WORLD ASSOCIATION FOR MEDICAL LAW

June Issue

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Artificial Intelligence in Health Care: A Global Landscape

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Introduction

The increasing application of Artificial Intelligence AI in the field of health care requires special multidisciplinary expertise to assess the ethical and legal implications. At the moment we still do not know how far this technology will advance, even in the near future. Artificial intelligence is undoubtedly a useful tool for researchers and clinicians, but patients also must be informed about it and should learn how Ai has been used in their case. The type of software and database behind AI may play an essential role in establishing a good diagnosis and effective therapy. Some fear that if healthcare is combined with AI it will not be transparent for the doctors and for the patients. However, the merge of bio- and techno-ethics could help in developing new informed consent procedures and data protection protocols related to AI assisted healthcare. The algorithms that AI uses work with health data and categories of patients that may be partial and biased, for example, towards white males, therefore AI assisted health care may even reinforce the already existing practices of discrimination. Thus, these databases and algorithms should be monitored on the basis of human rights principles. Apart national laws and ethical guidelines, there are also some attempts to adopt regional and global legal instruments. Council of Europe is drafting a Convention on *Artificial Intelligence, Human Rights, Democracy and the Rule of Law.* This Convention aims to protect fundamental rights against the potential harms of Artificial Intelligence (AI), and is expected to become a global leading convention, as non-European states are also considering becoming signatories. In addition,

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the European Union has already a proposal for regulating artificial intelligence.

In this newsletter several legal models of regulating the use of artificial intelligence in healthcare are presented in brief reports by distinguished experts and scholars from all continents, discussing the emerging legal and ethical landscape of the European Union, France, South Africa, Switzerland, Taiwan, the United Kingdom, and the United States.

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European Union

Artificial Intelligence, Fundamental Rights and Technological Development: Is There a Crowd in a Regulation?

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When, in April 2021, the European Commission released its proposal for a future European Union (EU) regulation on artificial intelligence (AI), the so-called Artificial Intelligence Act (hereinafter, the 'AIA'), experts and stakeholders from around the world held their breath. Curiosity was high (although the 2020 White Paper on AI had already shed some light on what was to come) and the anxiety of those who created a business based on AI technology was no less. Everyone knows what is at stake: the content of the future European regulation on AI can dictate the success (or failure) of many projects (business and otherwise) in Europe and beyond (due to the extraterritorial effects of the AIA).

The AIA's primary objective is to facilitate and develop the use of AI in the EU to create a true Digital Single Market, a long-held aspiration. However, this objective may be limited in its realization by another aspiration of the AIA: the protection of fundamental rights, European values, and ethical principles potentially threatened by AI. It remains to be seen whether the expected compatibility of purposes can be fulfilled by the AIA.

Despite some criticism pointing out the AIA's excessive 'business tenor', it actually seems more prone to the protection of rights than to technological leverage. The defense of fundamental rights and values is, obviously, commendable. However, it is worth asking what room for maneuver is left to European start-ups. Apart from testing environments (the 'regulatory sandboxes') and measures to encourage small and medium-size AI providers, there is not much encouragement for technological innovation. Most likely, the activities of research, manufacture, and commercialization of AI in the European space will suffer a hard blow, especially in the early days.

An immediately foreseeable problem is compliance with so many and so detailed rules, not just those of the AIA, but all other relevant rules, for instance, the Medical Device Regulation or the General Data Protection Regulation-GDPR, which frequently will come together in the particular case. Will a researcher, a manufacturer, or an entrepreneur be able to cope with so many simultaneous and eventually conflicting demands?

A parallel can be made with the GDPR: the level of demand in terms of requirements and limitations is at the maximum limit and the detail in regulation has no equivalent in the rest of the world, but in terms of practical outcomes, this came at a huge cost for innovation, especially data-driven innovation, and still many flaws regarding the protection of individual rights.

I fear that the AIA also becomes a hyper-regulation, with massive rules on practically everything, limitations that prevent the development of new technologies, excessive bureaucracy, absurd prohibitions and very heavy sanctions, without in the end necessarily resulting in greater protection for people's rights.

The AIA is still under discussion and the final version is expected at the end of 2023, but it seems the EU is determined to create another megalomaniac law. The existence of a legal framework for AI in the EU is an absolute need and the current draft act is a meritorious effort. However, there are no perfect outcomes, and the level of imperfection increases in the exact measure that the ambition of a project increases. The AIA is an ambitious project, both for its scope of application and for its level of detail, to which it must be added the complexity of a very new domain. We can only hope that in the end this high price brings some effective benefits for fundamental rights.

