with Public Administrations (data obtained from sociological studies of the Union of Retired and Pensioners of Spain and the Spanish Research Council-CSIC). To summarize, we can argue our people over 65 are not requesting this kind of aid programmes and they are not even ready for them.

Borrowing the title of this contribution from a National Health Service (NHS) Report (“Liberating the NHS: No decision about me, without me”), to my mind the e-Health programmes, although they may help our Health Administrations in terms of efficiency and expense -saving, may not be seen as the one and only way, and should be accompanied

by some others, in order to guarantee a full access to Health and Medical information by elder persons. Not doing so could cause indirect discriminations, absolutely unlawful under the National and the International legal instruments concerning Rights of the Patients and in the comprehensive model of patient-physician relationship. In this regard, a breach in the information procedure, before an informed consent, may jeopardize the autonomy of the patient. Besides, focusing all the public resources on e-Health may also affect the justice principle, in the optic of distributive justice.

Then, how can we resolve this? It is our proposal that there be the creation of technological mediators or facilitators to access health information and new Health programmes, as public servants with the main goal of connecting the analogical world of elderly people and our new digital environment of e-Health and/or e-Administration. Their tasks would go from teaching and training independent users of new technologies (some other sociological studies shows that elderly people do learn rapidly when they are trained), to problem-solving regarding the access to electronic services and serve as health mediators in case of disputes.

In addition, it is absolutely necessary for our Public Administrations and Political leaders, to make elderly people count, that is to say, make them take an important role in the design of new policies. They are almost 25% of the population, and they will be even more in the future; in fact, all of us will sometime be an elderly person; so, we cannot simply forget about them by creating a discriminating system.

I would like to offer some final greetings. I must say it is a great honor and a pleasure for a young jurist working on Health Law, to be invited to participate in the WAML Newsletter. I would like to thank the Board of Governors of the World Association for Medical Law for giving me this opportunity. I would also like to pay my respects to the University of Coimbra (Portugal) since my time there and the professionals I had the honor to meet in the “Centro de Direito Biomédico” (Biomedical Law Institute) are the main responsables for my value as a jurist.



Patient's rights to refuse treatment in Nigeria



Anu Toki LLB, BL, LLM

Member, Nigerian Bar Association

Research Fellow at the Center
for Medical Law Research and
Development

Medicolegal Consultant at Medical
Tutors Ltd an accredited CME provider
to the Medical and Dental Council
of Nigeria.

INTRODUCTION

The right of self-determination, that is the right to ultimately decide what will and will not happen to his or her body, is arguably the most important of a patient's right. A patient possessing the capacity to give consent to a medical treatment has a corresponding right to refuse such treatment even if refusal would lead to his/her death. The patient's right to refuse medical treatment is a universally recognized principle of liberty. The Nigerian patient's right to refuse medical treatment is protected by the Nigerian 1999 Constitution with particular reference to Sections 35, 37 and 38 which provide for the rights to personal liberty,

privacy, freedom of thought, conscience and religion.

THE NIGERIAN CASE LAW:

The world is tilting towards preserving the autonomy of the patient over medical paternalism. The Supreme Court of Nigeria buttressed this point in its decision in the case of Medical and Dental Practitioners Disciplinary Tribunal vs. Dr. John E. N. Okonkwo. In that case, 29 year, Martha Okorie (the patient), her husband and Dr Okonkwo were members of the Jehovah's Witness sect that disapproves of blood transfusion. The patient had difficulty walking and had severe pain in her pubic area consequent upon a delivery in a maternity home. The patient refused to give informed consent after warnings that her refusal to be transfused with blood may lead to her death. The doctor discharged her with a note stating that she refused to give consent to the treatment. She was taken to Dr. Okonkwo's hospital with a card directing that no blood transfusion be given to her. Her husband also signed a document stating that she may not be transfused with blood. They both released the hospital and its personnel from any liability on the issue. The respondent proceeded to

treat the patient without blood transfusion. She died 5 days later. The respondent was charged before the Medical and Dental Practitioner Disciplinary Tribunal on two counts of negligence and acting contrary to his oath as a medical practitioner and thereby conducting himself infamously in a professional respect contrary to the Medical and Dental Practitioner Disciplinary Act. The Tribunal found him guilty and suspended him from the profession for 6 months. The respondent appealed to the Court of Appeal which supported his appeal. The Tribunal thereafter appealed to the Supreme Court. Its appeal was denied. The court held that a patient may validly refuse medical treatments or procedures recommended by a doctor. Therefore, the doctor was held not liable.

