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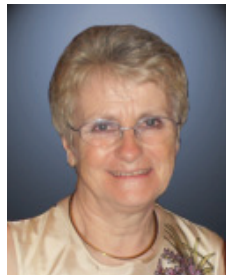
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Issue Editor



Anne Marie Duguet

Commercialisation of human body and body parts: A reality in some European countries

"Human body should not be used for commercial purposes... the human body is not an object and cannot be used as such, for instance blood and organs are not for sale" (opinion 21 of the French National Ethics Committee¹). Similarly, many international organizations, especially the World Health Organization² and the Council of Europe³, express disapproval of any trade transaction for the human body, organs and tissues. Despite these recommendations, in some countries, the compensation for organ donation and the commercialisation of tissues and organs, as well as the use of the human body, are becoming an acceptable reality in the general opinion.

The trade in organs and the trafficking

Because some countries

have no regulations, or a flexible legislation, allowing the donation between living persons under very wide conditions, donors and/or recipients move to these countries for the graft operation. The publication of some results of these activities encourages a veritable "transplant tourism" in several countries (Asia, India, Pakistan, Brazil, Philippines).

The report of Mrs. Vermot-Mangold⁴ for the Council of Europe (doc 9822 3 June 2003), shows that these practices have been conducted in Europe since 1980. She points out the shortage of organs and describes the conditions of organ traffic in Europe, especially the exploitation of poverty. The donors came from Moldova, Turkey, Ukraine, Bulgaria, Georgia, Russia, and Romania. Foremost among these practices, no medical monitoring is given to those donors whose health is deteriorating rapidly. Moreover, some former donors are promoting the trafficking.

In May 2010, the Sixty-third World Health Assembly (WHA63.22) condemned the buying of human body parts for transplantation and the exploitation of the poorest and most vulnerable populations. The assembly urged Member States to maximize donations from deceased donors and to protect the health and welfare of living donors with appropriate health-care

services and long-term follow up. Since 2004, a consensus statement (Amsterdam Forum), published by the Transplantation Society, on the care of the live kidney donor includes the obligation for the transplant center to facilitate the long term follow-up.

The utilisation of the body: the surrogate mothers

Some countries forbid surrogate motherhood in Europe (Germany, Austria, Italy, Switzerland, Spain, France), others tolerate this practice (Belgium, Denmark, The Netherlands), only the United Kingdom and Greece have a specific legislation. So a "tourism of procreation" started and surrogate motherhood, with compensation, became an internet business. For example "Surrogacy in Ukraine"⁵ says in its internet home page "Ukraine is one of the few surrogacy friendly states in Europe. It does not limit surrogacy related payments and does not require legal procedure to obtain court order. No adoption of your own child is required. The recipient family creates embryo using their or donated gametes through IVF (In-vitro Fertilization) that are transferred to gestational surrogate mother. Ukrainian law allows to issue birth certificate to intend(ed) parent's names regardless of their genetic links to the child".

Nevertheless, when surrogate motherhood is allowed by the law, the ethical concerns are not solved so far, especially the attempt to preserve the dignity of the surrogate mother (instrumentalization of her body).

The commercial use of cadavers and body parts

Human bodies are used for medical research and training students. Post-mortem donation is based on altruistic living will. Unfortunately, corpses have become rare scientific material and an international trade supplies research centres and universities.

Annie Cheney⁶ describes the highly profitable business of buying and selling cadavers and body parts in America. The American Uniform Anatomical Gift Act of 1968 and 1987 prohibits buying and selling of dead bodies. However, the act allows recovering the cost of storage, transportation etc... The cadaver trade supplies bodies and body parts to scientists, surgical equipment corporations, tissue banks, pharmaceutical companies, medical schools and researchers

Publicly paid exhibitions of real human bodies have been presented in the World (15 million visitors says the advertising for "Bodies. The Exhibition"). This use of dead bodies, out of the context of education or science research, is an ethical and a legal issue. The respect for the human body remains after death in all the cultures. The origin of the bodies presented in the exhibition is another concern, they were supposed to come from China.