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France

Ethical and Legal Standards to Use AI in Health: The Case of France

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Artificial intelligence (AI) is set to become an increasingly important part of medical practice in the coming years. Already routinely used in several areas of medicine, such as cancer, imaging or genetics, French policy is supporting research into its future development, while recalling the need to be cautious not to create undue hopes for patients and for the society. As with all innovations, major ethical debates are taking place in France at ethical, political, professional and technical levels. To date the French legal and ethical standards are developing mainly in the field of the medical diagnosis and regarding the patient-doctor relationships. Other sources of ethical tensions are recognized but not yet fully analyzed such as those arising from the use of AI in Public Health or for treatment.

The main ethical issues have been highlighted and summarized in the opinion adopted by the French National Ethics Advisory Committee (Comité consultatif National d'Ethique) together with the National Pilot Digital Ethics Committee (Comité National Pilote d'Ethique du Numérique) in their opinion 141 of November 2022 related to "Medical diagnosis and artificial intelligence: ethical issues". Recalling the European and international landscape already at stake regarding the use of AI in medicine, the committees assessed the benefits and risks of using artificial intelligence systems applied to medical diagnosis (AISMD) (excluding the fields of treatment and prevention). Emphasizing the need to ensure an enlightened consent (from patients, doctors and society), the Committees have argued for greater transparency in the use of AI tools to promote trust between doctors and patients/society, e.g. by mentioning the use of AISMD in the report of the consultations and calling for accurate evaluation including an ethics by design approach. They have insisted on the need for human oversight at all stages of the design and use of devices incorporating AI. Broader considerations towards greater inclusivity in the use of these techniques were also highlighted in the opinion notably through the establishment of a "digital auxiliary" to help individuals to better understand and be able to consent to the use of AI devices (this person should be trained in digital tools and could be a family member or a member of a patient association).

This opinion is in line with previous statements and reports adopted in particular 1/ by the National Council of Medical Doctors (White Paper on "Doctors and patients in the world of data, algorithms and artificial intelligence", 2018) which insisted on data collection, big data and data protection issues and made recommendations to ensure the quality of the medical relationship and 2/ by the report of the Parliamentary Office for Scientific and Technological Assessment (OPECST, "Toward a Controlled, Useful and Demystified Artificial Intelligence, 2017, not fully dedicated to health but applicable to it), in which parliamentarians called for AI to be controlled not at the national level but at the European/ international level, for AI to be useful and at the service of humans and of human values and for AI to be demystified through training of students and transparency towards the society. Finally, the High Authority for Health (HAS, 2020) has adopted technical standards prior to the granting of marketing authorization for medical devices incorporating AI. The shortcoming of these standards is that they only apply to medical devices offered directly to patients thus excluding those that are proposed to medical doctors which are the more numerous. However, these standards do contain some ethical vigilance points that could be used in future standardization processes.

This benefit-risk approach is also the one that has driven the adoption of the first legal provision introduced by the newly adopted revised Bioethics Law in August 2021. The new article L4001-3 of the Public Health Code article introduces new obligations for medical doctors to clearly inform patients about the use of AI

medical devices in their decision, for professionals to inform the medical doctors about the use of these devices and for developers to explain the decision-making process for the medical devices to end users.

In conclusion, France has started to frame the use of AI in health, providing the state of the art of ethical and legal issues, focusing on the medical decision-making process and on the need to protect the medical relationship and respect individual fundamental rights. The various opinions and statements recognize that the use of AI in medicine can be of great benefit to patients but remind us to be cautious when implementing these tools in daily practice or in policies. Adequate ethical/ legal safeguards should be put in place in the future to prevent any infringement of patients' autonomy or malpractices, taking into account the forthcoming requirements of the European AI Act.

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Japan

AI Regulation in Japan

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The Japanese government, academia as well as industries are aware of using AI in various improper and even negative ways, and they recognize that regulating AI is an urgent task.

There is the Basic Law on Promotion and Innovation of Science and Technology, in which AI is an important component. However, this act is for promotion and not for regulation. There is yet no legal regulation of AI, although some legislations are relevant to AI, such as the Protection of Personal Information Act. So far there are two guidelines, one by the Government and the other by an academic association. In addition, there is a document clarifying ethical considerations on AI in Medicine.

The Integrated Innovation Strategy Promotion Council established the "Social Principles of Human-Centric AI", which, announced Dignity, Diversity and Inclusion, and Sustainability as the basic values of an "AI-Ready Society", set up the following seven "Social Principles of AI", and established the Council for Social Principles of Human-centric AI for their implementation and continuous review:

1) Human Centricity

The utilization of AI must not infringe upon the fundamental human rights. AI should be developed, utilized, and implemented in society to expand the abilities of people and allow diverse people to pursue their well-being

2) Education and Literacy

An educational environment that fosters education and literacy to avoid disparities or divisions between people, especially those who are socially disadvantaged.