To consent to or refuse treatment, the patient must have the mental capacity to make the decision. That is, the patient must be an adult of sound mind possessing the ability to use and understand the information given by the health care provider to make a decision. For consent to or refusal of treatment to be valid, it must have been made voluntarily after the patient has been appropriately and adequately informed.

NIGERIAN LEGISLATION:

Section 23 of the National Health Act, 2014, provides that every health care provider shall give a user relevant information pertaining to his state of health and necessary treatment relating thereto. The information should include the user's health status except in circumstances where there is substantial evidence that the disclosure of the user's health status would be contrary to the best interests of the user. It should also include the range of diagnostic procedures and treatment options generally available to the user. It should state the benefits, risks, costs and consequences generally associated with each option, the user's right to refuse health services explaining the implications, risks and obligations of such refusal. The health care provider should also inform the user in a language that the user understands and in a manner which takes into account the user's level of literacy. The doctor should also inform the patient about necessity of treatment, probable duration of treatment and the prognosis.

The patient is therefore free to decide whether or not to submit to the line of treatment prescribed by the doctor for reasons which are rational or

seemingly irrational or for no reason at all. Where a patient fails to give informed consent, the medical practitioner may not proceed to administer the medical treatment or life preservative measure as it was in the above mentioned case. Where the patient's right to refuse treatment is not honoured, a suit premised on assault and invasion of privacy may be validly instituted against the health care provider.

In situations where a doctor is faced with a dilemma emanating from a patient's refusal to grant informed consent, the doctor may:

- i. Adhere to the patient's instruction on the type of treatment desired by the patient.
- ii. Terminate the doctor-patient relationship.
- iii. Refer the patient to another medical institution where necessary life preservative measures may be taken.

This paper recommends as follows:

1. The need to intensify efforts in promoting patient's rights.
2. Medical practitioners should adhere and be made more conscious of informed consent processes and protocols.

Anu Toki LLB, BL, LLM
Member, Nigerian Bar Association

The Establishment of the Nigerian Medical Law Report.



Abiodun Olayiwole, LLB, BL, LLM
Medical Law Consultant

Editor –in – Chief of Nigeria Medical Law Report.

Former Unit Head of the Medical Disciplinary Tribunal Unit.

Member, Medical Law Committee of the Nigerian Bar Association

Former Director of the Legal Unit of the Medical and Dental Council of Nigeria.

Retired Head of the Department of Administration and Human Resources of Medical and Dental Council of Nigeria.

In Nigeria today there are an extremely large numbers of law reports but until recently there were no law reports on the specialized field of Medical Laws.

The inspiration for Nigerian Medical Law Report Publications started in August 2014 in Nigeria after some Lawyers and Doctors attended the 20th World Congress on Medical Law at Bali in Indonesia..

The objective of the Report is the quarterly

publication of court decisions of all medical law suits in Nigeria in the form of volumes of law reports, thereby making law research in this area less irksome, quicker and more rewarding.

Medico-legal practice in Nigeria is gradually developing with rather few publications and research works produced in this regard. Most lawyers appearing before health regulated Tribunals such as Medical and Dental Practitioners Tribunal and Nursing and Midwife of Nigeria Tribunal often do not have enough materials and information for the proper defence of their clients and cases. The usual understanding of lawyers is to apply the same reasoning as in the Law of Tort to cases of medical law. While this position may not be absolutely wrong, medical law cases require deep understanding of medical procedures and the need to rely on experts in the multi-faceted field of medicine.

The Nigerian Medical Law Report is designed to be a working tool for legal and medical practitioners. It is planned to be a quarterly publication addressing issues relating to medical law in addition to reporting cases of medical malpractice and developments in the area of medical laws. It aims to provide necessary information

to professionals and researchers who are interested in this area of law.

