19th WORLD CONGRESS ON MEDICAL LAW
Maceió, Brazil . 7 - 10 August, 2012

ABDS
CONGRESSO BRASILEIRO DE DIREITO DA SAÚDE
07 A 10 DE AGOSTO DE 2012 - MACEIÓ - BRASIL

ABSTRACT BOOK

WCML / CBDS 2012

19th WORLD CONGRESS ON MEDICAL LAW

CONGRESSO BRASILEIRO DE DIREITO DA SAÚDE

MACEIÓ, BRAZIL (Aug06 – 10, 2012)

WAML / ABDS

19th World Congress on Medical Law

Congresso Brasileiro de Direito da Saúde (Brazilian Congress on Health Law)

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World Association for Medical Law

ABDS ASSOCIAÇÃO BRASILEIRA DE DIREITO DA SAÚDE

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August 07, 2012

ROOM 01 (SALA 01)

WAML SESSION 01 (ENGLISH 10:00 a.m. – 12:00 p.m.)

Session Coordinator: Radmyla Hrevtsova

1. Dependence of the independent ethical committees in modern Russia
Natalia Sedova – Russia

2. Beneficence beyond the grave?
Line Brune Juhi – Denmark

3. Creating a global library of health laws
Amir Attaran – Canada

4. Bias in research and expert opinions in the legal process
Jonathan Davies – Israel

5. Is the DNR (Do-Not-Resuscitate) order an international document?
Gérald Kierzek – France

6. The duty to perform a patient recall.
Dimitri Verhoeven – Belgium

WAML SESSION 02 (ENGLISH 01:00 p.m. - 3:00 p.m.)

Session Coordinator: Oren Asman

1. Disciplinary procedure in Medical Law: Could it ever be effective?
Katerina Cervena – The Czech Republic

2. A study on the malpractice compensation resolved by a third-party in the R.O.K.
Mi Jin Lee – South Korea

3. Adverse events, medical erros & patient communication: Ethical & legal issues involving disclosure and apology.
Marguerite A. Chapman – USA

4. The information rights of the patient in the European patients rights directive.
Herman Nys – Belgium

5. The application of international health regulation (2005) and international travelers rights in China.
Ye Jianzhong – China

6. The legislative and regulatory acts of the circumpolar region of Russia in the field of public health.
Konstantin Shapovalov – Russia

WAML SESSION 03 (ENGLISH 03:30 p.m. - 5:30 p.m.)

Session Coordinator: John Conomy

1. DFAF HIV
Zhad Chunzong – China

2. Discussion on the protection of human rights on AIDS patients.
Fan Kiaoli – China

3. Aging humanity and rights of elderly people.
Vugar Mammadov – Azerbaijani

4. A case commentary on Oliver Brustle v. Greenpeace E.U. – Case regarding patentability of Hesc Research.
Juli Mansnerus – Finland

5. Cameroon civil society advocacy for adoption of a law protecting human right and gender equality.
Victor Dada Faubit – Cameroon

ROOM 02 (SALA 02)

WAML SESSION 04 (SPANISH 10:00 a.m. – 12:00 p.m.)

Session Coordinator: Alain Garay

1. Aspecto médico legal de la muerte encefálica en el Paraguay
Natalia Cazal – Paraguay

2. La naturaleza jurídica del embrión humano frente a la crioconservación
Eduardo Javier Jourdain – Argentina

3. El derecho a la protección de la salud de pacientes pediátricos con cardiopatias en Venezuela.
Carlos Sanches Echeverria – Venezuela

4. El marco legal del derecho de los enfermos al final de vida en Francia (Comentarios sobre la Ley del 22 de abril de 2005).
Alan Garay – France

5. Manejo de datos sanitários en casos de interes clínico.
Josep Corbelle Duch – Spain
6. Situación jurídica del aborto en el Paraguay
Clara Maria Antunez Ramirez – Paraguay

7. El derecho de los pacientes en matéria de obtención de créditos Y seguros
Caroline Jay – France

WAML SESSION 05 (PORTUGUESE 01:00 p.m. - 3:00 p.m.)

Session Coordinator: Marianna Chaves

1. Acesso ao tratamento: o direito humano na saúde pública
Fabrizia da Fonseca Passos Bittencourt – Brazil

2. Acesso aos bens de saúde na jurisprudência do Supremo Tribunal Federal
Bruna de Cássia Teixeira – Brazil

3. Análise do impacto regulatório na saúde suplementar.
Ivandro Aguiar Campos – Brazil

4. Análise dos processos de auditoria do SUS na Grande Florianópolis registrados no DENASUS no período 2000 a 2010.
Flaviana Maria Vieira do Nascimento – Brazil.

5. Roubaram-nos a capacidade de sonhar? Deveres dos pacientes em tempos de crise sistêmica do capitalismo.
André Gonçalo Dias Pereira – Portugal

6. A incorporação de novas tecnologias no Sistema Único de Saúde.
Angélica Lúcia Carlini – Brazil.

WAML SESSION 06 (PORTUGUESE 03:30 p.m. - 5:30 p.m.)

Session Coordinator: Emerson Eugenio de Lima

1. Núcleo de apoio técnico para os tribunais de justiça na saúde suplementar: o equilíbrio do contrato e a proteção do consumidor.
Angélica Lucia Carlini – Brazil.

2. Medicamentos de referência vs Genéricos: A questão da extensão de vigência das patentes.
Célia Barbosa Abreu e Priscilla Menezes – Brazil

3. Inspeção de risco na área da saúde: A busca de evidência das práticas assistenciais para garantir a segurança do paciente e profissional de saúde.
Bruna Malagoli Martino – Brazil

4. Observatório do judiciário sob a ótica do direito à saúde: repensando o acesso à justiça e a dimensão processual desse direito fundamental.
Luciana de Paula Lima Gazzola – Brazil

5. O início da vida para o direito e as terapias com células-tronco.
Sérgio Nesser Nogueira Reis – Brazil

ROOM 03 (SALA 03)

WAML SESSION 07 (PORTUGUESE 10:00 a.m. – 12:00 p.m.)

Session Coordinator: André Gonçalo Dias Pereira

1.Testamento Vital entre o neoconstitucionalismo e o constitucionalismo andino.
Célia Barbosa Abreu – Brazil

2.Testamento vital: dignidade da pessoa humana versus inviolabilidade à vida.
Maiara Sanches Machado Rocha – Brazil

3.Testamento vital: uma possibilidade no direito brasileiro?
Fernanda Schaefer Rivabem – Brazil

4.Implicações jurídicas do processo de tomada de decisão de um paciente em cuidados paliativos
Lívia Abigail Callegari – Brazil

5.Prontuário eletrônico: um avanço ou uma invasão à privacidade do paciente?
Trícia Dias Perez – Brazil

6. Protecção legal promove a notificação de incidentes e eventos adversos?
Paula Bruno – Portugal

WAML SESSION 08 (PORTUGUESE 01:00 p.m. - 3:00 p.m.)

Session Coordinator: Emerson Eugenio de Lima

1. A questão das patentes e o acesso aos medicamentos enquanto exercício do direito à saúde: um aparente conflito de normas.
Daniela Novelli Scarpa – Brazil

2. A regulação da publicidade de medicamentos.
Arianne Vilanova Almeida Galo – Brazil

3. A situação do médico segundo o Código de Defesa do Consumidor.
Tricia Dias Perez – Brazil

4. A economia das doenças raras: Teoria, evidência e políticas públicas.
Giacomo Balbinotto Neto – Brazil

5. Saúde pública e escassez de recursos públicos: a quem cabem as escolhas trágicas? ***Célia Barbosa Abreu – Brazil***

6. O uso de agrotóxicos na produção de sementes transgênicas no Brasil: Aspectos da (des)regulação pelo Estado.
Sonia Barroso Brandão Soares – Brazil

ROOM 04 (SALA 04)

WAML SESSION 09 (ENGLISH 10:00 a.m. – 12:00 p.m.)

Session Coordinator: Berna Arda

1. Patient mobility in the EU: Recent developments.
Andre Den Exter – The Netherlands

2. Patients rights in the gap between Euthanasia and Disthanasia
Sanja Jakopcic Car – Croatia

3. Private financing of healthcare services in Poland.
Natalia Lojko – Poland

4. Private health plans and the right to health.
Arianne Villanova Almeida Gaio – Brazil

5. Studies on the alternative dispute resolution of physician-patient relationship
Qiao Shiming – China

WAML SESSION 10 (ENGLISH 01:00 p.m. - 3:00 p.m.)

Session Coordinator: Henriette Roscam-Abbing

1. Task shifting and patients rights. Experiences from The Netherlands
D.Y. Van Meersbergen – The Netherlands

2. Sharing Genetic Biobanks: Which Protection for rights of French patients.
Anne Marie Duguet – France

3. Systems of Patients – Rights Protection – A comparative view
Milan Markovic

4. New Belgian act on compensation for damage resulting from medical care.
Steven Liennan – Belgium

5. New patient safety regulations in Finland.
Lasse Lehtonen – Finland

6. New route for claiming compensation for medical malpractice in Poland – First experiences.
Natalia Lojko - Poland

August 08, 2012

ROOM 01 (SALA 01)

WAML SESSION 11 (ENGLISH 08:00 a.m. – 09:30 a.m.)

Session Coordinator: Vugar Mammadov

1. Protection of the rights of the international travelers carrying infectious diseases at entry ports during a pandemic.
He Jingjing – China

2. Recent developments in organ transplantation in Finland.
Terhi Hermason – Finland

3. Recent developments in Slovenian Mental Health law
Blaz Ivanc – Slovenia

4. The impact of presumed consent law on organ donation: An empirical analysis from quantile regression for longitudinal data.
Giacomo Balbinotto Neto – Brazil

5. Recent developments in the health regulation of the Republic of Serbia.
Marta Sjenicic – Serbia

WAML SESSION 12 (ENGLISH 10:00 a.m. – 12:00 p.m.)

Session Coordinator: Roy Beran

1. 40 years of Japanese Association of Medical Law – Change of topics in the annual scientific meetings.
Mitsuyasu Kurosu – Japan

2. A "fantastic voyage": Is the global regulation of nanomedical products adequate?
Jennifer Sarah Moore – New Zealand

3. A new style of end-of-life cases: A patient´s right to demand treatment or a physician´s right to refuse treatment? The futility debate revisited.
Christophe Lemmens – Belgium

4. Civil liability of gestational mother. Toward genetic parentes and embryo.
Mohsen Izanico – Iran

5. Civil liability of the pregnant tobacco user in relation to the unborn child.
Arianne Vilanova Almeida Galo – Brazil.

6. Claim work in the practice of regional department (Ministry) of Health of Russia.
Konstantin Shapovalov – Russia

WAML SESSION 13 (PORTUGUESE / SPANISH 01:00 p.m. – 03:00 p.m.)

Session Coordinator: Marianna Chaves

1. Aspectos éticos frente à satisfação do cliente hospitalizado.
Maria Auxiliadora Trevisan – Brazil

2. A crise paradigmática da judicialização da saúde e a emergência de um novo contencioso adequado ao estado de modernidade tardia.
Adler dos Santos Baum – Brazil

3. A regulamentação do setor de saúde suplementar no Brasil e risco moral: uma aplicação da regressão quantílica para dados de contagem.
Giacomo Balbinotto Neto – Brazil

4. A tutela do segredo médico pelo Conselho Regional de Medicina do Estado de Minas Gerais em um Estado democrático de direito e a manifestação do judiciário.
André Lorenzon de Oliveira – Brazil

5. Alta médica hospitalar e suas implicações legais e éticas ante o binômio autonomia e beneficência profissional.
Stela M. da Silva – Brazil

6. Protección de los derechos del paciente en Peru.
Rosa Mesa Vásques - Peru

WAML SESSION 14 (ENGLISH 03:30 p.m. – 05:30 p.m.)

Session Coordinator: Herman Nys

1. Legal aspects of medical experimentation on humans.
Vugar Mammadov – Azerbaidjan

2. Is all feticide not murder?
Ken J. Berger – Canada

3. Legal regulation of complementary medicine.
Ian Freckelton – Australia

4. Is it possible to promote death at home in Japan?
Kazunari Satomura – Japan

5. Legal regulation of the issue of the status of the patient.
Suren Krmoyan – Armenia

ROOM 02 (SALA 02)

WAML SESSION 15 (ENGLISH 08:00 a.m. – 09:30 a.m.)

Session Coordinator: Charles Hinnant

1. Recent developments on end-of-life guidelines in Japan.
Takeshi Miyashita – Japan

2. Rights of the patients in the russian legislation.
Margarita I. Litovidna – Japan

3. The ethics or non-ethics of an expert: the hired gun.
Alan C. Hoffman – USA

4. The euthanasia in East-Asia region: Based on observation of culture and experience.
Chan Rui – Japan

5. The comercial use of human material.
Nick Van Gelder – Belgium

WAML SESSION 16 (ENGLISH 10:00 a.m. – 12:00 p.m.)

Session Coordinator: Ken Berger

1. Confidential medical information problem of the Republic of Armenia.
Suran Krmoyan – Armenia

2. Discussing living donor organ transplantation. Legal regulation between husband and wife.
Wang Ping – China

3. Mortality among homeless and unclaimed bodies in Mangalore City – An insight.
Raghsvendra Babu YP – India

4. National Ethics Committees – Case of establishment and activity according to Serbian Health Law.
Hajria Mujovic-Zornic – Serbia

5. Neonatology and risk.
Jean-Baptiste Thierry – France

WAML SESSION 17 (ENGLISH 01:00 p.m. – 03:00 p.m.)

Session Coordinator: Annagrazia Altavilla

1. Disputable payment for participation of minors in pharmaceutical clinical studies.
Zuzana Candigliota – The Czech Republic

2. Duties and liability of a physician confronted with child abuse.
Thierry Vansweevelt – Belgium

3. The reform of liability for medical malpractice in the tort law of the People's Republic of China: its success and shortages.
Gong Zu-Kang – China

4. E-Health: Modern health care technology and bioethics and legal issues surrounding it.
Moein Montazeri – France

5. Embryos and genes on trial.
Judit Sandor – Hungary

6. Empowering children in the mental health setting.
Lynn Hagger – United Kingdom

WAML SESSION 18 (ENGLISH 03:30 p.m. – 05:30 p.m.)

Session Coordinator: Thomas Noguchi

1. Legal regulations related to clinical trials and ethical committees in Turkey.
Berna Arda – Turkey

2. Legal situation regarding end-of-life care in Japan: recent trends of euthanasia and death with dignity.
Mari Manobe-Honda – Japan

3. Lessons from recent public health scandals in France: the role of the National 4. Office for Medical Accidents (ONIAM).
Myriam Denieul – Canada

4. Living organ donation and minors: a major dilemma.
Nils Broackx – Belgium

ROOM 03 (SALA 03)

WAML SESSION 19 (PORTUGUESE 08:00 a.m. – 09:30 a.m.)

Session Coordinator: Marcos Coltri

1. Quantificação da indenização na responsabilidade civil por perda de uma chance de cura.
Daniela Pinto de Carvalho – Brazil

2. Responsabilidade civil do cirurgião dentista: Um novo paradigma.
Lívia Abigail Callegari – Brazil

3. Responsabilidade civil dos cirurgiões plásticos nas cirurgias estéticas: um estudo comparativo entre aspectos jurídico-civis no direito argentino e brasileiro.
Gustavo Silveira Borges – Brazil

4. Responsabilidade legal do médico – Civil, penal e administrativa.
Pedro Garcia Lopes Jr. – Brazil

5. Responsabilidade penal médica em Portugal. A conduta negligente nas equipas médicas.
Sónia Fidalgo – Portugal

WAML SESSION 20 (PORTUGUESE 10:00 a.m. – 12:00 p.m.)

Session Coordinator: Marcos Coltri

1. A aplicação da teoria da perda de uma chance na responsabilidade médica pela jurisprudência brasileira.
Paula Moura F. de Lemos – Brazil

2. A autonomia da vontade do paciente e o termo de consentimento livre e esclarecido na defesa do profissional médico.
Bárbara Lemos Lameiras – Brazil

3. A avaliação de desempenho na perícia médica – Instrumento de sucesso na proteção e defesa do profissional médico-perito.
Beatriz de Abreu Dallari Guerreiro – Brazil

4. A proibição da doação de órgãos post mortem: restrição abusiva ao princípio da autonomia da vontade.
Eudes Quintino de Oliveira Júnior – Brazil

5. A nano biotecnologia e a nova fronteira de tratamento. A proteção da sociedade e do consumidor. Aspectos bioéticos e a ascensão do princípio da precaução.
Henrique Freire de Oliveira Souza – Brazil

6. A decisão do Supremo Tribunal federal na ADPF 54 e a inviabilidade fetal além da anencefalia: A contribuição do patologista.
Luciana de Paula Lima Gazzola – Brazil

WAML SESSION 21 (ENGLISH 01:00 p.m. – 03:00 p.m.)

Session Coordinator: Anne-Marie Duguet

1. Female Pedofily. When a rose has only spines.
Simona Ricci. Italy

2. First aid as the problem of implementation of international norms into national legislation in "non-stop" regime.
Donika Alena – Russia

3. Genetic medical information: Legal and ethical responses (UK Perspective).
Ivandro Aguiar Campos – Brazil

4. Global shortage of transplants: History, problems, solutions.
Vugar Mammadov – Azerbaijani

5. Health care fraud, whistleblowing and federal sentencing in the United States.
C. Willian Hinnant Jr. – USA

WAML SESSION 22 (ENGLISH 03:30 p.m. – 05:30 p.m.)

Session Coordinator: Oren Asman

1. Loss of a chance in medical malpractice: can it jump the hurdle of causality?
Quinben De Raedt – Belgium

2. Medical documentation with special reference to sister documentation.
Snjezana Cerjan – Croatia

3. Medical corruption: the new problem in upholding medical law in Indonesia.
Sysefudin Ali Akhmed – Indonesia

4. Medical error and its consequences for the relationship between doctors, patients and the public – Current situation in Bosnia and Herzegovina.
Sanjin Dekovic – Bosnia and Herzegovina.

5. Medical fault ascertainment principle of choice of law value.
Han Xi – China

ROOM 04 (SALA 04)

WAML SESSION 23 (ENGLISH 08:00 a.m. – 09:30 a.m)

Session Coordinator: Thomas Noguchi

1. A comparative study of criminal liability of medical institutions in the legal system of Iran, France and United States.
Mohtaba Zaare – Iran

2. Austroads Guidelines for fitness to drive.
Roy G. Beran – Australia

3. Canine index: a tool for sex determination.
Shankar M. Bakkannavar – India

4. Cocaine: How medicine and law combined to give the world one of its leading cash crops and major médico-legal problems.
John P. Conomy – USA

5. International trends in death investigation.
Ian Freckelton – Australia

WAML SESSION 24 (PORTUGUESE 10:00 a.m. – 12:00 p.m.)

Session Coordinator: Marianna Chaves

1. Automutilação na adolescência: o acesso a tratamento médico como direito fundamental.
Priscila Menezes e Célia Barbosa Abreu – Brazil

2. Bioética, biodireito e reprodução humana assistida: A necessidade de regulamentação jurídica da fecundação artificial post mortem.
Alex Jordan Soares Mamede – Brazil

3. Considerações sobre fraude em medicamentos e seu tratamento jurídico penal no Brasil.
Daniela Novelli Scarpa – Brazil

4. Mitos sobre a gravidez de substituição.
Diana Poppe – Brazil

5. O direito de curar em Moçambique: O médico e a tinyanga.
Cecília Fonseca – Mozambique

6. O direito humano à saúde mental: compreensão dos profissionais da área.
Emanuele Seicenti de Brito – Brazil

WAML SESSION 25 (ENGLISH 01:00 p.m. – 03:00 p.m.)

Session Coordinator: André Gonçalo Dias Pereira

1. Health law and disability after the UN convention on the rights of persons with disabilities.
Aart Hendriks – The Netherlands

2. Health Law and Science of Health Law.
Wu Chongqi – China

3. Health status and health rights of the Roma minority.
Milan Markovic – Serbia

4. Higher Council of Health of Turkey and ginecology and obstetrics cases: a deontological analysis (2000-2005).
Berna Arda – Turkey

5. How to conduct a legal medicine consultation – A personal perspective.
Roy G. Beran – Australia

WAML SESSION 26 (ENGLISH 03:30 p.m. – 05:30 p.m.)

Session Coordinator: Roy Beran

1. End of Life Care: Ethical & Legal Issues Involving Hydration & Nutrition -- A Comparative Analysis.
Marguerite Chapman – USA

2. Medical liability. Expert reports in Bogota, Colombia.
Liliana Tamara Patiño – Colombia

3. Medical research with elderly patients: Dilemma between the right to equal access to medical research and the protection of vulnerable patients.
Anne-Marie Duguet – France

4. Exclusivity versus access: Does Europe get the balance right in promoting modern medicines?
Amanda Warren-Jones – United Kingdom

5. Brain Death; Neither Death nor Life, a Special Situation in Light of New Biomedical Technologies.
Mahmoud Abbasi – Iran

August 09, 2012

ROOM 01 (SALA 01)

WAML SESSION 27 (PORTUGUESE 08:00 a.m. – 09:30 a.m.)

Session Coordinator: Eduardo Dantas

1. O direito à informação e ao conhecimento da origem genética.
Tatiane Gonçalves M. Goldhar – Brazil

2. Direito fundamental à morte digna.
Catarina Oliveira – Brazil

3. Os limites entre o bem e o mal: a responsabilidade penal médica ante as lesões corporais provocadas na parturiente quando do uso do procedimento de episiotomia.
Natália Gonçalves Barroca – Brazil

4. Decisões sobre o fim da vida.
Hildegard Giostri – Brazil

5. As interfaces das práticas de terapia genética pré-implantacional e pré-natal e os direitos do embrião.
Taciana Cahu Beltrão – Brazil

WAML SESSION 28 (PORTUGUESE / SPANISH 10:00 a.m. – 12:00 p.m.)

Session Coordinator: Catarina Oliveira

1. Reflexões sobre a comunicação da equipe de saúde com o paciente terminal.
Lívia Abigail Callegari – Brazil

2. Reflexões sobre o dever de informar do médico no consentimento informado.
Ana Amélia Ribeiro Sales – Brazil

3. Celibatários e homossexuais como beneficiários das técnicas de reprodução assistida: Uma visão comparativa entre Brasil e Portugal.
Marianna Chaves – Brazil

4. Transfusões de sangue contra a vontade de pacientes da religião Testemunhas de Jeová: Uma gravíssima violação dos direitos humanos.
Starley Jonnes Pinho Fernandes – Brazil

5. Un estúdio de derecho comparado. La exigencia de responsabilidade penal por imprudências médicas en Inglaterra, Gales y España.
Virgílio Rodriguez-Vazquez – Spain

6. Gestión jurídica del riesgo médico.
Alain Garay – France

7. Rol de la documentación médica en graves denúncias contra cirurjanos y anestesistas.
Margarita Litovidna – Russia

8. **Empatia como fundamento ético no trabalho de enfermagem,**
Maria Auxiliadora Trevizan – Brazil

WAML SESSION 29 (PORTUGUESE 01:00 p.m. – 03:00 p.m.)

Session Coordinator: Everilda Brandão Guilhermino

1. Responsabilidade legal e ética do médico perito.
Hildegard Giostri - Brazil

2. A iatrogenia, intercorrência médica e o termo de consentimento informado na apuração da responsabilidade civil, criminal e administrativa do médico.
Miguel March Neto – Brazil

3. As Testemunhas de Jeová e as transfusões de sangue: uma análise do aparente conflito de princípios constitucionais.
Starley Jonnes Pinho Fernandes – Brazil

4. Autonomia do paciente e o conflito com a responsabilidade médica, em especial nas manifestações antecipadas de vontade.
Aline Bretas de Assis Minamihara – Brazil

5. Culpa médica e sua apuração processual: uma análise das teorias da prova.
Luciana de Paula Lima Gazzola – Brazil

6. Valor do diálogo enfermeiro-paciente para o cuidado ético e humanizado.
Isabel Amélia Costa Mendes – Brazil

ROOM 02 (SALA 02)

WAML SESSION 30 (ENGLISH 08:00 a.m. – 09:30 a.m.)

Session Coordinator: Vugar Mammadov

1. When the victim is a child: pedofily, pornography and cyberbullism in the Italian reality.
Simona Ricci – Italy

2. Who needs palliative care in Azerbaijan?
Vugar Mammadov – Azerbaijan

3.How to undergo ART in Brazil and arrive safely with your baby in USA.
Marianna Chaves – Brazil

4. The rise of stem cell in Mexico: ineffective enforcement of biomedical law.
Maria de Jesús Medina Arellano – Mexico

5. The protection of the physical integrity and the principle of inviolability of the human body regarding compulsory vaccinations.
Philippe A. P. M. Vanlangendonck – Belgium

6. The patients obligations and liabilities as the condition precedent for… the protection of their rights.
Radmyla Hrevtsova - Ukraine

WAML SESSION 31 (PORTUGUESE 10:00 a.m. – 12:00 p.m.)

Session Coordinator: Vinícius Santiago

1. Os avanços recentes na legislação do Sistema Único de Saúde brasileiro e as perspectivas de minimizar a judicialização na incorporação de tecnologias em saúde.
Eliete Maia Gonçalves Simabuku – Brazil.

2. Os direitos humanos dos portadores de transtornos mentais nas Américas.
Carla Aparecida Arena Ventura – Brazil

3. Para uma responsabilidade médica mais eficaz e mais favorável à redução do erro médico.
André Gonçalo Dias Pereira – Portugal

4. O direito à informação e o uso do consentimento informado nas relações médico-paciente: Uma análise do novo Código de Ética Médica e da jurisprudência do STJ.
Vinícius de Negreiros Calado – Brazil

5. O sistema de saúde no Brasil, entre o idealismo e a realidade: o papel do Poder Judiciário e das operadoras de planos privados de assistência à saúde.
Henrique Freire de Oliveira Souza – Brazil

WAML SESSION 32 (ENGLISH 01:00 p.m. – 03:00 p.m.)

Session Coordinator: John Conomy

1. The principle of "equivalence of care" in prison settings. Experience of international monitoring bodies for the prevention of torture.
Marrija Definin Gojanovic – Croatia

2. The problems of medical malpractice in criminal law in Japan.
Shigeki Takahashi – Japan

3. The role of the expert witness in legal medicine.
Roy G. Beran – Australia

4. Torture by introducing foreign object in rectum – A case report.
Mohd Kaleem Khan – India

5. Trauma masking sudden natural death: a case report.
Raghavendra Babu YP – India

6. Comparative description of "medical malpractice" cases and claiming behavior in the United States and Costa Rica.
Roy Espece Jr. – USA

WAML SESSION 33 (ENGLISH 03:30 p.m. – 05:30 p.m.)

Session Coordinator: Herman Nys

1. On the reasonable control of the surrogate behavior and use of legal regulation.
Wang Ping/ Guo Shuai – China

2. Patents on inventions related to embryonic stem cells: the public order and morality exclusion in Brustle vs Greenpeace.
Sarah Panis – Belgium

3. Pharmaceutical Law in the E. U. – The state of play.
Natalia Lojko – Poland

4. Physician-Patient communication in four dimensions.
Wu Chongqi – China

5. Regulating Iranian medical institutes: Towards a clear regulatory model.
Mahmoud Abbasi – Iran

6. A Glimpse of Teaching Medical Law in the Russian Federation and Ukraine.
Yuri Sergeyev - Russia and Radmyla Hrevtsova - Ukraine

ROOM 03 (SALA 03)

WAML SESSION 34 (ENGLISH 08:00 a.m. – 09:30 a.m.)

Session Coordinator: Anne-Marie Duguet

1. The market introduction of innovative high risk medical devices.
Irn Vinck – Belgium

2. The medico-legal dilemmas and pitfalls of the medical expert witness.
Georg M. Scharf – South Africa

3. The nature of medical obligations in the light of comparative study.
Mahmoudi Abbasi - Iran

4. The off-label use of medications: still not the final word on the Avastin-Lucentis debacle.
Rita-Marie Jansen – South Africa

5. Compensation for Damages caused by Improper Medical are Provision (Ukrainian Experience)
Iryna Senyuta

WAML SESSION 35 (ENGLISH 10:00 a.m. – 12:00 p.m.)

Session Coordinator: Anne-Marie Duguet

1. If the cure is worse than the aliviment. More than two decades of defective medical and pharmaceutical products in Europe.
Daily Wuyts – Belgium

2. Equity, rights and regulation: facing the public/private health system divide in South Africa.
Marius Pieterse – South Africa

3. Ethical, legal, and social implications. Research for personalized genomic medicine in Korea.
Hansah Kim - South Korea

4. Euthanasia – Perspectives in the 21st Century.
Sanjin Dekovic – Bosnia and Herzegovia

5. Next generation genetics: implications for the physician patient relationship.
M.C. Ploem and J.K.M. Gevers – The Netherlands

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AUDITORIUM 02 (AUDITÓRIO 02)

WAML SESSION 36 (ENGLISH 01:00 p.m. – 03:00 p.m.)

Session Coordinator: Natalia Lojko

1. The Myth of Informed Consent. How information and choice can reveal the true face of autonomy.
Eduardo Dantas - Brazil

2. Autonomy: a leading principle for the end-of-life decision making?
Helena Peterkova – The Czech Republic

3. Consent/Assent in paediatric research: standards and procedures in a global context.
Annagrazia Altavilla – Italy

4. The (limited) role of autonomy in the context of the legalisation of euthanasia and assisted suicide.
Sabine Michalowski – United Kingdom

5. Pain relief as patient right – Looking for balance in Ukraine.
Zoryana Chernenko – Ukraine.

6. Assisted suicide euthanasia, orthotanasia: the inadmissibility of the right to kill terminally ill patients. A South American Prospective.
Washington Fonseca – Brazil

7. Right of Children who are in the Hospital to have their Legal Representatives with them
Iryna Senyuta

WAML SESSION 37 (ENGLISH 03:30 p.m. – 05:30 p.m.)

Session Coordinator: Herman Nys

1. Unforeseen Ethical/Legal complications with screening tests in the capitation model of medical aid schemes.
Rita-Marie Jansen – South Africa

2. What dose telling a child about his câncer to the ADLT survivor?
Raz Raya – Israel

3. Why and how to make an international crime of medicine falsification.
Arnit Attaran – Canada

4. The state of medical law and bioethics teaching as a curricular essential medical training in Nigeria: A case for Africa and the developing world.
Yohanna Dangeta – United Kingdom

5. The study of the right to health in international medical law.
Mahmoud Abbasi – Iran

6. Restored allograft transplants after resection of renal cell carcinoma.
Keiko Irako – Japan

7. Sexual and psychological abuse in Italy: victims, cases social and legal aspects.
Simona Ricci – Italy

POSTERS

1. Informed consent in nursing in Japan.
Michiko Miyazaki – Japan

40 YEARS OF JAPANEASE ASSOCIATION OF MEDICAL LAW - CHANGE OF TOPICS IN THE ANNUAL SCIENTIFIC MEETINGS

Authors MITSUYASU KUROSU KUROSU [1]

Organization [1] Department of Bioeth - Department of Bioethics (Medical Ethics) Tokyo Medical Unive (TOKYO)

Abstract

The Japanese Association of Medical Law was established in 1969. Its current membership is about 450, with 60% of members from the legal profession and 40% from the medical profession. Its annual scientific meeting had been on one day for a long time, on one and half day at last few years. The topics in annual scientific meeting of the Japanese Association are as follows: in 1970s malpractice, health right, physician-patient relationship, abortion; in 1980s medical records, medical certificate, nursing care, home care for elderly, patient-medical staff relationship in psychiatric treatment; in 1990s medical law education in medical school, informed consent, pharmaceuticals, the prevention of the medical malpractice, medical information, clinical research, disclosure of medical records, surrogate decision-making on medical treatment; in 2000s governmental guidelines for regulating medical research, systems for preventing medical accidents, reexamination of the concept of medical procedure, current problems of organ transplantation, medical contract and medical accidents, medical information, medical accidents and criminal responsibility, making a rule of end-of-life, basic act on healthcare and patients' rights, medical practice and the family, quality of health care and professional autonomy. These topics have been discussed between the medical profession and the legal profession. In the future important subjects are institutionalizations of living will and reproductive assisted medicine such as surrogate conception, donation of eggs. Other problem is to increase members from the medical profession.

Key Words: association, change, topics

A "FANTASTIC VOYAGE": IS THE GLOBAL REGULATION OF NANOMEDICAL PRODUCTS ADEQUATE?

Authors Jennifer Sarah Moore [1,2,3]

Organization [1] CLPET - Centre for Law and Policy in Emerging Technologies (Wellington, New Zealand), [2] FL - Faculty of Law (Wellington, New Zealand), [3] UO - University of Otago (Wellington, New Zealand)

Abstract

Jurisdictions such as the European Union (EU), United States (US), Australia and New Zealand (NZ) have witnessed the launch of medical products containing manufactured nanomaterials (mNMs). There are also numerous nanomedicines in the third phase of clinical trials and analysts project that by 2014, the market for medical products containing mNMs will be US$18 billion per year. Nanorobots and other nanomedicines are touted to revolutionise healthcare. There is concern that the novel properties of some nanoscale chemical substances will bring unforeseen human and environmental health and safety risks. Given the possible market for nanomedicines and the growing evidence of their potential risks, it is important to have adequate regulation of nanomedicines in order to prevent adverse public health ramifications. This paper's primary aim is to investigate the adequacy of Australasian regulation of medical products produced by nanotechnology and containing mNMs. Comparisons will be made with other jurisdictions. I will analyse the recent changes to the regulation of medicines in Australasia, including the Australian and NZ governments' 2011 agreement to establish a joint regulatory agency for therapeutic products and the NZ government's Medicines Amendment Bill 2011. Are the proposed amendments sufficient to keep up with this rapidly developing field? Reviews initiated by governments in several jurisdictions such as the US, England, UK, Australia and New Zealand (co-authored by this paper's presenter), have identified legislative gaps in the coverage of nanomedicines. Nanoparticles, invisible to the human eye, are illuminating and exacerbating imperfections in the global regulatory instruments.