3) Privacy Protection

Careful discretion for handling of personal data following the level of importance and sensitivity of the data.

4) Ensuring Security

Awareness of the balance between the benefits and risks and endeavor to improve social safety and sustainability

5) Fair Competition

A fair competitive environment must be maintained to create new businesses and services, to maintain sustainable economic growth, and to present solutions to social challenges.

6) Fairness, Accountability, and Transparency

Ensuring fairness and transparency in decision-making, appropriate accountability for the results, trust in technology, and avoidance of undue discrimination or unfair treatment in terms of human dignity.

7) Innovation

To transcend boundaries such as national borders, industries, academia, governments, race, nationality, age, political convictions, and religion, and to promote globalization, diversification, and industry-academia-government cooperation.

The Japanese Society for Artificial Intelligence (JSAI) formalized in 2017 their Ethical Guidelines, in which nine principles are announced, such as (1) Contribution to humanity, (2) Abidance of laws and regulations, (3) Respect for the privacy of others, (4) Fairness, (5) Security, (6) Act with Integrity, (7) Accountability and Social

Responsibility, (8) Communication with society and self-development, and (9) Abidance of ethics guidelines by AI. JSAI members shall undertake and comply with these guidelines in their research and development.

The Japan Medical Association published its Report on Ethical Issues Taking into Account the Accelerating Development of AI in Medicine. The Report does not intend to declare any set of guidelines. However, it sets out the following six proposals: (1) Human dignity, commonality, inclusiveness, and fairness, (2) Respect for human will and the public nature of medicine, (3) Accountability of the medical decision, (4) Liability and responsibility, (5) Continuous development and improvement, and (6) Promotion of education and research on AI in medicine.

Finally, facing the recent development of Chat GPT, the Japanese government has just decided to set up a new Forum on AI Strategy acting as a control tower for the promotion and regulation of AI.

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South Africa

Artificial Intelligence in Healthcare in South Africa

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The use of AI-based technologies to advance healthcare in South Africa holds great promise. Healthcare provision in South Africa faces many challenges, including a shortage of healthcare resources, an increased burden of disease, a large proportion of the population living in rural areas, and a lack of education and primary healthcare. To reduce resource shortages and the scarcity of health professionals, AI-based health technologies offer significant advantages. These include, amongst others, the extending of healthcare access, contributing to early disease detection and prevention, assisting diagnostics, disease surveillance and public health monitoring, and providing alternative healthcare delivery methods. Notwithstanding these potential benefits, rapidly developing technologies of this kind pose a number of unique regulatory and governance challenges.

Although there is no sui generis AI legislation in place, or proposed, in South Africa, this is not to say that AI technologies within a healthcare setting in South Africa are unregulated. South Africa has legislation that governs national health, health professionals, health products and medicines, including medical devices, and health research. The South African Health Products Regulation Authority (SAHPRA) oversees medicines and medical device registration and is responsible for the regulation and approval of health products and medical devices. While the existing regulatory framework may go some distance in addressing the public health risks by including 'software' intended to be used for healthcare purposes, such as the diagnosis, prevention, or treatment of disease, in the definition of a 'medical device', the regulatory framework does not adequately address the novel and unique risks posed by software-as-a-Medical-Devices (SaMD) or AI-as-a-Medical Devices (AIaMD).

If the absence of clear AI regulatory guidelines and policies impedes the uptake of AI in the healthcare sector, provision by existing national health statutes and regulations, and the development of clear guidance by digital health policy documents, professional guidance from the Health Professions Council of South Africa, professional codes of conduct, and health research guidelines can assist by filling the regulatory void. To date limited, if any, guidance has been provided in South Africa on AI adoption in healthcare.

A close link exists between data and AI, as AI both generates large quantities of data—often personal and sensitive health data—and its development relies on datasets for its testing, training, and validation. As such, good AI governance is shaped not only by national health

and medical devices regulation but also by good data regulation and oversight. In South Africa, the collection, processing, and sharing of data is protected by the Protection of Personal Information Act which came into effect on 1 July 2020.

Despite these developments, ethical challenges remain in the design, development, and deployment of AI-based technologies including issues of algorithmic injustice, addressing bias in the data and the algorithm, the availability and access to high quality data, the use of under-represented, incomplete, or inaccurate datasets, and issues of access, inclusion, and distributive justice.