The first edition of the law report publication reviewed and reported cases of the Medical and Dental Practitioners Disciplinary Tribunal in a law report format in order to highlight some of the cases decided at the Medical and Dental Practitioners Tribunal and other cases of professional malpractice referred to the Nigerian Court of Appeal for determination.

After the maiden edition of Medical Law Report, published in November 2014, the second edition is to keep faith with the promise to publish quarterly. In this edition, apart from cases from the Disciplinary Tribunal and medical law cases from Court of Appeal and Supreme Court of Nigeria, it also includes as appendices, the Code of Ethics for Medical and Dental Practitioners 2008 and Disciplinary Tribunal Rules 2004 edition.

These two subsidiary laws are currently in use by the Medical and Dental Practitioners' Investigation Panel and Medical and Dental Practitioners' Disciplinary Tribunal.

The Editorial Board also resolved to review papers presented by members of the editorial board in national and international conferences particularly

presentations made at the World Congresses of Medical Law, alongside medico-legal articles from other medicine and law experts.

The Nigerian attendees at the 20th WAML congress in Bali Indonesia also resolved to inaugurate and establish a Society for Medicine and Law in Nigeria which will hopefully be recognized and affiliated with the World Association of Medical Law and other International Medical Law Organizations. The purpose of the Society is to bring together Nigerian Medical and Legal Experts as well as institutions interested in this emerging field of law and medicine in Africa's most populous Country.

The members of the Editorial Board of the Nigerian Medical Law Report are listed as follows:

1. Chief Gani Adetola-Kaseem SAN
2. Dr A. A. Ibrahim. Mni
3. Prof. A. Afonja.
4. Olaolu Osanyin. LLM, BL, CHP
5. Dr (Barr) E. M Osuagwu. BM BCH FFARCS LLB, BL
6. Dr Enejo Abdul. MB BCH
7. Dr H. Olaniyan. Phd, LLM BL
8. Emeka Ugwuowo LLB. BL.

9. Abiodun Olayiwole LLM, BL- Editor-In-Chief

The second edition came out with a remarkable increase in the subscribership of the Law Report which is a clear and commendable improvement on the previous edition and it is the aspiration of the editorial board to sustain and maintain the tempo and drive of the Nigerian Medical Law Report to further develop Medical Law in Nigeria.

At the 21st World Congress of Medical Law held in Coimbra, Portugal, a member of the Editorial Board of the Nigerian Medical Law Report- Barr Olaolu Osanyin was appointed as the first African member of the Board of Governors of the World Association for Medical Law. It is hoped that with his appointment, Africa will be able to host the World Congress on Medical Law soon and the enormous tasks to host the World Association for Medical Law in Motherland Africa has started in earnest!!!!



<http://www.facebook.com/thewaml>

THE NIGERIAN NATIONAL HEALTH ACT; The Creation of a Medicolegal Environment in Nigeria

Olaolu A. Osanyin BL, LLM, CHP

Since the re-enthronement of democratic governance in Nigeria in 1999, there has been a steady and consistent increase in lawsuits against Nigerian Doctors which has brought about a new medicolegal environment.

This "open season" of malpractice suits is one of the major factors that compelled the Nigerian Parliament to pass the National Health Bill into Law in October 2014. The legislation was enacted to provide for the regulation of a health system and also to set standards for rendering health service in Nigeria. Some of the salient provisions of the Act are as follows;

A. Requirement of Certificate of Standards:

The Law provides that, without being in possession of a Certificate of Standards, nobody shall establish, operate, modify or acquire a health establishment. It goes further to state that any person who performs any act without a Certificate of Standards shall be guilty of an offence and liable on conviction to a fine or imprisonment for a period not exceeding two years or both.

B. The duty to comply with quality requirements and standards:

Under this new legislation, all health establishments are expected to comply with the quality requirements and standards relating to human resources, health technology, equipment, hygiene, premises, and the delivery of health services, business practices, safety and the manner in which patients are accommodated and treated in health establishments.

C. The Duty to Refer

The law imposes the duty on a doctor/hospital to refer patients if the hospital is not capable of providing the necessary treatment or care to such patients. The hospital is further required by law to refer such a patient concerned to an appropriate health establishment which is capable of providing the necessary treatment or care.