In France, when the exhibition arrived in Paris (after Marseilles and Lyon), two associations acting against the death penalty and for solidarity with China claimed in court

to close the exhibition. The judge followed their request on the basis of the article 16-1-1 of the Civil Code: the respect of the human body does not end with death, the remains of deceased persons, including the ashes, must be treated with respect, dignity and decency. The decision has been confirmed by the Court of Appeal (Paris 30 April 2009), which established that the organisers cannot provide documents on the origin of the bodies and the consent forms. Moreover, according to the French law, dead bodies can be used only in public institutions for medical or scientific purposes and not for private activities, such as commercial public exhibitions.

Conclusion

The exploitation of poverty is the main issue regarding the use of human body. All international institutions promote the principle of unpaid donation for the use of human material. This recommendation is not applicable when the legislation of the country agrees with the principle of compensation as some European countries do.

The living kidney donor without any long term follow-up should be considered as a victim, in the same way as a surrogate mother without any psychological support. The principle of autonomy and the informed consent constitute an insufficient protection of their rights, in countries where there is no regulation.

The respect and the limitation of commercial use of the body after death is not protected in some countries, it seems to be more an ethical or cultural reflection than a legal issue.

WAML members could pay a major role by giving assistance to the requests of these countries for proposals of regulations, or guidelines.

⁵ <http://www.ccne-ethique.fr/docs/en/avis021.pdf>

² http://www.who.int/ethics/topics/transplantation_guiding_principles/en/index1.html

³ <http://conventions.coe.int/Treaty/EN/Treaties/Html/186.htm>

⁴ doc 9822 3 June 2003 Trafficking in organs in Europe <http://assembly.coe.int/documents/workingDocs/>

⁵ <http://en.surrogacy-ukraine.com/programs.php>

⁶ Annie Cheney Body Brokers: inside Americans underground trade in human remains. Broadway Books Random House Inc: 2006 <http://www.issuesinmedicalethics.org/151br40.html>

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Europe and international clinical research: Ethical requirements and regulatory actions



Annagrazia Altavilla

Clinical research is developing on an international scale. In 2009, the European Medicine Agency (EMA) published a report that analyzed Marketing Authorisation Applications (MAA) submitted to the EMA from January 2005 to December 2008. This report emphasized the phenomenon of the globalization of the research

and underlined that the number of patients, investigator sites and pivotal clinical trials conducted in Third countries (non EEA -European Economic Area countries) are increasing. The most favourite destinations for off-shoring of clinical trials are Middle/East Pacific Area (Russia, Ukraine), Africa, and South America (Brazil and Argentina).

Several reasons can be advanced to account for the general shift in many clinical trials away from the West and towards developing countries.

As far as the pharmaceutical industry is concerned: doing clinical trials in developing countries is 10-50% cheaper; regulatory constraints in developing countries are either less stringent or less actively policed; it is easier to find test subjects in developing countries, because participation in a trial is often the only treatment option, or because it offers the chance to make some money; test subjects in developing countries have less frequently already been exposed to similar medicines and this improves the reliability of the test results.; the governments of developing countries are also interested in the economic benefits of allowing clinical trials to be carried out in their countries. Finally, fewer and fewer people in Western countries appear to be prepared to take part in clinical trials, partly as the result of negative publicity related to unethical trial scandals.

This phenomenon raises important questions about the economical and ethical aspects of clinical research and the translation of trial results to clinical practice. Who benefits from the globalization of clinical trials? Which ethical standards are applied? What

is the potential for exploitation of research subjects? Are trials results accurate and valid and can they be extrapolated to other settings? Many reports have shown that the degree of transparency of clinical trials in developing countries is low.