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Switzerland

AI in Healthcare: Switzerland

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Artificial intelligence-based devices have the potential to fundamentally change many areas of social life, including those relating to healthcare delivery (diagnostic, prevention, and treatment of diseases and conditions). In Switzerland, there are currently no legal regulations on the use of AI in medicine. Discussions are taking place at different levels to determine the most adequate legal framework for this matter. In September 2022, the influential Swiss Medical Association (Foederatio Medicorum Helveticorum, FMH) issued a report on the impact of AI tools on the medical profession and proposed a list of 10 recommendations that should guide this area (see *L'intelligence artificielle dans le quotidien médical. Domaines d'application en médecine: utilité, défis et exigences de la FMH,* Bern, 2022):

1. AI systems should strengthen the physician-patient relationship, not replace it.
2. AI systems must be driven by the principle of evidence-based medicine.
3. The services provided by AI systems must be effective and adequate. They are expected to simplify administrative processes and relieve physicians from such tasks.
4. AI systems must be controlled periodically, and corrective actions must be taken immediately when needed.
5. Physicians, in dialogue with their patients, remain the decision-makers regarding the application and management of proposals made by AI systems.
6. AI systems must be accompanied by "instructions for use" for physicians, indicating clearly: the role attributed to physicians in the functioning of the system; the objectives for which the AI system can be used, as well as those for which they cannot be used; how the AI system has been trained, tested and validated; how the privacy and safety of data is ensured; to whom the physician can turn in case of problems and receive assistance.
7. Physicians must receive adequate training for the use of AI systems.
8. Physicians and patients should be associated with the development of AI systems in order to participate in the determination of the purposes of their use.
9. Physicians should be informed about the use of AI systems that may influence or monitor their work.
10. A database should be created at the national level to train and test AI systems by means of large sets of medical data of high quality, and to ensure the reproducibility of the results by a robust validation.

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Taiwan

Artificial Intelligence and Medical Practices in Taiwan

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Taiwan has promulgated several laws about medical practices for decades, such as the Physicians Act, the Pharmaceutical Affairs Act and relative regulations for the autonomy and privacy of patients. However, the recent application of AI in medical practices exist in some legal uncertainty. Till now, traditional legal disciplines still apply, but seem to be insufficient for accommodating new challenges brought by AI.

For now, some hospitals in Taiwan use AI to replace or assist repetitive administrative work or diagnosis, such as medical image interpretation. The radiology, pathology, and ophthalmology departments of many hospitals need to process a large amount of image data. Through AI, it assists doctors in screening thousands of medical images. This is also the current stage of development of smart medicine.

In the future there will be more smart medical solutions entering clinical applications and assisting medical diagnosis and decision-making. AI medical care will eventually be integrated into the entire health care value chain, from education, disease treatment to health promotion, everywhere. Also, it will be extended to communities and home areas. With the assistance of AI, precise detection, precise prevention, precise diagnosis, precise treatment, and precise care will be fully connected to achieve the vision of precise health.

Nevertheless, facing all these present and future applications of AI in medical behaviors, we seem to take AI just as another tool, and do not realize how it changes the doctor-patient relationship, and how it could reformulate the liability regime. For example, Dr. Pr. WU noticed that the legal liability of doctors and medical institutions for their medical decision-making mistakes will be more limited because of the use of AI. Instead, it will be the obligation of doctors and medical institutions to evaluate and verify AI medical software. Even, we will hold producers of AI products to be responsible.

In addition, doctors will confront various new legal risks. For example, the criminal risks that may be triggered are more important from a doctor's position. Pr. CHANG also proposes that by creating proper ethics guidelines of e-health, the obligation of doctors could be clearly settled.

Following the needs for regulation and international trends, the Cabinet of Taiwan has proposed an "Artificial Intelligence Basic Law" on 25 March 2023. Under the surveillance of the Ministry of Digital Development, this fundamental law will promote the legalization of AI ethics principles, regulations for the RD of AI. Furthermore, it will follow the principles of autonomy, transparency and safety. People estimate that this Act could be passed in three years.

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United Kingdom

Artificial Intelligence (AI) in Healthcare in the United Kingdom (UK)

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The UK will be heralding an interesting epoch of innovation and technological growth, especially in artificial intelligence (AI) in the forthcoming months. The UK government, on March 29, 2023, unveiled its first White Paper on AI regulation in the UK. The government states that its approach to an AI regulatory framework will be "proportionate and pro-innovation", focusing on the context in which AI is deployed. This is not surprising, considering that this builds upon the government's National AI Strategy, with the UK ranking highly globally for research and innovations in AI. It is also not surprising that the UK has employed an AI regulation approach that is very different to the EU Artificial Intelligence Act; and it is even more interesting that no new laws are being proposed.