D. Compulsory Emergency Treatment

The 2014 National Health Act clearly prohibits health care providers from refusing any person emergency medical treatment for any reason whatsoever and any person who contravenes this legislation shall be guilty of an offence and is liable on conviction to a fine or to imprisonment for a period not exceeding

six months or to both. In order to curb medical tourism, the act prohibits government sponsored overseas medical treatment.

E. The Rights of Health Care Personnel

The Nigerian Legislation recognizes the rights of the health personnel to claim conscientious exemptions in the performance of their professional duties. The law also imposes the responsibility of health establishments to implement measures to minimize injury or damage and disease transmission to the person and property of Health Care professionals;

With the exception for Psychiatric patients, health care providers under the law are allowed to refuse to treat patients who are physically or verbally abusive or who sexually harass them, and in such cases health care professionals are required to report the incidents to the appropriate authority.

F. Informed Consent

The duty is imposed on Nigerian Health Care Providers to give patients relevant information pertaining to their state of health and the necessary treatment relating thereto including:- the patient's health status ; the range of diagnostic procedures and treatment options available; the benefits, risks, costs and

consequences generally associated with each option; and the patient's right to refuse health services and right to be counselled on the implications, risks and obligations of such refusal.

The health care provider is also required under the law to inform the patient in a language that the patient understands and in a manner which takes into account the patient's level of literacy.

However the law also gives the health practitioner the discretion to determine the enormity of information required to give each patient if such information will negatively affect the health of the patient.

G. The duty of Proper Notification

Every private health care provider in Nigeria is now required to ensure that appropriate, adequate and comprehensive information about the procedures for making complaints; and the rights and duties of patients and health care practitioners are made available at conspicuous locations within such facilities.

H. The Duty of Confidentiality

The Law provides that all information concerning a patient is confidential and no person is permitted to disclose any information unless the patient consents to that

disclosure in writing; or a court order or any law requiring that disclosure; or in the case of a minor with the request of a parent or guardian; and in the case of a person who is otherwise unable to grant consent upon the request of a guardian or representative or where non-disclosure of the information represents a serious threat to public health.

The law further provides punitive measures for any defaulter of patients' confidentiality.

I. Other Provisions

The Nigerian National Health Act also provides for Protocols and regulations for the removal of tissues and blood or blood products from living persons. The Act expressly prohibits human cloning and regulates assisted Reproductive technology and Human Organ donations and Transplantations.

It is expected that with the proper implementation of the provisions of this law, the Nigerian health system will be more effective.

WAML President's Report



Thomas T. Noguchi,
President of WAML

As this year will be ending in a few weeks, I can now look back at how we were, and what a long way we have come in the last few years. The World Association for Medical Law (WAML) has been strengthened in management and is now becoming the world's leading organization on medical law. When I think about these changes, I begin with 2004, when I was first elected as Treasurer by the WAML Board of Governors during the World Congress in Sydney, Australia. President Carmi handed me a small amount of cash, a transfer of the WAML assets. However, that was the entire assets of the WAML. I carried the cash home, and immediately consulted my accountant, Cathie Bagwell, who suggested establishing the organizational account in the Bank in Pasadena, California. I then suggested, and the Board approved, annual paid membership, but, since WAML did not have credit card acceptance,

we struggled to collect any membership fees for many months.

Prof. Carmi, now our immediate past president, had established the Journal of Medicine and Law. The Journal production and its distribution were separate from the WAML. However, we felt our members should have a Journal subscription as part of their membership benefits. Subsequently, the Board approved inclusion of the Journal as a part of membership benefits. In 2010, Prof. Carmi stepped down from the position of the Editor-in-Chief after 30 years of dedicated service. He nominated a new editor, his colleague, Dr. Mohammed Wattad who became the next Editor-of-Chief. We attended the reception welcoming the new editor during the WAML Congress in Zagreb, Croatia.

Another need was to bring in an effective graphic designer. Raul Vergara has done an outstanding job to upgrade our organization by consistent image building through his graphic designing support. He said to me that it is important for the organization to establish an “organizational brand”, thus one can identify the WAML by the logo and unique color. He gave me the example of Coca Cola. Through our website, newsletter, and things we

do, we are mindful of the power of this excellent graphic designer. For the last 10 years, he has been consistently creating the brand image of the WAML.