Key Words: manufactured, nanomedicines, governments

A aplicação da teoria da perda de uma chance na responsabilidade médica pela jurisprudência brasileira.

Authors PAULA MOURA FRANCESCONI DE LEMOS PEREIRA [1], ANNA DE MORAES SALLES [1,2]
Organization [1] UERJ - UERJ (UERJ), [2] PUC-SP - PUC-SP (SÃO PAULO)

Abstract

A teoria da perda de uma chance surgiu com o intuito de assegurar a reparação integral da vítima do dano injusto. Na relação médico-paciente o ato médico pode lesar o doente de formas variadas, ensejando uma multiplicidade de danos de distinta natureza, entre os quais se inclui a lesão pela perda da oportunidade de cura ou de sobrevivência, que afeta diretamente sua vida e saúde. No entanto, essa teoria não está expressamente positivada no direito brasileiro, e apesar de certa resistência de sua aplicação pela dificuldade no seu enquadramento e mensuração do quantum indenizatório, tem se observado, nos últimos anos, um avanço paulatino nos Tribunais brasileiros, o que demonstra que os operadores do Direito têm buscado tutelar a dignidade da pessoa humana em sua plenitude.

Key Words: Responsabilidade médica, Perda de uma chance, Dignidade

A AUTONOMIA DA VONTADE DO PACIENTE E O TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO NA DEFESA DO PROFISSIONAL MÉDICO

Authors Bárbara Lemos Lameiras [1], Palova Amisses Parreiras [1]
Organization [1] PAAA - Palova Amisses e Advogados Associados (Belo Horizonte, MG)

Abstract

Tradicionalmente, o médico era visto pela sociedade como uma figura de respeito e até mesmo autoridade, inexistindo qualquer questionamento dos pacientes em relação a suas prescrições. No entanto, com a evolução da ciência e dos meios de informação, e principalmente após a popularização da internet, o paciente muitas vezes se auto-diagnostica, e procura o médico já sabendo os exames e até mesmo o tratamento que quer fazer. Assim, a concepção tradicionalista de autoridade do médico deu lugar ao absoluto respeito pela vontade do paciente, o que conhecemos hoje como autonomia da vontade do paciente. Essa autonomia é representada pelo termo de consentimento livre e esclarecido. Neste artigo procura-se demonstrar a importância de se colher o Termo de Consentimento Livre e Esclarecido antes da realização de qualquer procedimento médico, principalmente aqueles mais invasivos. O Termo de Consentimento ganha importância não só na aproximação entre médico e paciente, mas principalmente como meio de defesa em eventual demanda judicial ou administrativa proposta pelo paciente contra o médico, na medida em que é possível se afastar a responsabilidade do profissional da saúde em casos de insatisfação do paciente com o resultado obtido, notadamente quando o médico não contribuiu com culpa para a ocorrência do resultado. O presente artigo tem por fim demonstrar a importância do documento chamado Termo de Consentimento Livre e Esclarecido, que o médico deve colher do paciente antes da realização de qualquer procedimento médico, principalmente aqueles mais invasivos. O Termo de Consentimento Livre e Esclarecido, maior expressão da autonomia do paciente, ganha importância não só na aproximação entre médico e paciente, mas principalmente como meio de defesa em eventual demanda judicial ou administrativa proposta pelo paciente contra o médico, na medida em que é possível se afastar a responsabilidade do profissional da saúde em casos de insatisfação do paciente com o resultado obtido, notadamente quando o médico não contribuiu com dolo ou culpa para a ocorrência do resultado.

Key Words: Termo de Consentimento Livre , Termo de Consentimento Livre , Termo de Consentimento Livre

A AVALIAÇÃO DE DESEMPENHO NA PERÍCIA MÉDICA - INSTRUMENTO DE SUCESSO NA PROTEÇÃO E DEFESA DO PROFISSIONAL MÉDICO-PERITO.

Authors: Beatriz de Abreu Dallari Guerreiro [2], José Carlos Baccarin [2], Maria Esther Radaelli Brandespim [2], Valéria Pugliese [2]

Organization [2] DESS-SEMPLA-PMSP - DEPARTAMENTO DE SAÚDE DO SERVIDOR (RUA LIBERO BADARÓ, 282 - CENTRO - SÃO PAULO-SP)

Abstract

Hoje, na tão discutida "judicialização da saúde", é imprescindível que o perito médico tenha respaldo, tanto acadêmico, quanto jurídico. Com essa visão, a equipe multiprofissional responsável por servidores municipais, desenvolveu um programa de avaliação de desempenho utilizando um sistema eficiente de registros, qualitativo e quantitativo, voltado especialmente para a Divisão de Perícia Médica, mas que envolve, também, as divisões de Epidemiologia, de Promoção à Saúde e Jurídica, todas do departamento pericial. Como linha mestra, o procedimento pericial se baseia nos protocolos médico-técnicos, desenvolvidos especialmente para essa finalidade. O controle de qualidade da atuação dos peritos, deve ser entendido como constante capacitação e aperfeiçoamento. Um mecanismo que permita avaliar sua atuação e propiciar análise rápida e objetiva de suas ações. A instrumentalização desse projeto possibilita o registro diário das perícias realizadas e, após um determinado lapso temporal, os peritos procedem à análise dos registros efetuados por seus pares nos prontuários médico-periciais, com base nos protocolos técnicos existentes. Os dados apurados e registrados embasam as ações necessárias à atualização dos profissionais envolvidos, o registro de dados epidemiológicos para ações de promoção à saúde e qualidade de vida no trabalho e, de maneira específica, o respaldo jurídico de todos os profissionais envolvidos. O registro médico-pericial bem elaborado nos prontuários, é o importante instrumento de proteção, também do ponto de vista jurídico, pois constitui a prova documental da atuação do profissional de saúde. Ao profissional do Direito cabe orientar, visando a tranquilidade e a isenção da atuação médico-pericial, prevista legalmente. Esse sistema integrado, implantado anteriormente à vigência da "Lei da Transparência", tem demonstrado sua eficiência nos excelentes resultados já obtidos. Aos periciandos, sujeitos da perícia médica, possibilita aferir as ações que afetam diretamente sua vida funcional e os benefícios pecuniários, além da recuperação de sua saúde. Às equipes multiprofissionais, direciona as ações de promoção à saúde e melhoria da qualidade de vida no trabalho que, diretamente, propiciam a melhoria da qualidade de vida pessoal. Ao operador do direito, em sua ampla atuação como orientador e consultor dos profissionais médicos e da equipe multiprofissional, reduziu significativamente as demandas judiciais e ampliou os resultados favoráveis em ações judiciais existentes contra os médicos. E aos profissionais médicos, tem possibilitado maior tranquilidade pelo respaldo na sua atuação diária.

Key Words: Instrumento de Defesa, Perícia Médica , Perito Médico, Proteção

A case commentary on Oliver Brüstle v Greenpeace e.V. – case regarding patentability of hESC research

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Abstract

A case commentary on Oliver Brüstle v Greenpeace e.V. – case regarding patentability of hESC research In Greenpeace e.V. v Brüstle the German Federal Court of Justice ("Bundesgerichtshof") requested clarification from the European Court of Justice with respect to interpretation of Article 6.2.c of the Directive 98/44/EC. Greenpeace e.V. was seeking annulment of the German patent (German patent No. DE 19756864) held by Mr Brüstle, which relates to neural precursor cells and the processes for their production from human embryonic stem cells ("hESC") and their use for therapeutic purposes. This recent case touches upon highly controversial bioethical issues, among others providing a definition of a human embryo and considerably restricting prospects for patentability of hESC research. The case has raised a lot of debate within stem cell scientists and other policy makers in the biotechnological field. Generally speaking, many scientists find this judgment highly undesirable, as they fear that it may lead to disastrous effects upon endeavours to translate stem cell science into effective regenerative medicines. Undeniably, the judgment considerably restricts the patentability of cell products with embryonic origin making it especially difficult to ensure patent protection for cell lines that are directly or even indirectly derived from an embryonic origin. The debate around the case has illustrated that the status of a human embryo is an ethical as well as a legal concern and it is highly important to have a clarity on how it is defined, not at least because it has far-reaching consequences on permissibility of certain type of research and patentability of inventions arising out of such research. Thus far, many European states have not succeeded in incorporation of the term "embryo" in their legislations or have not provided a definition or they have left out certain embryos such as those created by somatic cell nuclear transfer or those which are not viable outside the scope of the legal definition. Hence, on the one hand this case is significant, because it harmonises the patenting practices with respect to interpretation of the article 6.2.c of the Directive within the EU and fills the gaps in national laws providing binding interpretation guidelines for the national courts within the EU. On the other hand, subsequent to the judgment, the margin of appreciation on important value-choice questions of the national courts has been significantly narrowed and it can be questioned whether this judgment truly reflects common European ethics.

Key Words: Article 6.2.c of the Directive 98/44/EC, hESC patents, "morality clause"

A COMPARATIVE STUDY OF CRIMINAL LIABILITY OF MEDICAL INSTITUTIONS IN THE LEGAL SYSTEM OF IRAN, FRANCE AND UNITED STATES

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Organization [1] MLAI - Medical Law Association of Iran (Tran, Tehran)

Abstract

Both public and private medical institutes must be responsible for negligence and violation of legal principles because they have an important role in healthcare system in each country. This accountability is a matter for criminal liability in medical institutes and it is not necessarily included general principles of crimes and penalty legitimacy. Namely first, that fait accompli is committed by an agent or medical institute's representative. A second, medical institute is criminated and finally the law recognizes it as a crime and culpable (punishable) act for medical institutes. Criminal liability of medical institutes has been studied an objective not subjective matter in Iran, France and US legal systems. Because we study a legal entity that has completed legislative process and has been enforceable for American and French criminal courts. It has been relatively identified in Iranian jurisprudence. We study criminal liability of medical institutes with a comparative approach that there is no precedent for it in Iran and there are many ambiguities in this area. It is used two methods: descriptive research and field research. The firs we study criminal liability of medical institutes and its component theoretically and then we analyze current situation through field research by using professional courts judgment and lawyers and judgs'opinion.

Key Words: Criminal Liability, Medical InstitutesIran, Iran, France, America

A CRISE PARADIGMÁTICA DA JUDICIALIZAÇÃO DA SAÚDE E A EMERGÊNCIA DE UM NOVO CONTENCIOSO ADEQUADO AO ESTADO DE MODERNIDADE TARDIA

Authors ADLER DOS SANTOS BAUM [1]
Organization [1] MC - Município de Cachoeirinha (RIO GRANDE DO SUL)

Abstract

O presente trabalho promove um enfrentamento da temática da judicialização da saúde. Questões como reserva do possível, mínimo existencial, dentre outras, foram tangenciadas na medida em que o texto se aproxima, em especial, do estudo das disposições constitucionais e infraconstitucionais que asseguram o direito à saúde no Brasil. À luz do estudo da Constituição Federal e da legislação infraconstitucional, em especial, da Lei 8.080/90, investiga-se a atual fase de judicialização, mais especificadamente, dos problemas encontrados neste paradigma em grave declínio, possivelmente decorrente da massificação e da judicialização indiscriminada das demandas da saúde. Mais do que um diagnóstico realizado a partir do estudo da jurisprudência, realizou-se um trabalho de campo na cidade de Cachoeirinha – RS, oportunidade em que se emprestou olhar atento para a totalidade das ações judiciais (120 ações judiciais) referentes à saúde no primeiro quadrimestre do ano de 2012. Na divisão destas ações em três categorias (fornecimento de medicamentos, atendimento e internação psiquiátrica), foi possível pontuar problemas específicos que vão desde e a propositura da ação até a própria prestação jurisdicional o que revela que a adequação saudável dos processos da saúde está a exigir a participação de todos os atores do processo tais como Advogados, Promotores de Justiça e Juízes. Diante do domínio destas informações, do mapeamento dos dados obtidos, do cruzamento de contradições e da exposição de paradoxos, foi possível apresentar, ainda que de forma incipiente, novos contornos de um contencioso adequado às possibilidades e às necessidades de um Estado Social de Modernidade Tardia. O desvelamento da solidariedade entre União, Estados e Municípios na prestação do direito à saúde e a possibilidade de acerto imediato de contas entre os respectivos Entes Federativos no próprio processo em que se discute o direito à saúde, conjugando-se a leitura do artigo 80 do Código de Processo Civil e art. 35, VII, da Lei 8.80/90, o aprofundamento da pretensão resistida, o interesse processual em ações de internação compulsória, a garantia de substituição de medicamento pelo correspondente genérico ou similar são apenas algumas entre tantas outras alternativas que se propõem na construção de um novo paradigma de viés efetivo do tão consagrado direito à saúde.

Key Words: temática da judicialização , Brasil, Cachoeirinha

A DECISÃO DO SUPREMO TRIBUNAL FEDERAL NA ADPF 54 E A INVIABILIDADE FETAL ALÉM DA ANENCEFALIA: A CONTRIBUIÇÃO DO PATOLOGISTA

Authors Luciana de Paula Lima Gazzola [1,2], Frederico Henrique Corrêa de Melo [1]

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Abstract

O Supremo Tribunal Federal, em 12 de abril de 2012, proferiu decisão histórica no bojo da ADPF 54, ajuizada pela Confederação Nacional dos Trabalhadores da Saúde, que objetivou a interpretação de dispositivos do Código Penal conforme a Constituição, assentada a premissa de que somente o feto com capacidade de ser pessoa pode tornar-se sujeito passivo do crime de aborto. O tema é um dos mais importantes já apreciados pelo STF, pois envolve a dignidade da pessoa humana, a liberdade, a autodeterminação, a saúde e o reconhecimento pleno de direitos individuais. Na ocasião, a Corte suprema decidiu, com base na incompatibilidade da anencefalia (doença congênita letal) com a vida plena extrauterina, que a antecipação terapêutica do parto, quando há diagnóstico da anomalia em comento, é fato penalmente atípico e não constitui aborto, uma vez que este tipo penal pressupõe potencialidade de vida extrauterina. “Anencefalia e vida são termos antitéticos”, afirmou o Relator da ação, Ministro Marco Aurélio de Mello, ao proferir seu voto em Plenário, decidindo pela procedência do pedido. Contudo, no atual momento em que tal assunto cresce em debate, importa ressaltar a existência de numerosas síndromes malformativas, também incompatíveis com a vida extrauterina, que devem ser objeto de regulamentação legal, a fim de se preservar o princípio da isonomia. Os Authors, anátomo-patologistas de hospital universitário brasileiro, com experiência em Patologia Perinatal, ressaltam a importância do diagnóstico sindrômico intraútero, além do estudo minucioso do produto da concepção, por meio de necropsia clínica realizada por equipe especializada. A necropsia perinatal, exame completo e sistemático do feto e neonato, permanece o padrão ouro para diagnóstico de anomalias congênitas. Na ampla casuística do serviço de Medicina Fetal e Patologia Perinatal do Hospital das Clínicas da UFMG, os Authors demonstram a frequência dos chamados “estados disráficos”, que comprometem o fechamento do tubo neural e originam síndromes congênitas letais, das quais a anencefalia é apenas um exemplo. Casos de craniorraquisquise total, mielosquise, holoprosencefalia com ciclopia, por sua incompatibilidade com a vida extrauterina, merecem o mesmo tratamento jurídico ao ora conferido aos fetos anencéfalos. Faz-se fundamental, portanto, informar a sociedade e a comunidade acadêmica acerca da questão, proporcionando-lhes conhecimento amplo do tema, a fim de privilegiar o debate e conferir tratamento jurídico semelhante a condições fetais mórbidas que, embora não tão vulgarmente conhecidas como a anencefalia, acarretam o mesmo impacto social e condições jurídicas análogas.

Key Words: Aborto, Anencefalia, Antecipação terapêutica do parto, Necropsia perinatal, Síndromes congênitas letais

A ECONOMIA DAS DOENÇAS RARAS: TEORIA, EVIDÊNCIAS E POLÍTICAS PÚBLICAS

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Abstract

Objetivos: O objetivo deste artigo é realizar uma revisão teórica e empírica da Economia das Doenças Raras e das Drogas Órfãs buscando analisar as implicações econômicas destes tipos de doenças e dos medicamentos utilizados para tratá-las. Através de evidências empíricas apresentadas na literatura se pretende identificar qual a magnitude do problema, sua importância atual e descrever os principais incentivos e instrumentos governamentais para o desenvolvimento de tratamento medicamentoso. Metodologia: Abordar definições e contextualizar o assunto doenças raras e drogas órfãs a partir de diferentes pontos de vista e apresentá-los de forma harmônica, coordenada e informativa, destacando as principais implicações econômicas. Será utilizado o método de compilação, no qual se procura levantar, compilar e criticar ordenadamente a maior parte da bibliografia relacionada, procurando expô-la de modo claro e objetivo numa visão abrangente sobre o tema em seus mais distintos aspectos. Resultados: Raras são as doenças que apresentam baixa prevalência em uma determinada população. São em geral degenerativas, cronicamente debilitantes e necessitam de tratamento contínuo, afetando as capacidades físicas, mentais, sensoriais e comportamentais do paciente. Drogas órfãs são medicamentos usados para o diagnóstico, prevenção e tratamento das doenças raras. A raridade implica dificuldades para a comprovação da eficácia clínica destes medicamentos. Dados sobre as doenças raras e drogas órfãs no Brasil e no mundo mostram as principais considerações econômicas relacionadas. Os sistemas de regulação para doenças raras vigentes nos Estados Unidos e na União Europeia serão analisados, bem como a sua influência sobre o desenvolvimento de medicamentos órfãos. Conclusões: Concluiu-se que os mecanismos de regulação são capazes de estimular o desenvolvimento de drogas órfãs. Por outro lado é necessário intensificar o debate sobre as doenças raras no Brasil, uma vez que não existe uma política pública voltada para esta problemática no país.

Key Words: Economia das Doenças Raras, Drogas Órfãs , Tratamento medicamentoso

A IATROGENIA, INTERCORRÊNCIA MÉDICA E O TERMO DE CONSENTIMENTO INFORMADO NA APURAÇÃO DE RESPONSABILIDADE CIVIL, CRIMINAL E ADMINISTRATIVA DO MÉDICO

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Abstract

"A partir de meados da metade do século XX, a relação entre médico e paciente foi se distanciando, sendo a amizade existente entre assistente e assistido substituída pelo conceito de produto. Esse fenômeno aliado à disseminação do conhecimento e propagação da cultura questionadora, fez com que cada vez mais as condutas dos médicos fossem questionadas, principalmente nos casos de insucesso no tratamento. Contudo, o mesmo ato que pode ter repercussão nas esferas administrativa (ética), civil e criminal do Direito, podendo ser punível em todas elas, em apenas algumas ou mesmo em nenhuma delas. Os danos decorrentes das condutas médicas não puníveis pertencem a dois grupos: Iatrogenia e Intercorrência Médica. Danos verdadeiramente iatrogênicos são aqueles decorrentes dos tratamentos em que prevendo o seu acontecimento, o médico vislumbra evitar um dano maior. Esses danos subclassificam-se conforme sua origem direta, quais sejam: conduta humana e farmacológica, exemplos: Conduta humana: amputação do pé diabético (necrosado) com o objetivo de preservar a vida do paciente; e Farmacológica: alopécia (perda de cabelos) em decorrência do tratamento de radio e quimioterapia contra o câncer. Intercorrência Médica é o dano imprevisto, decorrente de um tratamento médico, cuja previsão não era prevista pelo médico. Exemplo: Paciente inconsciente, recebe medicação e sofre uma reação alérgica. Os danos classificados como iatrogênicos ou provenientes de intercorrências médicas não são puníveis, seja na esfera administrativa, civil ou criminal, no entanto, paraa efetivação da excludente de ilicitude, é necessário que o médico tenha, dentro de suas possibilidades, produzido documentos que comprovem a lisura e legitimidade de sua conduta profissional. Logo, surge o termo de consentimento informado. Salvo as discussões sobre a cirurgia plástica estética (embelezadora), sem cunho corretivo, os serviços médicos caracterizam-se como atividade de meio e não de fim, logo, caso a terapia não surta os efeitos esperados, o médico não poderá ser punido por isso. Contudo, ao paciente cabe o direito de saber tudo o que se passa com o seu corpo e, dentro de um limite, também decidir sobre ele. Por isso, nos casos em que for possível, deve o médico explicar ao paciente todas as possibilidades de tratamento e quais as consequências sobre cada um deles e solicitar formalmente o seu consentimento sob pena de ser responsabilizado, mesmo que o dano seja de ordem iatrogênica ou uma intercorrência médica."

Key Words: Intercorrência Médica, Iatrogenia, Conduta humana

A INCORPORAÇÃO DE NOVAS TECNOLOGIAS NO SISTEMA ÚNICO DE SAÚDE.

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Abstract

A Lei 12.401 de 2011 disciplina a incorporação de novas tecnologias na área da saúde pública no Brasil. O objetivo é racionalizar a utilização dos recursos públicos de modo a permitir o acesso de maior número de usuários às tecnologias e medicamentosinovadores em saúde. O surgimento de novas tecnologias e medicamentos tem preocupado os poderes públicos em boa parte dos países do mundo, em razão dos altos custos que acarretam e pelo fato de queas tecnologias têm caráter acumulativo, porque não evitam a utilização de tecnologias já consagradas pela experiência médica. A decisão pela utilização de uma nova tecnologia ou de um novo medicamento no Brasil é restrita ao profissional médico, que é o único agente social com poder legal para dizer o que deve ser utilizado pelo paciente. Decisões médicas com indicação da utilização de determinada tecnologia em saúde tem sido discutidas no Poder Judiciário, por partes que entendem ter direito a utilização do recurso independentemente dos custos e do impacto destes, embora o Estado brasileiro tenha argumentos para contestar o pedido sob a alegação de que apesar do alto custo os resultados da tecnologia ou do medicamento nem sempre estão satisfatoriamente testados e comprovados e, não são confiáveis sob o aspecto científico.A nova lei introduziu a necessidade de protocolo clínico e diretriz terapêutica. Também determinou a necessidade de evidências científicas sobre a eficácia, acurácia, efetividade e segurança dos medicamentos, produtos ou procedimentos que serão analisados pelo relatório da Comissão Nacional de Incorporação de Tecnologias do SUS. Em outras palavras, a incorporação de novas tecnologias e medicamentos após a entrada em vigor da legislaçãoficou na dependência da existência de evidências, de pesquisas científicas que comprovem eficiência e segurança para os pacientes. Mas a qualidade da pesquisa produzida e a isenção científica são suficientemente confiáveis no mundo contemporâneo para que se possa incorporar tecnologias e medicamentos com base em resultados científicos? O trabalho discute problemas que as evidências científicas poderão apresentar e medidas que o Estado deverá adotar para tentar inibir a aprovação de tecnologias e medicamentos que sirvam para favorecer as indústrias que os elaboram. O trabalho discute a importância da ampliação do debate, com participação popular e utilização de princípios fundamentais da economia da saúde para comprovar a necessidade de utilização de novas tecnologias e medicamentos.

Key Words: saúde pública , recursos públicos , poderes públicos

A nano biotecnologia e a nova fronteira de tratamento. A proteção da sociedade e do consumidor. Aspectos bioéticos e a ascensão do Princípio da Precaução

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Abstract

Se o desenvolvimento da nanotecnologia e da biotecnologia tornará possível a materialização de inúmeras ideias antes consideradas como de ficção cientifica, a junção dessas duas linhas de desenvolvimento tecnológico, dando origem a chamada nano biotecnologia, irá aproximar o homem da criação da vida. Embora as repercussões da evolução da nano biotecnologia alcancem inúmeros campos da vida social, o presente estudo focará, apenas, em alguns aspectos da aplicação da nano biotecnologia no tratamento médico no Brasil, em especial: o "novo" papel do médico; a necessidade de proteção da sociedade e do consumidor; e a ascensão do princípio da precaução. A relação do médico com o paciente tende a ser cada vez mais informada pela tecnologia, uma tecnologia em mudança e ainda não suficientemente conhecida, o que irá impor a necessidade da obtenção de um consentimento cada vez mais especifico, não se restringindo a informação apenas aos efeitos dessa tecnologia no paciente, mas também, nos seus efeitos na sociedade, em especial nos eventuais riscos para o meio ambiente. Em razão disso, será que a ética e a bioética passariam a ser informados também pelo princípio da precaução? Mais do que a discussão da aplicação ou não do princípio da precaução, será que o Código de Defesa do Consumidor, neste novo mundo nano biotecnológico, e quando aplicado à atividade médica,estaria adequado? E mais, adequado para quem: sociedade, médico ou consumidor? O presente estudo, em linhas bens gerais, abordará tais temas de maneira concisa e objetiva, buscando levantar e marcar a discussão mais do que esgotar inteiramente tema.

Key Words: nanotecnologia, biotecnologia , ficção cientifica

A NEW STYLE OF END-OF-LIFE CASES: A PATIENT'S RIGHT TO DEMAND TREATMENT OR A PHYSICIAN'S RIGHT TO REFUSE TREATMENT? THE FUTILITY DEBATE REVISITED.

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Abstract

Conflicts in an end-of-life context between a physician and a patient have almost always been about the physician wanting to start or continue providing treatment and the patient wanting to refuse that same treatment. Up to date this type of case poses relatively few problems, because a competent adult patient's right to refuse medical treatment, even when his life hangs in the balance, is a principle of law that has been established for some time now. The doctrine of informed consent, grounded upon the patient's right to bodily integrity or self-determination, results in the fact that a physician cannot start treatment without the patient's informed consent. It is clear that the patient has a negative right to be free from unwanted medical interventions. However, advancements in end-of-life law and patient rights have led to the birth of a new type of end-of-life case in which the physician and the patient again take an opposing viewpoint but in which their roles have shifted entirely. This time it is the physician who is refusing treatment based on a futility judgment whereas the patient is demanding to start or continue providing treatment. The patient's right to self-determination evidently collides with the physician's professional autonomy and contractual freedom. The question thus arises whether a patient can compel a physician in doing something that the latter determines to be medically futile. In other words, does the patient's right to bodily integrity also encompasses a positive right to demand treatment? The situation becomes even more delicate when the patient is no longer competent and has left an advance directive containing certain positive wishes. Most of the time the predominance of the physician's judgment is stressed. In this article the futility debate is revisited starting with a clean slate. The different definitions or forms of 'futility' are explained and the predominance of the physician's judgment critically analysed. The article shows that the will of the patient or his advance directive cannot be completely discarded based solely on its positive character and in effect plays an important role in finding a just solution for this new type of end-of-life case.

Key Words: END-OF-LIFE, TREATMENT, DEBATE

A PROIBIÇÃO DA DOAÇÃO DE ÓRGÃOS POST MORTEM: RESTRIÇÃO ABUSIVA AO PRINCÍPIO DA AUTONOMIA DA VONTADE

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Abstract

O homem, na sua inesgotável dimensão, passa por uma série de mutações em seu comportamento ético e moral. O dinamismo, que é próprio de sua natureza, propulsiona-o para frente, obrigando-o a incorporar novos pensamentos, desde que convenientes. Pode-se até dizer que, na realidade, não se trata de uma fusão de novas tendências e sim do aperfeiçoamento das existentes. A palavra etiké, originária do grego, traduz com sobras o significado que se busca. Interpreta o pensamento sempre correto, o caminhar em linha reta, sem desvios, sem qualquer movimento pendular, mirando o infinito e nele incorporando toda a conquista que seja considerada significativa para o homem. É, portanto, mais um exercício de maturidade e aprimoramento do próprio viver. O primeiro e até o mais importante predicado que reveste o homem é relacionado com a autonomia da sua vontade, no sentido de atribuir a ele, com o discernimento necessário, as melhores condições para se definir diante das opções criadas pela sua própria volição. Seria, guardadas as proporções, a vivência da liberdade em sua forma mais primitiva, onde cada um realizava sua vontade, sem se importar com a alheia. Aplicá-las de imediato, sem uma prévia análise do mundo exterior, seria até um contrassenso, pois além de não produzirem o resultado almejado, criariam conflito com as regras já existentes que governam a comunidade e se apresentam como proibitivas. Nesta linha de pensamento, em que se outorga ao homem poder de decidir a respeito dos assuntos que lhe são pertinentes, coloca-se em discussão sua autonomia decisória a respeito de doar os órgãos, tecidos, partes e até mesmo seu corpo seu post mortem. Será que é detentor exclusivo do direito de consentir a respeito da doação de seus próprios órgãos? Será ele o único proprietário deste latifúndio chamado de corpo humano ou divide a titularidade com o cônjuge, ascendente ou descendente? Não será, na realidade, um mero possuidor de seu corpo, enquanto a propriedade ganha um caráter eminentemente público e passa para o domínio estatal? Assim, o corpo humano, de regra, com a devida aquiescência de seu titular, devidamente esclarecido, pode ser alvo de experiências médicas e científicas que busquem condições melhores para a saúde e a vida. Pode,também o titular, com sua aprovação em vida, doar órgãos, tecidos e partes do seu corpo, desde que sejam procedimentos que não coloquem em risco sua saúde. Porém, post mortem, não será reconhecida nenhuma manifestação de vontade expressa pelo titular em vida para doação de seus órgãos. Para equacionar o problema suscitado, busca-se uma análise ética da autonomia da vontade da pessoa, acompanhada de uma leitura bioética focada em seus princípios e um denominador legal ditado pela legislação brasileira.

Key Words: DOAÇÃO DE ÓRGÃOS, ÓRGÃOS POST MORTEM, etiké

A QUESTÃO DAS PATENTES E O ACESSO AOS MEDICAMENTOS ENQUANTO EXERCÍCIO DO DIREITO À SAÚDE: UM APARENTE CONFLITO DE NORMAS

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Abstract

Quando se trata do exercício do direito à saúde dos brasileiros, deve-se lembrar que faz parte desse direito o acesso aos medicamentos que são necessários aos diversos tratamentos médicos. Como se sabe, os medicamentos geralmente são desenvolvidos por laboratórios privados, que muitas vezes configuram grandes corporações multinacionais, as quais, dada a capacidade econômica, são capazes de despender enormes somas com a pesquisa e produção, acarretando novas drogas que são usadas em prol da humanidade. Enquanto detentores das patentes por tais drogas, esses laboratórios possuem direito de exclusividade na sua produção, que de acordo com a legislação, pode perdurar até vinte anos, conforme o artigo 40 da Lei nº 9.279, de 14 de maio de 1996. Nesse período, buscam os laboratórios o ressarcimento do investimento feito no desenvolvimento e produção de novos medicamentos, bem como obter lucro, tendo em vista que se tratam de entes jurídicos com fins lucrativos. Muitas vezes entretanto, isso significa um obstáculo à população no acesso ao medicamento que necessita, tendo em vista que seu preço se torna exorbitante às camadas menos favorecidas. Num país de desigualdades sociais como o Brasil, o alto preço exigido pelos laboratórios por medicamentos que muitas vezes são necessários à sobrevivência em meio a determinadas doenças, acaba por acarretar o perecimento dos cidadãos que não têm capacidade econômica para adquiri-los. Todavia, diante do interesse social evidente, o legislador pátrio incluiu na Lei 9.279 dispositivo que prevê o licenciamento compulsório de patentes, para exploração pelo Poder Público (artigo 71). O licenciamento compulsório pode ser concedido de ofício, apenas em casos de “emergência nacional” ou “interesse público”, e a licença concedida nessas condições será “temporária” e “não exclusiva”, buscando ainda não prejudicar os direitos de seu titular. Assim, toda vez que estiver demonstrado o devido interesse público, deve o governo proceder ao licenciamento compulsório de medicamentos em prol da saúde pública, garantindo todavia que o uso do medicamento será não-comercial, não-exclusivo e sua exploração, temporária, mas prorrogável enquanto perdurar o interesse público, assegurando-se a remuneração devida ao detentor da patente. Para finalizar, deve-se lembrar que a lei de patentes não deve impedir que medidas de proteção à saúde pública sejam tomadas em detrimento da patente de um medicamento, visto que as patentes encontram limitação nos direitos sociais

Key Words: PATENTES, EXERCÍCIO DO DIREITO, CONFLITO

A REGULAÇÃO D PUBLICIDADE DE MEDICAMENTOS/ADVERTISEMENT OF MEDICINES

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Abstract

The formal and original concept of health established by the World Health Organization (WHO) refers to a comprehensive physical, mental, and social well being, instead of the absence of disease, as a human right. Currently, as a result of the technological and scientific advances that took place since the past century, it became necessary to incorporate principles associated with the ultimate value of the "dignity of the human being". The new concept of health encompasses the complexity of the knowledge and the condition of the human being as a whole. Thus, the need to consider the individual as more than simply a biologically complex being becomes increasingly evident. Rather, the individual is fundamentally social, whose, values are diverse, often requiring distinct relationships under the just protection of the State and the society. The profit through the exploration of the business activity is a legitimate economic right and, in order to be achieved, it requires the dissemination of information on its products and services, which are regulated differently in each sector. The scope in the regulation of advertisement in the pharmaceutical industry is related to fundamental constitutional warranties, such as live, health, and biological safety of the individual. Given the magnitude of the bestowed rights, it is necessary to discuss whether the laws comply with their protective social function, or if they are exceedingly weak in their punishments, falling short of their pedagogical function in discouraging the execution of illicit civil acts. The article is structured in the presentation of a new concept of health and reports on the constitutionalization of the right to health, dealing with the fragility in the regulating laws of the sector, discussing if it is good in relation to the regulation of the structure of the advertisement initiatives and the severity in the punishment of illicit acts, discussing if it discourages the disrespect to the law, and if it prevents the establishment of multiple social losses that can become impregnated in the behavior of citizens. More specifically, the goals of this work are: i) to present a present-day concept of health; ii) to report on the constitutionalization of the right to health; iii) to investigate if the legislation that regulates the sector is weak or sufficient in the punishment of illicit acts; iv) to demonstrate that advertisement can influence the buying habits in a deleterious fashion, in kind. To this end, a method of bibliographical and legislative surveys at the national level is adopted, reviewing the Brazilian advertisement production from the monarchy period to the present, as well as case studies.