In the healthcare sector, a White Paper on AI in healthcare was published in 2020, and at such time, already stated that any policy

or regulatory framework should employ the AI lifecycle approach. Through the work of the NHS AI Lab, which was established to address the various challenges of AI in health and care, there appears to be significant attention given to the use of AI in healthcare. Whilst there appears to be some specific regulations for AI in healthcare, for example, the AI and Digital Regulations Service for health and social care, and requirements for AI and software used in medical devices, some legal and ethical concerns, such as liability for negligence, data protection and privacy of patient information (this is also likely to attract the application of the Data Protection Act 2018), and informed consent of patients (as examples) are covered under different areas of common law, such as tort law, and the 'privacy' laws (referred to as tort of misuse of private information), and product liability laws. In the absence of a unifying and harmonized legal position for AI applications, the regulatory landscape may appear to be fragmented, with different regulators for different industries applying different standards and rules.

For example, there are questions as to how we should deal with health/medical AI and its intersection with informed consent. How much information must a medical professional disclose to a patient, and must the disclosure also encompass justifications or reasonings that AI or machine learning was used in the process of diagnosis? In medical negligence under tort law, another example would query if the standards of duty of care of medical professionals (established in seminal cases such as Bolam and Bolitho) may be displaced if AI technologies did indeed drive the decision-making capacity of such professionals. Are patients consumers, for the purposes of breach of product liability, for example, for a failure of AI-driven AIMDs (Active Implantable Medical Devices) and for enforcement of their 'consumer' rights under the Consumer Rights Act 2015?

It remains to be seen over the course of the next few critical months as to whether the new UK AI regulation will begin to yield outcomes needed for a suitable and robust regulatory framework. What is critical is for a co-creation approach with end users (potential patients), considering that health or medical AI will impact patients in the most profound ways; and if left unchecked, will cause some very serious breaches of human rights.

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United States

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The artificial intelligence (AI) horse is out of the barn and regulators are not fast enough to corral it. AI is everywhere – analyzing our aggregated personal data and spitting out recommendations to optimize our lives. Nowhere are the consequences of AI implementation greater than in healthcare. AI-enabled treatment recommendations, AI-fueled diagnostic tests and hospital workflow optimizations promise unprecedented speed, efficiency, and accuracy. Regulators have the herculean task of helping to realize these promises while preventing harm from biased and incorrectly trained algorithms, cyber-attacks, and data shared without permission.

The United States has yet to develop a comprehensive approach to AI regulation in healthcare or any other sphere. The federal government has introduced several bills but none have gained significant support. The Trump administration took a free market approach to give the U.S. an edge in AI development. The Biden administration has approached with more caution, putting forth the "AI Bill of Rights" to strike a balance between striving for life-optimization and protecting citizens against exacerbation of

inequities. But this Bill of Rights is just a hortatory values statement. Until more explicit AI oversight rolls out, AI for healthcare is being imperfectly retrofitted into existing regulatory frameworks.

The federal Health Insurance Portability and Accountability Act (HIPAA) protects health data privacy, but it only applies to covered health entities, which do not include data-collecting giants like Amazon, Google, and Facebook. HIPAA also allows free sharing of de-identified data without addressing data reidentification. There have been calls to update the nearly three-decades old HIPAA, but none successful yet. Only five states have been proactive in passing legislation modeled on the European General Data Protection Regulation (GDPR) to protect citizen's rights to privacy and data control.

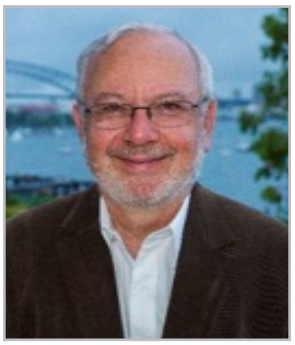
The Food and Drug Administration (FDA) has purview over AI-driven diagnostic and treatment-recommendation tools—"software as a medical device"—but focuses too much on products when the risks of AI-health tools are embedded in their processes. The FDA acknowledges the importance of scrutinizing training data and algorithm construction, but to date has only hinted at moving toward a product life-cycle approach.

U.S. Intellectual property law arguably promotes innovation through competition, but AI requires data sharing to make useful big data sets, and knowledge sharing to prevent broken algorithms from harming patients. Awarding patents to tech behemoths for their AI-health endeavors ensures their premature monopolization.

Limited court-made law so far has suggested that clinicians and potentially their institutions will remain on the hook for harm from AI tools. Those wary that robots will replace doctors need not fear yet – expert humans will have to stay in the patient-care loop. But it is not clear how far this liability will extend. What constitutes adequate informed consent when your oncologists can't explain their own treatment recommendations?

The U.S. legal landscape for healthcare-AI has not yet figured out how to promote individual rights, the public's health interests, and the blistering pace of private technological innovation.

President's Report



Roy G. Beran AM

It seems like only yesterday that I wrote the last presidential report for the Newsletter but I lose sight of the fact that, since then, I had an unfortunate illness which forced me out of action for about a month. It is very different being the patient, rather than the doctor, but being such does underpin the very real objective of the World Association for Medical Law (WAML), namely a better understanding of health law, legal medicine and bioethics which are the fundamentals of our very existence in the WAML.