The Newsletter, started 6 years ago, now regularly carries messages and news to the members. The newsletter idea also came from Cathie Bagwell, the accountant who had assisted me to establish the basic WAML management system.

We felt that the previous arrangement of on-and-off paid membership would not create a cohesive organization. But it was not easy to make this conversion to a solid organization. Cathie Bagwell suggested that we need to start a newsletter circulating among members to increase membership communication. Since then, the WAML Newsletter has been regularly published quarterly employing guest editors who bring articles from every part of the world.

Beginning in 1994, the WAML Congresses were held every other year, but the Board of Governors met annually. Usually, Board meetings were held in the host country where the next World Congress would be held. When we think about that now, we realize that we spent too much time inspecting the facility to

be used. The traditional WAML arrangement for designating the next Congress had some other drawbacks. The Board decided which Governor could host it depending upon who had the financial resources to host and who was willing to take a financial risk. We now think this led often to a delay in selecting the scientific program. This arrangement was concentrated on achieving a onetime financial success of the meeting, but we felt it to be lacking organizational continuity.

The Congress would go to the host country where the funds were available. However, this meant a lack of consistency in quality and continuity of the educational programs. Because the host for the Congress spent so much effort and energy to assure financial support, the program was often not ready at the time of the Congress.

Another advance to the WAML came when Denise McNally joined and established the management system in late 2009. She established a membership database and applied standard administrative procedures.

Another event which pushed us to upgrade the WAML was when Cathie Bagwell advised me in 2010, that tax regulation had become more stringent and

unless the organization was established and recognized as a not-for-profit organization, any WAML assets would be subject to taxation.

The Executive Committee approved the establishment of a legal entity. I consulted my lawyer and longtime friend, Godfrey Isaac, who was counselor to a law firm. He introduced me to Mr. Albert Golbert, a recognized international tax lawyer and multi-linguist who agreed to help me. It is a miracle to me that we have now top legal service gratis. Now the WAML has a corporate counsel and in 2011, the WAML officially became a legally not-for-profit recognized global organization. We are very thankful to Mr. Golbert and his legal staff for this service. When you attend the 2016 Congress, you will have a chance to meet him.

Another major improvement was that in 2014 the Board of Governors approved annual Congresses starting with the 2015 Coimbra Congress. The EC discussed finding someone who could run a meeting with such a short time to prepare. Fortunately, Treasurer Andre D. Pereira agreed to do this with the newly centralized and standardized WAML management. Instead of using and paying a

meeting manager in the country where the Congress was held, the 2015 Congress was entirely managed by Denise, our meeting planner and manager. If we had used a local meeting manager, we would not have had the positive revenue we enjoyed. Because Dr. Pereira could concentrate his efforts on the scientific program, the Coimbra meeting was much more cohesive and at an academically higher level than earlier Congresses.

The WAML has overcome crises in past, but in January 2014, we were told that the new publisher for the Journal of Medicine and Law would no longer continue publishing. As a rescue measure, the EC approved WAML taking over the Journal production, maintaining the existing editorial staff with the WAML doing layout and sending the Journal in digital format to our members. The EC committee has taken the leadership role in updating the editorial policy.

Finally, the Journal of Medicine and Law is now under the management of the WAML. The WAML Executive Editorial Team consists of Secretary General Roy Beran, Richard Wilbur, Professor David Townend and Rael Strous.

The Bylaws (statutes) of the WAML were updated

in 2011, and again in 2014 by the General Assembly. Their preparation was due in large part to a great contribution by Golbert and Associates.

In the November of this year, we began having the Board of Governors Meetings online. Due to the large number of Governors who reside in all corners of the world, we divided the Board into Governor Groups I and II. With successful Board of Governors meetings online, we will be consulting with the Board frequently.

I cannot stress enough how important it is that we have the Executive Committee members working together, reaching the goals and objectives of the WAML. My thanks to all Governors and to EC members, Roy Beran, Oren Asman and Andre Pereira. The Administrative Office, led by Denise, has supported the EC. We would like to express our thanks to Denise.