Key Words: PUBLICIDADE, constitutionalization, MEDICAMENTOS

A REGULAMENTAÇÃO DO SETOR DE SAÚDE SUPLEMENTAR NO BRASIL E RISCO MORAL: UMA APLICAÇÃO DA REGRESSÃO QUANTÍLICA PARA DADOS DE CONTAGEM

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Abstract

Key Words: Planos de Saúde, Risco Moral, Regressão Quantílica para Dados de Conta

A SITUAÇÃO DO MÉDICO SEGUNDO O CÓDIGO DE DEFESA DO CONSUMIDOR

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Abstract

O trabalho em questão tratará da situação do médico e sua profissão diante do Código de Defesa do Consumidor, e suas relações com pacientes ,estabelecimentos de saúde. Sua posição quanto ao impacto do referido Código nas prestações dos seus serviços e contratos, onde o instituto de sua responsabilidade tange como meio de prevenção de condutas indesejáveis ou como mecanismo de distribuição de riscos a atividades úteis, que não são suficientes para resolver o problema da reparação de danos considerados injustos com esse profissional, acarretando, em um vertiginoso enfraquecimento da carreira médica. Que já encontrava-se assolada por hospitais públicos sucateados e abandonados. O médico no Brasil é cada vez mais dirigido para o preenchimento do quadro de empresas médicas privadas onde a primazia é a aferição do lucro através da exploração do risco saúde. Através da padronização do atendimento, do limite de tempo para as consultas e valores irrisórios pagos pelas empresas privadas em nome da sustentabilidade do negócio. O profissional responsável pela medicina brasileira passa a traduzir uma mensagem de consumo de um serviço em detrimento de uma preocupação governamental com a saúde da população. Alterando acentuadamente o papel do médico na sociedade brasileira. Sabemos, que a vida e a saúde, são bens intrínsecos ao ser humano, indisponíveis e inalienáveis. Contudo, as relações profissionais que envolvem esses bens merecem que a proteção do código de defesa do consumidor esteja legalmente compatível com a relação médico-paciente, dando dignidade e segurança para que esse profissional possa exercer sua profissão.

Key Words: Legislação Médica; Relação de Consumo e o Médico; CDC e o Médico; Relação Medico-Paciente/Cliente; Direito do Paciente

A STUDY ON THE MALPRACTICE COMPENSATION RESOLVED BY A THIRD-PARTY IN R.O.K.

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Abstract

1. Objectives The purpose of this study is to estimate the total cost for medical disputes resolved by third parties from 2008 to 2010 and to estimate each medical departments and fee for service ratio. 2. Methods The malpractice data resolved by third parties is obtained from written judgments, remedy data of Korea Consumer Agency, compensation material of the Korean Medical Association during 2008-2010. Data is, extracted medical departments of the accident, reasons of malpractice and costs for compensation, and analyzed by using SAS. 3. Results During 2008-2010 the total cost for medical disputes resolved by third parties was sixty billion won(about $53 million). The medical clinic part was 76.98%, the dental clinic part was 8.74%, the oriental medical clinic part was 7.98%, and pharmaceutical part was 0.2%. The most reasons of malpractice type were the surgery(28.8%), treatments of medical clinic part(16.21%), misdiagnosis of medical clinic part(6.65%) and anesthesia(5.21%). 4. Conclusions By estimating the total cost for medical disputes resolved by third parties, each medical departments and fee for service ratio, practical medical malpractice disputes and basic data for prevention are presented. 5. Key words Medial dispute; Third party; Compensation; Malpractice

Key Words: STUDY, MALPRACTICE, R.O.K.

A TUTELA DO SEGREDO MÉDICO PELO CONSELHO REGIONAL DE MEDICINA DO ESTADO DE MINAS GERAIS EM UM ESTADO DEMOCRÁTICO DE DIREITO E A MANIFESTAÇÃO DO JUDICIÁRIO.

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Abstract

Introdução. Este tema livre tem por objeto expor relato de caso no qual o segredo médico garantido no ordenamento jurídico e deontológico médico brasileiro, fora inobservado em ato normativo administrativo Portaria exarada por Autoridade Policial, motivando o Conselho Regional de Medicina do Estado de Minas Gerais a intervir por meio de audiência pública junta a ALMG e posteriormente recorrer à tutela jurisdicional de Estado buscando a efetividade deste direito enquanto desdobramento dos princípios da dignidade humana, da autonomia e do consentimento. Desenvolvimento. Da Portaria exarada pela Autoridade Policial: "CONSIDERANDO a necessidade da realização de Exames de Corpo de Delito para confirmação da materialidade dos delitos que deixam vestígios, sendo referido exame indispensável para a prova; CONSIDERANDO que não existe Instituto Médico Legal nesta Comarca de XXX e o encaminhamento dos examinados para outra cidade se faz inviável; CONSIDERANDO que o Código de Processo Penal permite, no artigo 159, §1º, ao Delegado de Polícia a nomeação de peritos ad hoc, para realização de Exames de Corpo de Delito; RESOLVE: Art. 1º - Nomear os Médicos Plantonistas do Pronto Socorro Municipal para realização de Exames de Corpo de Delito, os quais deverão prestar atendimento em seus respectivos plantões, em vítimas e Authors de crimes, Autos de corpo de Delito ser encaminhados posteriormente à Delegacia de Polícia para ser juntados aos procedimentos investigativos. Art. 2º - O descumprimento desta Portaria ensejará responsabilização administrativa e criminal." Como médicos daquela cidade inconformados com situação posta, acreditando que violariam o dever de sigilo, notificaram o CRMMG, este discutiu a questão em audiência pública junto à ALMG com os sujeitos envolvidos expondo motivos bioéticos, legais, constitucionais e deontológicos e buscando a revogação da Portaria. Como o resultado não foi favorável, o CRMMG ajuizou ação ordinária com pedido de antecipação de tutela. Discussão. Atos normativos legais, administrativos e deontológicos, se alicerçam em princípios e fundamentos comuns. Neste contesto, a discussão no âmbito administrativo e jurídico mostrou-se a ponto de obter decisão judicial favorável.

Key Words: SEGREDO MÉDICO, DEMOCRÁTICO, JUDICIÁRIO, SIGILO PROFISSIONAL

ACESSO AO TRATAMENTO: O DIREITO HUMANO NA SAÚDE PÚBLICA

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Abstract

O homem é um fim em si mesmo2. Sua dignidade – o mínimo lhe é devido, por suportar, a condição humana3 – serve de vetor axiológico para atuação dos Poderes Executivo, Legislativo e Judiciário, reúne as Nações em compromissos transnacionais (tratados, acordos, termos de compromissos e afins) para garantir um conteúdo mínimo de direitos e garantias a cada um de nós. 4 O Direito Humanizado, característico do "Neoconstitucionalismo", apresenta o cenário protetivo dos direitos humanos, aonde se insere o direito à saúde. Acredita-se não ser mais passível de questionamento a sua estreita ligação com o direito à vida digna5. Um traçado comparativo-valorativo dos ordenamentos jurídicos latino- americanos, demonstra a inserção da saúde pública no contexto deste Direito Humanista e a necessária tutela do tratamento médico digno para o cidadão. Haveria correspondência entre o Direito que consagra antropológicos / humanistas na América Latina e a atuação judicial brasileira para garantia do acesso ao tratamento médico? Em que medida a tutela da pessoa humana filosófica e juridicamente acolhida está efetivamente sendo assegurada pelo Judiciário, quando as questões são: o acesso ao tratamento médico e o direito à saúde pública? Em meio às indagações propostas, será feito um importante estudo de caso.

Key Words: homem é um fim em si mesmo, a condição humana, Legislativo e Judiciário

ACESSO AOS BENS DE SAÚDE NA JURISPRUDÊNCIA DO SUPREMO TRIBUNAL FEDERAL

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Abstract

O direito à saúde é tomado na Carta Política como direito-dever do Estado e da sociedade perante o cidadão. Observa-se que suas disposições acerca do direito à saúde apresentam conteúdo valorativo relacionado à busca pela justiça social. Em função da atuação do Ministério Público e da jurisprudência que vem se consolidando na aplicação dos dispositivos relativos ao direito à saúde, surgiu uma zona de conflito entre as atribuições/competências dos Poderes Judiciário e Executivo no que concerne à escolha e aplicação das políticas públicas. Um número cada vez maior de direitos subjetivos geradores de deveres estatais na área da saúde surge não só em função dos avanços normativos alcançados pelo Poder Legislativo, como também em virtude dos avanços interpretativos do Poder Judiciário. Nesse contexto, o Poder Judiciário acaba por se tornar uma "porta de entrada" não oficial ao Sistema Único de Saúde (SUS) para os que visam acesso integral aos bens de saúde. O problema dessa pesquisa consiste em analisar o eventual direcionamento jurisprudencial do Supremo Tribunal Federal (STF), sobretudo após a realização da Audiência Pública nº 04/2009, no que diz respeito aos seguintes temas: (i) acesso a medicamentos; (ii) tratamentos no exterior e; (iii) argumentos do poder público contrários à concessão de prestações e/ou bens essenciais à saúde ("reserva do possível" e a impossibilidade de penhora do orçamento público). A metodologia aplicada é a da análise jurisprudencial e a pesquisa bibliográfica. A partir da análise das decisões, foram levantados e agrupados os dados obtidos a partir dos conectivos acima referidos. Como marco teórico sobre "judicialização da saúde" analisou-se, dentre outros textos, a degravação da Audiência Pública nº 04/2009, que esclarece questões técnicas, científicas, administrativas, políticas e econômicas relacionadas à tensão existente entre os aplicadores do Direito e gestores da saúde. Os dados coletados até agora apontam preliminarmente que: (i) o STF reconhece a prevalência do direito à saúde sobre os interesses financeiros do Estado; (ii) os principais fundamentos constantes nos acórdãos são: (a) o direito ao acesso universal à saúde; (b) o direito à vida; (c) a dignidade da pessoa humana; (d) a responsabilidade solidária dos entes federativos; (e) o periculum in mora inverso e; (f) a inexistência de ofensa à separação dos Poderes.

Key Words: SAÚDE, JURISPRUDÊNCIA, SUPREMO

Adverse Events, Medical Errors, & Patient Communication: Ethical & Legal Issues involving Disclosure and Apology

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Abstract

This paper utilizes a comparative approach in analyzing data involving adverse medical events, hospital and medical errors, and the ethical and legal issues involving the disclosure of "bad outcomes," including errors, to patients or their families. The paper chronicles the enactment of "I'm sorry" health care provider apology laws. The paper examines the literature associated with efforts to encourage physician and institutional health care providers to disclose, apologize, and, in some instances, offer remuneration to patients who have been harmed. In the U.S., seven hospitals in Massachusetts have just announced the initiation of a "Disclosure, Apology, and Offer" program patterned after one at the University of Michigan, whose officials reportedly have eliminated $2 million in litigation costs and whose medical liability claims have declined 40%. Stanford University's hospitals and clinics have utilized a similar program and report a savings of $3.2 million in annual medical liability insurance premiums. The paper will discuss training programs for medical students and residents involving the disclosure of medical error and barriers to implementing a disclosure and apology program.

Key Words: Adverse Events, Medical Errors, Patient Communication, Ethical & Legal Issues, Disclosure and Apology

AGING HUMANITY AND RIGHTS OF ELDERLY PEOPLE

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Abstract

Humanity is steadily aging. Worldwide, life expectancy is gradually increasing and birth rate is falling. According to the UN data, over the past 50 years, average life expectancy in the world increased by nearly 20 years, from 46.5 to 66 years. The number of older people aged 60 and older reached 688 million in 2006 and is projected to grow to almost 2 billion by 2050. Over the next 50 years, global average life expectancy will increase by 10 years and in 2045-2050 it will reach 76 years. Also by 2050, it is projected to double the number of people aged 65 years. There are no separate rights of the elderly. Internationally recognized human rights apply to everyone. They include - civil rights: the right to life, prohibition of torture, prohibition of interference in private and family life, security of home, privacy of correspondence and protection from unlawful attacks on honor and reputation, the right to national and cultural identity, freedom of conscience, thought and religion, freedom of movement and residence, the right to a legal protection and a fair trial, prohibition of discrimination; - political rights: the right to participate in managing state affairs and equal access to government service, voting rights (active and passive), the right of association and freedom of assembly, freedom of expression and information, the right of appeals or petitions; - socio-economic rights: free enterprise, private property right, labor rights, the right to form unions and strike, the right to social maintenance, the right to an adequate standard of living (including the right to housing and food), the right to health protection and medical care; - cultural rights: to education, artistic freedom, the right to participate in cultural activities, academic freedoms, the right to a healthy environment. Nevertheless, we have to consider a situation in which millions of older people in the world face unequal treatment or non-compliance with fundamental rights, especially in conditions of chronic poverty, violence and abuse, lack of education, as a result of which they have little or no access to the law and are excluded from social and political life, the question of the rights of the elderly is becoming more and more sensitive to the global community. In Azerbaijan legislation the rights of elderly citizens are protected by several laws.

Key Words: Humanity is steadily , RIGHTS OF ELDERLY , political rights

ALTA MÉDICA HOSPITALAR E SUAS IMPLICAÇÕES LEGAIS E ÉTICAS ANTE O BINOMIO AUTONOMIA E BENEFICÊNCIA PROFISSIONAL

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Abstract

É crescente a demanda de processos judiciais e éticos envolvendo médicos e pacientes. A pessoa é, ao mesmo tempo, ser físico-biológico e ser sócio-cultural, e neste contexto, as relações interpessoais norteiam-se pelos direitos e deveres, pela confiança mútua e pelo respeito. Especificamente, na prática clínica médica, os profissionais médicos deparam-se com o dilema de qual conduta tomar ante a solicitação do paciente ou de seus representantes legais para a concessão da alta médica. De um lado poder-se-ia concordar com a solicitação, tendo em vista o direito à vida, à liberdade, à saúde, à personalidade e à capacidade, respeitando assim o exercício da autonomia de vontade do paciente. De outro; também poderia o médico se recusar a conceder a alta, em decorrência da gravidade ou do iminente risco à vida do paciente, afinal, '' o médico é o único árbitro da alta hospitalar''(Parecer 17/2003, do CREMESP/RS). Contudo, se vier o médico a concordar com o pedido de alta do paciente, ficará o médico anuente responsável pelas consequências danosas relativas à alta. Neste impasse que se instala no exercício da prática clínica médica, visa este estudo demonstrar que a ALTA MÉDICA constitui uma terminologia específica, referente a um ato exclusivo praticado pelo médico, e que a expressão comumente usada '' alta a pedido'', se acompanhada da anuência do médico, não o desonera; mas neste momento traz novamente para si a responsabilização sobre o paciente.

Key Words: processos, éticos, sócio-cultural

ANÁLISE DO IMPACTO REGULATÓRIO NA SAÚDE SUPLEMENTAR

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Abstract

1. Introdução e Breve Escorço Histórico A denominada Análise de Impacto Regulatório (AIR) se consubstancia numa ferramenta para obtenção de informações úteis para aqueles que vão tomar a posição política e regulatória. A concepção do instituto AIR remonta aos filósofos utilitaristas ingleses do século XIX, especialmente Bentham (1781), precursor dos princípios da análise Custo-Benefício. No Brasil, o Decreto nº 4.176, de 28 de março de 2002, que estabeleceu normas e diretrizes para a redação e o encaminhamento ao Presidente da República de projetos de atos normativos, representou um "rascunho" do primeiro AIR brasileiro. 2. Metodologia 2.1 Quem elabora o AIR? AIR é preparada pelos reguladores, ou seja, Grupo de Especialistas, com expertise em diversas áreas do conhecimento (economistas, médicos, juristas etc). 2.2 Características do Sistema AIR: •Tem o objetivo de melhorar a qualidade dos novos atos normativos, bem como aprimorar os normativos já existentes;•Mune o processo regulatório com informações de qualidade;•Amplia a transparência. 2.3 Quando e onde se faz a AIR? Considerando que a AIR é um exercício de análise de opções possíveis, deve ser feita no início da discussão sobre uma possível intervenção regulatória. Para a confecção da AIR são ouvidas todas as partes envolvidas e afetadas por aquela intervenção. 2.4 Quem valida o Relatório AIR? •Quando o Relatório AIR está pronto (na Agência Nacional de Saúde Suplementar, a mencionada peça é chamada de Sumário Executivo de Impacto Regulatório) , havendo concordância, o Ministro ou Diretor da Agência Reguladora validará o processo, assumindo plena responsabilidade pela opção escolhida ou rejeitada. 3.Resultados Esperados: Existe uma expectativa positiva com a introdução desta nova ferramenta regulatória, quanto à verificação dos seguintes resultados: se a AIR permitiu obter informações sobre o problema a resolver, se apresentou opções viáveis, e se concretizou o objetivo de transparência da decisão política/regulatória. 4. Estudo de Caso Concreto vivenciado na Saúde Suplementar 4.1 Tema do AIR: Regulamentação do Direito previsto no artigo 33 da Lei nº 9656, de 03 de junho de 1998, in verbis:"Art. 33. Havendo indisponibilidade de leito hospitalar nos estabelecimentos próprios ou credenciados pelo plano, é garantido ao consumidor o acesso à acomodação, em nível superior, sem ônus adicional".

Key Words: Análise de Impacto Regulatório, Ônus excedente, Sumário Executivo de Impacto

ANÁLISE DOS PROCESSOS DE AUDITORIA DO SUS NA GRANDE FLORIANÓPOLIS REGISTRADOS NO DENASUS NO PERÍODO DE 2000 A 2010

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Abstract

Este estudo teve como objetivo analisar as auditorias, registradas no DENASUS, realizadas na Grande Florianópolis de 2000 a 2010. O estudo constituiu-se de pesquisa documental no banco de dados do DENASUS – Departamento Nacional de Auditoria do SUS, disponível através do site http://sna.saude.gov.br. Os processos de auditoria foram analisados quanto à causa, objeto de estudo, tempo de execução e considerações relatadas. Foi observada maior ocorrência de atividades com demanda externa (87,5%), por denúncias por parte do cidadão, Conselho de Saúde ou Ministério Público (maior demandante), em detrimento de auditorias internas (12,5%), programadas para a verificação e prevenção de não conformidades no Sistema de Saúde. Isto não é observado nos últimos relatórios nacionais do DENASUS, que mostram maior proporção de demanda interna (55,2%) nas auditorias no Brasil. O principal objeto das auditorias foi a assistência geral, o que é semelhante ao encontrado nos dados nacionais.

Key Words: análise, auditoria, sus

AS INTERFACES DAS PRÁTICAS DE TERAPIA GENÉTICA PRÉ-IMPLANTAÇÃO E PRÉ-NATAL E OS DIREITOS DO EMBRIÃO.

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Abstract

Os avanços decorrentes da biotecnologia ao mesmo tempo em que permitem a superação dos obstáculos decorrentes da infertilidade, provocam inúmeras discussões em torno dos direitos atribuídos aos sujeitos envoltos no recurso à reprodução humana assistida. De um lado, enfoca-se o direito à procriação assistida, sem se descurar, todavia, em contrapartida, dos direitos atribuídos aquele ente vulneravelmente considerado que é o embrião ou o futuro filho que nascerá. Portanto, pretendemos com a presente comunicação trazer à tona as discussões que atualmente estão sendo travadas, sobretudo no âmbito internacional, a partir da interpretação da Declaração Universal do Genoma Humano e dos Direitos Humanos, em torno dos caminhos ético-jurídicos que devemos tomar face às terapias de diagnóstico genético pré-implantação e pré-natal. Conforme demonstraremos, tais técnicas permitem que sejam detectadas previamente doenças de fundo genético de que possam provavelmente ser portadores os embriões submetidos às práticas de reprodução humana assistida. Frente a tal situação poderíamos indagar: Diante do diagnóstico de uma doença genética, seria possível descartar a utilização desses embriões, portadores de má-formação, deixando de implantá-los no útero materno? Tal prática não seria uma espécie de eugenia? Poderiam tais embriões descartados serem utilizados para experimentação? A este respeito a Lei brasileira de Biossegurança, cujo art. 5º. foi julgado constitucional pelo Supremo Tribunal Federal, prevê a possibilidade de utilização de células troncos embrionárias obtidas de embriões humanos, considerados inviáveis, produzidos por fertilização in vitro. Ora, quais os critérios existentes e utilizados para se definir a inviabilidade do embrião? A vagueza deste termo inserido em nossa Lei de Biossegurança não poderia dar azo às práticas discriminatórias em razão de caracteres genéticos? Estas e outras reflexões serão objeto da presente comunicação, ocasião em que buscaremos tratar do conflito entre o direito à procriação assistida e os direitos do embrião, enquanto sujeito de direitos e vulneravelmente considerado.

Key Words: biotecnologia, reprodução humana , infertilidade

AS TESTEMUNHAS DE JEOVÁ E AS TRANSFUSÕES DE SANGUE: UMA ANÁLISE DO APARENTE CONFLITO DE PRINCÍPIOS CONSTITUCIONAIS.

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Abstract

Em muitos lugares hoje, o paciente tem o direito inviolável de decidir que tipo de tratamento ele aceitará. A lei do consentimento informado tem sido baseada em duas premissas: primeiro, que o paciente tem o direito de receber informação suficiente para fazer uma escolha informada sobre o tratamento recomendado; segundo, que o paciente pode escolher aceitar ou rejeitar a recomendação médica. Este trabalho apresenta as bases legais para tal recusa, analisando o aparente conflito de princípios constitucionais entre o direito à vida, à liberdade de consciência e crença, à privacidade, entre outros.

Key Words: Transfusões de sangue, Testemunhas de Jeová, Princípios Constitucionais

ASPECTO MÉDICO LEGAL DE LA MUERTE ENCEFÁLICA EN EL PARAGUAY

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Abstract

La muerte encefálica es un concepto reciente en medicina que ha despertado una intensa controversia ética, biomédica, ética y cultural que interesa no solo a los neurólogos, trasplantologos o jueces, sino a toda la colectividad medica y a la propia sociedad, debido a que está de acuerdo a las culturas se debe respetar a los muertos y el fin último es la de la ablación de órganos de pacientes diagnosticados con muerte cerebral. Esto significa un gran reto para el médico, pues deberá utilizar métodos de diagnósticos clínicos y para clínicos que puedan ayudar al diagnostico de la muerte. El concepto de muerte ha sufrido grandes cambios a lo largo de la civilización; para la cultura griega era el cese de la funcionalidad cardiaca, para la judaica cristiana era el cese de la respiración, en la edad media era la separación del cuerpo del alma y se empezó a dudar de la ausencia de pulsación cardiaca y la respiración. Son numerosos los escritos medievales manifestando el terror de ser sepultados vivos por diagnósticos mal hechos por familiares y amigos. En la ciudad del cabo se realizó el primer trasplante cardiaco en 1967, a partir de un donante con funciones vitales activas pero en muerte cerebral, con un profundo impacto bioético. A partir de ahí se unifico el concepto vigente hoy que lo define como el cese irreversible de las funciones cerebrales incluyendo al tallo cerebral. Mallaret y Goulon sugirieron estado mas allá del coma, Beecher, Adams y Sweet sugirieron el término de muerte cerebral, existiendo criterios para determinar dicha muerte difundida por todo el mundo, conocidos como criterios de Harvard. Estos criterios han originado Controversias pero sin lugar a dudas lo más importante es la validez de ella. En cuanto al marco legal la legislación paraguayo se ha ocupado del tema mediante la ley de trasplante y ablación de órganos 1248/98 que regula la donación de órganos y criterios de muerte encefálica, así como las legislaciones internacionales, aunque estos criterios puedan variar en las mismas.

Key Words: LA MUERTE, ENCEFÁLICA, PARAGUAY

ASPECTOS ÉTICOS FRENTE À SATISFAÇÃO DO CLIENTE HOSPITALIZADO

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Abstract

As instituições de saúde podem ser consideradas como organizações complexas porque precisam estar preparadas para receber e satisfazer o paciente. Este se distingue dos clientes de outras organizações porque, se tivesse escolha, não utilizaria o serviço de um hospital. Também se diferencia porque, muitas vezes, não é ele quem determina os serviços e os produtos que irá usar durante o período de sua internação. Embora ele seja o cliente, geralmente quem decide o serviço ou o produto a ser consumido por ele são os profissionais de saúde. Diante destas considerações, percebe-se o desafio de cuidar em Enfermagem com base na competência, na eficiência e na ética. Esta reflexão crítica tem o propósito de chamar a atenção para a relevância dos aspectos éticos da atuação do enfermeiro que envolve a satisfação do paciente com os cuidados de enfermagem. Neste trabalho, destacam-se a responsabilidade do enfermeiro de desenvolver ações respaldadas na ética frente ao compromisso de gerir e assistir com qualidade, comprometimento e eficiência. Emergiram desta reflexão possibilidades de ações indispensáveis, tais como: o fornecimento de informações fidedignas e atuais ao cliente, a respeito de norma, rotinas cuidados, exames e outros; bem como a educação do cliente no sentido de conduzi-lo ao um maior envolvimento e participação nas decisões relativas à assistência para ele planejada. Acreditamos que assumir este paradigma significa uma transformação no desempenho do papel gerencial e assistencial do enfermeiro que, possivelmente, terá que observar atitudes até então deixadas em segundo plano na maioria dos serviços prestados.

Key Words: CLIENTE HOSPITALIZADO, ASPECTOS ÉTICOS, SATISFAÇÃO DO CLIENTE

ASSISTED SUICIDE, EUTHANASIA, ORTHOTANASIA: THE INADMISSIBILITY OF THE RIGHT TO KILL TERMINALLY ILL PATIENT. A SOUTH AMERICAN PROSPECTIVE

Authors Washington Fonseca

Abstract

This study aims to address the legal aspects in the treatment of terminally ill patients through the use of techniques related to euthanasia and orthotanasia with focus in countries of South America. The effectiveness of Law depends directly on the dynamics established between law and social relations. Discussions related to ethical and legal limits are linked to the dignity of the patient regarding the extension and/or shortening of his life. These are some aspects of the human evolution, which are in vogue. Much is said regarding the right to live, which is considered the greatest value to be protected socially and legally. However, although life is considered a supreme asset, is it worth nothing if apart from other precept is currently much used: the human dignity. Discussions about ethical-legal limits attached to the patient's dignity in the extension and / or shortening their lives. Also, appreciation of assumptions inherent in human rights is discussed. Constitutional and civil rights applicable in Brazil and other countries are object of study. Where is the border line of the State in order to interfere or allow the patient to decide the best treatment to itself? How Brazil and other South American countries manage this issue through their legislation? Also, this study aims to discuss how the Brazilian society treats the theme. Another point is worth mentioning: how to protect the exercise of rights of patients who find themselves in vulnerable situation in situations where discernment is reduced or even there is no discernment at all? is The subject of this study is to evaluate whether active or passive conducts accelerates the decision to keep a patient alive or if its better to straighten his path to death. Would it be shortening the life the best treatment for the patient? Would it be worth to terminally ill patients (in a situation of vulnerability) such decision? Also, criminal aspects of orthotanasia and euthanasia before Brazilian and other countries legal systems´ are analyzed. It concluded that, with use of palliative care, the search for euthanasia is unnecessary. The dignity of the human person is embodied in the autonomy of the patient's will shall be above all treatments provided by science.

Key Words: Suicide, Euthanasia, Orthotanasia. Palliative Care. Right to die. Living Will. South America, Brazil

AUSTROADS GUIDELINES FOR FITNESS TO DRIVE

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Abstract

After nine years, Austroads has published new guidelines for fitness to drive. The guidelines include a preamble, which includes a legal disclaimer that denies any culpability for those who designed the guidelines. They also warn of the legal responsibility for health professionals to satisfy their obligations, the need to be current with both relevant medical and legal expectations and to protect if there is doubt by seeking guidance from medical defence organisations. The guidelines are divided into Parts A and B with A providing broad overview and background information while B deals with specific entities, such as blackouts, epilepsy or sleep disorders. This paper will examine the guidelines and offer an appraisal of their content, their relevance to health practitioners and an assessment of their role in assisting to improve road safety.

Key Words: Driving, Conditional Licenses, Fitness, Legal Responsabilities, Guidelines

AUTOMUTILAÇÃO NA ADOLESCÊNCIA: O ACESSO A TRATAMENTO MÉDICO COMO DIREITO FUNDAMENTAL

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Abstract

Todo homem tem direito de desfrutar de padrões de saúde para que possa exercer seu direito fundamental de viver dignamente. O direito à saúde integra o rol de direitos fundamentais. Embora existam poucas estatísticas sobre o assunto mundialmente, não se pode ignorar o crescimento de automutilações, que podem ser definidas como quaisquer comportamentos intencionais envolvendo agressão física direta ao próprio corpo sem intenção de suicídio. É importante analisar os casos de automutilação estimulados por doenças não identificadas e tratadas a tempo e que, devido a uma cultura tolerante, se tornaram fenômenos da moda, cultuados principalmente entre os adolescentes. O ordenamento jurídico brasileiro veda autolesões que acarretem diminuição permanente da integridade física ou contrariem os bons costumes, mas não há atenção para aquelas lesões menores, frequentes, oriundas de episódios traumatizantes, tais como: abuso emocional, físico, sexual, depressão, ansiedade, abuso de álcool e drogas. Parte do desinteresse pelo tema é alimentado por pesquisas que apontam para a solução "natural" do problema, já que 90% das pessoas que se agrediam na adolescência abandonaram a prática na vida adulta. O que não se pode perder de vista é que o direito à integridade é a tutela que o ordenamento jurídico garante ao corpo humano, à psiquê e à inclusão social do indivíduo, e esta proteção independe do grau da lesão ou de eventuais sequelas, definitivas ou não. Mesmo que seja um problema mais incidente na adolescência, a Constitucionalização do Direito Brasileiro assegura ao ser humano, independente da idade, o direito de ter sua doença subjacente diagnosticada e tratada, para evitar que se inflija durante anos autolesões, que acarretam, dentre outros problemas, isolamento social e dificuldade de desenvolvimento. Uma vida digna passa pelo acesso pleno a tratamento médico adequado e pela tutela jurídica da saúde.

Key Words: AUTOMUTILAÇÃO, ADOLESCÊNCIA, TRATAMENTO

AUTONOMIA DO PACIENTE E O CONFLITO COM A RESPONSABILIDADE MÉDICA EM ESPECIAL NAS MANIFESTAÇÕES ANTECIPADAS DE VONTADE

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Abstract

Hoje muito se debate sobre autonomia do paciente, dever de informar, consentimento livre e esclarecido. Temas como Testamento Vital ou Diretivas Antecipadas de Vontade surgem cada vez mais nos debates médicos e jurídicos, porém não a como negar a existência dos conflitos que surgem na relação médico-paciente, cada dia mais buscamos respeito à autonomia do paciente, cujo interesse central do tema é a garantia a dignidade da pessoa humana. Todavia, a preocupação que muitas vezes surge é quanto a seus efeitos na esfera da responsabilidade civil do médico e dos demais profissionais da saúde, quanto ao respeito desta autonomia e a preservação do bem da vida. Por isso, a necessidade de informar o paciente, para melhor realizar suas escolhas, garantindo sua autonomia já que o pressuposto desta é a informação, e deve ser fornecida adequadamente à compreensão.

Key Words: AUTONOMIA DO PACIENTE, RESPONSABILIDADE MÉDICA, MANIFESTAÇÕES ANTECIPADAS, VONTADE

AUTONOMY – A LEADING PRINCIPLE FOR THE END-OF-LIFE DECISION MAKING?

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Abstract

Autonomy of a competent patient is often presented as an overwhelming argument in the end-of-life debate, regardless whether in the context of active euthanasia or in the decision making about withdrawal or withholding of medical treatment. Despite of the general opinion, that decriminalization of direct active euthanasia is legitimately based on the respect for the patient´s wishes to die, even in the world most liberal end-of-life law of Benelux countries the legal concept of decriminalised active euthanasia seems to be built in a considerably different and more sophisticated way, as it does not solely rely on the request of the patient to be administered the lethal dose. Basically, the will of a competent patient is to be understood as a reason for the doctors to omit the further medical treatment, even if this omission leads to death of the patient. To the contrary, no actively caused death, as well as actively caused serious injuries which are not an acknowledged lege artis treatment (as among others i.e. the life – rescuing leg amputation by the late stage of diabetes could be) can be pleaded lawful with the reference to the consent of the patient. With this paper, the extent of patient´s autonomy concerning the specific law of euthanasia in some European countries is to be examined to prove the perhaps far too overestimated factual impact of the autonomy principle in the medical law.

Key Words: autonomy, end-of-life, decision

BENEFICENCE BEYOND THE GRAVE?

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Abstract

When a genetic counselor has to assess whether or not a patient is at risk of having inherited a genetic predisposition for a specific disease, it is neces-sary to obtain information about the medical history of the patient's family members. This way the counselor can determine if the family's collective medical history indicates that there is a hereditary disease running in the family. If so, the patient will be at risk of having inherited the mutation causing disease. To know for certain, the patient will have to undergo a genetic test. The mu-tation is often specific to the individual family, and the genetic counselor has to know the exact mutation in order to be able to examine the patient's DNA. Thus, in order to be able to carry out the test at all, it can be necessary to obtain a blood sample from a member of the family who is already ill and therefore certain to have inherited the mutation. All in all, when performing genetic diagnostics, health information from family members is often necessary to obtain, and from a health law perspec-tive it is relevant to consider, to what extent this is legal. This paper exam-ines the current Danish regulation in this regard. However, the situation is often complicated in real life, because some mem-bers of the family might already have passed away – maybe even because of the disease. As a general rule consent has to be given in order to process in-formation, but in this case consent is obviously impossible to obtain unless the deceased has left instructions, which is rarely the case. In some situations it is possible to obtain information without consent based on a weighing and balancing of the patient's rights against the right of the relevant family member. However, the remaining family members might not all agree on this matter. Therefore, it is discussed how to obtain health information from deceased family members under the current Danish regu-lation – and if the remaining relatives have a say at all. European guidelines are included where relevant.