In this context, to avoid unethical clinical trials and the exploitation of developing countries, Regulation (EC) n. EC/726/2004 states in recital 16 that “...with respect to clinical trials conducted outside the Community on medicinal products destined to be authorised within the Community, at the time of the evaluation of the application for authorisation, it should be verified that these trials were conducted in accordance with the principles of good clinical practice and the ethical requirements equivalent to the provisions of the Directive 2001/20/EC”. Furthermore, paragraph §8 of the Preamble – Introduction and General Principles of Annex 1 to Directive 2001/83/EC states: “...during the assessment of an application, clinical trials, conducted outside the European Community, which relate to medicinal products intended to be used in the European Community, shall be designed, implemented and reported on what good clinical practice and ethical principles are concerned, on the basis of principles, which are equivalent to the provisions of Directive 2001/20/EC. They shall be carried out in accordance with the ethical principles that are reflected, for example, in the Declaration of Helsinki.” Finally, the latest version of Directive 2001/83/EC requires to submit, in the application for Marketing Authorisation, a statement confirming that clinical trials carried out

outside the European Union meet the ethical requirements of Directive 2001/20/EC (article 8(3) (ib))

The EMA Work Programme for 2008 (http://www.ema.europa.eu/pdfs/general/direct/emeawp/EMEA_Work_Programme_2008_full.pdf) set out a number of objectives relating to the acceptance, in MAAs submitted to the EMA, of clinical trials conducted in countries outside the European Economic Area (EEA) on medicinal products for human use. All such trials are required to meet internationally agreed ethical and data quality standards. These objectives need to be built into the process of clinical development. They need to be addressed before and during the conduct of the clinical trials and not only by assessment and inspection at the time of MAA by which point the trials have been completed, in some cases several years earlier.

In Dec 2008 the EMA published a strategy paper “Acceptance of clinical trials conducted in third countries for evaluation in Marketing Authorisation Applications” (<http://www.ema.europa.eu/Inspections/docs/22806708en.pdf>). In 2009, the EMA set up a Working Group on Third Country Clinical Trials in order to clarify ethical standards for clinical research conducted outside the EEA and included in MAAs. Practical steps to be undertaken during the provision of guidance and advice in the drug development and Marketing Authorization phases were established.

To this aim, a “Reflection paper on ethical and GCP (Good Clinical Practice) aspects of clinical trials of medicinal products for human use

conducted in third countries and submitted in marketing authorization applications to the EMA” was drafted. It integrates all the relevant ethical and legal sources recognized at European and international level, clarifies ethical standards to be taken into account and proposes some actions to be undertaken in the context of EMA activities, including Scientific Advice, Orphan Product Designation and Paediatric Investigation Plans through to the finalisation of the CHMP opinion on the MAA, and post-authorisation activities.

This document highlights and emphasizes that the best approach to achieve an ethical supervision of research across the world is to ensure that a robust framework exists for the oversight and conduct of clinical trials, no matter where in the world the clinical investigators’ sites are located and patients recruited.

The Reflection Paper highlights and emphasizes the need for cooperation between Regulatory Authorities involved in the supervision of clinical trials and the need to extend and link networks to support these activities. An international network of regulators from all countries involved, working together to share best practices, experiences and information and working to standards agreed and recognized by all, can provide an effective platform for such a robust framework.

To achieve these objectives and to guarantee a large participation of stakeholders, the EMA submitted the document for public consultation until the 30th of September 2010 and during the same period organised an international workshop with the

aim to discuss and provide feedback on this reflection paper. Comments on the paper could be provided using this template. The completed comments form should be sent to ctrefpaper@ema.europa.eu

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The importance of law for pandemic preparedness in Europe



Robyn Martin

Introduction

Although institutions such as the World Health Organization (WHO), the European Commission and ECDC, all play a role in disease prevention and control, final responsibility for disease surveillance and the management and control of disease outbreaks lies with individual states. In relation to a possible influenza pandemic, in particular H5N1, each state in Europe has a pandemic preparedness plan outlining

measures to be taken for prevention and control of pandemic disease. Such plans inevitably contain proposals for non-medical interventions such as compulsory screening, quarantine, detention, closure of facilities and, in some states, compulsory vaccination and medical treatment, to support medical disease control measures.

Law and pandemic preparedness

Pandemic preparedness plans are important but they are policy documents and in most states do not have the force of law. Many of the interventions proposed would, without legal authority, constitute criminal or tortious (delict) acts. Detention and quarantine without consent might well amount to false imprisonment for example, and compulsory screening or treatment without consent, to assault. It is essential that states proposing such interventions provide, alongside their preparedness plans, legislation authorising disease control measures.