As 2016 World Congress Program Chair, I now call for 2016 abstracts. I urge your abstract submission. For this year, we want to release the final program by June 1, 2016. As a result, we do not intend to extend the deadline abstract submission of April 1. We urge you to start drafting your abstract soon.

Looking forward to seeing you in Los Angeles. Wishing you and your family: Happy Holidays.

Thomas T. Noguchi, MD
President, WAML

WAML Secretary General's Report



Prof. Roy Beran,
WAML Secretary General

This Secretary-General's report will be somewhat abbreviated, as I have also contributed another report, setting out some of the new arrangements for the Executive Editorial Committee for the Journal, Medicine and Law.

I do not want to belabour the point but the Journal is going through an evolutionary change with the aim of upgrading its calibre and attractiveness to a wider audience. For that we encourage all of our members to put the Journal first and to contribute your BEST papers for our review process. We also seek to widen our resource of referees and ask you to volunteer to be on our panel of referees.

The World Association for Medical Law (WAML)

continues to grow both in its sphere of influence and its capacity to interact with other like-minded organisations. We have arranged reciprocity, such that WAML membership carries with it significantly greater rewards. WAML members can register at members' rates at a host of other meetings, including both the American College of Legal Medicine and the Australasian College of Legal Medicine as well as the International Academy of Legal Medicine to name but a few.

The Executive Committee has remained extremely active and the President, Professor Noguchi, has initiated a new vehicle for enhanced communications. He has established regional Board of Governors electronic meetings. Unfortunately, I was unable to attend the one to which I was assigned, as I was at an Investigators' Meeting re a new clinical trial, in Taiwan, and the time of the meeting could not be accommodated. The feedback reflects a very positive attitude towards such closer ties at managerial level.

Recognising that it is almost the end of 2015 I wish those celebrating Chanukah in early December, a wonderful Festival of Lights, for those celebrating Christmas I wish a Merry Christmas. For those

anticipating the New Year on 31st December, I wish you a fabulous 2016 full of all that you wish for yourselves. For those anticipating the Chinese New Year, I wish you a great Year of the Monkey. For those of Armenian heritage, I wish every happiness for all three Christmases, that on 25th December, that of the Orthodox Church and the Jerusalem Christmas.

All those who miss out on a special celebration at this time of year, I invite you to celebrate with us in one of the above. There are never enough celebrations! I would love to think that our road to peace might come from celebrating with our friends and acquaintances. More of this type of activity might breed enhanced tolerance and less of the base brutality we have seen in places like Paris and Africa. This is a time to reach out, link arms and defeat those who would crush humanity, tolerance, brotherhood of man and woman-kind (accepting brotherhood as a generic term to mean sibship amongst all) and universal caring for our fellow inhabitants of this small planet. Remember a smile is far more empowering than is a frown.

Finally, plan for August 2016 in Los Angeles. Bring your wit, your contribution and your friendship to the next

World Congress for Medical Law.

Yours,

Roy G Beran
Secretary-General
World Association for Medical Law

Message from Acting Editor-in-Chief Medicine and Law

Prof. Roy Beran,
WAML Secretary General

The World Association for Medical Law (WAML) has had its own journal, Medicine and Law, started by Professor Amnon Carmi and published by Yozmot, subsequently renamed Probooks. When Professor Carmi stepped down from the Presidency of the WAML, he also relinquished his role as Editor-in-Chief of Medicine and Law. He identified Dr Mohammed Wattad as his successor and Dr Wattad fulfilled the role until very recently when he also stepped down. The WAML wants to acknowledge both Professor Carmi and Dr Wattad for all their hard work in making the Journal what it has become.

Probooks was sold and the new owners severed ties with the WAML. Our Administration Officer, Mrs Denise McNally, established links with a new publisher, Hein Online, to produce an electronic version of the Journal. Those still

wanting a hard copy can do so, for an additional small premium.