Key Words: BENEFICENCE, BEYOND, GRAVE

BIAS IN RESEARCH AND EXPERT OPINIONS IN THE LEGAL PROCESS

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Abstract

The writing of an expert opinion for legal purposes is a judicial process in which the expert tries to influence the outcome of the proceedings. The expert opinion should be supported by medical records and data collected according to Evidence Based Medicine (EBM) rules and rely on medical literature and studies published in scientific text books and journals. We all like to think that the expert witnesses are objective scholars who base their opinion entirely on their credibility, experience and achievements, without prejudgments or secondary benefits. Any expert Opinion is influenced by unconscious or cognitive bias of the expert that could influence the outcome, particularly the interests of the parties. Therefore, contractual relations between the interested party and an expert create a built-in conflict of interests between expert's loyalty to party and his professional duty to maintain objectivity. Courts cannot ignore the influence of Bias in research create an integrated conflict of interests over Expert opinions especially in medical malpractice cases. For instance the expert can be be impartial if he belongs to a specific medical guild or is unwilling to confront with experts of one of the parties, particularly if expert is well known and holds an important position or influence; if expert holds a particular school of thought that doesn't coincides with the common knowledge or his willingness to accept a particular position that is inconsistent with his opinion. Biased research especially in the pharmaceutical industry may influence experts that relay on misleading publication and therefore has a negative impact on public and may influence court decision. This paper aims to examine how biases affect medical literature or research and can influence expert in the process of decision making and how this can lead to influence legal procedures. We try to examine what's behind the desire to influence opinions of expert opinions and how biased opinion can influence the results of the trial. We demonstrate our arguments with examples in several well known cases in which there was an attempt to influence research and show the impact of biases on legal procedures. Also we examine how ethical institutions such as the Ministry of Health and Medical Association handle this phenomenon. Finally we suggest a simple mechanism to reduce the fear of conflicts of interest and structured cognitive biases in appointment of the court expert in medical malpractice claims.

Key Words: BIAS IN RESEARCH, EXPERT OPINIONS, LEGAL PROCESS

BIOÉTICA, BIODIREITO E REPRODUÇÃO HUMANA ASSISTIDA: A NECESSIDADE DE REGULAMENTAÇÃO JURÍDICA DA FECUNDAÇÃO ARTIFICIAL POST MORTEM

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Abstract

A Bioética é um ramo da ética sinteticamente compreendida como responsável pela compleição de um arcabouço teórico capaz de problematizar as nuances filosóficas irradiadas pelos experimentos médico-científicos na contemporaneidade. Associado a isso, fornece o substrato adequado e necessário para empreender essa discussão com vistas à regulamentação de atos capazes de atentar contra a dignidade da pessoa humana. No intento dessa regulamentação ocorre a irrupção do Biodireito, disciplina jurídica recente, porém fulcral, diante dos problemas postos pela ciência hodierna. Este ramo do Direito deverá sopesar as implicações sociais, jurídicas e axiológicas dos procedimentos médicos assaz relevantes para a sociedade como, por exemplo, a Reprodução Humana Assistida(RHA). Ressalte-se demonstrar, neste cenário, a importância fulcral da Bioética na propositura de princípios éticos e normas morais para nortear, de maneira racional, a busca de soluções necessárias para dirimir os problemas emergentes na sociedade hodierna. Conquanto os princípios da Bioética sejam precípuos para uma atividade médica pautada na observância do princípio da dignidade da pessoa humana, é demasiado admitir que seja suficiente. A forma abrupta pela qual evoluíram as técnicas de RHA não permitiu a necessária elaboração legislativa para reger as descobertas biotecnológicas. Neste ínterim, a RHA solapou a anacrônica compreensão da paternidade adstrita ao aspecto biológico, dado a emergência do liame socioafetivo em detrimento do enlace biológico das relações familiares, facultada pelas inovadoras técnicas de RHA. A despeito das possibilidades trazidas pelas técnicas de RHA, a ausência de uma regulamentação jurídica desses procedimentos reveste esta nova seara de uma ampla insegurança jurídica, mormente, no que tange a fecundação artificial homóloga post mortem. Outrossim, esta modalidade de fecundação coloca a criança – gerada desse processo – diante de uma séria insegurança, dado a indefinição jurídica, no que concerne ao reconhecimento dos seus direitos fundamentais basilares, a saber: direito ao estado de filiação e direito à herança.

Key Words: Bioética, médico-científicos, Biodireito

CAMEROON CIVIL SOCIETY ADVOCACY FOR ADOPTION OF A LAW PROTECTING HUMAN RIGHT AND GENDER EQUALITY

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Abstract

OBJECTIVE: -Educate key stakeholders on the importance of human rights in the context of HIV / AIDS -To take into account respect for human rights and gender equality in the process of adopting the law on HIV / AIDS in Cameroon. METHOD: -Organization of a sensitization seminar for civil society Search-documentaries on human rights and HIV / AIDS -Critical analysis of the bill before the Department of Public Health -Held a workshop to validate the proposed law drafted by civil society organizations -Organization of the restitution of works of Dakar 2008 -Organize a working session with the NAC 2-Holding meetings with the parliamentary committee of AIDS TB and Malaria RESULT: -The actors of civil society have understood early the importance of ensuring respect for human rights in the process of adopting the draft bill prepared by the Department of Public Health in 2002 -The operation of the existing literature in the field of human rights has to be fixed on the information available. thus we could obtain documents relating to UN recommendations, the legislation already adopted or under preparation in ten African countries -The working group after thorough analysis of the draft bill of 2002 has developed a bill taking into account the recommendations of UNAIDS in 2008 and positive points noted in the legislation already adopted in other countries. This bill has been validated in the heart of a seminar by forty actors of civil society from all regions of the country -The bill of civil society has been popularized through the publication of three specialized newsletters, publishing articles in newspapers, the participation of many local seminars and organizing a press conference. This allowed to widen the circle of our allies - A working session was held with officials of the NAC. Working papers including the various production coalition were delivered to the NAC to operate. -The return of the Dakar workshop has served to remind the body of standards key players of the United Nations on human rights and UNAIDS guidelines that framed so far the response to the epidemic. -The Parliamentary Committee on 3 disease included in its 2011-2012 action plan the preparation of a draft law on HIV / AIDS to be submitted to the adoption of the national assembly.

Key Words: society have understood , Department of Public Health, Organization

CANINE INDEX: A TOOL FOR SEX DETERMINATION

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Abstract

The question of personal identity frequently arises in the courts of law not only in the identification of criminals but also in the identification of other persons and dead bodies. In case of mass disasters resulting in loss of lives, the law enforcement agencies, public safety and health officials always have the responsibility for identifying the human remains found at the scene, to be handed over to their families. The problem of identification of the dead arises in case of dismembered or mutilated bodies. Tooth dimensions are a useful adjunct in identification. Canines, which are the teeth least used in the oral cavity, less affected by periodontal disease and least frequently extracted with respect to age, play a highly valuable role in identification. Canines have also been reported to survive in air crash and hurricane disasters. They are perhaps the most stable teeth in the oral cavity because of the labiolingual thickness of crown and the root anchorage in the alveolar process of the jaws. The crown portions of the canines are shaped in such a manner that promotes cleanliness. This self-cleansing quality and efficient anchorage in the jaws tend to preserve these teeth throughout life. These findings indicate that canines can be considered as the 'key teeth' for personal identification. They bear the greatest degree of sexual dimorphism. Hence, their exclusive use in odontometric sex assessment using the Mandibular Canine Index (MCI) has been advocated before. The MCI is derived as the ratio of the mesiodistal (MD) dimension of canines and the inter-canine arch width. This study has established the standard MCI for Karnataka population in South India which helps in assessing the sex on a sample from this part of the world. Measurements were obtained from 500 subjects comprising of 250 males and 250 females, in the age-group 15–25 years. This age group was selected as all the canines would have erupted by this age and attrition is expected to be minimal. Intercanine distance & width of both right and left mandibular canines were measured intra orally as well as on the impressions taken on the coloured drawing sheets of the same subjects & the mandibular canine index was calculated. Independent samples descriptive statistics (mean standard deviation, frequencies and measurement of agreement) and comparison of group means revealed significant sexual dimorphism in the MCI. The definite statistically significant sexual dimorphism existed in the mandibular canines irrespective of measurements taken intraorally or on the impressions taken on the coloured drawing sheets.

Key Words: Identification, Sexual dimorphism, Tooth dimensions

CIVIL LIABILITY OF GESTATIONAL MOTHER TOWARD GENETIC PARENTS AND EMBRYO

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Abstract

Who is the mother? The response is important in determining the liability of gestational mother against genetic parents. According to article 1 of Iranian Civil Liability Act, like article article 823 of BGB, liability arises when tortfeasor by his intentional or negligent act, violates a legal right of victim which causes damage to him. Response to " Who is mother?" determines, the holder of the right of motherhood. Quite contrary, the determination of the mother is not important in case of the liability of gestational mother against embryo; Child born to the Surrogate pursuant to the terms of the agreement. Even if the gestational mother is real(legal)mother of the embryo, she will be liable toward her; like many other countries, there is no doctrine of parental immunity in Iranian law, and the law recognizes the liability of the real mother against her embryo. Presupposing that the legal mother is the genetic mother, as this is the dominant view before Shiite jurisconsultes, the gestational mother would be liable toward genetic parents in certain circumstances. If the surrogacy contract is valid, the liability will be, normally, contractual. But in spite of the validity of contract, certain terms of the contract could be regarded as against right of privacy, autonomy and liberty of the mother and, consequently, void. The liability of the gestational mother is not then, always, contractual. It is extra-contractual in several cases(invalidity of contract or its terms). It is not easy to determine the exact scope of this extra-contractual liability because of the conflict between the right of privacy, autonomy and liberty of the gestational mother with the right of life of the embryo. The problem of civil liability is , as Starck says , the problem of the conflict of rights of the tortfeasor and the victim. But how to resolve this conflict when the two rights(right of the gestational mother and the embryo) are fundamental , inalienable, constitutional rights, protected by the human rights documents? The conflict could be resolved as follows: if the surrogate acts in charitable way and receives no consideration for her service, she will be immune from liability, except in case of intentional harm, because of the doctrine of the charitable immunity rooted in Islamic law(Ihsan). If the contract is bilateral, the gestational mother is liable toward the genetic parents when the damage is the result of an intentional act to cause the harm or a criminal act (like consuming drugs) or a wanton negligence.

Key Words: Gestational Mother, Civil Liability, Conflict of Rights

CIVIL LIABILITY OF THE PREGNANT TOBACCO USER IN RELATION TO THE UNBORN CHILD

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Abstract

The analysis of the civil responsibility of the smoker pregnant mother in relation to the fetus is a theme of social and legal interest that is compatible with the country's legal orger, either at the infra-constitutional level (civil code and the child and teenager statute), or at the constitutional level due to the assurance for the right to health, as well to the general foundation on the principles of the dignity of the human being (art 1, item iii from federal constitution) to constitutional solidarity (art. 34 item i from federal constitution). The unborn has the unequivocal right to life and health and, given that, by the risky behavior of the mother, submitting herself to the tobacco use during pregnancy, it therefore generates harm to the new person, the reparation will ensue. The unborn could, could even take measures during pregnancy, with the goal of avoiding the harmful behavior from the mother could have during pregnancy. The medical doctrine, associated with the empirical proof of several cases of tobacco proven harm to the fetus give creedence to this legal possibility. The goal of this study, therefore, it to demonstrate such risks and the consequences from this harmful behavior and to bring answers assured by the legal order. The theme approach was regulated by the civil responsibility and by the health right guaranteed by the Federal constitution article 6, reinforced by the Child and Adolescent Statute assigning to the parents the duty to attend the child basic necessities, according to the articles 4 and 7.In this track, indispensable the demonstration of the medical recent studies that shows the smoking effects during pregnancy, not only to the mother´s health, but especially to the fetus life and its future reflexes.Furthermore, the State is limiting some human conducts, as verified by the National Policy Smoking Action and more recently, the law that punishes the parents for violence against the child.The Law, always alert to the social transformations cannot act as a mere pectator, but must be a protagonist to stimulate the consciousness and the behavior of a healthier society.The used method was the use of the applicable legal and medical doctrines, based on scientific experience.

Key Words: CIVIL, PREGNANT, CHILD

Claim work in the practice of regional department (ministry) of Health of Russia

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Abstract

In certain cases, you need permission to disputes between the regional ministry (department), Health and the supplier of goods and services to submit the dispute to a court or tribunal within the pre-trial (claim or otherwise) about the settlement of disputes [1, 2]. New Arbitration Procedure Code of the Russian Federation of 24.07.2002 № 95-FZ (NW, 2002, № 30, p. 3012), which came into force on 01.09.2002 (hereinafter referred - APC), in Part 5 of Art. 4 retained the previously established APC 1995 rule that pre-trial dispute resolution procedure applies in cases where it is set by federal law for certain categories of disputes, or when such a procedure is stipulated by the contract [3, 4]. Claims by the parties under the contract and consider them one of the manifestations of economic calculation, part of the legal work of the Legal department (LD) of the Ministry of Health of the Republic of Komi (MH RK). The immediate objectives of claims work are: a) Restoration of violated rights and the protection of the legitimate interests of organization; b) Identify the causes and conditions involving non-compliance with treaty obligations, and the output of goods of inadequate quality, theft of property and other violations, c) the Prevention of violations of planned and contractual discipline, the current legislation; d) Improving the economic performance of economic activities of organizations; e) Reimbursement by those responsible for damage caused to the organization. The legal form in which is expressed complaints, a complaint - a written request to the supplier directly with the requirement to restore the violated rights and lawful interests without the intervention of jurisdictional bodies. In commercial practice, the presentation of a claim is usually the first step in resolving disputes arising between the parties. It was only after denial of the claim (or the response to it in due time) the claim is. The latter is an appeal to the courts for protection of the violated rights of a legally protected interest. In the event of the supplier of property rights and legal interests of the RK Ministry of Health of the relevant department, service, prepared a draft for mandatory submission of claims to the counterparty with a proposal to repay, reimburse or to pay damages provided for in existing legislation or contract penalties. The method of continuous monitoring of the analysis work, the structure and dynamics of the 139 claims filed by MH RK suppliers of goods and services in 2009-2011. During 2009, 50 suppliers exhibited claims only in connection with the failure to supply goods to the amount of 101 531 997.47 rubles. Most were not bona fide suppliers number 2 and number 3. The first one led by the number of claims (13) and ranked second on the amount of short supply (25 886 773.97 rubles), And the second, giving the number (12), significantly greater than the sum of the first (34 691 745.09 rubles)

Key Words: PRACTICE, WORK , HEALTH

COCAINE: HOW MEDICINE AND LAW COMBINED TO GIVE THE WORLD ONE OF ITS LEADING CASH CROPS AND MAJOR MEDICOLEGAL PROBLEMS

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Abstract

Conomy, Cocaine at the forefront of promulgating cocaine as a therapeutic substance and were stars of advertising cocaine products along with Popes, Presidents and Entertainers. The effective legal regulation of the medical uses of cocaine was not undertaken until the 1920's and was not broadly regulated until after World War II. Today this derivative of an Andean shrub, Erythroxylon coca, is a yearly multi-billion dollar clandestine industry and a major, continuing cause of addiction, murder and mayhem about the world. The history lesson in the Cocaine Story is the tale of the probability of unintended consequences of the interactions of medicine and law. To what extent it will be repeated with issues like hormonal and antibiotic infusion of foods, tolerance of atmospheric poisoning and widespread use of radiation and vaccination is unknown. Remember that cocaine was once heralded as the drug of the millennium, a safe and effective remedy for many of the woes of mankind.

Key Words: Cocaine, therapeutic, substance

COMPARATIVE DESCRIPTION OF "MEDICAL MALPRACTICE" CASES AND CLAIMING BEHAVIOR IN THE UNITED STATES AND COSTA RICA

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Abstract

This paper ventures a comparative description of “medical malpractice” cases and claiming behavior in the United States and Costa Rica. It also traces the possible implications—generally it is difficult to recover in either jurisdiction but drastically more so in Costa Rica-- of these differences for U.S. residents who seek medical care abroad. “Medical malpractice” in the U.S. refers to a civil action for medical negligence in the overwhelming majority of cases. The analog of a “medical negligence” case in Costa Rica is actually simultaneous pursuit of a criminal and civil case against the health care provider. The basic steps in a U.S. case are: complaint in civil court, extensive discovery, possible dispositive motions, trial (usually before a jury), and possible appeal(s). This process can take approximately 1 to 5 years. The basic steps in a typical Costa Rican case are: criminal complaint by the victim and simultaneous filing of a civil suit before the same court; prosecutor gathering of evidence, interrogation of witnesses, and service of a summons on the defendant requiring an appearance; preliminary hearing stage during which the judge determines whether the case shall proceed to trial; intermediary stage where there is first an investigation and finding by the State’s forensic department (which can involve internal appeals) as well as an attempt to reconcile the matter, and, if that fails, dismissal by the judge or preparation for trial; trial before a three judge panel; and possible appeals. It would seem that a Costa Rican plaintiff would be advantaged by the government’s efforts of his behalf, but in practice the forensic department seems to be strongly biased in favor of health care providers, and, if one gets over this hurdle, these cases typically last approximately ten years. If damages are ever awarded, they are small compared to compensation in the U.S. It is not surprising, then, that, based on the limited Costa Rican data available in the literature and government reports, claiming behavior is much less frequent in Costa Rica than in the U.S. One can nevertheless speculate that Costa Rica could experience a growth in “medical malpractice” cases just as occurred in the United States. Some Costa Rican providers are moving to obtain insurance to encourage medical tourism, attorneys are becoming more conversant with this type of litigation, and Costa Rica is experiencing a continued growth in its medical system and technology.

Key Words: MEDICAL MALPRACTICE, CLAIMING BEHAVIOR, COMPARATIVE DESCRIPTION

COMPENSATION FOR DAMAGES CAUSED BY IMPROPER MEDICAL CARE PROVISION (UKRAINIAN EXPERIENCE)

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Abstract

According to the European Convention on Human Rights a person has a right to fair compensation. The European Charter of Patients' Rights, guarantees each individual a right to receive sufficient compensation within a reasonably short time whenever he or she has suffered physical or moral and psychological harm caused by a health service treatment Under Ukrainian legislation a person, who was damaged as a result of her civil right violation, has a right to have these damages recovered. When extrapolating this way of defense to the sphere of health care, one can take notice of a special legal regulation – paragraph "I" of article 6 of the Principles of Ukrainian Health Care Legislation, which guarantees the right to recovery of damages caused to one's health as an element of a right to health care. Key points: **1. Quality of medical care.** When denoting the category of "improper medical care provision" the basic definition is "quality of medical care", i.e. proper (according to standards and clinical protocols) fulfillment of all measures which are safe, reasonable, acceptable from the point of view of expenditures and are applied in this society as well as influence the mortality, morbidity and disability. Control over medical care quality is conducted by the clinic-experts commissions. **2. Recovery of moral damages and the problem of proving their amount.** Psychological examination, which apart answering other questions has to define possible amount of monetary compensation for moral damages, can serve as one of the new legal instruments of proving moral damages and their amount. This mechanism is gradually implemented into the law enforcement practice of Ukraine. 3. **Tort and contractual responsibility in the sphere of health care.** Contractual and tort responsibility is differentiated by the rule according to which if there are contractual reasons for a suit, tort claim is excluded. A decision in favor of a contractual responsibility is passed in case there is a contractual obligation between the parties. Not less is the problem when there is no conflict between tort and contractual claims. In this case a newly appeared tort obligations and contractual obligations between injured person and medical care provider, are differentiated by the criterion of the violated civil rights and their object (material or immaterial welfare).

CONFIDENTIAL MEDICAL INFORMATION PROBLEM OF THE REPUBLIC OF ARMENIA

Authors SUREN KRMOYAN [1]
Organization [1] MHRA - Ministry of Health of Republic of Armenia (ARMÊNIA)

Abstract

Key Words: Armenia, confidential medical , qualitative and quantitative

CONSENT / ASSENT IN PAEDIATRIC RESEARCH: STANDARDS AND PROCEDURES IN A GLOBAL CONTEXT

Authors ALTAVILLA A.1, HIRSCHFELD S.2, CECI A.3, GIAQUINTO C.4

Abstract

Many legal provisions were established at European and international level to encourage research in children while guarantying the protection of such a vulnerable population. According with ethical principle of the respect for persons, special attention has been paid to the "informed consent" procedures.
The International Convention of the Rights of the Child recognizes the need to give due weight to the view of the child in accordance with his/her age and maturity.
Given the lack of legal capacity of the minors, international guidelines introduced the concept of the "assent" of the child. Is there a clear definition of this concept? How has it been integrated in the legal frameworks?
Previous studies carried out by a large European Network (TEDDY Task-force in Europe for Drug Development for the Young) have shown that the European legal context is jeopardized and that, in this field, EU Member States have a large margin of discretion. Notwithstanding the implementation in Europe of the Directive 2001/20/EC, integrating GCP (Good Clinical Practices), national legislations attribute a different value to the will of the child called to take part in clinical trials. In spite of the general rule of the written authorization of the legal representative of the minor, in some countries only the assent of the child is required to be included in the trial, within specific conditions and on the basis of cut-off ages (fixed by the domestic legislation). The United States and Canada adopted different measures in this field. Since they grant both latitude and responsibility to the investigators and Institutional Review Boards, these different and sometimes contradictory provisions raise critical questions related to the respect of the will of the child. So, actions should be undertaken to find a balance between respect of the autonomy of the minor and the responsibilities related to parental and institutional protection.
GRIP (Global Research In Paediatrics) is a Network, funded under the European Research Framework Programme (FP7), aimed at implementing good research for children on a global horizon, putting together experiences gathered in Europe, North America and East Asia. GRIP is currently developing and evaluating proposals to favour harmonization in a global context.

Key Words: Consent, Assent, Pediatric

CONSIDERAÇÕES SOBRE FRAUDE EM MEDICAMENTOS E SEU TRATAMENTO JURÍDICO PENAL NO BRASIL

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Abstract

Sem a pretensão de esgotar o tema da "fraude em medicamento", nem tampouco a questão social do Brasil, o presente trabalho pretende, a partir da normatização do Direito à Saúde, examinar os aspectos jurídicos do tema no ordenamento jurídico brasileiro, visando demonstrar o tratamento por ele recebido, com o objetivo de apontar sugestões de melhorias necessárias para trazer o combate aos delitos relativos ao tempo atual. O Brasil ostenta uma reputação desfavorável perante o mundo quando o assunto é falsificação. "O primeiro registro de falsificação de medicamento no Brasil data de 1877, sendo o produto falsificado a água inglesa..." (NOGUEIRA; VECINA NETO, p. 119). A pratica de crimes que impedem, na maior parte das vezes sub-repticiamente, que o cidadão exerça seu direito à saúde, constitucionalmente assegurado, como sendo um direito fundamental, é um fenômeno que vem aumentando gradativamente com o transcorrer dos anos, sendo um desses crimes, objeto do presente trabalho denominado como fraude em medicamentos. Pode-se conceituar a fraude como sendo o uso de artifício malicioso para enganar uma pessoa e levá-la a praticar uma ação, sem o qual não a praticaria, sendo seu resultado um lucro ilícito do agente, e a violação dos direitos e garantias individuais dos cidadãos. Em se tratando de medicamentos e produtos similares, a fraude pode atingir a própria composição do medicamento, (o fármaco, geralmente em associação com adjuvantes farmacotécnicos) ou seus caracteres exteriores, tais como marca, embalagem, etc. Pode-se classificar as fraudes em medicamentos em corrupção, adulteração e alteração (SEADI, 2002, p. 66-67). A Lei n. 9.695, de 20 de agosto de 1998, tornou crime hediondo a falsificação, corrupção, adulteração ou alteração de produto destinado a fins terapêuticos ou medicinais, enquanto que a Lei n. 9.677, de 2 de julho de 1998, alterou os arts. 272 e 273 do Código Penal, adequando o tratamento dado à matéria, inserindo-a propriamente sob o título "Falsificação, corrupção, adulteração ou alteração de produto destinado a fins terapêuticos ou medicinais". Além do Código Penal, das leis supracitadas, tem-se outros diversos mecanismos que visam coibir a fraude em medicamentos, como resoluções, instruções, normativas e portarias, que serão tratadas em momento oportuno no corpo do trabalho. É fato que a fraude em medicamentos é crime contra a saúde pública, portanto, a nota característica é o perigo de dano à saúde de um número indeterminado de pessoas.

Key Words: FRAUDE EM MEDICAMENTOS, TRATAMENTO JURÍDICO PENAL, BRASIL

CREATING A GLOBAL LIBRARY OF HEALTH LAWS.

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Abstract

Part of the reason that health law is not well-developed as a discipline is that the field has done a poor job of developing shared knowledge resources. Since the demise of the WHO Digest, today there is no global library or collection of various countries' health laws. Thus it is very difficult to compare health laws between countries, which in turn makes it difficult to share best practices on legislation to improve public health, such as laws to affect the social determinants of health in accordance with the Rio Political Declaration. This lecture will expand on our recent paper in The Lancet (2011; doi:10.1016/S0140-6736(11)60069-X) in which we described a network-based model to collect and publish health laws on a global scale.

Key Words: well-developed, global library , social determinants

CULPA MÉDICA E SUA APURAÇÃO PROCESSUAL: UMA ANÁLISE DAS TEORIAS DA PROVA

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Abstract

A responsabilidade civil do médico é tema relevante na sociedade moderna, tendo-se notado considerável incremento nas demandas judiciais que versam sobre a questão. Com a crescente complexidade nas relações de saúde, a prova da culpa médica em demandas judiciais é tarefa de fundamental importância, porém sempre difícil, devido às peculiaridades ínsitas ao ramo do Direito Médico. Nesse ínterim, de interesse acadêmico é a análise das teorias que regem a produção processual da prova da culpa médica, como a teoria estática codificada, os modos de distribuição do ônus da prova, sua inversão e a teoria das cargas probatórias dinâmicas. Dentre as formas jurídicas de abrandamento dos pressupostos da responsabilidade civil, enquadra-se, ainda, a teoria da perda de uma chance, que confere especial ênfase ao resultado lesivo. A referida teoria é merecedora de destaque por acarretar um agravamento da responsabilidade civil do médico, uma vez que promove um alargamento do nexo de causalidade, com a consequente possibilidade de se condenar o médico mesmo quando o nexo causal é incerto, devendo, portanto, ser judicialmente aplicada com parcimônia. Após breve análise de todas as teorias pertinentes, procurar-se-á demonstrar que a teoria dinâmica amolda-se às tendências do processo atual, no intuito de se compartilhar o encargo probatório entre os litigantes, a fim de que se adote uma postura ativa e participante na colheita de provas, de forma bilateral e consentânea com os ditames da justiça material e da boa-fé objetiva, que traz consigo os deveres anexos de proteção, informação e, sobretudo, cooperação e cuidado entre as partes que litigam. Consentâneo e favorável à tese ora esposada é o argumento de que a solução dessa "vexata quaestio" da repartição do ônus da prova há de se radicar no conceito de colaboração das partes na produção das provas, o que vai de encontro à teoria das cargas probatórias dinâmicas.

Key Words: Culpa médica, Ônus da prova, Responsabilidade civil, Teorias da prova

Dependence of the Independent Ethical Committees in modern Russia

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Abstract

Ethical committees are a relatively new phenomenon in Russia. Such situation is typical for most of young pluralistic countries. Ethical expertise in Russia has a complicated structure: • According to its subject, the expertise can be divided into expertise of clinical trials (therapeutic and non-therapeutic ones), clinical practice and health care services management. • Considering the territorial aspect, we can distinguish the governmental level, regional level and local (hospital) level. • According to initialization – an expertise commissioned by pharmaceutical companies, health care organizations, therapeutic or research institutions, medical staff and patients or any organizations acting to their interest. • According to the forms of expertise execution – open or closed (confidential). • According to the performance methods – document analysis, case analysis, interview and observation. Each section of this structure can have its own substructure. The problem is that the standard procedures (protocols) of ethical committees are developed without taking into account the structure, so the procedures have to be revised all the time. Ethical committees are not unanimous in their estimation of the standard procedures. Therefore, we find it a matter of principle to define who created these committees, what for, how and, finally, whom their functioning particularly depends on. One can point out some social subjects that are important for the ethical committee functioning. They are: 1. Foreign companies (and, recently, domestic-owned firms) and companies marketing drugs and medical technology in Russia. 2. Russian research organizations and individual researchers who cooperate with these companies. 3. High level Ethical committees. 4. State bodies of public health services. 5. Legislative and executive authorities represented by institutions and individual officials that supervise issues of cooperation in the sphere of medicine and public health services. 6. Examinees and patients. It should be emphasized that the given sequence reflects, in the first place, the chronological order of interests concerning the existence of ethical committees in Russia; it and also highlights the real attitude towards the protection of examinees' and patients' rights. Ethical committees do not have and cannot have absolute independence from these subjects as each of them either provides orders or money to pay for the work of these committees, or can affect their activity. Hence, it is necessary to define the extent and nature of their dependence and to apply the well known "the least evil" principle to the functioning of ethical committees. But real independence of ethical committees can be provided only by the special law on them. Such law in Russia is not present and the international help in its working out is necessary.

Key Words: clinical trial, ethical committee, independence, law

DFAF HIV

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Abstract

Key Words: 指管标本, 只, 蚤

DISCIPLINARY PROCEDURE IN MEDICAL LAW: Could it ever be effective?

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Abstract

A patient who is not satisfied with the provided health care has several possibilities how to deal with this situation. Apart from filing a civil lawsuit or a crime notification, there is usually a possibility to file a complaint to the respective professional chamber. In practice, we can meet with a number of problems in the procedure of complaints handling. Among them we should especially mention the excessive length of procedures of complaints handling or opaque investigation of complaints, including, not notifying the patient of who is the person investigating the complaint or who are the expert commission members, etc. Furthermore, the patients may find themselves struggling with the impossibility getting to the punishment. In 2010 The Czech Medical Chamber obtained 988 complaints and only 2 % of them were successful. And in only half of these cases a fine was imposed. In the rest a reprimand was issued. The professional solidarity seems to be more than strong. Concerning this, the question arises whether it is reasonable to ask professional chambers to punish their members. Could it be ever effective?

Key Words:

DISCUSSION LIVING DONOR ORGAN TRANSPLANTATION. LEGAL REGULATION BETWEEN HUSBAND AND WIFE

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Organization

Abstract

The living organ transplantation between husband and wife is allowed by law, but the living organ transplant of medical practice, as a dynamic legal relationship, leads to continually the legal issues, such as the identification of relations between husband and wife, treatment organ couples, foreign marriage, and organ transplant tourism, the scope of informed consent for the persons provided and received and decisions, the interests security related of close relative of the donor. Ethical review of medical institutions has only made a written examination. To protect the donor security and the relevant interests of the close relatives, the legislature should establish the statutory standards of effectiveness compensation of human organ transplants as early as possible.

Key Words: The relations of husband and wife; Organs marriage; Similar mercenary marriage; Effectiveness compensation

Discussion on the protection of human rights of AIDS patients

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Abstract

Talking about AIDS, people often fear, avoid, also eschews. As a special group -- AIDS patients, they not only have to bear their own physical suffering, but also time to keep this secret, lest in exchange for others with strange and despised eyes. In the face of this group, the government and the society be one's unshirkable responsibility, must take seriously highly, make the life of AIDS patients for health and human rights protection. Therefore, the author through absorbing the domestic and foreign policies and the views of experts and scholars, from the pathology of AIDS, the spread of AIDS, AIDS status quo, human rights and how to protect the human rights of AIDS patients have discussed, hoping that the article to our country aids protection is some help. Key words: AIDS; human rights protection

Key Words: AIDS, human, country

DISPUTABLE PAYMENT FOR PARTICIPATION OF MINORS IN PHARMACEUTICAL CLINICAL STUDIES

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Abstract

Both, the legislation of the European Union and the Czech Republic prohibit financial incentives for a participation of minors in clinical studies. Only an interest of a child and not financial matters is then motivation for parents to let their children to participate in a research. There is only one exemption to this rule. The family can receive a financial compensation for real expenses. In the Czech Republic, we experience that a Czech families receive relatively high lump-sum "compensation" that can be in fact financial motivation. The Czech authorities refuse to deal with that problem. They even refuse to disclose information about who approved this relatively high compensations. The question is how we should calculate these compensations and where is a line between a financial incentive and compensation.