This week, I returned to my full hospital duties and I did so with a new and renewed perspective. One thing one soon learns is that those who belong to an organisation, such as the WAML, have an extended family who care for you and whose warmth and kindness goes a long way to help the therapeutic process of recovery. I take this opportunity to remind all of our members, within the WAML, that you are part of this extended family and, together, we must look after each other. If any of you find yourselves in a situation in which you feel alone or in which you are in need of help, please feel free to let your WAML family know so that we can offer whatever support is possible.

It is not long to go before we are due to meet, face-to-face, at the 27th World Congress for Medical Law (WCML) in Lithuania and I sincerely look forward to seeing as many of you as possible in Vilnius. Remember this is where you touch base and rub shoulders with your WAML family and, I for one, am looking forward to meet and to greet as many of you who are able to come to me and introduce yourselves. This is not a place at which to be shy but rather a place where we can talk, plan, exchange ideas and build for the future. This is where you can use your WAML connections to organise activities, in your home country, designed to foster health law, legal medicine and a better understanding of bioethics with the WAML offering advice and assistance. It is a rare opportunity for those who come from places where these disciplines are less well developed to learn and to garner information in both the formal and informal educative setting. We, on the WAML Executive Committee of the WAML, are, to quote King

Charles at his recent coronation, "There to serve, not to be served!" We are there to help you advance the principles that are at the very foundation of the WAML. The same applies to the members of the Board of Governors who serve as the ambassadors of the WAML and who are a very approachable source of knowledge and experience and are all available should you have a need for their input.

We have far in excess of 100 high calibre submitted and accepted abstracts for the 27th WCML which bodes well for academic component of our meeting. It is important to appreciate that the WCMLs are more than just a forum for academic exchange although the raison d'etre for these WCMLs has always been to offer a level intellectual platform at which to exchange ideas and to share knowledge. As someone who has formal training as a teacher, one of the fundamental lessons which I learnt was that informal education is at least as important as is formal education. It is often said that at meetings, such as the WCMLs, it is what one learns over tea or coffee or during the lunch breaks or over the social dinner that provides far greater dividends than are attached to the formal presentations. One can only accrue these benefits by being there, by sharing ideas that may not yet have been fully developed and by discussing such concepts the airing of which may allow one to develop the nucleus of world changing ideas that otherwise would have remained dormant.

I know that the local organisers have taken seriously the idea that a World Congress must be more than a exchange of class room lectures and materials and must also offer the opportunity for social intercourse, for growing as an individual and for fostering connections that can endure, long after the formal meeting has drawn to a close and the delegates have returned to their respective corners of the globe, recognising that a globe is round and has no corners. The local organisers have aimed at developing a comprehensive programme that meets the expectations of all concerned and will serve to make this 27th WCML a very memorable experience and one that I sincerely look forward to share with you.

I conclude this Presidential report in much the same way that I have tried to conclude most such reports that I prepare with an invitation to each one of you to become more active in what is your organisation, your world body, your WAML family. Should you have ideas or suggestions which you feel would help the WAML grow both in stature and influence, then I invite you to communicate with me, to write to me and to let me appreciate your ideas so that, if possible, together we can make them a reality. Please feel free to email me via the WAML office and through our administrative officer, Ms Denise McNally at worldassocmedlaw@gmail.com. We rely on your input and I look forward to receiving it.

Roy G Beran
President

The World Association
for Medical Law

WAML Secretary General Report

Jonathan Davies, Adv.

This is my third report as SG presented to the WAML newsletter since the Executive Committee (EC) was nominated back in December 2022 at Gold Coast WCML.

The EC is in process of reshaping WAML both academic and demographic.

EC is seeking to enlarge the number of BoG governors that will represent more countries. The current Bylaws allow up to 30 BoG members. The rapid changes and developments of Medical Law calls for a change.

EC also seeks more proactive involvement of the BoG members. Governors are encouraged to involve as many peers from their countries and call for more interaction between WAML members during the WCML meetings and beyond. EC has decided to encourage members of the BoG to act as ambassadors of the WAML and make it a precondition to continue serving on the BoG. We expect BoG members to act and represent their region of the world. This could be a breakthrough for the BoG to be more active in the day-to-day activities of WAML.

We are in the process of reorganizing WAML committees. EC has approved 6 new committees that will be led by new chairs; Audit Committee, Bylaws Committee, Education Committee, Newsletter Committee, Program Chairs Committee and Social Media Committee. We call BoG members for more involvement in WAML committees.