With Dr Wattad retiring, it left a vacuum and the Board of Governors (BoG) decided the Secretary-General, yours truly, would need to assume the role as Acting Editor-in-Chief. While prepared to step up to the plate, I realised I could not do what Professor Carmi and Dr Wattad had done, without considerable additional help. I convinced Dr Richard Wilbur, the Editor-in-Chief of the quarterly WAML Newsletter, to join an Editorial Executive Committee, thereby forging closer links between the Newsletter and the Journal. In addition, I also invited Professor David Townend, Professor of Law and Legal Philosophy in Health, Medicine and Law Sciences, Department of Health, Ethics and Society in Maastricht University, the Netherlands, to join the Executive Editorial Committee as the Legal Editor. To complete the membership of the Executive Editorial Committee, I invited Professor Rael Strous, an Israeli Professor of Psychiatry, from Tel Aviv, to be the Medical Editor. Both David and Rael accepted the invitations, such that we had Richard (affectionately known as 'Dick') and myself, as dual qualified in medicine and law, together with a Legal and Medical Editor to

function in an executive role to oversee the further evolution of the Journal.

The aim is to build on the reputation of the Journal, to garner an impact factor to increase submissions of medically-oriented papers and to enhance the stature of the Journal as a first-line publication within the domain of health law, legal medicine and bioethics. Having established the Executive Editorial Committee, the goal is to continue the hard work of Professor Carmi and Dr Wattad. We will need a wider pool of referees to assess submitted articles, for consideration for publication, and ask each, and everyone, of you to contact the Journal, nominating your areas of expertise and your willingness to referee papers which have been submitted to the Journal. The aim is to increase the standard of papers, offer top quality refereeing and to provide prospective authors with a timely and educative feedback.

Having established the Executive Editorial Committee we realise that the road ahead will not be easy. We have been left big shoes to fill and hope that we make Professor Carmi and Dr Wattad proud of our contribution to the legacy they left us. We are aiming for the top of the tree and thus we also encourage all of you, reading this Newsletter, to consider sending us your manuscripts to be

considered for publication to the Journal. Papers will be reviewed and only the cream will be accepted as without top quality papers we cannot achieve our aspiration of being of superlative quality. We want those who publish in Medicine and Law to be more than proud of their publication within our Journal, as it is not only our Journal but Your Journal.

We need your co-operation and help to make this the lead 'go-to' journal in health law, legal medicine and bioethics. Your enthusiasm is vital to our success.

Roy G Beran
Acting Editor-in-Chief
Medicine and Law
World Association
for Medical Law

WAML Meeting Planning and Administration

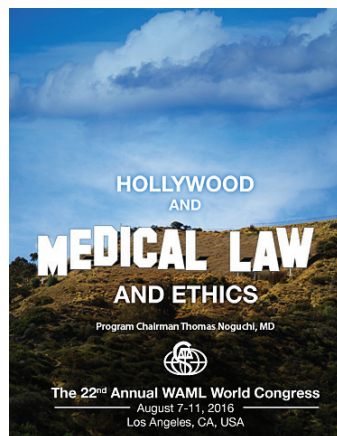


Denise McNally,
WAML Administrative Officer
and Meeting Planner

WAML Meeting Planning
and Administration

JOIN us at the 22nd World
Congress on Medical Law
(WCML)

"Hollywood and Medical Law and Ethics"



August 7 – 11, 2016

Los Angeles, California
(USA)

Important Dates:

Abstract Submission

Deadline: 11:59

Central Time, April 1, 2016

We encourage you to submit your abstracts online at <https://waml.conference-services.net/authorlogin.asp?conferenceID=4927&language=en-uk>

Notification to Authors:

May 1, 2016

All educational sessions will take place at Millennium Biltmore Hotel Los Angeles and will commence with a Welcome Reception Sunday evening August 7, 2016. The Welcome Reception is the perfect venue to meet with colleagues. We recommend staying at the hotel where the program and all functions will be provided. The Gala Dinner and Awards Ceremony will take place Wednesday, August 10, 2016 with planned workshops

Thursday, August 11, 2016. Plan to check into the hotel during the day Sunday, August 7 so that you may attend the Welcoming Reception and checking out Friday, August 12, 2016 to enjoy the entire day attending workshops. You may also want to extend your stay to bring the family to Los Angeles, California for vacation. The city is cutting-edge in every respect - whether it's fashion, food, or business trends, Los Angeles is a city with limitless options. Its landmarks are known the world over, and include the Hollywood Walk of Fame, the Nokia Theater, the Dolby Theater, the Getty Museum, the Los Angeles Zoo, Griffith Observatory, the Aquarium of the Pacific and Universal Studios. Of course, you can't forget theme parks such as Disneyland, Legoland California, Six Flags Magic Mountain and Knott's Berry Farm.