Even where legislation authorises behaviors that might otherwise infringe individual autonomy, there will be constraints on the extent to which states can prioritise the public good over individual rights for the purposes of disease control. These constraints come from the need to exercise public health practice, within a framework of public health ethics, and from the abiding principles of human rights enshrined in documents such as the European Convention on Human Rights and Fundamental Freedoms. In the case of *Enhorn v Sweden*¹ the European Court of Human Rights confirmed that states must recognise human rights laws in

the exercise of public health powers. Hence, no state can afford to conduct its public health programmes without recourse to public health law to underpin public health measures and to constrain over-zealous exercise of public health interventions.

Pandemic influenza threatens to test societies to the extreme. Public health laws are likely to be critically important tools in supporting disease prevention and control and in regulating social and individual behaviour that threatens security during a crisis.

What is public health law?

Public health law is based on the state's responsibility to protect its citizens from foreseeable threats of harm. Powers and duties within the realm of public health law are framed in ways that address populations and govern the organised efforts of the state to provide services and interventions aimed at population health.² Public health operates within an ethical framework of communitarianism and utilitarianism, presupposing both that there are circumstances in which the greater good of the community justifies the overriding of autonomy of the individual and that the intervention which results in the greatest health benefits for the greatest number is the most appropriate.

The International Health Regulations (IHR)

The Constitution of WHO confers upon the World Health Assembly the authority to adopt regulations "designed to prevent the international spread of disease".³ These regulations enter into force for all WHO Member States

that do not affirmatively opt out of them. The revised IHRs 2005 impose disease reporting duties, duties in relation to the handling of epidemiological data and responsibilities on States to strengthen surveillance and response capacities. The WHO has powers to determine when a disease constitutes a public health emergency, to make recommendations and to respond to disease events. The IHR 2005 also recognise the constraints of human rights on public health interventions, requiring all public health measures to be evidence based and that health measures not be more restrictive or invasive than reasonably available alternative measures. The IHR 2005 prompted all signatory States to revisit their public health legislation, to enable them to act to control the spread of disease in a pandemic.

The PHLawFlu project

It was nevertheless unclear the extent to which States within Europe had at their disposal laws to support pandemic planning. One objective of the EU co-funded PHLawFlu project was to study laws underpinning human pandemic influenza preparedness across 27 member States plus Croatia, Turkey, Iceland, Liechtenstein and Norway. The methodology included a detailed questionnaire on state public health laws and workshops examining the cohesion between preparedness plans and disease control laws within States, as well as the cohesion between public health laws across States in Europe.

The project found a number of disconnects and differences of approach to pandemic planning and disease legislation across States. While

some States are reliant on 19th century laws updated for IHR compliance, others have new laws designed with pandemic disease in mind. Some States have general powers enabling any proportionate measure for a public health purpose. In only two of the States studied were all measures proposed in plans supported by specific legal authorisation.

Some States operate their public health laws at national level while in others, with devolved systems, regional laws are more important. Six Schengen States' plans consider a pandemic to constitute a serious enough threat to public policy or internal security to justify reintroduction of internal border controls. Ten States have laws that would authorise border closure in a pandemic. There was a range of interventions planned across the States including surveillance, compulsory treatment, medical examination, vaccination, quarantine and isolation. Some States proposed using emergency powers in a pandemic. In some States there was the potential for proposed interventions to infringe human rights.

One of the most important findings was that most States lack expertise in public health law. Participants in project workshops called for increased research and training in public health law in Europe.

Conclusion

Pandemic planning policies must be framed within laws that enshrine public health ethics and human rights. Previous disease outbreaks, in particular SARS, demonstrated that, across the world, public health laws are out of date and inappropriate.

ate to contemporary disease threats. The IHR 2005 have initiated global disease law reform but a paucity of teaching and research in public health law, particularly in Europe, has inhibited effective revision of disease laws. Law is a useful tool for public health but as yet there is little capacity to exploit it. We need to include teaching and research in public health law in both law and public health schools to build capacity in public health law expertise, to assist not only in pandemic preparedness but also in the control of other communicable and non-communicable diseases across Europe.