Key Words:

DUTIES AND LIABILITY OF A PHYSICIAN CONFRONTED WITH CHILD ABUSE

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Abstract

The reason for this paper is a recent Belgian case in which a physician of a university hospital examined a two-year old boy by whom she diagnosed burns on the shoulder, the arms and the back. Because the parents could not give any explanation for this, the physician suspected child abuse by (one of) the parents. After consulting a governmental office for child abuse, she informed the prosecutor who took the case before the juvenile court. This court decided to entrust the child to the hospital for 14 days. After this period the child recovered and the parents could take their child home. The parents sued the hospital for misdiagnosis and malicious/abusive reporting. This important and quite unique case will be examined on two perspectives. First of all the problem of professional secrecy must be tackled. The physician stands before a dilemma. Should he observe his duty to secrecy or should he neglect this duty and preserve the interests of the child? In some countries the physician has the right to speak when confronted with a state of emergency, but the physician can also choose to remain silent. In other countries the physician has a duty to speak and alert the police when the life or physical integrity of a person is at stake. The pros and cons will be examined. Secondly, I will analyze the possible liabilityof a physician who informs the prosecutor of a possible child abuse. The mere reporting of a possible crime does not in itself amount to negligence. But a physician is not immune for liability when reporting a possible crime to the police. Most countries make a difference between malicious and abusive reporting. In an action for malicious reporting the claimant must show that the defendant falsely and maliciously gave information about an alleged crime to a police officer. An action for abusive reporting implies no intentional element, but a frivolous conduct which no physician should ever show. In my paper I will examine several elements and circumstances which are relevant to define these actions. In this comparative research I will analyze the law of the US, the UK, France, the Netherlands, Germany and Belgium.

Key Words: Belgian, physician of a university hospital , child abuse

E-HEALTH: MODERN HEALTH CARE TECHNOLOGY AND BIOETHICS AND LEGAL ISSUES SURROUNDING IT

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Abstract

Countries around the globe are increasingly using Information and Communication Technologies (ICT) to improve individual and public health, to strengthen health care systems, in the world. This advancement could also have problems that besides the threat to public norms have endangered dignity, personal freedom and people's civil and basic rights. Hence, it is required for researchers in law and ethics field to investigate the roots of those threats and provide legal and ethical guidelines and standards to protect human rights. Today, one of these modern technologies that have raised many questions in the field of bioethics is electronic health (E-health). This term is used to describe the application of information and communication technology (ICT) in the health sector. It encompasses a couple of purposes ranging from purely administrative to the delivery of health care. For example: 1. Electronic administration of patient information systems, as part of hospital care. 2. Tele-control systems and remote vital signs as part of home care. 3. Use of computer systems for patient monitoring, medical records and electronic prescribing, as part of primary care A fundamental component of all these applications is Electronic Health Record (EHR), which allows sharing of necessary information among care professionals from different disciplines and medical institutions. There are other important uses of e-Health in the field of continuing medical education and public health education. Because health information, products, and services have the potential both to improve health and to do harm, organizations and individuals that provide health information have obligations to provide high quality content and protect users' privacy. Regarding these issues, some questions could be raised: How the activities of health care technology adapt for bioethical issues? What measures implement by the executive operators of this system to protect patients' rights? What judicial and ethical measures perform to protect the privacy of people who put their information in this cyber space? How these measures are implemented to control security of data? How the level of access to the data are defined and implemented? In this paper, we investigate ethically and legally the threatening problems of patients' rights that associate with this emerging technology and to provide some solutions in order to solve these problems.

Key Words: E-health, Bioethical issues, technology

EL DERECHO A LA PROTECCIÓN DE LA SALUD DE PACIENTES PEDIÁTRICOS CON CARDIOPATÍAS EN VENEZUELA

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Abstract

Para evaluar la eficacia del derecho a la protección de la salud de las personas, enunciado en el artículo 83 de la Constitución de la República Bolivariana de Venezuela (1999), se realizó el análisis de: 1º) un caso judicial decidido en julio de 2001 que ordenó restablecer este derecho a niños, niñas y adolescentes con cardiopatías que requerían intervenciones (cirugía cardiovascular y cardiología intervencionista) en Caracas, y 2º) la respuesta que ha dado el Estado venezolano al 2011. La concepción normativa de los textos constitucionales adoptada en los últimos procesos constituyentes de Iberoamérica ha generado un debate en torno a la eficacia jurídica de los llamados derechos sociales, y hasta su propia condición de «derechos», debido a que la fórmula lógica «A tiene derecho a X frente a B» con que se aplican los derechos en sentido tradicional en este caso presenta escollos, fundamentalmente, derivados de la justicia distributiva y de considerarlos como obligaciones de medios y no de resultados a cargo del Estado. De hecho, en 2004 se decretó la ejecución forzosa, sólo cesando la presión ante el Poder Judicial a partir de agosto de 2006, cuando el Estado inauguró el Hospital Cardiológico Infantil Latinoamericano «Dr. Gilberto Rodríguez Ochoa» (HCIL). El caso aporta elementos reales que pueden contribuir al redimensionamiento del término «derecho» en el constitucionalismo contemporáneo. MÉTODOS: Se revisó el expediente judicial y la base de datos del área de información de salud del HCIL a fin de determinar: 1º) si hubo algún mecanismo coactivo judicial eficaz e inmediato entre 2001 y 2006; y 2º) un margen de cumplimiento expresado en valores absolutos, respectivamente. RESULTADOS: 1º) No hubo ningún mecanismo coactivo judicial eficaz e inmediato, sólo remisiones a una mesa de diálogo. 2º) A nivel nacional, de un número de 141, 202, 300 y 556 intervenciones realizadas en 1998, 1999, 2000 y 2001, respectivamente, se pasó a 561 (2002), 540 (2003), 444 (2004) y 596 (2005). 3º) A partir de 2006: (i) a nivel nacional: 1005 (2006), 1595 (2007), 2092 (2008), 1787 (2009), 1684 (2010) y 1602 (2011); (ii) entre el HCIL y otros hospitales de Caracas: 509 (2006), 1166 (2007), 1392 (2008), 1369, (2009), 1588 (2010) y 1490 (2011). CONCLUSIONES: 1º) La solución estatal se debió a una ejecución voluntaria, no forzosa. 2º) Con los resultados obtenidos entre los años 2006 y 2011, puede decirse que se hizo con niveles altos de eficacia, lo que apoya la idea de que el derecho estudiado constituye una nueva categoría y cuya eficacia tiene mayor énfasis en el sentido político y sociológico, por sobre el jurídico, cobrando protagonismo la participación ciudadana en los asuntos públicos. 3º) La protección de la salud de las personas a cargo del Estado, de manera gratuita y con eficacia es posible.

Key Words: PROTECCIÓN, LA SALUD, PACIENTES PEDIÁTRICOS, CARDIOPATÍAS

EL DERECHO DE LOS PACIENTES EN MATERIA DE OBTENCIÓN DE CRÉDITOS Y SEGUROS. / PATIENTS RIGHTS REGARDING CREDIT AND INSURANCE IN FRANCE

Authors Caroline Jay [1]
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Abstract

Los organismos de crédito y las aseguradoras están habilitados para evaluar los factores que influyen el riesgo de fallecimiento o de enfermedad de un paciente con el fin de aceptar o rechazar una propuesta de préstamo o de seguro. Ahora bien, estos últimos no han sabido adaptar su práctica a la magnitud que han adquirido recientemente ciertas patologías como el cáncer. Se debe constatar que el flagelo del "cáncer" es la primera causa de fallecimiento prematuro en Francia y que la Organización Mundial de la Salud estima que la frecuencia de cánceres podría aumentar en un 50% en el mundo, con 15 millones de nuevos casos por año en 2020. Sin embargo, cualquier persona con un diagnóstico de cáncer, remitido o declarado como sanado, representa un "riesgo agravado" y no podrá satisfacer las exigencias medicales clásicas de un contrato de seguro-prestatario ordinario. Deberá suscribir contratos especiales sujetos a condiciones generalmente poco razonables. Se trata de evocar, por un lado, la desaparición silenciosa de las barreras legislativas prexistentes tendientes a limitar ciertas prácticas invasivas. La cuestión que se examina es saber hasta dónde el intermediario de la aseguradora o del banco puede evaluar la salud de su cliente con fines de discriminación legal: compartir los datos de salud, el lugar del médico experto, la realidad del secreto profesional, la utilización de test genéticos, el impacto de detecciones precoces, … Y, por otro lado, de presentar el dispositivo de reacción de urgencia del Gobierno con el Plan Cáncer y la ley n° 2007-131, del 31 de enero de 2007, relativa al acceso al crédito de las personas que posean un riesgo grave de salud. Cuando los individuos no sean capaces de regular sus acciones estando en juego intereses financieros, le corresponde al derecho arbitrar las relaciones con el fin de evitar los abusos y de no dejar a los individuos a la suerte de estas estructuras de decisión.

Key Words: PATIENTS' RIGHTS, CREDIT , INSURANCE

El marco legal del derecho de los enfermos al final de vida en Francia (comentario sobre la ley del 22 de abril de 2005)

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Abstract

El legislador francés al votar por unanimidad la ley n° 2005-370 del 22 de abril de 2005 relativa a los derechos de los enfermos y al final de la vida ha tratado de elaborar un sistema "equilibrado", traducción de un amplio consenso social. Si subsiste la tentación de despenalizar los actos llamados "eutanásicos", el legislador, por el momento ha optado por un concepto material sobre cómo hacerse cargo de las situaciones de "final de vida". Más allá de los principios que están en juego, el dispositivo legal instituye procedimientos precisos con el fin de reducir las tensiones que no dejan de aparecer. Como expresión del reconocimiento de los derechos de la persona en el "final de vida", la ley del 22 de abril de 2005 expresa una etapa importante de la cultura de los "cuidados terminales".

Key Words: enfermos al final de vida, marco legal del derecho, Francia

Embryos and Genes on Trial

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Abstract

In the presentation my aim is to show how Courts (in different jurisdictions) can deal with the cases when human body parts, tissues, organs, embryos, gametes are the subject of legal disputes. Moving away from the classical problems in reproduction, new technologies provoked the extension of personality rights in the cases when disputes around in vitro embryos, blastocytes, gametes and human tissues occur. By mapping cases that focus on the issues when embryos and gametes are disputed in the context of reproduction, research and in patent applications one can see that recent judicial cases show not only expectations to these new forms of biosocial entities but they call for new concepts and solutions within the law. Independent treatment of these fragmented biological entities have much significant repercussions in law and gender. Objectification, commercialization of the human body shows much more complex effects to the legal notion of the human body as such. On the other hand we can witness a slow "emancipation" of DNA, human tissues by granting them quasi personal rights. Today judicial interpretation often has to analyze scientific activities in a complex way and to separate scientific advances from commercial interests, to peel off the legacy of an older, paternalistic professional tradition, and to deflect eugenic and reductionist thinking. Reproductive and regenerative medicine is an especially contested field for legal interpretation. New reproductive technologies raise the question of how to determine the frontiers of the human body – and not only in physical, biomedical terms but also in time. A person's cells and tissues can be stored for a very long time after her or his death, making those almost immortal. And the multiplication of these cells and tissues make it possible to distribute these cells and tissues across many scientific laboratories and biobanks in the world at the same time. What legal model would encompass these challenges? Should we extend personality or property rights? Or should we develop an entirely new legal model?

Key Words: embryo, cells, commercialization, courts, patents

EMPATIA COMO FUNDAMENTO ÉTICO NO TRABALHO DA ENFERMAGEM

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Abstract

Empatia é a habilidade de entender o comportamento e as reações do indivíduo, compartilhar os sentimentos e transmitir essa compreensão para o paciente. O objetivo desse trabalho foi identificar as características dos profissionais de Enfermagem quanto a sua empatia na prática profissional. Estudo não experimental, exploratório e descritivo. Seguidos os preceitos éticos a coleta de dados foi realizada em dois hospitais gerais, um público e um privado, no interior do estado de São Paulo/Brasil. Os dados foram coletados pelos próprios pesquisadores, em data pré-estabelecida, nos diversos turnos de trabalho, junto a todos os profissionais da Enfermagem que concordaram com a realização do estudo através de um questionário de caracterização sócio-demográfica e do Inventário de Empatia (Falcone, 2008). Dos 295 profissionais da Enfermagem em atividades, 159 participaram do estudo. Dentre eles 124 (78,62%) eram do sexo feminino, com idade média de 39 anos. Com relação à categoria profissional 49 (31,01%) eram Enfermeiros, 31 (19,62%) Técnicos de Enfermagem e 78 (49,37%) Auxiliares de Enfermagem. Quanto à formação 155 (98%) possuem mais de uma formação em Enfermagem, com tempo médio de 14 anos de formados e de 12 anos na função. Os gráficos de associação demonstraram como menos empáticos: 1) profissionais que trabalham no período noturno em sistema de rodízio de escala; 2) que possuem idade mais avançada e 3) com maior tempo na função. Os profissionais mais empáticos foram os Enfermeiros e Técnicos de Enfermagem que trabalham em apenas um turno e no período diurno. Não houve diferenças entre sexos e instituições. Na amostra o tempo de formação e na função, assim como o turno de trabalho modificam a empatia dos profissionais. Nesse sentido, estratégias de ensino gerenciais que proporcionem o aperfeiçoamento profissional e identifiquem propostas de distribuição da equipe necessitam ser criteriosamente revistas.

Key Words: EMPATIA, ETICO, ENFERMAGEM

EMPOWERING CHILDREN IN THE MENTAL HEALTH SETTING

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Abstract

There have been many calls for the increased participation of children in personal, and other-regarding, decision-making in recognition of their autonomy, particularly in the healthcare setting. Despite domestic and international instruments to support these claims, and burgeoning evidence of children's abilities, progress on this issue in England and Wales remains slow and inconsistent. This point has particular resonance in the mental health setting. Here, it might be thought that assessing a child's capacity is superfluous given that even legally competent adults will have their wishes overruled in cases where their compulsory detention and subsequent treatment is deemed to be desirable in view of the symptoms presented by their mental illness. This paper will argue that determination of children's capacity is crucial when they suffer from a mental illness to avoid the double jeopardy of unavoidable incarceration and less than optimal engagement in decision-making once this takes place. Assumptions are often made that mentally ill children lack capacity and the many opportunities for decision-making, even in an institutional setting, may then be denied. This group of children already lead blighted lives as a result of their illness and there are strong arguments that suggest society should be obliged to maximize their autonomy as a means of ensuring they can fully realize their potential and employ their residual rights.

Key Words: EMPOWERING, CHILDREN, HEALTH

End of Life Care: Ethical & Legal Issues Involving Hydration & Nutrition - A Comparative Analysis

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Abstract

This paper will recent developments involving the clinical, ethical, and legal issues implicated by decisions to initiate or to forego artificially provided hydration and nutrition in terminally ill or severely brain injured or persistently unconscious patients. The implementation of the Federal Patient Self Determination Act and state health care provider "conscience" laws in the U.S. will be chronicled, along with developments in the aftermath of the Cruzan and Schiavo cases. The paper will encompass selected medical and legal cases from other jurisdictions outside the U.S., including Australia, Canada, Germany, Itality, South Korea, and the U.K.

Key Words: end, life care, Hydration , Nutrition

Equity, Rights and Regulation: Facing the Public/Private Health System Divide in South Africa

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Abstract

Like elsewhere, the South African health system reflects severe inequalities in the extent and quality of access to health care services. These inequalities are reflected and exacerbated by the gulf between the private (for profit) and public health sectors respectively. Achieving the right to health and associated development goals requires that this gulf be urgently addressed. This paper considers regulatory attempts to achieve greater equity between the public and private health sectors in South Africa. It considers the different ways in which constitutional norms and human rights, especially the right of access to health care services, impact on regulatory efforts at health system reform. In particular, the paper focuses on the extent to which reforms must respect existing rights of health care professionals relating to the practice of their profession, as well as the rights of patients to the continued availability and accessibility of care. Over and above the limitation of private interests in the pursuit of an equitable health system, the paper pays attention to the question of the elaboration and enforcement of private obligations under health-related constitutional rights.

Key Words: access to care, private health system, equity, regulation, private obligations

EUTHANASIA - PERSPECTIVES IN THE 21ST CENTURY

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Abstract

It is irrefutable that there has been a shift in the comprehension of euthanasia in the new millennium. From an ethical point of view, the issue of euthanasia is always complex, and a decision about it is personal, emotional, as well as complex and should be approached with sufficient consideration. From the point of view of a larger number of world religions it is unacceptable. The technological progress of medicine and its great possibilities on the one hand, but limited economic resources on the other, costs of maintenance of the terminally ill, very expensive intensive care for seriously ill newborns greatly exceed the economic capabilities of the community because of which a restriction of such economic expenditures for health care becomes necessary. On the other hand, there are also increasingly stronger personal desires for death with dignity. Since the right to life is one of the basic human rights, there is also the right to death that every person that wants it has, therefore ensuring the right to a decision on life and death for individuals or their legal representatives is one of the greatest achievements of euthanasia. However, the dilemma about the boundary between life and death remains, as well as who could, and when to, without abuse, with a clear and peaceful conscience, as well as morally, legally and professionally, determine that boundary. Conclusion: In the 21st century, euthanasia shall remain an issue that its advocates and opponents will continue to discuss for a long time. There certainly will be no global solution. However, we believe that in the time that is coming, it could gain greater significance and that the human desire for death with dignity could overcome the desire for mere existence. This could lead to a shift in the whole medical profession in the 21st century in relation to principles that guided it not only in the past century, but also from its creation.

Key Words: euthanasia, Analyze the perspectives , voluntarily decide

Exclusivity versus Access: Does Europe get the balance right in promoting modern medicines?

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Abstract

Once a new medicine is invented and this becomes known, social pressure immediately focuses upon gaining access to it. In consequence, one of the most debated issues affecting modern medicine is how society can gain access to originator medicines (new chemical-based pharmaceuticals and biologics) where the existence of these medicines so often relies upon the legal creation of periods of market exclusivity. Solving this conundrum fundamentally rests upon reconciling the exclusivity afforded to originator medicines with the introduction into the market of competitors (parallel imports, generics and biosimilars). While access to medicines has become an issue which is concerned with shifting global markets, as one of the leading producers of originator medicines it is crucial that Europe can secure foreign and domestic markets by providing early access to novel, effective and affordable medicines. To determine if Europe can achieve this aim, this assessment concentrates upon the key forms of exclusivity afforded to originator medicines: patent protection; supplementary protection; and data exclusivity, and considers their scope for regulating between the interests of originator companies and their competitors. This analysis identifies that these forms of exclusivity are intended to provide a market lead, rather than regulate market dominance, but they do not totally secure against misuse or prolongation of the market advantage inherent in leading the field. If Europe is to ensure early access to the best medicines there must be: a broader awareness of the process of innovation in assessing the impact of regulation; greater oversight of industry practices; and greater promotion of generics/biosimilars.

Key Words: Pharmaceuticals, patents, supplementary protection, data exclusivity, Europe

FEFERTILITY MARKETS - WHO PAYS THE PRICE? WHO IS RESPONSIBLE?

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Abstract

Thousands of people are traveling to another country to obtain reproductive treatment, yet the problems of operating an international market of fertility treatments, as well as the market's implications on women suppliers of reproductive services (egg donors and surrogates), have not been fully addressed. I argue that the negative implications on supplier in other countries are not treated since they happen out of the affluent state's territory, whose regulation constructs further use of the procedure. In the global market what was known as a private family sphere becomes a scene of market transactions, involving more actors in the creation of the family. I compare reproductive markets with other transnational phenomena that involve the exchange of money in order to raise a family: mail order brides and inter-country adoption. Social meaning and state regulation construct the commodified family. I show that each phenomenon has different social meanings that determine the social acceptance of market interactions within the family. An accepting social meaning makes it easier for consumers to pay for the creation of a new family. Supportive social meanings of infertile couple's misery, the "save a child" narrative regarding inter-country adoption – all further establish lack of condemnation. Regulation in affluent states affects the national shortage of means to establish families, thus contributes to transnational market of commodified families. National laws in affluent countries add restrictions on families' access to fertility treatments (or to national adoption). These services are privately paid for in a global commodified sphere, governed by global economy, where international abiding norms encourage trade according to liberal market values. Policies regarding new families in affluent countries have their implications on people external to the political-national framework and on power relations within the transaction.Globalization strengthens citizen's access to new, ex-territorial suppliers of services in poor countries, who are willing to take part in such transactions: become a mail order bride, relinquish a child or supply fertility services. Under the conditions they live in, these transactions are not always the worse way for earning money. Potential exploitation is even greater when transactions involve unbalanced relations. Domestically, affluent states would protect people who would take part in such transaction, even parties that had arrived from poor countries (e.g the mail order bride, or the adopted child).

Key Words: inter-country , Supportive social , global economy

FEMALE PEDOFILY. WHEN A ROSE HAS ONLY SPINES.

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Abstract

When we usually speak about abuse is easier to think about it as a male who acts with a deviated behaviour and on the other side there is a victim. Sometimes it can happen that the abuser is a female and tje consequences both moral and social can have a different way. This reality is harder to understand because of the role that a female has in the society: she is a woman, a mother, she gives protection, love. But what does it happen when the abuser is a woman? There are differences in the behaviour of the abuser?The authors, throught the presentation of specific cases and the experience of brilliant psycologist will try to give an explanation and a contribution to this “special” reality.

Key Words: usually speak, abuse is easier, think about

"FIRST AID" AS THE PROBLEM OF IMPLEMENTATION OF INTERNATIONAL NORMS INTO NATIONAL LEGISLATION IN "NON-STOP" REGIME

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Abstract

The article comments on the provisions of the normative regulation of first aid, enacted by a new Federal Law in 2011year "On the basis of health protection in the Russian Federation» (№ 323-FL). The introduction of an alternative form of care in the context of life saving in accidents on the one hand extends the range of persons able to provide it; on the other hand it legally confirms omissions of accident witness in situations of life-threatening conditions for the victim. Such implementation of international norms is inconsistent with Russian mental values. In our opinion it is necessary to consider separately the powers of the persons obligatory to provide first aid in connection with their professional responsibilities (security agencies, rescue workers) with all subsequent organizational aspects of learning, attestation, responsibility, etc. But raising the question of "the right to provide" first aid only to a limited circle of persons is inhumane, cynical and against Russian national values. What kind of civil society, based not only on democracy and freedom, but also empathy, compassion, mutual aid can we say, if such regulatory framework limits the ability of citizens to exercise them?

Key Words: first aid, ethical judgment, moral values, law, accidents

GENETIC MEDICAL INFORMATION: LEGAL AND ETHICAL RESPONSES (UK PERSPECTIVE)

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Abstract

It has been part of the conventional wisdom that medical treatment depends on trust. Discretion is a very important component of the doctor-patient relationship. And especially with regard to information on genetic diseases, the diagnosis may well be of relevant interest to other family members. Thus, there is a common perception that this kind of information is special on the basis that it is predictive of an individual's susceptibility to ill health. This paper will present different views on this issue. Whether the patient and/or the doctor should or must inform relevant members of the patient's family about a genetic condition is certainly a looming area of medico-legal controversy as it was pointed out by Bell and Bennett (in the article 'Genetic Secrets and the Family' (2001) 130 Medical Law Review). This paper will address confidentiality, privacy and data protection issues related to medical practice. The discussion will emphasize the ethical and legal considerations that must be balanced in order to determine whether to disclose or protect genetic information. There is little case law in the UK on the unauthorized disclosure of genetic medical information. Therefore, a critical analysis will be conducted on how the law should be applied when a legal action is brought claiming that a doctor has disclosed such information without the patient's consent (also anticipating some legal guidance).

Key Words: medical treatment , genetic diseases, diagnosis

GLOBAL SHORTAGE OF TRANSPLANTS: HISTORY, PROBLEMS, SOLUTIONS

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Abstract

Globally, in all over the world two main issues exist in transplantation. Both related with organs donation: a shortage of donor materials and high price. From websites of national organ transplant waiting lists in USA, UK and other developed countries it is seen that only one third of patients on waiting list can get transplant. Such situation favors to development of transplant tourism because people in need who cannot get donor organs are not just simply waiting. They are looking for other options how to survive, how not to die. Thus increasing organs demand creates the black market. Taking advantage of countries that have nebulous definitions of brain-death and often don't enforce organ trafficking laws, those in need of organs will often travel to places such as Israel, India, Eastern European and Asian countries to purchase organs illegally. In South Africa, those arriving for transplant tourism often receive their transplants in hospitals that are more akin to luxury hotels than transplant centers. Criminal organizations instantly have assessed the situation when human body parts became an expensive commodity. Fortunately, world community pays attention to this problem and asses negative impacts of criminalization and tries to keep control over it adopting the Declaration of Istanbul On Organ Trafficking and Transplant Tourism. The Istanbul Declaration proclaims that the poor who sell their organs are being exploited, whether by richer people within their own countries or by transplant tourists from abroad. Moreover, transplant tourists risk physical harm by unregulated and illegal transplantation. Participants in the Istanbul Summit concluded that transplant commercialism, which target the vulnerable, transplant tourism, and organ trafficking should be prohibited. And they also urged their fellow transplant professionals, individually and through their organizations, to put an end to these unethical activities and foster safe, accountable practices that meet the needs of transplant recipients while protecting donors. The countries from which transplant tourists originate, as well as those to which they travel to obtain transplants, are just beginning to address their respective responsibilities to protect their people from exploitation and to develop national self-sufficiency in organ donation. The Declaration reinforces the resolve of governments and international organizations to develop laws and guidelines to bring an end to wrongful practices. «The success of transplantation as a life-saving treatment does not require - nor justify - victimizing the world's poor as the source of organs for the rich». In the presentation picture of the current situation with the transplant in some CIS countries including the existing problems in this area and national legislation. Some possible solutions are also offered for consideration.

Key Words: Globally, transplantation, transplant centers

HEALTH CARE FRAUD, WHISTLEBLOWING AND FEDERAL SENTENCING IN THE UNITED STATES

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Abstract

Health care fraud in the United States has been estimated to cost the government as much as $850 billion annually. Schemes run the gamut from clearly illegal billing for services never rendered to mere technical violations of the Federal Antikickback Statute and Stark Self-Referral Laws. In the 1970's after enactment of the Medicare Program, the Federal False Claims Act ("FCA"), an older statute never applied in the health care arena, was resurrected in order to prosecute false claims for payment filed with the U.S. Government. Carrying a substantial bounty for so-called "whistleblowers," the FCA is now commonly utilized in healthcare fraud prosecutions. With a civil and criminal component, the FCA offers the government distinct leverage in these prosecutions, usually leading to plea agreements, consent decrees and/or corporate integrity agreements, compliance with which is mandatory to avoid program exclusion. There are also substantial civil monetary penalties, the possibility of trebled damages and forfeiture provisions, all factoring into generally financially devastating consequences for the alleged offender. While the deterrent effect is notable, these offenses continue with ever increasing creativity. In the criminal arena, use of the Federal Sentencing Guidelines provides the potential for not only significant periods of incarceration, but prolonged periods of supervised release as well. Guidelines' sentencing, while now only advisory can be complex, challenging counsel to seek departures in defending these clients This presentation will focus on the common mechanics of American Health Care Fraud, its detection, its consequences and the mechanism through which the government has gained prosecutorial leverage in addressing these very common offenses.

Key Words: Health Care Fraud, Criminal Law, Whistleblowing, Qui Tam Actions, False Claims Act

HEALTH LAW AND DISABILITY AFTER THE UN CONVENTION ON THE RIGHTS OF PERSONS WITH DISABILITIES

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Abstract

Thanks to the support of such countries as Brazil, the Convention on the Rights of Persons with Disabilities (CRPD) was adopted in 2006. In 2012, 111 countries had ratified this convention, whereas 63 countries had adopted its Protocol allowing individuals to file complaints. The CRPD no longer defines disabilities exclusively in terms of medical conditions. Instead, the CRPD acknowledges that disabilities are also social constructs and that the main obstacle people with disabilities face is not always a lack of medical care, but insufficient human rights protection. Does this mean that disability is no longer an issue for health law? This conclusion cannot be drawn from the CRPD. The right to health – the one and only human right enshrined in the Constitution of the World Health Organisation (1946) – is one of the core provisions of the CRPD. At the same time, however, the CRPD is aware of the fact that human rights violations of people with disabilities typically occur in a medical setting, that is to say while people with disabilities undergo health care or reside in a care institution. People with mental disabilities are particularly prone to human rights violations. In response, the CRPD entails a number of rights and principles meant to protect people with disabilities against health care providers, besides bestowing them with entitlements. In this paper, the rights of people with disabilities with respect to health care will be explored, in an effort to examine the new relationship between health law and disability since the adoption of the CRPD.

Key Words: mental disabilities , mental disabilities , mental disabilities

HEALTH LAW AND SCIENCE OF HEALTH LAW

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Abstract

World Association for Medical Law was established as early as 1960th in Belgium. It has not answered the question for over half a century: Is medical sciences an academic discipline? For the last 20 years since 1988 I have been exploring and studying the important and historic subject of Health Law and the Science of Health Law. In the prefaces of the two books for which I am the editor in chief I have tried to answered the important subject in depth gradually and the two books have been published six editions. I would like to put forward this subject for discussion at the 19th world Congress on Medical Law hoping that this subject will achieve some common understanding for the WAML from the discussion of the international experts and scholars. This paper explains the inner contents, features, coordinating subjects, performing, application and law procedures of the health law, its status and role in the state legal system, its relationship with other departmental laws. The science of health law studies the origin, existence, history, features, development and the future.

Key Words: health, health law, Medical Law , science of health law, building of Chinese health law

HEALTH STATUS AND HEALTH RIGHTS OF THE ROMA MINORITY

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Abstract

Internationally provisioned right to health (right to health care) presumes special attention and sensitiveness for health rights and needs of marginalized social categories. Due to its unfavorable status in the Serbian and other regional societies, the Roma minority is affected by numerous problems in enjoying health care, realizing its health status and preserving a satisfactory level of physical and mental health. Statistics and in field findings show the extent of a problematic situation in which low standards of housing, nutrition, access to health care and health documents, sanitation and health prevention and education affect the overall quality of health and life of this large minority group. The article will employ the human rights approach in assessing low standards of health status and implementation of health rights in the Roma population in Serbia.

Key Words: level of physical , mental health, minority group

HIGHER COUNCIL OF HEALTH OF TURKEY AND GYNECOLOGY AND OBSTETRICS CASES; A DEONTOLOGICAL ANALYSIS (200-2005)*

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Abstract

The aim of this study is to analyze the cases related to Obstetrics and Gynecology which were evaluated in Turkish Ministry of Health, Higher Council of Health between 2000 and 2005, from deontological point of view. Cases were analyzed after the official permission of Higher Council of Health through a documentation study performed in the archives of the Higher Council at the Turkish Health Ministry General Directorate of Health Education, between the period 11.03.2010 and 20.07.2010. The result of this study revealed that, 283 cases (24,54%) were related to Obstetrics and Gynecology among total of 1153 cases during five years period. Obstetrical requests were 211(73,6%) which was the dominant category in the events of all 283 cases. Expertise demand often comes from Criminal Courts (238 cases- 84,1%). The distribution of these expertise decisions according to health personnel type was evaluated. A detailed distribution of cases was performed according to the articles of penal code valid between 2000 and 2005. The analysis was revealed that the total of 331 physicians were accused in 256 of the cases and it was followed by the nurses (113 nurses). As a conclusion of the analysis, Obstetrics and Gynecology is determined to be the most common specialty in medicine in which juridical and disciplinary procedures were issued. The analysis resulted that, the most common deficiencies in healthcare were operative mistakes, inadequate evaluation before operation, inadequate examination and evaluation. Moreover, it is observed that a long juridical procedure is needed until the expertise demand for the case is delivered to the Council, which may create an obstacle for the motivation of seeking justice.

Key Words: Deontology, Gynecology, Higher Council of Health, Malpractice, Obstetrics

HOW TO CONDUCT A LEGAL MEDICINE CONSULTATION – A PERSONAL PERSPECTIVE

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Abstract

A legal medicine consultation may simply require review of documents to provide an expert opinion or to go further and ask the expert to both conduct a clinical consultation with the patient as well as review relevant documentation pertinent to the case. Both require critical appraisal of documents provided by one, or other, side within a given case. The consultation that includes a clinical examination of a patient implies greater responsibility for the legal medicine practitioner. Where a clinical evaluation is required, in addition to review of documents, it is a personal preference to ignore any provided documentation until after the patient has been seen, a proper history taken, physical examination undertaken and any additional investigations examined. Only then are documents reviewed, including review of questions being asked by the lawyers. Only after each of these steps has been completed can an informed, unbiased opinion be proffered.

Key Words: Legal Medicine, Consultation

IF THE CURE IS WORSE THAN THE AILMENT. MORE THAN TWO DECADES OF DEFECTIVE MEDICAL AND PHARMACEUTICAL PRODUCTS IN EUROPE.

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Abstract

The European Product Liability Directive (85/374/EEC) came into force on the first of March 1988 and has thus been in effect across the European member states for over twenty years. In it's global objective to approximate the different product liability regimes of the member states the Directive has also had a considerable impact on the pharmaceutical and medical sector. Over the course of those twenty years different important decisions by the courts of the member states as well as by the European Court of Justice, have given a broad interpretation to the key constitutive elements of the Directive. In doing so these courts have elevated the Directive to an important instrument in the protection of consumers/patients who suffer damages caused by defective medical devices/products, defective medicines and even by defective body material used in a treatment. This paper will examine the purview of the protection offered by the Directive, with particular reference to the mentioned industries. First will be discussed to what extent medical materials can be considered as a product in the definition of the Directive. Special attention will thereby be given to the jurisprudence of different member states, which classified body materials such as infected blood as a defective product. Second, attention will be drawn to the criteria that are used by the Directive as well as by the courts to determine whether or not a product is defective. Especially in a medical context the consumer expectation test and the role of inadequate warnings for possible side effects, deserve a thorough examination. Since medical materials are often used in the provision of a medical service, it is also important to establish if the Directive also applies to the use of defective products within the effectuating of these services or if they are rather to be considered an accessorium of the provided service. Once the principled liability of the producer has been established, the last question that needs answering is on which grounds he can free himself from liability. In aspiring a fair apportionment of the risks inherent in modern technological production, the Directive provides a limited number of defences. These defences will be analysed in proportion to their significance for high-technology industries. Key words: product liability, medical/pharmaceutical products

Keys: CURE, PHARMACEUTICAL, PRODUCTS

IMPLICAÇÕES JURÍDICAS DO PROCESSO DE TOMADA DE DECISÃO DE UM PACIENTE EM CUIDADOS PALIATIVOS

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Abstract

Os constantes avanços científicos tem trazido alternativas para o prolongamento de vida, fazendo tomar vulto a cultura da imortalidade, dentre outras distorções da forma de pensamento. No entanto, não consegue colocar obstáculo ao que é mais implacável a um ser vivo: a finitude da vida. Na atual sistemática, devem-se romper barreiras levando a conscientização sociedade na preparação e abordagem de questões relativas ao fim da vida, desde que valorados preceitos de respeito ao próximo, autonomia do indivíduo, dignidade e qualidade de vida. Portanto, encontrar-se em condição terminal não é quesito suficiente a distanciar o indivíduo da íntima relação com sua dignidade, para, inclusive, com base na sua autonomia de vontade direcionar e resolver sobre um eventual tratamento, por meio de tomada de decisão isenta de máculas. Destarte, especial e holística atenção deve ser dada ao paciente, que dentro das particularidades de seu quadro clínico, possa buscar alternativas terapêuticas e condutas médicas, sem que isso implique ficar, em absoluto, desguarnecido de cuidados. Com efeito, não se pode associar a tais circunstâncias entendimento açodado e sem profunda análise da magnitude do tema. Para tanto, indispensáveis são os investimentos governamentais a consumar a estrutura vigente aos cuidados paliativos, para promover reflexões bioéticas e imediato diálogo entre as Ciências da Saúde e o Direito, diante da indispensável multidisciplinariedade, eis que o principal objeto colimado nesse diálogo é atingimento da dignidade da pessoa humana, analisada de maneira integral.