When it comes to LA attractions and events, Millennium Biltmore Hotel Los Angeles is a thriving hotel centered near the Nokia Theatre, Staples Center, and more must-see Los Angeles attractions.

HOTEL RESERVATIONS:

The Millennium Biltmore Hotel Los Angeles is offering a reduced group rate of \$199US (Single/Double) that is NOW Available! Hotel rooms can now be booked at

the reduced rate for the WAML 2016 World Congress. To book your reservations, please click on the link below. The reduced group rate is available until July 5, 2016, after this date you may reserve rooms at the standard hotel rate only and based on availability.

To begin the process and reserve your room click the link below:

<https://reservations.millenniumhotels.com/ibe/details.aspx?hotelid=13606&langid=1&checkin=8/7/2016&nights=5&rooms=1&adults=1&group=1609wamela>

Thomas Noguchi, M.D. will be your Program Chairman.

The program theme is "Hollywood and Medical Law Ethics" with subthemes of:

- 1) Patient Rights and Patient Safety
- 2) BioGenetics
- 3) Legal Medicine's Contributions to Society
- 4) Other

Program Chair Thomas Noguchi, M.D. is also planning an optional organized group run/walk activity Tuesday, morning 6 AM – 7 AM, August 9, 2016. The group would see the center of Los Angeles and historical monuments.

Please check the website <http://wafml.memberlodge.org/page-1638556> often for program updates. See you in Los Angeles, CA (USA)!

2017 WAML Congress will be held in Baku, Azerbaijan with Vugar Mammadov, M.D. as your program chairman. Dates and additional information will be provided when available.

Membership Dues

The purpose of the World Association for Medical Law (WAML) is to encourage the study and discussion of health law, legal medicine, ethics and forensic medicine, for the benefit of society and the advancement of human rights.

You recently received a notice that your 2016 membership dues were owed by January 1, 2016. If you have not done so please log into the WAML website and renew your membership. Membership in WAML is Annual and for 2015 your membership dues are \$150. WAML members enjoy many benefits which include access to quarterly E-Newsletters, discount registration fees to the WAML Congress, notice of upcoming events, active website information and the "Medicine and Law" electronic Journal. Members may access the HeinOnline URL at <http://wafml.memberlodge.org/page-1841449>.

FUTURE MEETINGS

Of Affiliated National Associations and Collaborating Organizations

American College of Legal Medicine
Health Law in the 21st Century: Issues with Vulnerable and Special Populations

February 25-28, 2016

Austin Texas

Website: www.aclm.org

Euthanasia 2016

May 11 – 14, 2016

Amsterdam, Netherlands

Website: www.euthanasia2016.com

Fourth International Conference on Ethics Education

May 25th-27th, 2016

Logroño, Spain

Website: <http://4iaee.cibir.es>

23rd International Academy of Legal Medicine

June 21 – 24, 2016

Venice, Italy

Website: www.ialm.info

22nd Annual WAML World Congress

August 7-11, 2016

Los Angeles, CA (USA)

Website: www.thewaml.com

50th Annual Meeting of the National Association of Medical Examiners

September 9-13, 2016

Minneapolis, MN (USA)

Website: www.thename.org

10th International Symposium Advances in Legal Medicine (ISALM) combined with the 96th Annual Conference German Society of Legal Medicine

September 11-15, 2017

Düsseldorf/Cologne, Germany

Website: <http://www.isalm2017.de>

51st Annual Meeting of the National Association of Medical Examiners

October 13-17, 2017

Scottsdale, AZ, USA

Website: www.thename.org

2017 (dates to be announced)

6th International Conference on Evidence Law and Forensic Science

Baltimore, MD (USA)

**Do You
Have an Idea,
Comment, or
Suggestion?**

Please contact
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<http://www.facebook.com/thewaml>



<http://twitter.com/thewaml>

22nd | World Congress
on Medical Law

HOLLYWOOD
AND
MEDICAL LAW
AND ETHICS

Los Angeles, California U.S.A.
August 7-11, 2016



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