As reported in previous reports EC decided to set up a "Program Chairs Committee" where recent WCML chairpersons can contribute from their experience to the next program chairs.

EC suggested that the Education Committee should interact with the Programme Chair to select the topics for the WCML, rather than leaving it completely to the local committee. This interaction can nourish the relationship between the BoG and the Program Chair in future meetings.

Educational Committee chaired by Prof André Dias Pereira, suggested that Committee is planning an international intensive course on Health Law and also is discussing the creation of a summer school in Coimbra University. The main topics will be legal medicine, health law, Public health Law etc.

The bylaws committee, Chaired by Dr. Dick Wilbur has already changed a few drafts updating the bylaws to the new age post Covid situation adding Public Health Law to main issues that WAML considers. The committee will present final draft of bylaws at Vilnius meetings at the 27th WCML for the approval of the BoG.

We live in a global society where regional problems suddenly became global issues that concern all of us. Pandemics such as Covid, Sars, FASD, Diabetes, Obesity, Cancer, Medical errors and the ramifications of Global warming (i.e. water shortage) are indifferent to national or geopolitical interests. These phenomena call into question our organizational commitments to discuss the effect of Humanitarian challenges that will influence the foundations of democratic societies and issues such as autonomy and equality, transparency, solidarity, fairness, and the rule of law.

Dealing with crises in the Public health sector requires collective action. Covid pandemic illustrated that the willingness to self-isolate and vaccinate in order to avoid the spread of the pandemic based on solidarity and humanity; that is, on a sense of community and identification, which leads to willingness to act for common good. These discussions are applicable in every society but especially in WAML and can bring to the table experience and evidence based knowledge that can fertilize our collaboration.

As I wrote previously, WAML can serve as a platform for exchange of views between peers and promote discussions on topics that influence Public Health Law issues for the benefit of the people of the World.

On behalf of the EC, I wish WAML members a good meeting and collaboration.

Looking forward to seeing you in Vilnius, Lithuania in August 2023!

WAML Treasurer Report

Prof. Berna ARDA (MD MedSpec PhD)
Ankara University Faculty
of Medicine
Ankara
TURKEY

Dear colleague

As the treasurer, I would like to give brief information about the financial situation of WAML.

The main income sources of WAML are; annual dues, congresses, royalty for our Journal and some irregular income such as donations.

The largest and most regular sources of income for WAML are annual membership fees and congressional revenues. Congresses alone generate revenue; it is very important as they also enable to gain new members during congresses. In the last three years, WAML has been deprived of this important source of income and the opportunity to gain new members from the countries where the congress was held has disappeared. With the Gold Coast congress in December 2022, we started to hold our face-to-face annual meetings again. We can hope that this situation will enable the Association to regain regular income.

Medicine and Law, as our official journal, is a prestige element for WAML. It has reached the 42nd volume, is regularly published and has international recognition. Our members can access the journal free of charge. Although there are royalty checks that our publisher - Hein pays for the Journal, this amount changes every year; does not constitute a fixed and regular income heading; for example royalty (Oct.2022- March 2023) is USD 7263,53.

Our monthly income (Feb-May2023, USD), mostly based on congress registration and membership fees, is as follow;

February 2.000

March 8.275

April 7.275

May 17.275

Association's regular expenses are such as administrative, graphic, congress preparations. In the context of all these; I would like to emphasis that WAML takes care not to spend other than very necessary expenses.

Relevant to the other financial information based on the official documents of March 31, 2023;

Concerning with the budget vs actual sheet (Jan15-March31),

Total income 46.679,50, total expense 11.295,19, net ordinary income is 35.384,31

Total assets, (Bank of America) $289,269.95

As a result; I would like to remind that we have limited economical sources. With respect to the membership dues we have to focus some effort to increase our member number base and consider whether there is a more effective ways of collecting annual payments. The resumption of world congresses on an annual basis, starting from December 2022, will directly increase our income. As the treasurer, I will be happy if the Vilnius Congress is as profitable as it is an academic success.

See you in Vilnius

Prof. Berna ARDA

WAML Meeting Planning and Administration

Denise McNally,
WAML Administrative Officer and Meeting Planner

Join us for the 27th World Congress on Medical Law (WCML)

August 2 – 4, 2023 Vinius, Lithuania

The Destination

This year, the World Association for Medical Law (WAML) Annual Congress will take place on August 2–4 in Vilnius, Lithuania. This is the 27th WAML World Congress. WAML, founded in 1967, brings together lawyers, scientists, attorneys, and medical practitioners from all over the world, in both academic and practical fields. The WAML World Congress is a prestigious event with a long tradition, held each year in a different country around the world.