Key Words: IMPLICAÇÕES JURÍDICAS, DECISÃO, PACIENTE

Informed consent in nursing in Japan

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Abstract

Background: Informed consent is “an agreement reached after provision of sufficient information”. Not only does the care provider require this agreement from the patient, but agreement should be reached only after clarification of the content of medical treatment and the exchange of opinions between medical staff and the patient. Thus, proper communication between the patient and medical staff should be the basis for such an agreement. In this regard, in team medical care, it is the nurse who is often in closest contact with the patient and who supports decision making. Therefore, it is important that the current conditions regarding informed consent in nursing is well understood and that future problems involving the protection of patient rights be clarified. Aim: To clarify the current conditions regarding informed consent in nursing in Japan. Method: A search of original papers in the Japana Centra Revuo Medicina medical documentation retrieval system was conducted for the previous 5 years (2007-2011) under the keyword “informed consent” and content analysis was performed based on the abstracts identified. Results: A total of 309 relevant articles were identified, of which 136 (44%) were related to pediatric nursing, 22 (7%) to treatment, 32 (10%) to patient/family/nurse relations, 30 (10%) to cancer nursing, and 89 (29%) to other subjects. Those articles related to pediatric nursing dealt largely with preparation, those to treatment dealt with chronic kidney failure, those with patient/family/nurse relations dealt with informed consent and those related to cancer nursing dealt largely with end-stage care. Conclusion: With regard to nursing, informed consent appears to exist in terms of the protection children’s rights through preparation, the support of the patient/family decision-making with regard to treatment and care options, and as a means of communication between the patient/family and nursing staff.

Key Words: Informed consent, nursing, Japan

Inspeção de Risco na área da Saúde: a busca de evidência das práticas assistenciais para garantir a segurança do paciente e profissional de Saúde

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Abstract

O presente trabalho tem como objetivo analisar comparativamente a evolução da metodologia de Inspeção de Risco realizada por uma empresa de consultoria de riscos formada por equipe multiprofissional (advogado, médico, dentista, farmacêutico) para suporte à subscrição de risco de clientes para uma Seguradora. Durante a Inspeção de Risco é possível determinar se a Organization de Saúde possui uma visão sobre os cuidados mínimos necessários, isto é, se o conceito "gerenciamento de risco" existe na diretriz institucional. Por este tipo de gestão ser uma metodologia relativamente nova na área da saúde, oriundo dos processos de Acreditação, percebeu-se a necessidade de ações estruturadas para redução e prevenção de eventos. Através de uma pesquisa descritiva foram coletados dados das inspeções de risco realizadas pela empresa desde 2001. O objetivo principal deste levantamento foi comparar as mudanças na metodologia de inspeção aplicada pelos auditores na busca de evidências que comprovem a qualidade da assistência prestada ao paciente, como também garantir a possibilidade de defesa em possíveis processos contra pessoa física e pessoa jurídica. As etapas constituintes da inspeção de risco envolvem primeiramente a elegibilidade da Organization; solicitação e análise de documentos legais; avaliação in loco mediante entrevista, busca de evidências documentais e observação; elaboração de relatório com informações e sugestões para o cliente, no caso a Seguradora, sobre a aceitação, aceitação com restrição ou não aceitação da Organization de Saúde como segurada. Os critérios abordados na avaliação in loco foi um dos pontos que mais sofreu alterações no progresso das atividades do setor "Gerenciamento de Risco" pertencente a empresa de consultoria de riscos estudada. Isso se deve às constantes atualizações de legislação e boas práticas nacionais e internacionais. A rotatividade de profissionais responsáveis por essa atividade no setor também foi um fato influente e positivo nas variações. Pode-se perceber, também, a importância do planejamento das técnicas de Inspeção de Risco. Tal conjunto precisa estar alinhado ao objetivo de coletar evidências sustentáveis para subsidiar, através de documentos e estrutura eficaz, o estabelecimento e seus profissionais, fornecendo-lhes a possibilidade de comprovar a boa prática profissional.

Key Words: evolução, Inspeção, Risco

INTERNATIONAL TRENDS IN DEATH INVESTIGATION

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Abstract

The investigation by the state of unexpected and unnatural deaths of its citizens is undertaken for several reasons, all of which are important – to determine whether criminal conduct has occurred, to resolve community concerns about the causes and circumstances of deaths, to make a formal record of the occurrence and relevant details of deaths, and to evaluate whether steps can be taken to reduce the potential for comparable deaths in the future. In a number of countries influenced by the English legal system coroners who conduct public hearings in relation to deaths described as inquests are the principal mechanism for investigation of deaths. However, in many countries there is a also a host of specialist death investigators – for instance, into marine, aircraft, workplace and military deaths. Coronership is an ancient institution. However, in many respects it has become outmoded and has needed to change fundamentally to satisfy modern needs in the last quarter of a century. The paper describes the major aspects of such changes in England, Canada, Australia and New Zealand, comparing the institution in those countries to that which exists in the United States and in Europe. It identifies the most recent and important changes, including its emerging accountability and in some jurisdictions its capacity to mandate responses to recommendations made by coroners. The paper reflects upon the attributes of death investigation that most effectively meet the needs of contemporary society.

Key Words: investigation, state, important

IS ALL FETICIDE NOT MURDER?

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Abstract

Should the criminal justice system protect the unborn child from intentional harm? The fetus is vulnerable and should be protected, limited by the legitimate interests of the mother's health and reproductive liberty. How can the criminal law reflect modern science and contemporary moral values? The existing criminal law born alive rule can give complete immunity to those who intentionally harm the unborn. Prosecutions depend on the fetus being born alive. The archaic rule of law is arbitrary and inconsistent. Punishment ignores the moral blameworthiness of each accused. The same crime is treated differently depending on whether the fetus lives temporarily outside or dies inside the womb. Modern science has rendered the born alive rule obsolete. There are several provisions in the Criminal Code relating to the unborn child, but none are adequate or deal consistently with this unsolved problem. The legal issues: actus reas, mens reas, and causation, need to be consistent with established principles of criminal law. The application of the Criminal Code, the state's most blunt and powerful instrument should be never be so vague and inconsistent. A prosecution or conviction can be obtained for attempted murder of a corpse. However, if a fetus is not born alive, even an attempted murder charged is barred as the fetus in law has no legal status until living outside the womb. Balancing the legitimate reproductive and health rights against crimes against the unborn can now be modernized, to do away with requiring the fetus to be born alive prior to any criminal prosecution or conviction.

Key Words: mother's health , criminal justice , criminal law

IS IT POSSIBLE TO PROMOTE DEATH AT HOME IN JAPAN?

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Abstract

In Japan there is an insurance system that applies to a nation's entire population. All people can go to hospital with small fee. And about 90% of over 65 years old people dies in hospitals. Rapid increase of old people, it becomes difficult to provide end-of-life-care to all people who want to receive it in the hospitals. And 85% of old people wants death at home. Japanese government promotes death at home or deathwatch at home. The government plan to take care of the terminal stage by their family doctors. Increasing aged people living alone and double income families, there are a few families who can take care of their old families. Family doctors' offices are mainly self-employed and it is difficult to go to take care of terminal care at their home. What is worse, a large part of family doctors becomes old in several places and it makes difficult to visit patients in their home. Even in the hospital, families' death makes emotional complaints of the family against doctors. It may happen some troubles in death at home, as it is difficult to make rapid response by their family doctors. In present situation, it is difficult to promote death at home. Also present law, medical doctors can write a death certificate within 24 hours after last examination. To avoid troubles between doctors and families, some new law should be necessary.

Key Words: Rapid increase , government, emotional

IS THE DNR (DO-NOT-RESUSCITATE) ORDER AN INTERNATIONAL DOCUMENT?

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Abstract

Introduction The Do-not resuscitate order (DNR) is one of the pillars of the principles of personal autonomy, confirmed by law since 1991 in the United States. (Patient Self-Determination Act) The DNR allows every patient to express his/her wish in anticipation of a situation when he/she will not be able to do so, particularly when refusing all cardiopulmonary resuscitation, as in the case of cardiac arrest. Due to increased tourist exchanges, it is justifiable for the French emergency doctors but also for all inernational physicains to question the value of the DNR regarding a foreign patient presenting with cardiopulmonary arrest. The objective of this study is to compare the effects of the DNR order with regard to French and American laws and to determine the applicable law. Materials and Method Analysis of French, American and European literature on the subject (legislation, jurisprudence and medical and legal literature). Resolutions of the applicable law and recommendations on the steps to take for French emergency practitioners faced with this hypothesis. Results International law and the position of European judges confirm that the DNR has no legal effectiveness on French soil. The French judge is the only one qualified to decide, and the jurisprudence on the subject of refusal of care in emergency care is strict. Under French law, the directive not to resuscitate does not exist as such and "advance directives" cannot be reconciled with the anticipated directives allowed by the French law of April 22, 2005 on patients' rights and end of life. In fact, the scope of these last directives excludes the emergency medical situation and only represents an indication for the doctor who is not responsible to follow them. In conclusion, the foreign patient carrying a DNR does not travel with their rights and the emergency practitioner would not be held responsible for the mere fact attempting to resuscitate. The principal of autonomy is thus tempered by the absolute protection of the right to life. Each country sees their legislation applied and the DNR is not an international document.

Key Words: DNR, ORDER, DOCUMENT

La naturaleza Jurídica del Embrión Humano frente a la Crioconservación

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Abstract

La condición jurídica del embrión, desafía visiones tradicionales sobre el origen de la concepción humana, en primer término, porque alrededor del mismo se encuentran y se oponen las opiniones más extremas sobre la definición y límites de la persona humana. Un factor determinante ha sido el desarrollo que la genética molecular ha tenido en estos últimos años, especialmente en la reproducción humana. ¿El embrión es un ser humano? ¿Cuando comienza la vida humana? ¿En qué etapa del desarrollo el embrión es persona? ¿El embrión posee el alma desde su concepción? ¿El embrión es objeto o sujeto de derechos? En nuestros días la concepción y la maternidad ya no dependen del azar, como así tampoco en todos los casos, se inicia en las profundidades del cuerpo femenino, sino que en varias ocasiones comienza en un laboratorio, donde genes, embriones y fetos son cuidadosamente fiscalizados por un control médico. Esto a su vez planteó un nuevo interrogante, el respeto a la vida humana en una instancia anterior al nacimiento, hasta ahora limitada a la figura del aborto, ¿es lícita la interrupción de la vida de un embrión aún no implantado en el útero femenino? ¿Es lícita la manipulación de embriones? ¿Es moralmente correcta su manipulación? La crioconservación ¿es un derecho, una obligación o una facultad de los padres? Hemos llegado al momento de poder elegir un embrión para trasplantarlo posteriormente, y esto supone un cambio cualitativo en relación a la simple fecundación “in vitro” y otras técnicas de procreación asistidas, que buscan un niño para una pareja estéril y ese niño es siempre producto del azar. No podemos desconocer los beneficios que plantea el avance científico, pero también plantea una situación de desconcierto, ya que el hombre se descubre ante un poder que anteriormente no poseía sobre la vida, y aquí surge un planteo, ¿qué es lo bueno? y ¿qué es lo malo? Pues bien, es evidente que la relevancia constitucional de las cuestiones debatidas por la bioética vendrá dada, principalmente, por su conexión con el derecho a la vida y a la integridad física y moral del embrión. En un marco contextual donde la genética humana, ha permitido intervenir no solo en la vida de las personas, sino en el propio futuro de la especie humana. Siendo la dignidad del embrión el principal objeto de discusión, en una sociedad donde las leyes cada vez son más estables, y los progresos de la ciencia aplicada más vertiginosas. Podemos coincidir, que el inicio de la vida ha dejado de ser un asunto netamente médico, para asumir connotaciones éticas, religiosas, filosóficas, y legales que tornan complejo su abordaje, y que nos proponemos revisar en la presente obra.

Key Words: jurídica, embrión, concepción humana

LEGAL ASPECTS OF MEDICAL EXPERIMENTATION ON HUMANS

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Abstract

Conducting clinical experiments, i.e., medical trials is important to the development of medicine. Such experiments on humans can be divided into four types 1) the empirical, practical, supervisory experiment; 2) the experiment as a therapeutic manipulation of the individual clinical situation for the good of the subject; 3) the experiment as a scientific manipulation of the experimental situation for the common progress of science and presumptive social benefits; 4) the experiment as a manipulation without therapeutic purposes for ideological, political, and/or military objectives. Today, in addition to the Nuremberg Code (1947), many international agreements establish social controls, based on ethical or legal norms and require a clear definition of when, how often, and with what degree of risk human subject research is permitted. These agreements include the Geneva Convention (1947) and the Additional Protocols to the Convention (1977), the Tokyo Declaration (1949), the Declaration of Helsinki (1964 and revisions), and the Venice Declaration (1983).

Key Words: Conducting clinical , development of medicine, therapeutic manipulation

LEGAL REGULATION OF COMPLEMENTARY MEDICINE

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Abstract

Complementary approaches to healthcare are becoming increasingly popular. Many add constructively to the armamentarium of therapies available for patients; moreover, today's iconoclasm can become tomorrow's orthodoxy. Such approaches are practised by mainstream practitioners and well credentialed and qualified alternative health care practitioners, but they are offered also by quacks, charlatans and hucksters. This paper reviews risks that have translated into legal action against practitioners providing dubious healthcare in a variety of countries. Many have resulted in deaths from unscientific health practices engaged in by persons who, while proclaiming themselves to be medical pioneers unfairly discriminated against by "the establishment", have misrepresented the potential efficacy of their therapies and who have profited financially thereby. In an era in which representations made on the Internet have the potential to attract the attention, trust and money of the desperate, the potential for exploitation of vulnerable patients requires fresh consideration to be given to effective means of regulating health practitioners when they misrepresent the nature and likely effectiveness of their therapies. This paper outlines the challenges and potential regulatory responses to the risks posed by those complementary therapies which are inefficacious and unscrupulous

Key Words: Complementary, becoming, therapies

Legal Regulation of the issue on legal status of the patient

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Abstract

The most important phase of legal regulation of the public health is legislation of RA directed to protection of freedoms and rights of a human and a citizen. Provision of human and civil constitutional rights and freedoms, improvement of the legislation, protection of citizens' rights allows solving not only problems related to national security but also to make steps towards integration into the global community. According to opinions of many scientists the system of the right to health is formed around a common idea – protection of patients' rights. The Constitution of the Republic of Armenia stipulates: The human being, his/her dignity and the fundamental human rights and freedoms are an ultimate value… The state shall be limited by fundamental human and civil rights as a directly applicable right. This norm of the Constitution defines the one of the most important principles – supremacy of human and civil rights. The most important legal act which defines the patients' rights is RA Law on Medical Care and Services to the Population. This document stipulates the patients' fundamental rights. The capacity of these rights can be restricted in accordance with benefits of the patient, others people and society which is stipulated by other laws. In this case it refers to special legal status of the patient, i.e. the status of a separate group of patients - adolescents, pregnant women and mothers, soldiers, prisoners who are engaged in specialized activities, patients with HIV/AIDS and tuberculosis, as well as people with disabilities. It should also be mentioned that civil rights in public health system are personal inalienable subjective rights. The rights are personal as they allow the holders to use such personal non-economic values as life, health, quality medical care. The concept of inalienable shows that the mentioned rights can not be transferred to others, and that rights can be used only by that person. In public health sphere the civil rights are formed in the framework of legal communications with the government from birth to death and used if needed. This is a concept with wide content. Patients' rights are narrower. These rights occur when the citizen seeks medical care or provides it. Some rights to health at the same time relate to both general civil subjective rights and patient's rights. Patient's rights can be divided into social rights and personal rights. Social rights are connected with social obligations, which were assumed by the Government, public and private organizations to provide medical care to the population. In this case the volume, availability and quality of the medical assistance are determined by political, social, cultural and economic indicators. Social rights are community's value. They are conditioned by the general level of development of the community.Personal rights are legal rights people have over their own bodies such as the right to personal safety, the right to privacy, etc.

Key Words: legal regulation , legislation, global community

Legal Regulations related to clinical trials and Ethical Committees in Turkey

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Abstract

The first legal regulation related to clinical trials in Turkey is the by-law entering in force in 1993. This by-law necessitated to establish ethical committees and take approval from these committees for clinical trials. This by-law brought establishment of a Central Ethical Committee and Local Ethical committees in the provinces within the body of Ministry of Health, to agenda. Members of both committees were proposed to consist of various professional and expertise groups in accordance with multidisciplinary approach. Due to rapid developments in the field of clinical trials, coming protection of right and well-being of volunteers into prominence and other different problems, incapacity of this by-law was brought to agenda and 15 years later, a more comprehensive by-law came into force. It was stated that new by-law had been prepared to comply with scientific and ethical principles at all stages of clinical trials and especially to protect rights of volunteers within the scope of standards of European Union and good clinical practices. This by-law included not only new concepts of volunteer, adverse event, adverse effect, etc but also special sections about clinical trials to be conducted on disabled people, children, and pregnant, confined and breastfeeding women as well as taking informed consent from volunteers. Furthermore, it had detailed information related to establishment and operation of ethical committees, as well. However, this by-law was abolished after a while due to a suit filed by Turkish Medical Association, which is a medical trade body, against cancellation of some articles. The last regulation in this field is a by-law published in 2011 and this by-law is a more detailed and comprehensive regulation in comparison to the previous one. This by-law divides the ethical committee into three categories according to fields of clinical research; Ethical Committee of Pharmacological Clinical Trials, Ethical Committee of Bioavailability-Bioequivalence Researches and Ethical Committee of Non-pharmacological Clinical Trials. The by-law has not turned to one year, yet; however, number of ethical committees established throughout the country is more than 60. Developments in this field have been continuing and reflections of this last amendment on the field have been followed. Any biomedical research to be conducted requires to comply with international regulations, scientific and ethical principles, to protect rights and safety of volunteers, and to contribute general health of the community. Therefore, legal regulations, that enable ethical committees to be independent from central authority and any kind of external effect in terms of both structure and operation, are required.

Key Words: clinical trials, ethical committees, legal regulations, Turkey

Legal situation regarding end-of-life care in Japan: Recent trends of euthanasia and death dignity

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Abstract

Key Words: legal situation , end-of-life care, euthanasia

LESSONS FROM RECENT PUBLIC HEALTH SCANDALS IN FRANCE: THE ROLE OF THE NATIONAL OFFICE FOR COMPENSATION FOR MEDICAL ACCIDENTS (ONIAM) AND THE ISSUE OF PHYSICIANS' LIABILITY

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Abstract

Two major crises involving health products, namely the Mediator and PIP breast implants, have recently raised concerns in France with regards to compensation for damages induced by drugs and medical devices. The Mediator (or benfluorex) scandal involves a drug marketed for overweight patients with diabetes, which was largely used off-label as an appetite suppressant despite the risk of developing pulmonary and valvular diseases. In the PIP affair, a French company in charge of manufacturing breast implants fraudulently used a cheaper unapproved silicone gel, which resulted in inflammatory reactions and increased risks of ruptures. These two cases have shed light on two interesting aspects regarding compensation: the peculiar role assigned to the National Office for Compensation for Medical Accidents (ONIAM) and the issue of physicians' liability in damages linked to health products. A specific compensation fund attached to the general ONIAM scheme has recently been created in order to ease and fasten the reparation process in the Mediator case. Because of the efficiency and convenience of such a compensation scheme for victims, the wish to create a similar system in the PIP affair has been expressed by several stakeholders. However, as it will be demonstrated, this may not be possible due to the peculiarity of the case. The PIP and Mediator affairs also raise the issue of physicians' liability. More specifically, the physicians' potential liability for off-label prescriptions is at stake in the Mediator case. The approach adopted by French courts, which proceed in such cases to a risk/benefit analysis of the off-label use, will be examined. Furthermore, physicians' failure to inform patients about risks posed by health products can constitute negligence. This ground of action might be invoked in the Mediator case since patients may not have been informed of the increased risks induced by the off-label prescription of benfluorex as an appetite suppressant. The possibility to seek surgeons' liability for failure to inform in the PIP affair will also be discussed, since it has been argued that physicians were - or should have been - aware of the increased risk of rupture of these implants before the product's withdrawal. Finally, the patients' chances to obtain reparation in these two cases will be assessed.

Key Words: involving, products, namely

LIVING ORGAN DONATION AND MINORS: A MAJOR DILEMMA

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Abstract

Organ transplantation is often considered to be the treatment of choice for organ failure. However, the demand for transplantable human organs far exceeds the supply. This well-known problem results into ever growing waiting lists. It is clear that solely relying on deceased organ donors no longer suffices. It is generally accepted that a partial solution to the organ shortage is to use living donors as a complementary source of transplantable organs. This raises inter alia the question whether minors may act as living organ donors. Although medically speaking the organs of a minor (e.g. single kidney or liver lobe) could be used to save a patient's life or at least greatly improve a patient's quality of life, it is clear that the minority status complicates matters significantly. One possible answer is to simply prohibit living organ donations by minors. Although this position provides a maximum protection for the physical integrity of minors, it completely disregards the minor's right to self-determination and the high benefits for the potential recipient in some cases. Therefore, a less strict solution is worth examining. The key question is which benefits can weigh up against the risks and how this balance can be translated into legal safeguards. Potential safeguards are: only allowing donation to siblings, not allowing donation of non-regenerative organs and/or only allowing donation by a minor when the recipient's life is in immediate danger and when there is no alternative. Special attention needs to be paid to the requirement of informed consent. In this regard, a distinction can be made between minors who are neither legally nor factually competent, and those who are not yet legally, but already factually competent to make a thoughtful decision on their own. In both cases the question remains which role the parents and other parties, such as a judge, should play in the decision-making process. These issues will be discussed, using case law and statutes from the United States, the United Kingdom, France, Belgium and the Netherlands as a starting point.

Key Words: ORGAN DONATION, MINORS, MAJOR DILEMMA

LOSS OF A CHANCE IN MEDICAL MALPRACTICE: CAN IT JUMP THE HURDLE OF CAUSALITY?

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Abstract

In medical malpractice cases, causality is often a hurdle too high to take for the claimant. This is due to the fact that there is often incertitude about the exact cause of one's injury or death. Even if a claimant can prove that without the malpractice he had a 49% chance of recovery, he does not fulfill the burden of proof and will therefore be left with no compensation at all. If he would succeed in his burden of proof, than he would receive full compensation. Since this all-or-nothing system can result in unfair and possibly unwanted situations, doctrine and case law have sought ways to lower this hurdle posed by the traditional system. One of these alternatives is found in the loss of a chance doctrine. This doctrine states that the damages should be reframed as the lost chance for a better outcome (e.g. lost chance of survival). When the claimant can prove that there is a causal link between the medical malpractice and his lost chance, he will be rewarded compensation proportional to his lost chance. Because this doctrine interferes with the traditional rules of causation, it has been and still is a much debated topic. The first part of the paper examines why some countries do accept this theory in medical malpractice cases and why others don't. A comparison will be made between the USA, the UK, the Netherlands, France and Belgium. The second part of the paper examines the boundaries of the doctrine, since the applications that can be made with the loss of a chance doctrine can be very far reaching. Recently a Belgian court accepted the liability of a physician for throwing away some tissue. This tissue would have enabled the patient to prove that he did in fact have a survival chance without the malpractice, something that could not be proven anymore now. This poses the question whether the loss of a chance doctrine can be applied to itself: is it possible to claim the loss of a chance to prove the loss of survival chances?

Key Words: LOSS, MALPRACTICE, HURDLE

MANEJO DE DATOS SANITARIOS EN CASOS DE INTERES CIENTÍFICO

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Abstract

Una sentencia dictada el 30 de septiembre de 2008 por el Tribunal Superior de Justicia de Asturias condenando a la Administración pública titular de un Hospital donde se atendió a un recién nacido afectado por el síndrome de Jacobsen con deformación facial, padeciendo además atresia nodular con páncreas anular, por no haber impedido que los médicos del servicio de pediatría donde fue atendido el menor, publicaran un comentario sobre el caso, con fotografía incluida, en una revista de información científica de la Asociación Española de Pediatría, sin el previo permiso de sus padres, abre la posibilidad de platear diversas cuestiones en relación a la difusión, en el ámbito puramente científico, y con las debidas cautelas de enmascaramiento i de anonimato, de aquellos casos y experiencias que se presentan en la vida diaria del profesional, y que pueden servir como guía o pauta para la actuación en situaciones análogas o semejantes. El Tribunal de Asturias estima que el interés científico, por muy elevado que sea, no justifica cualquier actuación. Considera que la historia clínica es un instrumento destinado, fundamentalmente, a garantizar una asistencia adecuada al paciente, y que en este caso se han utilizado los datos de la historia clínica con finalidades diferentes de las asistenciales, sin ninguna autorización, porque el artículo científico no es una actividad asistencial, y, por ello, sus Authors deben obtener la autorización del enfermo antes de proceder a su redacción y publicación. De esta forma el Tribunal estima que se ha vulnerado el derecho a la intimidad de los padres y del menor, y condena a la Administración titular del centro al pago de una indemnización de 9.000 €, por daños morales. Por ello nos preguntamos si, previamente a la redacción de un comentario científico sobre enfermedades y/o tratamientos, y a pesar de utilizar los datos sanitarios disociados de los datos personales, resulta necesario, siempre y en cada caso, pedir previa autorización al paciente para su utilización en el estudio y en la publicación del mismo. Si este consentimiento debe incorporarse con el consentimiento a la intervención médico-asistencial, o si debe gestionarse en documento a parte. Si la autorización puede (o, debe) incluir la previsión de pago de un canon o indemnización por la utilización de los datos sanitarios, su manejo y divulgación. O si el enfermo debe participar, de alguna manera, como autor de la publicación

Key Words: situaciones análogas, síndrome de Jacobsen , Asociación Española

MEDICAL CORRUPTION: THE NEW PROBLEM IN UPHOLDING MEDICAL LAW IN INDONESIA

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Abstract

Every pillar of living in Indonesia is mostly ensured to be infected the Chronic Disease of Corruption since it has been the world pandemic and endemic for this nation. Corruption have destroyed character of Indonesian people. Three department relating character building of nation is the most corrupted department that is ministry of health department, religion department and education departement. From generation to generation, this disease has been developed rapidly and improved significantly in its quantity and quality. This matter could cause a new problem in law enforcement of medical discipline as this disease has either struck the law enforcers including the investigators, lawyers, judges or even the doctors, themselves. In addition, this disease has made the law paralyzed, got it into the deep sleep, and put the law apart until commercialized it at the end. The only thought of profits by commercializing any single thing has penetrated into every brain of all living parts of the society, bureaucrats, authorities, academicians, politicians, including to professionals such as doctors and lawyers. The real impact of corruption is the law accomplishment which becomes farther from the justice value which makes the law seems to lose its soul. In the area of medicine will be equal with the area of judicial for the phenomenon of 'markus' (makelar kasus or case broker) alike, because of 'dorkus' dokter rakus or greedy doctor also may appear. As a result, the more uncontrolled medical service will significantly increase the practice of medical corruption of which characteristics are improving the wealth of themselves (doctor prefer to dangle about the bonus), misusing their authorities by doing many actions and therapies not based on the medical indications, betraying the trusts (mandate) and breaking their own oaths, generating the public loss (patient) in a form of defensive medicine and discriminated service, so that the poor are asked to go home soon and just given an customary service. The last characteristic of medical corruption is done secretly and systematically, so that it is hardy proven. Moreover, if the corruption network has involved the judge, prosecutor, lawyer, and police, it will indeed be difficult in enforcing the law especially for medical law discipline. Eventually, the medical service will be colored by medical error cases, malpractice, and negligence in which their accomplishments depend on the extraordinary treatments out of the law and prone to the bribes. Medical corruption can be a new problem which becomes a modus of general operation in any violations of ethic, discipline, and law done by paramedics. Furthermore, Medical corruption also can generate a new matter on the medical law enforcement in Indonesia if the doctors who are either the law graduates or expert of medical law become the doers of medical corruption.

Key Words: CORRUPTION, LAW , INDONESIA, MEDICAL

MEDICAL DOCUMENTATION WITH SPECIAL REFERENCE TO SISTER DOCUMENTATION

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Abstract

Abstract: Medical documentation is a collection of recorded data on patient health. Neatly guided medical documentation from a legal point of view is primarily health care professionals and health facilities that in the event of legal proceedings in which to examine the correctness of treating patients, demonstrate that the treatment complies with the rules of the profession. Medical records and patient serves the purpose of proving a causal connection between the omission in the work of health workers and damage, what is the importance of medical documentation as evidence is very important. It is the duty of keeping and maintaining medical records, as well as the patient's right of access to their medical records required by positive law Croatian Republic. However, when we mention the term "medical records", it reminds us on doctors as health care workers who produce this documentation, and more recently, in our healthcare system and introduce the concept of 'nursing documentation', which also forms part of the medical records, but this documentation created nurses. This way of keeping medical records is only a pioneer in the Croatian health care, and in practice the question of where the boundaries between medical and nursing documentation, i.e., long reach competency medical and nursing professions. The nurses identified and incorporated into a nursing diagnosis of a health care plan, as defined by general health care plan, nurses can choose the health care diagnosis. General Plan nurse runs through the collection of documents and data required for the selection of appropriate targets and quality, and proper intervention. A nurse, who plans to health care, makes it individually for each patient, choosing from a variety of factors listed options, those options are the most appropriate priority for a patient whose plan prepared in accordance with the possibilities of health facilities and its adaptation to the patient. The nurse assesses the patient's condition on a daily basis which is classified under the category of factors that describe the needs and demands of patients, depending on the degree of need for health care and seriousness of the condition of the patient. Croatian Nurses Association has identified competencies for nurses in the implementation of general health care, created a sister list, made the categorization of patients and prescribe standardized procedures in health care, and finally established nursing diagnoses, all of which are relatively new in the Croatian health care system, because all recent legislation, and nursing documentation itself the responsibility of the application by July 2012. Year, which certainly requires a special emphasis on patient care, not only doctors, but also with the sister. Key Words: medical documentation, medical records, nursing documentation, nurses, medical law, patient, health care

Key Words: medical documentation, nurses, nursing documentation, patient, health care

MEDICAL ERROR AND ITS CONSEQUENCES FOR THE RELATIONSHIP BETWEEN DOCTORS, PATIENTS AND THE PUBLIC - CURRENT SITUATION IN BOSNIA AND HERZEGOVINA.

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Abstract

Introduction: Medical errors represent an unavoidable part of the medical profession in all its areas, and they are possible to occur in spite of the best intentions that a doctor has towards a patient. Although these errors often remained unnoticed in our part of the world, there has been an increase in the number of lawsuits against doctors in Bosnia and Herzegovina in the last decade too, some of which have also had a great echo in the public. Paper objective: Review the current situation in Bosnia and Herzegovina and the relationship between doctors, patients and the public in cases in which it is believed that a medical error has been committed. Discussion: Although they were almost untouchable in the past century, in the first decade of the new millennium, with patients' ability to review and check everything that a doctor does with regard to their health, doctors in Bosnia and Herzegovina are often becoming targets of attacks, even when a medical error has not been truly committed. Exploiting the general dissatisfaction with the socio-economic situation in the country, the sensationalism-hungry media get involved very quickly, and consequently we are witnessing true persecution campaigns against doctors, while a first conviction to imprisonment was imposed this year against a female doctor, anaesthesiologist, for negligent treatment resulting in death. A large number of cases of an alleged medical error are still exaggerated, sensationalistically represented, often completely unfounded, and conducted under the influence of certain circles or persons antagonistic to doctors, so it creates a great distrust between a doctor and a patient. All this in BiH today has led to a situation where the former "heroes in white", as doctors were called during the war in BiH, have become maximally cautious and increasingly more inclined to work in a world known as "defensive medicine" in order to avoid a possible risk of lawsuits or damage claims. Conclusion: In the coming period, it can be expected that doctors in Bosnia and Herzegovina will be more and more exposed to lawsuits, as well as damage claims and increasing pressure from the media. Establishment of a system of accountability that will protect a doctor from unfounded accusations, but also protect a patient from negligent acts of certain doctors poses urgency. It is of exceptional importance to introduce a compulsory insurance of healthcare institutions and doctors from harmful events, which has not yet been implemented in an adequate manner in Bosnia and Herzegovina

Key Words: medical error, patient, the media

MEDICAL FAULT ASCERTAINMENT PRINCIPLE OF CHOICE OF LAW VALUE.