¹[2005]E.C.H.R. 56529/00

²See L.O.Gostin, *Public Health Law: power, duty and restraint*, Berkeley: University of California Press; 2000

³Articles 21(a) and 22

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WAML Secretary General's Report



Prof. Roy Beran,
WAML Secretary General

I am delighted to provide this, the first Secretary General's report, following the 18th World Congress on Medical Law (WCML). It was an

extremely successful conference and the whole Croatian team MUST be congratulated on a great meeting. Its importance was highlighted by the fact that the President of Croatia, himself, opened the WCML and there was of the order of 400 delegates from around the world.

It was also a monumental meeting for the World Association for Medical Law (WAML) as Professor Amnon Carmi stepped down from the Presidency and from the Board of Governors after more than 20 years at its helm. To commemorate this event, the WAML created and presented the inaugural Amnon Carmi Award, created to perpetuate the name of a man who was, and is, the epitome of the WAML for so long. The recipient of the Award was Professor Bernard Dickens from Canada. Professor Dickens was unable to attend the WCML due to health problems but he too stepped down from the Board of Governors after many years of devoted service to the WAML.

On only the fourth occasion, in the half-century history of the WAML, the Raf Dierkens Medal, named after the founding father of the WAML, was awarded and the recipient was Professor Thomas Noguchi, who has attended the WCMLs since the very first meeting, all those years ago, in Ghent. Tom, as he is better known, was also elected as the next President of the WAML and presided over the Board of Governors meeting that immediately followed the General Assembly (GA) in Zagreb, Croatia.

The GA was a very lively meeting and the democratic way in which it was conducted bodes well for the future of the WAML. There

was healthy debate from the floor and the value of having established statutes, to map out our future, was reinforced. The GA elected new blood onto the Board of Governors, significantly lowering the average age, well below mine, which is a good thing and most encouraging for our future. Adv. Samuel Wolfman stepped down from the Audit Committee and the new Committee was ratified, including Dale Cowan (USA), Anne-Marie Duget (France) and the new member Itzhak Zaidese (Israel). The venue for the 2012 World Congress for Medical Law (WCML) was confirmed as Maceio, in Brazil, and that of the WCML in 2014 will be Bali, Indonesia. This reaffirms the global nature of the WAML.

At the Board of Governors meeting, following the GA, the executive was elected and consisted Tom Noguchi from USA (President), Roy Beran from Australia (Secretary General), Oren Asman from Israel (Treasurer) and David Collins from New Zealand (Executive Vice President). This maintained significant consistency on the Executive, with continuing members of the team, although half of them in different jobs. It reflects the confidence held by the Board of Governors that the Executive can provide a team necessary to ensure that the administration of the WAML will continue without too much upheaval following the monumental change of Presidents. It ensures that we can maintain the high standards necessary to fill those large shoes vacated by Professor Carmi. Personally, let me take this opportunity to thank all those who have supported me, as the Secretary General, and allow me to confirm my commitment

to ensure that the WAML will continue to grow and to go from strength to strength.

New blood was introduced into the ranks of the Vice Presidents and I can assure all those reading this newsletter that our future looks very bright with a new face Board of Governors and an enhanced level of enthusiasm and vitality from all those on the team.

During the 18th WCML there was a special celebration of the 30th Anniversary of our WAML journal 'Medicine and Law'. This was presided over by Dr Mohammed Wattad, who spoke about adopting Professor Carmi's "baby" and promising to be a good parent. Mohammed was married, just days before the meeting, and the whole of the WAML wishes him and his new bride, and now their adopted "baby", every happiness and success. We know the journal is in good hands and we are confident that it will also go from strength to strength

At the time of writing this report there has not yet been a week since my return from Zagreb and I cannot keep up with the flurry of email activity generated from our new President. Tom Noguchi, whom so many described to me as an 'old man', has the energy of a 20 year old and puts me to shame. He will drive us all into the ground with his boundless enthusiasm and absolute commitment. Denise McNally, the new Administrative Officer, was worth her weight in gold while in Zagreb and, since then, has not been allowed to surface to take breath. Oren Asman, who served me so faithfully as Deputy Secretary General and as an ex-officio member of the Executive, is now the new

Treasurer, to replace Tom Noguchi, and has promised to do both this task and continue to act as my Deputy. He has raised so many exciting new concepts, such as Facebook, U-tube and Twitter – terms new to an old soul like me but clearly evidence of a ‘time of change’ and a new season for the WAML.