The Vilnius Congress will discuss a wide range of issues in legal medicine, such as the challenges and successes of ongoing health system reforms to ensure access to quality health care; the role and responsibility of

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civil society in the health sector; new challenges to health systems in the post-pandemic period; the protection of patients' rights; and the role of forensic medical experts in the investigation of war crimes.

The Congress will not only become a great opportunity to get to know Vilnius – the capital of Lithuania, celebrating its 700th birthday this year, with its rich historical traditions and the designation of its historic center as a UNESCO World Heritage site, but it will also provide an excellent platform for new partnerships in the academic field and closer cooperation of representatives from medical and legal professions. The Vilnius Congress will create ample opportunity for young scientists to meet like-minded fellows to work on future projects.

Themes

1. Protection of Patients' Rights - Challenges and Responsibilities of the State and Civil Society
   - The legal and ethical limits of scientific developments and progress in medicine.
   - Technological developments and patient data protection. The right to privacy versus public interest.
   - The role of Civil Society in raising awareness and disseminating information to promote patient rights.
   - Fostering more effective resolutions for disputes between patients and healthcare institutions.
   - Contemporary issues pertaining to healthcare service provider liability.
2. Transformations in Healthcare Systems as an Inevitable Process in Achieving Excellence
   - International organisations and new initiatives to adjust national healthcare systems in the face of global challenges. The role of healthcare policies in fighting the global challenges – pandemic, climate crisis.
   - Fostering sustainability in healthcare systems.
   - Redesigning the legal frameworks of national healthcare systems following the latest achievements of biomedical science and fighting social and economic inequalities.
3. New Challenges for International Cooperation in the Field of Legal Medicine (Forensic Medicine)
   - International cooperation in mitigating natural and man-made disasters.
   - New challenges for legal medicine in combating terrorism, organised crime, war crimes.
   - Technological and scientific research innovations in legal medicine

Registration for the 27th World Congress for Medical Law is Now Open!

Please use the relevant links below and follow the instructions.

Register for WCML (2 - 4 August, Vilnius): https://wafml.memberlodge.org/event-3836997

Registration information may be found online at World Association for Medical Law - Registration Information

Book Hotel Accommodation: Radisson Blu Hotel Lietuva will be the Lodging and Congress Venue. Room rates are 110,00 € Single and 120,00 € Double. Room rate includes a breakfast buffet, wireless internet and usage of the fitness area including sauna. Room rates do not include City Taxes (1 EUR per person). Reserve your Room HERE. **Promotion Code: WAML23**

Tours and Excursions: https://www.waml2023.eu/tours-excursions/

Executive Committee Meeting, Board of Governor Meeting and Program Dates during 2023 WCML (Vilnius, Lithuania)

- Monday, July 31, 2023 – Executive Committee Meeting
- Tuesday, August 1, 2023 – Board of Governor Meeting
- Tuesday, August 1, 2023 – Welcome Reception
- Wednesday, August 2, 2023 – Congress Program
- Thursday, August 3, 2023 – Congress Program

- Friday, August 4, 2023 – Congress Program
- Friday, August 4, 2023 – Gala Dinner

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 your 2023 membership dues were due by December 31, 2022. Membership dues are $150. If you received a notice that your membership has lapsed you still have the ability to login to your profile, generate a dues invoice and pay.

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, the "Medicine and Law" electronic Journal and discounted access to activities of affiliated organizations.

We encourage you to log into the WAML website http://wafml.memberlodge.org/ and pay. After logging in choose 'View Profile' (located top right), click 'Membership' and then "Renew'. You also have the option to pay by check or wire transfer.

If your membership dues are paid, thank you!

Join us for the 27th World Congress on Medical Law (WCML)

August 2 – 4, 2023

Vilnius, Lithuania

https://www.waml2023.eu/

FUTURE MEETINGS

Of Affiliated National Associations and Collaborating Organizations

UN SDGs, AI, and the Future of Legal Professions: Fostering Equality and Access to Law
June 26, 2023
Geneva, Switzerland
Website: https://un.scla.world/

27th Annual WAML World Congress
August 2 – 4, 2023
Vilnius, Lithuania
Website: www.thewaml.com

57th Annual National Association of Medical Examiners Meeting
October 13 – 17, 2023
San Jose, California (USA)
Website: https://www.thename.org/annual-meetings

28th Annual WAML World Congress
August 8 – 11, 2024
Toronto, Canada
Website: www.wcml2020.com
www.thewaml.com

58th Annual National Association of Medical Examiners Meeting
September 19 - 23, 2024
Denver, Colorado (USA)
Website: https://www.thename.org/annual-meetings

29th Annual WAML World Congress
August 6 – 8, 2025
Istanbul – Turkey
Website: www.thewaml.com

30th Annual WAML World Congress
2026
Antwerp, Belgium
Website: www.thewaml.com

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