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Abstract

Medical negligence law that cannot be single use what is called a rule, consideration must be given to the interests of both patients and doctors, to consider the social characteristics and the characteristics of the times, to choose the existing that the principle of value of the times. The author thinks, medical negligence is identified to achieve both with the present social characteristics and safeguard the dignity of the law, not only maintaining patients' rights interests and does not damage the medical workers to pursue medical science and technology peak and exploration of medical unknown domain knowledge positive purpose. The article has been accepted for the medical negligence law cognizance rigidity and auxiliary principle one by one analysis, discuss its practical application in the choice of value.

Key Words: medical negligence , law cognizance , choice value

MEDICAL LIABILITY, EXPERT REPORTS IN BOGOTA, COLOMBIA

Authors Liliana Tamara Patiño [1]

Abstract

We present the statistic of expert reports in connection with the investigation of alleged medical liability made in the period between 2006 and 2010 in the Group of Clinic of Bogotá Regional, National Institute of Forensic Medicine and Science Forensic of Colombia. We show some Sociodemographic characteristics of affected individuals, who set up to demands, characteristics of health care providers, authorities, the medical specialties involved, the most common diagnoses, the characteristics of the reports and the conclusions reached. These results seek feedback to the health sector and justice from the expert reports of alleged medical liability. Cases reflect the situation not only in Bogota, but the national level, so that information is available to guide policy, programs and projects that address patient safety. When health care fails, blaming an individual does little to make the health system safer and prevent others from committing the same error still. Preventing errors and improving patient safety require a systems approach to change the conditions that contribute to errors.

Key Words: medical liability

MEDICAL RESEARCH WITH EDERLY PATIENTS: DILEMMA BETWEEN THE RIGHT TO EQUAL ACCESS TO MEDICAL TO MEDICAL RESEARCH AND THE PROTECTION OF VULNERABLE PATIENTS

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Abstract

Elderly patients, losing their capacity of discernment become vulnerable people, are protected by international recommendations for medical research: article 17 of the Helsinki declaration, guidelines 9 and 13 of the CIOMS, article 17 of the Oviedo Convention.

Medical research with elderly patients is essential for the treatment of specific diseases such as Alzheimer and cannot be performed on other patients groups. According to the *European directive 2001/20/EC regulating the clinical trials for medicinal products,* the elderly vulnerable/ incompetent patient involved in a clinical trial should have a direct benefit in participating. Without direct benefit, the patient can be involved in research for the benefit of other patients with the same medical status, when the risks are minimal. Ethics committee would not allow the research when the risks are not minimal. Such exclusion would be an obstacle to the knowledge of the disease, and can be considered as a discrimination because the patients with Alzheimer should have the same access to innovation as other patients.

Regarding the capacity to consent, clinical trials on Alzheimer's disease pose challenges as never before to research ethics. In fact, the development of the disease progressively reduces the patient's ability to make choices: the latter is no longer capable, but is not totally incapacitated.When elderly patients become unable to consent themselves, they should be protected by the law. Then the legal representative consents for the elderly patient. On the other hand, the patient must be informed in an appropriate manner of the research and can express his or her refusal. The autonomy of the incompetent patient is respected because the research cannot be conducted when the patient has expressed his or her refusal.

For patients unable to consent who do not have legal representative, some European countries especially France, allow a proxy/trustee to consent. Give consent for another person is a heavy responsibility. The person who advises or represents the patient has an obligation of caution: the incompetent subject's participation must be reasonable and fair. The dignity and private life must be protected in the decision making.

Key Words: ethics in research ,informed consent, incompetent patient, Alzheimer, autonomy

MEDICAMENTOS DE REFERÊNCIA VS GENÉRICOS: A QUESTÃO DA EXTENSÃO DA VIGÊNCIA DAS PATENTES

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Abstract

A proteção dos direitos oriundos da propriedade intelectual hoje é vista como um importante instrumento de política econômica, cujo arcabouço jurídico pode ser moldado de acordo com os interesses estatais. Sob este prisma, se pode afirmar que a propriedade intelectual não é um fim em si mesma, mas uma valiosa ferramenta apta a contribuir para o crescimento e desenvolvimentos das Nações. Todos os países devem se beneficiar do desenvolvimento econômico, social e cultural, aliado às noções de acessibilidade às inovações tecnológicas e recompensa aos seus idealizadores. Países em desenvolvimento, embora agrupados sob esta denominação, abrigam realidades bem distintas, principalmente no que concerne ao estágio de desenvolvimento tecnológico e estrutura econômico-social. No que se refere especificamente à indústria farmacêutica, uma importante questão está sendo debatida: a possibilidade de extensão das patentes, também conhecidas como pipeline. O assunto se torna de suma importância, principalmente porque muitos remédios importantes estão prestes a ter esgotado o prazo de exploração exclusiva, findo o qual a cópia estará autorizada (possibilitando a produção dos genéricos). O presente trabalho busca explorar os potenciais de fomento econômico que a proteção da propriedade intelectual pode viabilizar aos países em desenvolvimento. Na América do Norte, a indústria farmacêutica movimentou 319 bilhões de dólares em 2009, enquanto na América Latina a quantia foi de somente 48,7 bilhões de dólares no mesmo período. Também analisaremos a questão da extensão das patentes e do crescente mercado de genéricos, iniciado na década de 1960 nos EUA e que hoje, servindo de modelo a países como Brasil, atende a 60% das prescrições médicas, contando com mais de 16.000 espécies de medicamentos. É claro que os grandes laboratórios precisam ter incentivo para investir em pesquisas e oferecer ao mercado novos medicamentos, de melhor qualidade e mais eficazes. Este incentivo é obtido através da concessão de um período para exploração econômica exclusiva, a fim de recuperar o capital empreendido. Porém, não podemos perder de vista que, é dever dos Estados prover saúde aos seus cidadãos, através, dentre outras formas, do acesso a medicamentos de qualidade e custos baixos.

Key Words: MEDICAMENTOS, GENÉRICOS, PATENTES

MITOS SOBRE A GRAVIDEZ DE SUBSTITUIÇÃO

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Abstract

A medicina não pára de avançar e aumentar as possibilidades de reprodução.No Brasil a reprodução medicamente assistida (RA) é prática comum em várias clínicas especializadas. Entretanto, quando o problema da reprodução não está limitado à fertilização, mas, também à gestação, a Resolução CFM 1.957/2010, é restrita no que se refere à gravidez de substituição. Esse estudo trata, exclusivamente, do caso de casal heterossexual cuja mulher não pode gerar um filho por problemas de saúde comprovados, apesar de ter óvulos passíveis de serem fecundados por seu parceiro. Nesse cenário específico: Quando não se pode contar com um parente até o segundo grau, o que pode fazer a pessoa que deseja e, não pode, gerar seu próprio filho? No Brasil hoje não há norma em vigor e, portanto, nada pode ser feito legalmente.Entretanto, há questões que precisam ser avaliadas para se solucionar essa negligência do Estado. Uma delas é que deixe de ser vedada uma remuneração à doadora temporária de útero. Atualmente não existe Lei específica tratando do tema e a mencionada resolução do CRM proíbe qualquer forma de gratificação à gestante. Por que? Basicamente porque se teme: 1)A mercantilização do corpo; 2) A coisificação da criança; 3) A criação de uma indústria global da "barriga de aluguel"; 4) Que a gestante ao firmar o contrato, ainda não estando grávida, não tenha condição psicológica de obrigar-se a entregar o bebê que gerou porque é durante a gravidez que podem ser criados vínculos afetivos entre gestante e feto. O presente estudo trata de cada uma dessas hipóteses e pretende agregar posições que impliquem na modificação da normatização do CRM, como primeiro passo para uma legislação sobre o tema. Vale salientar que no Brasil o planejamento familiar ainda é precário e conforme revela pesquisa em fase de elaboração, coordenada pela Escola Nacional de Saúde Pública da Fiocruz só 45% das mães queriam realmente engravidar. Nesse cenário, condenar quem deseja ter seu filho a não tê-lo é aviltante. É notório que na prática muitas barrigas são "alugadas" através de contratos que não prevêem gratificação, mas estas são combinadas "por fora", o que só gera riscos e inseguranças às partes, principalmente à criança que vai nascer. Seria muito mais simples o enfrentamento dessa realidade e as inúmeras possibilidades que a medicina disponibiliza, e que a questão passasse a ser avaliada de forma prática, objetiva e segura para todos os envolvidos.

Key Words: gravidez de substituição

Mortality among homeless and unclaimed bodies in Mangalore city – an insight

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Abstract

Homelessness is a social as well as legal stigma on a Country's development index. In addition homeless people are exposed to increased incidence of diseases and accidents. Mangalore city, a bustling city located in Southern costal region of India, has seen tremendous growth in the past few years; with this the problem of migrants and homeless has also increased. This has invited a spectrum of problems relating to law and order including frequent incidences of unclaimed dead bodies, both due to natural and unnatural causes. This autopsy based study tries to highlight the situation of picture of homeless deaths in Mangalore and the problems faced by the Law enforcing authorities.

Key Words: Homelessness, Autopsy, unclaimed body

NATIONAL ETHICS COMMITTEES – CASE OF ESTABLISHMENT AND ACTIVITY ACCORDING TO SERBIAN HEALTH LAW

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Abstract

The present paper refers to legal issues concerning the work of Ethics Board of Serbia (EOS), which was founded five years ago by the law and initiated specifically by the Ministry of Health, as one of the bodies designed to deal with ethical issues in biomedicine. The Health Care Act of Serbia (2005) for the first time included several provisions about the medical decision-making at both the institutional and national level. During the past it was only possible to recognize some uncertain elements of this kind of decision making. Ethical considerations made a visible part of medical practice, but still not organized in a formal and legal sense. Ethics board of Serbia was set up by the Serbian Parliament in 2007. At the beginning of its work, the principles of medical ethics were adopted, as first ethics regulatory act in general. It had positive influence on implementation of Code of professional ethics (2007), and on regular work in the boards of lower instance. However, short analysis in this paper will aspire to research good and bad sides of its activity. Namely, the EOS is evidently a new institution without any previous practice. Observing the law and practice, it seems that there are still unclear relationships of this board considering the other boards in health institutions, or considering ethics board of the National Agency for drugs and medical devices. The competencies of the board are strict and defined by law, but the right, critical and analytic approach doesn't exist yet. It is necessary to review to which extent those legal provisions are adequate in terms of what current medical practice needs. This will be the subject of the hereby proposed paper.

Key Words: medical practice, medical practice, medical practice

NEONATOLOGY AND RISK

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Organization

Abstract

Key Words: neonatology, risk

NEW BELGIAN ACT ON COMPENSATION FOR DAMAGE RESULTING FROM MEDICAL CARE

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Abstract

A Belgian act of March 31th, 2010 introduces a new alternative compensation scheme for victims of medical accidents. This act is expected to enter into force in the second half of 2012. It allows patients suffering from abnormal and serious damage due to the provision of health care services to seek a full compensation without the need to prove negligence anymore. Furthermore, the new act provides for an advice and compensation procedure before a newly created Fund for the Medical Accidents. Its free character and brief terms may encourage patients to give preference to this alternative procedure over the judicial one. The Fund does not only compensate victims of a no‐fault medical accident, but also grants compensation for damages linked to health care triggering the liability of a caregiver a) who is not sufficiently insured, b) if the liability (for serious damages) is challenged by the caregiver or his insurance company or c) if the insurance Company of the caregiver offers compensation that the Fund finds to be manifestly insufficient. The paper explains the history of the act and its relationship to medical malpractice law. It focusses on the most fundamental legal concepts and conditions for compensation set forth by the act, like medical care, abnormal and serious damage. Finally, it analyses the procedure before the Fund for the Medical Accidents.

Key Words: Belgian, medical, Accidents

NEW PATIENT SAFETY REGULATIONS IN FINLAND

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Abstract

The ministry of Health and Social Affairs in Finland published the national strategy for patient safety in January 2009. According to the strategy, patient safety should be defined as a major objective in social and health care. Patient safety is considered as the basis for the good quality of medical care. Established medial methods should be used in such way that the treatment does not cause any unnecessary harm to the patient. The national strategy was the basis for the new legislation. In Finland the new Act on Health Care (Act 1326/2010) was implemented from May 1, 2011 onwards. This act includes specific regulations on patient safety in the article 8 of the act. All public health care institutions (hospitals and primary health care centers) are required to develop a specific plan for patient safety enhancement. The law was followed by a specific decree including detailed instructions on the minimum contents in the patient safety plan. Accordingly, the plan should describe the system, processes, resources and persons in charge for patient safety within the institution. The plan should also include the ways for co-operation with social services. The health care institutions in Finland have from 2011 onwards developed their patient safety plans. Major focus in most of the patient safety plans is to improve the reporting system for medical errors and patient safety incidents. The information on medical errors that has been gathered will form the basis for local and regional feedback that will be dealt with by the management and staff on a regular basis. The aim of the low-threshold reporting is a continuous improvement of the quality and safety of care. Therefore, information about adverse events and near misses will be used in further development of the health care activities The new legislation is likely to enhance the reporting of medical errors in the Finnish medical practice and improve the patient safety practices in the country.

Key Words: Social Affairs in Finland, January 2009., Established medial

NEW ROUTE FOR CLAIMING COMPENSATION FOR MEDICAL MALPRACTICE IN POLAND – FIRST EXPERIENCES

Authors Natalia Lojko[1]

Abstract

Based on French and Scandinavian experiences, Poland introduced extrajudicial route for claiming compensation for medical malpractice pursued in front of administrative bodies – medical claims boards.

The new procedure was established in order to deal with problems marring judicial route for claiming compensation for medical malpractice: excessive length, formality and costs of proceedings. The new law has already been subject to much critic – including the very concept of medical events, lack of proper judicial review of decisions of medical claims boards, uncertainty as to public status of the boards, lack of clarity as regards the nature – private or public – of the proceedings, limitation of the scope of the proceedings to hospital cases only.

The new law came into force 1st January 2012 and the boards – one for each region and comprising professionals with medical and legal background – have been instituted on this date.

Half year of the functioning of the boards and new law on which they are based gives a good opportunity to analyze first experiences as well the very concept of extra-judicial proceedings for claiming compensation for medical malpractice.

Key Words:

NEXT GENERATION GENETICS: IMPLICATIONS FOR THE PHYSICIAN-PATIENT RELATIONSHIP

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Abstract

The developments within the field of genetics, facilitating whole or broad DNA-analysis, are promising: they are expected to improve diagnostics, and to create new opportunities for (personalized) prevention and treatment. Whereas, presently, genetic testing in the form of a specific test (and not in the sense of a whole genome analysis) is offered to a restricted category of patients, it is most likely that in the near future a broad genetic test will be offered to the majority of patients, presenting themselves with medical complaints. This will change medical practice in a fundamental way. Eventually, every medical treatment will start with the collection of genetic information, i.e. sequencing an individual's genome an analysing it completely, or at least a large part of it (this counts also for screening and prevention). The latter has important implications for the physician-patient relationship, i.e. for the responsibilities of care givers (who are becoming partly geneticists) and for the rights of patients (who will be confronted with questions and sometimes difficult dilemma's in relation to the availibility of their genetic information, and sharing it with their family members). This paper focuses on the elementary duties of care givers – to obtain informed consent, to provide care (duty to warn), to store medical data and keep them confidential and to respect the privacy rights of patients (right on access and destruction of their data, right to know and not to know). What does the duty to inform patients imply in this new (genetic) setting? Is it the patient, or his treating physician who decides how broad the patient's genome will be analyzed, and whether he and/or his family will be informed about the results? And how should unsolicited findings which ermerge from a genetic test will be dealt with? In dealing with these and other issues, we will discuss how the physician-patient relationship could be adjusted to the new context of next generation genetics.

Key Words: generation, genetics, treatment

NÚCLEO DE APOIO TÉCNICO PARA OS TRIBUNAIS DE JUSTIÇA NA SAÚDE SUPLEMENTAR: O EQUILÍBRIO DO CONTRATO E A PROTEÇÃO AO CONSUMIDOR.

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Abstract

A Resolução 31 do Conselho Nacional de Justiça orientou os magistrados de todo país para consolidarem seus conhecimentos na área da saúde e, para se municiarem de dados que permitam decisões judiciais consistentes, bem fundamentadas, que não impactem os orçamentos públicos e, na mesma medida, as reservas atuariais das operadoras de saúde suplementar. A criação de Núcleos de Apoio Técnico (NAT) para auxiliar os magistrados em decisões judiciais cujo conteúdo seja exclusivamente de caráter médico-científico está sendo realizada em alguns estados federativos, com objetivo de racionalizar a utilização de recursos no âmbito da saúde pública. Mas há necessidade que a mesma estratégia seja utilizada no âmbito da saúde suplementar porque a judicialização da saúde nessa área já é uma realidade no país. A reflexão se desenvolve a partir do pressuposto que a saúde suplementar está fundamentada no equilíbrio dos contratos, para garantir que consumidor tenha a confiança de que os fundos atuariais organizados pelas operadoras e seguradoras estejam sempre saudáveis, em condições financeiras de suportar os custos dos procedimentos de saúde indicados pelos médicos. Mas decisões judiciais que não levem em conta a fundamentação científica ou, que se sustentem apenas no parecer médico do assistente do consumidor poderão, a médio prazo, inviabilizar as atividades de saúde suplementar no Brasil ou, torna-la acessível apenas para pequena parcela da população brasileira em vista dos altos preços que o setor praticará como decorrência dos custos excessivos e de difícil administração, porque decorrentes de acolhimento de pedidos de tutela antecipada que nem sempre permitem o exercício do contraditório em razão da alegada urgência ou emergência. Os núcleos de apoio técnico poderão fornecer dados confiáveis, obtidos por meio de análise de evidências que permitam ao magistrado subsidiar sua decisão com maior segurança e em condições de solucionar a difícil equação matemática que ocorre entre o direito do consumidor e os recursos finitos que atormentam a atividade da saúde suplementar em todo o mundo.

Key Words: Justiça, magistrados, saúde

O DIREITO À INFORMAÇÃO E O USO DO CONSENTIMENTO INFORMADO NAS RELAÇÕES MÉDICO-PACIENTE: UMA ANÁLISE DO NOVO CÓDIGO DE ÉTICA MÉDICA E DA JURISPRUDÊNCIA DO STJ

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Abstract

ABSTRACT Este estudo parte da relação médico paciente considerando-a uma relação de consumo, estabelecendo que se faz necessário caracterizar a informação como direito subjetivo do paciente, analisando de que modo pode, e deve, ocorrer a materialização deste dever pelo fornecedor, no caso o médico. Assim, busca-se demonstrar que o direito à informação constitui-se como um direito fundamental do paciente-consumidor, havendo inclusive regras deontológicas que versam sobre a matéria, para, ao final, verificar como deve ser manifestado seu consentimento para que se considere adimplida a obrigação médica informacional, segundo a doutrina brasileira e a jurisprudência do STJ. Conclui-se que o Poder Judiciário brasileiro e a doutrina aceitam como prova o Termo de Consentimento Informado - TCI e que a sua eficácia probante é relativa.

Key Words: direito à informação, código de Ética Médica, jurisprudência brasileira

O DIREITO DE CURAR EM MOÇAMBIQUE: O MÉDICO & O TINYANGA

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Abstract

Abordamos o tema das ciências médicas no contexto histórico e cultural de Moçambique, centrando-o no tópico do direito de curar e o correspondente direito a ser curado. Este direito de curar não se fundamentará em qualquer plano subjectivo, mas antes no plano objectivo da qualidade de estar apto a fornecer uma cura. O caso de Moçambique surge-nos como um bom exemplo de estudo: verificando-se uma falta gritante de infra-estruturas e de pessoal médico, no âmbito da qualificação ocidental, respondeu-se com o reconhecimento oficial do conhecimento dos tinyanga (curandeiros) através da criação do Instituto de Medicina Tradicional, instituindo planos e regulamentação próprios de forma a garantir e trabalhar a credibilidade do saber curar tradicional. Os "médicos tradicionais" ou "curandeiros" assumem uma importância cimeira tanto na prestação de cuidados de saúde como na mediação de conflitos no seio da comunidade e dos seus utentes. Sendo este um dado adquirido, e verificando-se a ausência de infra-estruturas em geral, o plano estratégico que se desenhou para um país que enfrenta graves e urgentes desafios no plano da saúde - o controlo do HIV; da malária; da tuberculose – passa por definir e construir uma aliança fundamental para veicular informação e a prestação de cuidados médicos adequados no tempo e no espaço. É o desafio e exercício da sobrevivência que se impõe. A complementaridade dos dois saberes (o ocidental e o tradicional moçambicano) surge não só como uma resposta necessária no plano logístico, mas ainda a nível de comunicação mais próxima das populações. Sendo o tinyanga um elemento de definitiva influência respeitada pelas populações, tal facto não deve passar, de forma alguma, despercebido de uma política oficial de saúde adoptada – no seu sentido legislativo e no seu sentido executivo. A importância estratégica da aliança surge fundamentada com a existência do Instituto de Medicina Tradicional – órgão integrante do Ministério da Saúde da República de Moçambique (MISAU) – que integra não só os "médicos tradicionais" como ainda conta com a integração de biólogos e químicos, prevendo também como necessário, num futuro próximo, ainda a integração de médicos e antropólogos (estes estudando e intervindo em acções ligadas à cultura e saúde). Quais as tendências no conhecimento da medicina, o que deve ser afastado ou acompanhado?

Key Words: DIREITO, CURAR, MOÇAMBIQUE

O DIREITO HUMANO À SAÚDE MENTAL: COMPREENSÃO DE PROFISSIONAIS DA ÁREA

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Abstract

O movimento de reforma psiquiátrica consolidou-se no Brasil com a Lei 10.216 de 2001, formalizando assim, um novo modelo em rede de assistência à saúde mental. Nesse contexto, esta pesquisa descritiva com abordagem de dados qualitativa apresentou como objetivo identificar como os profissionais de saúde que trabalham em um hospital psiquiátrico de um município do interior do Estado de São Paulo, Brasil, compreendem os direitos humanos elencados na Lei 10.216/2001, que dispõe sobre a proteção e os direitos das pessoas portadoras de transtornos mentais e redireciona o modelo assistencial em saúde mental. Utilizou-se para a coleta de dados de entrevista semi-estruturada e observação participante e a análise dos dados foi realizada a partir da análise de conteúdo. Foram entrevistados 33 profissionais de saúde que participam do processo de hospitalização e cuidados ao paciente, enfermeiros, auxiliares e técnicos de enfermagem, médicos, assistentes sociais, psicólogos e terapeuta ocupacional. Os resultados demonstram que os participantes não conhecem os direitos dos portadores de transtorno mentais. Conclui-se assim que não basta a existência de legislação que garanta o respeito aos portadores de transtornos mentais. O conhecimento da legislação de saúde mental pelos profissionais de saúde mental é de extrema importância para a implementação efetiva da lei, sendo necessário, portanto, promover ações de conscientização direcionadas aos profissionais de saúde sobre os direitos dos portadores de transtornos mentais, bem como sobre as mudanças no modelo de atenção trazidas pela Lei 10.216/01.

Key Words: Direito à saúde, Saúde Mental, Direitos do paciente

O INICIO DA VIDA PARA O DIREITO E AS TERAPIAS COM CÉLULAS-TRONCO

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Abstract

NESTE ESTUDO ANALISAMOS AS TEORIAS SOBRE O INÍCIO DA VIDA HUMANA, COMO A CONCEPTUALISTA, NATALISTA, DA FORMAÇÃO CEREBRAL, BEM COMO NO CÓDICO CIVIL. DEFENDENDO QUE A TERAPIA COM CÉLULAS-TRONCO UTILIZANDO EMBRIÕES CONGELADOS EM CLÍNICAS DE REPRODUÇÃO ASSISTIDA OU DE FERTILIZAÇÃO "IN VITRO" ESTÁ GARANTIDA NO PRINCÍPIO CONSTITUCIONAL DA LIBERDADE DE PESQUISA, BEM COMO NO DIREITO A SAÚDE.

Key Words: CÉLULAS-TRONCO, DIREITO, INICIO DA VIDA

O Sistema de Saúde no Brasil, entre o idealismo e a realidade: o papel do Poder Judiciário e das Operadoras de Planos Privados de Assistência à Saúde.

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Abstract

Caso um estrangeiro tivesse acesso a vigente Constituição da República Federativa do Brasil e dela destacasse os artigos correspondentes ao Direito à Saúde (Artigos 196 e seguintes), poderia perfeitamente concluir estar em um País onde TODOS têm acesso gratuito a um sistema público de saúde, sem prejuízo da atuação da iniciativa privada. Se este mesmo estrangeiro, ainda buscando em fontes oficiais, por um acaso encontrasse a Carta de Direitos e Deveres dos Usuários de Saúde (Portaria Ministério da Saúde nº. 1820) iria facilmente concluir que, no Brasil, não somente TODOS têm acesso gratuito a um sistema público de saúde, mas que este sistema público garante, efetivamente, um tratamento digno, respeitoso e de qualidade a TODOS. Há no Brasil, hoje, um grande hiato entre o idealismo constitucional e a realidade social, hiato esse que vem sendo, por um lado, preenchido pelo Poder Judiciário e, por outro, disfarçado pela transferência para o setor privado de obrigações e ônus que originalmente seriam de responsabilidade do Estado. Quanto à atuação do sistema privado, o que se vem observando é que este sistema vem sendo desnaturado pelo poder público: de um lado, os serviços de saúde privados cada vez mais são obrigados a atender pacientes que seriam da responsabilidade do sistema público e, de outro, as operadoras de planos privados de assistência a saúde cada vez mais estão sendo obrigadas a cobrir custos que originalmente seriam da responsabilidade do sistema público, inserindo-se aqui a discussão do chamado “ressarcimento ao SUS”. Esse hiato entre o idealismo constitucional e a realidade social vem ao final, onerando a sociedade como um todo e, em especial, o cidadão, seja enquanto consumidor ou usuário do sistema público. O presente estudo, em linhas bens gerais, abordará tais temas de maneira concisa e objetiva, buscando levantar e marcar a discussão mais do que esgotar inteiramente tema.

Key Words: Constituição, Direito à Saúde , Usuários de Saúde

O USO DE AGROTÓXICOS NA PRODUÇÃO DE SEMENTES TRANSGÊNICAS NO BRASIL: ASPECTOS DA (DES)REGULAÇÃO PELO ESTADO

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Abstract

O presente trabalho discute a produção e comercialização das sementes geneticamente modificadas no Brasil, especialmente da semente de soja Roundup Ready da empresa Monsanto, levando em consideração os princípios da Bioética e o poder-dever de regulação do Estado e a relação disso com o aumento da utilização de agrotóxicos no Brasil. A autora suporta seus argumentos nos estudos de Bioética e no sistema regulatório da biossegurança no Brasil, provando que as promessas originais de redução do uso de agrotóxicos que adviriam do uso das sementes geneticamente modificadas não se tornaram realidade posto que os agricultores tiveram que lidar com externalidades negativas tais como o aumento da quantidade de dinheiro gasto em royalties e na aquisição de outros herbicidas, além do Roundup, para prevenir a infestação por ervas daninhas, tais como a Buva, que se tornaram resistentes ao referido herbicida, tornando a colheita menos proveitosa e muito mais onerosa. Recente documento da ABRASCO (Associação Brasileira de Saúde Coletiva) já evidencia o Brasil como um dos maiores utilizadores de agrotóxicos em suas lavouras, o que, evidentemente, decorre do processo regulatório envolvendo a produção e comercialização de soja e outras commodities agrícolas em nosso país. O artigo pretende concluir que o processo regulatório não levou em consideração as regras básicas da Bioética, tais como os princípios da precaução e da não-maleficência, ao deixar ao encargo das grandes multinacionais de sementes (Monsanto e Bayer) fornecer os relatórios de impacto ambiental dessas novas culturas transgênicas, evidenciando falhas do processo regulatório (omissões) que poderão ensejar sérios danos à saúde dos agricultores e também dos consumidores.

Key Words: produção, comercialização, geneticamente

OBSERVATÓRIO DO JUDICIÁRIO SOB A ÓTICA DO DIREITO À SAÚDE: REPENSANDO O ACESSO À JUSTIÇA E A DIMENSÃO PROCESSUAL DESSE DIREITO FUNDAMENTAL

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Abstract

Os direitos fundamentais assegurados constitucionalmente outorgam ao indivíduo o direito a prestações estatais, fundamentando a ideia de justiciabilidade desses direitos, ora avaliados sob a égide do direito à saúde, e outorgando ao Judiciário importante papel em sua efetivação. Entendendo o acesso à justiça como garantia de efetividade dos direitos individuais e coletivos e partindo da hipótese de que tal acesso depende da ação da sociedade e do Estado, é propósito deste trabalho analisar os meios de facilitação do acesso à justiça em matéria de saúde, por meio do processo. No âmbito da dimensão individual e coletiva do direito à saúde, observa-se que os Tribunais têm adquirido crescente visibilidade social: não são a única via para a efetivação de interesses legítimos; contudo, a sociedade os enxerga como titulares da obrigação de colaborar com o restante do Estado na formulação de políticas públicas, promovendo, em conjunto com o Executivo, a inclusão social. Devido à necessidade de se observar a reformulação do sistema de justiça após a explosão de litigiosidade observada com a democratização do país, realizar-se-á um diagnóstico da prestação jurisdicional no tema da saúde, por meio da análise do que se denominará "âmbito processual de proteção do direito à saúde". Nesse contexto, o Judiciário apresenta-se como o ponto de comunicação entre Estado e sociedade, sendo relevante analisar a forma como tem se dado esse contato. Para estes fins, foram analisadas decisões judiciais em matéria de saúde proferidas no âmbito de Tribunais regionais e superiores, realizando-se um diagnóstico da prestação jurisdicional em saúde, com foco na questão ligada ao fornecimento de medicamentos e tratamentos de alto custo pelo Estado. Dessa forma, foi possível verificar causas de não efetividade da jurisdição em matéria de saúde, explicitadas, sobretudo, no conhecido problema da morosidade da prestação jurisdicional, ressaltado pela inadequação entre o longo tempo processual e o tempo social, o que demanda mecanismos de reforma que visem a duração razoável do processo. O Judiciário é um dos mecanismos sociais para a criação de vínculos com a sociedade e com o futuro. Contudo, não se mostra devidamente preparado para operar seu papel de inclusão social, o que acarreta inefetividade parcial da jurisdição e crise de descrédito na justiça. Os Tribunais, como organização do sistema jurídico e político, não apenas decidem demandas; devem também estar equipados para operar sua gestão em prol da inclusão social e do acesso à justiça. Um modelo gestionário de administração da justiça que permita desburocratizar procedimentos, bem como conciliar celeridade com segurança jurídica, é uma das soluções preconizadas para aparelhar o Judiciário com vistas a enfrentar os desafios do presente século.

Key Words: Acesso à justiça, Acesso ao tratamento, Direitos fundamentais, Observatório do Judiciário

ON THE REASONABLE CONTROL OF THE SURROGATE BEHAVIOR AND USE OF LEGAL REGULATION

Authors Wang Ping[1]

Abstract

Artificial reproductive technology as a modern medical means, in terms of treatment of infertility show a strong function of its unique Energy. However, the implementation of surrogate technology will inevitably lead to a surrogate contract, identified as the surrogate parenting, surrogacy and surrogate privacy right and a series of legal problems, will inevitably impact on the traditional legal systems and challenges. Surrogacy contracts should be improved as soon as possible, family status determined, the relevant legislation on protection of rights.

Key Words: Surrogate behavior; Surrogate contract; Parent-child identity

OS AVANÇOS RECENTES NA LEGISLAÇÃO DO SISTEMA ÚNICO DE SAÚDE BRASILEIRO (SUS) E AS PERSPECTIVAS DE MINIMIZAR A JUDICIALIZAÇÃO NA INCORPORAÇÃO DE TECNOLOGIAS EM SAÚDE.

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Abstract

Com a entrada em vigor, em outubro de 2011, da Lei nº 12.401/2011, foram incorporadas alterações na Lei nº 8.080/1990 (a Lei do SUS), sendo uma das mais relevantes a criação da Comissão Nacional de Incorporação de Tecnologias no SUS - CONITEC, destinada a assessorar o Ministério da Saúde na incorporação, exclusão ou alteração de novos medicamentos, produtos e procedimentos, bem como na constituição ou na alteração de protocolo clínico ou de diretriz terapêutica, atividade até então exercida pela Comissão de Incorporação de Tecnologias do Ministério da Saúde - CITEC. A referida Lei também conferiu à Comissão importantes requisitos relativos à celeridade processual, transparência e participação social, destacando-se: (i) o estabelecimento do prazo de 180 dias para decidir sobre as solicitações, prorrogável, caso necessário, por mais 90 dias; (ii) a realização de consulta pública e, quando relevante, audiência pública antes da decisão; e (iii) a necessária participação de representantes do Conselho Nacional de Saúde - CNS e do Conselho Federal de Medicina - CFM. Entretanto, a própria Lei nº 12.401/2011 sinalizou que não é todo medicamento ou tecnologia em saúde que pode ser incorporado, ao estabelecer requisitos técnicos que devem ser observados pela CONITEC: (i) as evidências científicas de eficácia, acurácia, efetividade e segurança do medicamento, produto ou procedimento objeto do processo; e (ii) a avaliação econômica comparativa dos benefícios e dos custos em relação às tecnologias já incorporadas. Além disso, o inciso II do art. 19-T veda expressamente a dispensação, o pagamento, o ressarcimento ou o reembolso de medicamento e produto, nacional ou importado, sem registro na Agência Nacional de Vigilância Sanitária - ANVISA. No Decreto nº 7.646/2011 o Poder Executivo regulamentou os arts. 19-Q e 19-R da Lei do SUS avançando ainda mais na busca da efetivação da política pública de saúde ao estabelecer que, havendo a decisão favorável sobre determinada solicitação, o Ministério da Saúde deve efetivar a disponibilização pelo SUS no prazo máximo de 180 dias a contar da decisão. Este trabalho analisa sob quais aspectos essas mudanças legais podem contribuir para a redução da judicialização da incorporação de tecnologias em saúde, que tanto afeta a gestão do SUS, na medida em que aperfeiçoa os principais aspectos questionados atualmente, quais sejam, as barreiras de acesso às tecnologias de saúde, a morosidade na incorporação, a falta de transparência, a baixa participação social e a falta de efetividade das política públicas.