At the Board of Governors meeting, preceding the GA, it was decided to canvass organizations interested in health, law and ethics around the world. Jonathan Davies, who was re-elected as Chair of the Council of Presidents (CoP), and I will write to as many as 1,000 organizations, to offer affiliate status with the CoP. There will be a two year moratorium on any charges to these bodies so as to ensure wider global representation for the WAML. Organizations seeking affiliation will still be encouraged to advocate individual memberships, which can be achieved over the WAML web-pages. Should anyone, reading this newsletter, be part of an appropriate organization or institution which could benefit from WAML affiliation, they are encouraged to contact our Administrative Officer, Denise McNally, to register the interest of that organization and we will make it our business to make contact.

Also in Zagreb, Dr Richard Wilbur, one of the most positive supporters of the WAML, over many years, was elected and accepted the role of Editor-in-Chief of the Newsletter, in conjunction with the issue specific editors. I truly look forward to the ongoing work with Dick. He is an inspiration and a real role model.

Amnon Carmi is not totally relinquishing his duties for the WAML and will direct an

‘Education Committee’ as one of a number of new committees to be formed. This will capitalise on his experience in the UNESCO Chair in Bioethics and his many years as an academic and teacher. Should any of our members want to serve on any of the newly formed committees or wish to nominate the formation of a new committee that they envisage would be to the future benefit of the WAML, they are encouraged to either contact me, as Secretary General or Tom Noguchi, as your President.

From the above, it can be seen that the changing of the guard at the top of the WAML really does offer a very positive opportunity for change, building on the very solid foundations provided by Prof Carmi. You, our members, can be confident in the future of your Association and the WAML is destined to achieve great things. As always, I conclude with a call to arms and I seek your continued and enhanced efforts to make this, your Association, the best it can be and for you to contribute in any way that you can.

Roy G Beran
Secretary General WAML

President’s message



Thomas T. Noguchi
WAML President

As your newly elected President, I would like to convey a special message to you. First, I would like to urge you to encourage your colleagues

to become members of the WAML. The more members that we have will provide more resources and talents to engage in active educational projects, setting standards, and accreditation for educational efforts. We have the WAML membership brochures in pdf or hard copy for a membership drive.

I am open to any suggestions from the membership to improve the management and organization of the WAML and would like members to participate in future programs of the WAML.

Brazil will host the next World Congress. Congress President Eduardo Dantas spoke at the last World Congress in Zagreb, Croatia and pointed out that the 19th Congress will be the first Congress to be held by the WAML in Latin America. It is my great pleasure to invite you and your colleagues to attend the World Congress on Medical Law in Maceió, Brazil in August 9 - 13, 2012. Many of you may already have met Denise McNally during the Congress in Zagreb, Croatia. She has recently joined the WAML as Administrative Officer and Coordinator for membership services. Please do not hesitate to contact her for any suggestions or requests. Her E-mail address is mcnallyd@cvalley.net.



have started the preparation for the next Congress, to be held in Brazil, in the city of Maceió, in August 2012.

We are proud to host, on behalf of WAML, the first World Congress on Medical Law in Latin America. We believe this is the ideal opportunity to create bonds on both sides of the Atlantic, strengthening cooperation among researchers, associations and universities, thus encouraging the study and discussion of problems concerning health law, bioethics and legal medicine.

In the upcoming months, we will send information about deadlines, main themes, and registration at special rates for WAML members. Our website can be accessed at www.2012wcml.com, and there you will be able to contact the organizers, and find useful information for planning your trip.

More than that, we hope to have your active participation in this process, with your comments, suggestions and ideas. The commitment of each one of us is important to help the WAML grow stronger, reaching its goals, developing Medical Law, Legal Medicine and Bioethics and the advancement of human rights.

On behalf of the organizing committee, I’d like to welcome you all to Maceió, to Brazil, to Latin America.

Eduardo Dantas
Vice-President of WAML
2012 Congress President



Following the successful meeting we had last month in Zagreb, I am happy to announce that we already