Key Words: Comissão, Ministério da Saúde , Conselho Federal de Medicina

OS DIREITOS HUMANOS DOS PORTADORES DE TRANSTORNOS MENTAIS NAS AMÉRICAS

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Abstract

Atualmente, estima-se que os transtornos mentais correspondem a 12% da carga global de doenças. Dessa forma, uma em cada quatro pessoas possui um tipo de transtorno mental, o que representa uma proporção elevada de anos de vida com qualidade perdidos em função de deficiência ou transtorno. Ressalta-se, também, que além do sofrimento vivido pelos portadores de transtornos mentais em razão do transtorno, existe um ônus oculto de estigma e discriminação, gerando violações aos seus direitos humanos e liberdades básicas. Nesse contexto, esta reflexão teórica descreve os instrumentos de proteção aos direitos humanos dos portadores de transtornos mentais na região das Américas. Destaca-se, inicialmente, o Protocolo Adicional à Convenção Americana de Direitos Humanos, concernente aos direitos sociais, econômicos ou culturais (Protocolo de San Salvador) de 1988 que se referiu especificamente às pessoas com deficiências. De acordo com o Protocolo, os países signatários concordaram em empreender programas voltados a fornecer às pessoas com deficiências os recursos e o ambiente necessário para alcançar o mais alto desenvolvimento possível de suas personalidades, bem como treinamento especial aos familiares. Posteriormente, a Convenção Interamericana sobre a Eliminação de todas as Formas de Discriminação contra Pessoas com Deficiência de 1999 estabeleceu como objetivos prevenir e eliminar todas as formas de discriminação contra pessoas com deficiências mentais ou físicas e promover sua plena integração à sociedade. Foi a primeira convenção internacional a tratar dos direitos de pessoas com transtornos mentais. Ainda, em 2001, a Comissão Interamericana de Direitos Humanos emitiu Recomendação sobre a Promoção e Proteção dos Direitos Humanos de Pessoas com Deficiências Mentais, solicitando que os países ratificassem essa Convenção, promovessem e implementassem, mediante legislação e planos nacionais de saúde mental, a organização de serviços comunitários de saúde mental, a fim de obter a plena integração de pessoas com transtornos mentais à sociedade. Quanto às resoluções e declarações não compulsórias, é relevante salientar a Declaração de Caracas de 1990, aprovada por diferentes instâncias da sociedade civil em reunião da Organização Pan-Americana da Saúde. A Declaração dispunha sobre a necessidade de respeito aos direitos humanos dos portadores de transtornos mentais sugerindo possibilidades de tratamento extra-hospitalar. Constata-se, então, que os instrumentos internacionais detalhados neste estudo representaram um marco para a consolidação dos direitos dos portadores dos transtornos mentais na região das Américas, facilitando reformas nos sistemas nacionais de saúde mental dos países da região, visando a desinstitucionalização destes pacientes e o resgate de sua cidadania.

Key Words: DIREITOS HUMANOS, PORTADORES, TRANSTORNOS

Pain relief as patient right – looking for balance in Ukraine

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Abstract

Pain relief is serious problem in Ukraine. Dignity of person is a base of International documents of human rights, of Constitution of Ukraine. Ukrainian patients (not only palliative patients) can't receive enough pain relief medication. Such situation is result of number of rules that has Ukrainian legislation. Police has very strong power to control doctor's activity and physicians afraid of possible criminal investigations. They don't want to take risk and they prescribe pain relief medication rarely. The same argument is basic for most drugstores. Private drugstores don't want have deal with police, because legislation of licensing are very complicated and not clear. State's drugstores are mostly closed on all territory of Ukraine. Ministry of health didn't put none standards about pain management. Mostly in Ukraine used injected medicine Morphine that has dose limitation (50 ml - recommended by producer). Patients using it at home can't take bigger dose. Patients at hospital receive enough pain relief but places are limited. Nowadays situation with patients rights are between state drug policy and human right for dignity and for pain relief. First of all we need to remove regulatory barriers that prevent patients from receiving pain medication. However authority in Ukraine has opposite position. State's basic argument is that if they give to everyone pain relief, they will receive increasing criminal drug market. There can be proposed three levels of possible strategic of solving this problem - organizational, educational and medical. On organizational level are recommended to force Ministry of health of Ukraine to open drug stores in each regional district of Ukraine, make more modern conditions of storing medicines at healthcare facilities. On educational level - each physician need to know basic information about pain-management and human rights. On medical level in Ukraine we need to create pain treatment guidelines, provide registration of different forms of pain relief medicines, first of all oral morphine.

Key Words: Pain Relief, Ukraine , Patient Right

PARA UMA RESPONSABILIDADE MÉDICA MAIS EFICAZ E MAIS FAVORÁVEL À REDUÇÃO DO ERRO MÉDICO

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Abstract

O sistema tradicional da responsabilidade médica, assente no princípio da culpa, não parece estar a cumprir os seus objetivos: não contribui eficazmente para o controlo deontológico dos profissionais, não repara os danos daqueles que são vítimas de má-prática e não pune as violações dos bens jurídicos. Com efeito, a responsabilidade civil mais se assemelha a uma "lotaria". O aumento da conflitualidade e médico tribunal pode ter o resultado inverso do que se poderia imaginar: em vez de melhores resultados, a intensificação do sistema traria mais conflitualidade nos tribunais, menos confiança na relação entre os médicos e os doentes, mais "medicina defensiva"; traria, ainda, a falência dos sistemas modernos de redução do erro médico e dos riscos próprios dos sistemas complexos. Assim, tem-se questionado: a responsabilidade civil deverá abandonar o modelo tradicional baseado na procura de um agente culpado? A moderna teoria das organizações tem mostrado que muitos comportamentos individuais são induzidos pelo sistema em que se integram e que a procura e castigo judicial do culpado tende a fazer esquecer as melhorias de que a organização carece; o castigo judicial do culpado não ajuda à redução dos erros médicos. Iremos discutir se a responsabilidade civil devia iniciar uma transformação no sentido da responsabilidade sem culpa – um movimento que já foi iniciado em vários países (França, Bélgica, Polónia, Países Escandinavos e Nova Zelândia)?

Key Words: sistema, médica, deontológico

PATENTS ON INVENTIONS RELATED TO EMBRYONIC STEM CELLS: THE ORDRE PUBLIC AND MORALITY EXCLUSION IN BRÜSTLE VS. GREENPEACE.

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Abstract

This paper examines the morality exclusion in prohibiting patents on inventions concerning embryonic stem cells. It focuses on the recent decision of November 18, 2011 by the European Court of Justice on the patenting of stem cells, i.e. Brüstle vs. Greenpeace. Three questions on the application of art. 6, par. 2, sub c of the Biotechnology directive were referred to the Court for a preliminary ruling. This provision contains one of the reasons why an invention is not patentable based on the fact that human embryos for industrial or commercial purposes were used. In answering these questions, the Court for the first time had to define the term "embryo" in patent law. Subsequently it interpreted "industrial or commercial purposes". Finally, the court gave its opinion on the meaning of "use" of an embryo. Still, many uncertainties remain, which are analyzed thoroughly in this paper and are followed by some recommendations. Brüstle vs. Greenpeace is considered a landmark case because it defines for the first time the term "embryo". It is also unique in that it is the Court of Justice and not the European Patent Office that ruled on patents and on the concept of ordre public and morality in patent law. Bearing in mind that a similar morality exclusion does not exist in the US, a comparative analysis with US policy on patents related to embryonic stem cells is carried out. The need for a morality provision in patent law is therefore discussed. Finally, the paper looks into the situation after this important decision. The consequences of this case on the current and future embryonic stem cell research and patents in Europe and outside Europe are explored.

Key Words: Biotechnology, human, Greenpeace

Patient mobility in the EU: Recent developments

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Abstract

Last year, European Parliament approved a new directive on patient's rights to cross- border healthcare as proposed by the European Commission. It followed a series of rulings made by the European Court of Justice beginning in 1998, which entitled patients to obtain healthcare in any other EU Member State and to have these healthcare costs reimbursed by their own health systems in their home country. This presentation will explore the past, present and future of cross-border health care in the EU by analyzing the content of the Directive and explaining the current practise and future challenges on patient mobility in the EU.

Key Words: Andre den Exter, Erasmus University Rott, European Parliament approved, patient's rights

PATIENTS RIGHTS IN THE GAP BETWEEN EUTHANASIA AND DISTHANASIA

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Abstract

The paper discusses the historical, legal and bioethical aspects on the issue of euthanasia, as a method for relief and reduction in suffering of incurable patients, the question of disthanasia as excessive prolonging of suffering, agony and delay of death, of ortothanasia, as a dignified death without a shortening of life, but without additional suffering. It also deals with a patient's right to refuse certain medical procedures according to Croatian law and international agreements that are ratified and came into force in Croatia, with a critical review on the Croatian Law on Protection of the rights of patients. The paper also discusses euthanasia in Croatian Penal law and the question of admissibility of passive euthanasia under Croatian law.

Key Words: patient's, euthanasia, disthanasia

PHARMACEUTICAL LAW IN THE E.U. – THE STATE OF PLAY

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Abstract

In spite of only minor competence of the EU as regards healthcare as pronounced in Articles 6 and 168 of the Treaty on the Functioning of the European Union, much of the pharmaceutical law has been harmonized on EU level, based on provisions enabling "*approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market*" (Article 114 of the Treaty).

Harmonization has been achieved in almost all phases of the life cycle of a medicinal product - starting from a clinical trial, through manufacture, authorization for marketing, data exclusivity, advertising, wholesale distribution, inspections to principles of pricing and reimbursement. However, Member States still diverge in the manner pharmaceutical legislation has been implemented.

The lecture will describe both the current state of affairs as regards pharmaceutical legislation in Europe as well as most recent developments - proposed directives, recent rulings of the Court of Justice and early political initiatives. It will also address a question as to how much harmonization would be optimal and whether market based approach is proper in the harmonization of healthcare.

Key Words:

Physician-patient Communication in Four Dimensions

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Abstract

In China, ineffective communication between physician and patients has been the main factor resulting in physician-patient disputes. Physician-patient communication should be improved from four dimensions which are taking the humanistic spirit as the soul, the rights as standard, the systems as guarantee, and emphasizing the skill and art of communication. Take the humanistic spirit as soul. The core of humanistic spirit is human-orient—concerning people, caring people and serving people, which emphasizes respecting human beings' rights and individuality and defending personal dignity. Even though a person is sick, his or her rights and dignity should not be disparaged. On the contrary, because they are patients, they should be treated with special protect and care. Only when this compassion is imprinted in the hearts of the medical personnel and integrated into their blood, can the implementation of legal systems be supported by inner power, can mutual emotion exist between physicians and patients, and can the gate of physician-patient communication really open. Take right as standard. The right and respect between physicians and patients are mutual. Both physicians and patients should take the other party as the entity of right and the other party's rights as standard, ensuring the realization of the other's rights by fulfilling their own obligation. Surely, taking the highly professional medical technology into account, the medical party should shoulder more communication obligation. Take legal system as guarantee. Effective communication between physicians and patients should be guaranteed by legal systems, while communication according to the laws is a necessary part of practice of medicine in conformity with laws which includes the form, the content and the responsibility of communication. In deed, the realization of humanistic spirit in medicine, as mentioned above, and the right and obligation of both physicians and patients cannot be separated with the guarantee of legal systems. Emphasize the skill and art of communication. To maximize the effect of communication, the physicians and the patients should cooperate on building a communication platform of equality, humanism, mutual respect, mutual trust and mutual understanding. On this basis, the physicians should honestly listen, carefully observe, patiently introduce, based on different individual and illness, and reasonably take use of language, psychology, emotion, environment and other factors to realize standardization and individuation of communication. As a skill and art, communication can be acquired by means such as learning, training and observing. In addition, good physician-patient communication is in need of cooperation and support from other social factors and social systems.

Key Words: China, physician-patient , patients

PRIVATE FINANCING OF HEALTHCARE SERVICES IN POLAND

Authors Natalia Lojko[1]

Abstract

Historically, Polish patients had an unlimited right to healthcare services financed from public funds. There was no list of healthcare services covered by public insurance system nor a common standard for such services. Lack of 'public healthcare services basket' resulted from the lack of political will to take potentially unpopular decisions as to which services should – and which should not – be provided under public healthcare insurance. The Constitutional Tribunal assessed this state of affairs unconstitutional – i.e. going against the right to health and the very nature of insurance. Following the ruling, a positive list of healthcare services financed from public funds was established.

The precise contents of healthcare basket is still, however, unclear, as it is determined not only by the Minister of Health, but also through specific contracts between public healthcare insurer (National Health Fund) and hospitals. Thus, in practice, the precise scope of a healthcare basket must be construed *vis-a-vis* individual patients, taking account of their specific medical conditions.

Linked with the problem of precise determination of the 'basket' of public healthcare services is the problem of co-financing of healthcare services by patients. It is generally accepted that double payment (by patients and by public insurer) should be avoided. Where there are no clear limits of what is included in the 'basket', co-payment is hard to implement. Additionally, in Poland, it remains contentious whether patients may pay for healthcare services provided by public hospitals and not included in such specific public insurance basket. In the past, the courts used to prohibit such payments invoking constitutional right to equal access to healthcare services financed from public funds – and claiming that allowing private payments would go against this right. This however means that the most technologically advanced treatments to which patients would not be entitled under public insurance or which they would not be able to receive (e.g. because of their medical condition, excessive waiting time etc.) would not be available at all.

During the lecture I will examine problems concerning public insurance system in Poland – but typical for many Central and Eastern European countries. I will first address problems resulting from the lack of specific list of healthcare services financed from public funds, including – in the light of the case law of the European Court of Justice. Second, I will analyze the implications of the prohibition to accept private payments in public hospitals – for specific patients and for healthcare system in general.

Key Words:

Private health plans and the right to health

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Abstract

The Federal Constitution brilliantly added better benefits in the area of human dignity by bringing, in addition to its insurance, the promotion of means in order for this and the remaining fundamental human rights could be respected as a result of the State enforcing them in a coercive manner. Such idea is confirmed throughout its articles by making explicit reference to health as a fundamental part of the public interest and as a principle/warranty to benefit the citizen. The social order treated by the Federal Constitution is thus subdivided into norms, including in health care (beyond Social Security and Social Assistance), which are subordinate to the democratic character and the decentralization of the administrative management and to the principles of personal dignity and respect. The flexibilization of the universalist system occurs, therefore, due to the high cost of maintaining the public health system, making it possible for the private sector to become organized under the basic forms of insurance and pre-paid medicine and its derivations. The uncertainty and the precariousness of the public health services led citizens to join a model of service providing in which health plans act as "middlemen", intervening in the physician/patient relationship and being responsible for transferring the honoraria to the professionals provided the user pays a monthly fee to the health care provider. In this way, the participation of the private sector in health care was constitutionally guaranteed, in the terms of article 199: "… which delegates to private institutions the possibility of health care", thus being legally considered as a legal entity of private rights and providers (article 3rd – CDC) which are subject to the supervision by the CDC according to the Law 9656/98. In a free-market framework, health care providers exert constant interference in the physician-patient relationship in an attempt to limit the number of requested exams and procedures, such that the State confers health care providers the "administration" of the health of the population, whereas the professional shares its costs with the patient. The following question is therefore in order: how is it possible to guarantee health given such interference, with its implications on the fundamental right to the dignity of the human being by the professional physicians? The new determination of the ANS, through its normative summary number 16, seeks to increase the rigor in the fight against interference and flagrant embarrassment imposed on health professionals, seeking the effectiveness to the right to health by the citizen. Stimulating the demand for quality services reveals its fundamental importance in contrast to a State that is still lethargic despite possessing sufficient legal tools to ensure fundamental rights to its citizens.

Key Words: Private health plans, right to health, RIGHTS

PRONTUÁRIO ELETRÔNICO, UM AVANÇO OU UMA INVASÃO A PRIVACIDADE DO PACIENTE

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Abstract

No contexto deste trabalho, abordaremos um assunto que esta despertando a atenção da comunidade médica e jurídica, chamado Prontuário Eletrônico. Até bem pouco tempo, as pessoas se quer imaginavam a junção destas duas palavras, e muito menos sabiam explicar o seu significado; mas devido ao excesso de informações e necessidade de resguardo jurídico para médicos, hospitais, atores da área da saúde e até do próprio paciente, viu-se a necessidade de adequação, precisando adentrar em um mundo quase que abstrato, deste tema tão novo em nosso país. A importância do prontuário eletrônico e suas implicações éticas legais estão especificadas nas resoluções do Conselho Federal de Medicina :Resolução CFM nº 1.638/2002, Resolução 1639/2002 e da Resolução CFM nº1.821/2007, sendo disposições que abordam o tema e suas definições. Saindo do âmbito destas resoluções, pouco consenso e informações existem sobre a informatização dos prontuários e o registro eletrônico em saúde. Sendo assim, abordaremos temas como o dever de execução, o dever de guarda e o dever de confidencialidade, que muitas vezes não estão totalmente claros, tanto para juristas, quanto para os médicos, que tendem a centrar-se no atendimento do paciente e no contexto que gira ao redor deste binômio relacionado à saúde-doença, deixando sem muitas informações o seu principal resguardo, o prontuário do paciente. Que nos dias de hoje é um dos grandes aliados, na relação médico-paciente, que passou da tradicional figura central do profissional da área da saúde, para o paciente e seus direitos. Por fim, falaremos da instalação do prontuário eletrônico no projeto SAÚDE FOZ, no município de Foz do Iguaçu-PR, experiência que mesmo estando em estágios iniciais, já demostra sinais claros de sucesso, e mesmo com toda a informação de dados dos pacientes, não há invasão de sua privacidade ou quebra de sigilo, pois os devidos cuidados são tomados para que não ocorra nenhuma falha no sistema e quebra de informações, onde somente pessoas habilitadas podem ter acesso a estas informações.

Key Words: Legislação Médica, Privacidade do Paciente, Sistemas Eletrônicos de Registros Médico, Prontuário Eletrônico do Paciente

PROTECÇÃO LEGAL PROMOVE A NOTIFICAÇÃO DE INCIDENTES E EVENTOS ADVERSOS ?

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Abstract

Resulta dos vários estudos internacionais que 8% a 12% dos doentes internados em hospitais são afectados por eventos adversos resultantes dos cuidados de saúde recebidos e não da doença. A insuficiente segurança dos doentes constitui um grave problema de saúde pública mundial e representa um pesado ónus económico para os recursos da saúde. A medicina é reconhecidamente uma atividade complexa que comporta muitos riscos, causa sofrimento, danos, incapacidades e mortes. Para atingir melhores níveis de segurança dos doentes as organizações internacionais (OMS e UE) e outras de cariz científico, recomendam aos Estados a implementação da Gestão do Risco (Risk Management) nas unidades prestadoras de cuidados de saúde, designadamente a notificação em larga escala dos incidentes e eventos adversos que ocorrem, de modo a permitir identificar, avaliar a frequência, a severidade e reduzir/eliminar os riscos de danos nos doentes. Mais recomendam essas organizações e a vasta literatura científica internacional, que os sistemas de notificação garantam a confidencialidade do que é notificado e a não punibilidade dos profissionais, sob pena de não merecerem a adesão dos profissionais de saúde. Constata-se que os sistemas de notificação de incidentes e eventos adversos não se têm revelado eficazes, concorrendo para o fenómeno da subnotificação o receio que os profissionais de saúde têm dos processos judiciais e disciplinares, segundo refere a literatura internacional “shame and blame” por muitos Authors associado ao regime da responsabilidade jurídica existente nos países. MÉTODO Face à reconhecida importância dos sistemas de notificação na melhoria da Qualidade e Segurança, pretendemos descrever: as características e princípios dos sistemas de notificação; a existência do fenómeno da subnotificação; analisar a experiência internacional em sistemas de notificação; analisar a legislação aprovada noutros países sobre confidencialidade dos sistemas de notificação (Direito Comparado); analisar em face na legislação existente as possíveis implicações jurídicas da implementação do sistema de notificação de incidentes e eventos adversos em Portugal. Apresentar estudo exploratório, com base na recolha de dados mediante a técnica de inquérito por questionário, aplicado a 200 profissionais de saúde (médicos/enfermeiros), em quatro Hospitais acreditados Portugueses do Serviço Nacional de Saúde, com o objectivo de apurar: a frequência das notificações; os obstáculos existentes à notificação de incidentes e eventos adversos; o efeito que a proteção legal pode ter nas notificações dos profissionais de saúde; as opiniões dos médicos e enfermeiros sobre a implementação do Sistema Nacional de Notificação de Incidentes e Eventos Adversos.

Key Words: internacionais, segurança, doentes

PROTECCIÓN DE LOS DERECHOS DE LOS PACIENTES EN PERÚ

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Abstract

Si bien es cierto, desde el año 1997 se inicia la incorporación en la legislación peruana de los derechos del paciente, es recién en el año 2009 que por primera vez se emitió una norma especial al respecto, de manera específica y autónoma. A partir de esa ley, el Estado fomentó los derechos de los usuarios de servicios de salud, instaurando el día del paciente a nivel nacional, creando y afianzando defensorías de los pacientes según el sistema de salud correspondiente, además de realizar una serie de modificaciones normativas como es el caso del Código de Protección al Consumidor, que no sólo otorgó una rigurosa tutela a nivel de prestación de servicios de salud sino que además, estableció mecanismos alternativos de defensa cuando los mismos se vean vulnerados. Este nuevo escenario condicionó un empoderamiento de los pacientes ya que encontraron que el sistema jurídico peruano les otorgaba, según el objetivo deseado, distintas vías de acción para reclamar sus derechos, ya sea una indemnización por daños, una sanción ética al médico o personal de salud, una condena penal, una sanción económica o una medida correctiva en contra del profesional o el establecimiento de salud. En nuestro ordenamiento, el usuario de servicios de salud puede elegir utilizar una vía de acción o varias a la vez, esto último genera una colisión de pronunciamientos jurídicos ya que muchas veces el sentido de los mismos resultan contrarios entre sí, lo cual, aunado al desorden con el que se han promulgado las normas tuitivas, han originado inseguridad jurídica en los proveedores de servicios de salud, con lo cual se creó una distorsión en el mercado, ya que éstos en su intento de protegerse ante estas contingencias, encarecieron el servicio. Lo anterior, debido a que no existe un seguro que cubra los riesgos del ejercicio profesional ni la responsabilidad de los establecimientos de salud. Es así que en el Perú existe una cultura del reclamo, que se ve promovida por los medios de comunicación, que constantemente se toman la atribución de calificar casos médicos como negligencias, a pesar que éstos aún no han sido investigados por la autoridad legal competente, lo cual se ha convertido en un arma de desprestigio y por ende de coerción. Este tipo de situaciones demandan un reordenamiento del sistema jurídico, cuyas alternativas de solución se abordarán en el texto de la presentación.

Key Words: DERECHOS DE LOS PACIENTES, PROTECCIÓN , PERÚ

PROTECTION OF THE RIGHTS OF THE INTERNATIONAL TRAVELERS CARRYING INFECTIOUS DISEASES AT ENTRY PORTS DURING A PANDEMIC

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Abstract

In the early stages of pandemic, in order to block the entry of infectious individuals from abroad and limit the spread of infection, one of the common measures taken by many countries is implementing health quarantine measures at the ports of entry for travelers from affected countries, including temperature monitoring for all travelers, medical examination for suspected cases, isolation and treatments for confirmed cases, quarantines for the closed contacts and so on. In these cases, the rights, such as the right of personal liberty, informed consent, privacy, the right to self-determination, of the travelers, especially the suspected cases and confirmed cases, are restricted in a certain degree. While the entry travelers are a special group of people coming from different countries and ethnics, having different customs, religious beliefs, and education backgrounds, the understanding and aspiration of patients' rights are significantly different between them. When they enter the ports, some of them would be resistant to the quarantine measures, and not cooperate with quarantine officers, causing the contradiction of patients' rights and public health interests.The author discussed how the health quarantine measures influence the rights of the entry travelers, especially among the suspected and confirmed cases of Influenza A (H1N1), in the early stages of the 2009 Influenza A (H1N1) pandemic in China, and analyzed the contradictions of patients' rights and public health interest under emergency condition. From the perspective of protecting patients' rights, the legislative proposals were given out combined with China's relevant laws.

Key Words: infection, medical examination, education backgrounds

QUANTIFICAÇÃO DA INDENIZAÇÃO NA RESPONSABILIDADE CIVIL POR PERDA DE UMA CHANCE DE CURA

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Abstract

O presente trabalho apresenta o andamento da pesquisa que objetiva a definição dos critérios para a quantificação da indenização na responsabilidade civil pela perda de uma chance de cura. Para tanto, parte da definição dos contornos da teoria da perda de uma chance e a sua aceitação no direito brasileiro, como também da própria chance como objeto da reparação, apresentando as modalidades de perda de uma chance, dando destaque a perda de chance de cura, com a posição da doutrina e dos tribunais brasileiros quanto a esta espécie de dano e sua extensão, para , ao fim, elencar os critérios que devem ser observados no momento da quantificação. A responsabilidade civil do médico pela perda de uma chance se divide em perda de uma chance de cura, onde a conduta culposa do profissional retira do paciente a chance de continuar vivo ou de não ter sequelas dentro de um tratamento, e na decorrente da falta de informação, que esta diretamente relacionada com o dever de informar, ocorre quando o dano é experimentado pela parte por esta não ter tomado a melhor decisão, que estaria ao seu alcance se outra pessoa que teria o dever de informar ou aconselhar o tivesse cumprido. Dentre as duas espécies, os tribunais brasileiros vem se posicionando pela aceitação da reparação dos danos no caso da perda de uma chance de cura, e também na doutrina estão sendo superados os obstáculos a aceitação desta teoria, em especial por restar definido que nestes casos o que deve ser reparada é a própria chance de cura destruída, e não o resultado final. Contudo, falta a definição quanto ao que deve ser levado em conta no momento de indenizar, sendo que neste ponto é que centraremos o nosso trabalho, juntamente com a definição in concreto deste dano. A metodologia adotada é composta pela pesquisa bibliográfica e documental. A conclusão e pela observância do princípio da reparação integral dos danos, devendo ser observado qual a probabilidade de cura existente no momento da conduta lesiva, e com base neste delimitar os contornos do dano a ser reparado, mas sem esquecer os seus limites, como o grau de culpa e a situação do ofendido, com a indenização sendo composta apenas pelo que realmente foi perdido pela parte, além de observar que esta é devida apenas quando este tiver os contornos de seriedade e realidade, e não quando envolvida esperanças e possibilidades.

Key Words: indenização, responsabilidade civil, direito brasileiro

RECENT DEVELOPMENTS IN ORGAN TRANSPLANTATION IN FINLAND

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Abstract

Finland organ transplant results are excellent in international comparison but there is a big lack of organ donors. For example, 10 – 15 % of patients waiting for a heart die before receiving a trans-plant. The activity of hospitals in recognizing potential donors and consent issues are essential. A great majority (83 %) of Finns would like to be organ donors in case of brain death but in 2009, only 17 % had signed an organ donor card and, in about 20 - 30 % of cases the relatives decided against do-nation. In 2010 Finland moved from an opt in policy of consent to opt out: All individuals are considered to consent to organ donation after death unless they recorded opposition whilst alive. Transplantation rates have not yet increased because – among other reasons - the new policy is difficult to apply in practice. Relatives' refusal still often overrides the decision and presumed consent does not change this attitude. Finnish transplantation policy is bound by the European Convention on Human Rights and Biomedicine and the EU Organ Donation Directive. In 2009, Finland ratified the Convention and its Protocol on Organ and Tissue Transplantation. The directive must be implemented into national legislation by August 2012. The Directive is a European requirement that aims to bring all EU countries up to the same high quality and safety standards. Finland already fulfils these standards, but it yet has to create the required formal regulatory framework for the transplantation system. For Finland, the Directive creates extra bureaucracy, and its benefit lies mainly in legalizing Scandiatransplant, the Nordic organ exchange organization. The Convention provides minimum protection. This means that ratifying countries may grant stricter protection for its citizens but they may not override minimum requirements. Already before rati-fication, Finnish national legislation was in most parts in line with obligations of the Convention. Finland participated actively in the preparation of the treaty system as a member of the Council of Europe. Furthermore, during that preparation of almost 20 years, Finnish biomedical legislation had been altered in order to correspond to the pan European provisions, including the Act of Transplantation of Human Organs and Tissues. Therefore, by the time of the ratification Finland was no longer in need of making major legislative changes. For the moment, ratification does not mean much for Finland. However, by ratifying, Finland made an informed decision to guarantee the protection set by the Convention and its Protocols not only for now but also in the future. Finland is committed to abide by this European treaty system, and thus join the growing group of States that believe that important ethical principles need to be enforced by binding rules.

Key Words: transplant, transplantation, Transplantation of Human Organs

RECENT DEVELOPMENTS IN SLOVENIAN MENTAL HEALTH LAW

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Abstract

Recent legal development in the mental health area was determined by the enactment of the Mental Health Act in 2008 and the new Penal Code in 2009. The Article presents the most important solutions that were introduced by the Mental Health Act, such as the new procedure for the involuntary commitment of persons to a mental institution, the role of patient rights advocates, ethical review etc. The Penal Code was supplemented in 2011 with special provisions dealing with mentally ill perpetrators of criminal acts. Recent case–law of regular courts and of the Constitutional Court dealing with mental health cases is analysed in the third part of the discussion. One part of the task of protecting the rights of the mentally ill patients is given to the Ombudsman's that has to carry out actual review of persons that are treated not only in the closed wards of psychiatric hospitals but also in senior homes. Finally, the Author discusses open issues that still have to be addressed by the legislator

Key Words: development in the mental, Penal Code in 2009, Constitutional Court dealing

RECENT DEVELOPMENTS IN THE HEALTH LEGISLATION OF THE REPUBLIC OF SERBIA

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Abstract

Until 2005, acts and bylaws of the Republic of Serbia in the health area were remnants of the legislation from the nineties of the last century. The Health Care Act and Health Insurance Act from 1992 had passed through a number of changes. However, even thus changed, they could not follow all the social and economical changes that have been going on on the territory of the Republic of Serbia, nor to respond to all the challenges and changes of the European legislation.One of the consequences of the disintegration of the Yugoslavian state was also the incursion of a considerable number of refugees and displaced persons into the Serbian health system. In order to respond to this and other contemporary challenges, health care and the health insurance system had to be changed, in practice, as well as on the paper.The changes of the health legislation have been initiated, lasting continuously since 2005 till today. This article points out the recent most important changes in the Serbian health legal system, whether these changes refer to the already existing acts, such as Health Care Act (2005) and Health Insurance Act (2005), or they are related to the absolutely new acts in Serbian legal surrounding, such as the Act on Infertility Treatment through Procedures of Assisted Reproduction (2009), Act on Cell and Tissues Transplantation (2009). They introduce some important changes into the Serbian health system in institutional and organizational sense. Through these changes the Directorate for Biomedicine has been established, as well as the Directorate for Screening Programs. Directorate for Biomedicine covers several considerable and important areas, such as: transplantation of organs, tissues and cells and assisted reproduction. Directorate for Screening Programs is competent for implementation of the organized cervical, colorectal and breast screening. Obviously, Serbian health legislation went through some very important changes. A considerable number of legislative solutions is very good, but, there are also some issues which need improvement through better or more detailed legal regulations.

Key Words: health legislation, health care, health insurance, assisted reproduction, cell and tissues transplantation

Recent Developments on end-of-life care guidelines in Japan

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Abstract

This paper will address the issues on end-of-life care, especially some new reports in Japan. During the last decade, several reports dealing with this matter have been issued from different organizations. For example, the Ministry of Health formulated a guideline on terminal care in 2007, the Japanese Association for Acute Medicine made a recommendation on terminal care in acute medicine in 2007, the Japan Medical Association published a guideline on end-of-life care in 2008, and, the Japan Hospital Association proposed guidelines on end-of-life treatment in 2009. For all the difference in these reports, they share some common perceptions, that is, improvement of consulting system for patients and their family, consensus formation through discussion between healthcare professionals, patients and their family, and, educational efforts to healthcare professionals. These reports dealt with end-of-life care including nutrition and hydration, but these main concerns were life-sustaining treatment, especially respirator. The Japan Geriatrics Society has revised the view about end-of-life care for the elderly and then published “Guidelines on Decision-Making Process for Geriatric Care” in early 2012. These guidelines focus on artificial hydration and nutrition through a gastrostomy tube. They mention that medical professionals should consider as an option the withdrawal or withholding of artificial hydration and nutrition through a feeding tube in geriatric care. I will make the outline of the guidelines and the underlying reason for them, and analyze matters of concern about them.

Key Words: DEVELOPMENTS, END-OF-LIFE, JAPAN

REFLEXÕES SOBRE A COMUNICAÇÃO DA EQUIPE DE SAÚDE COM O PACIENTE TERMINAL

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Abstract

A relação médico-paciente sofreu alterações fundamentais, ao trazer papel diferenciado a efetiva participação do paciente e familiares no processo da tomada de decisão. Nesse sentido, a necessidade de aprimoramento na comunicação foi passo fundamental para que houvesse mudança de patamar na relação a se respeitar a autonomia. No entanto, apesar das tentativas para humanização no sistema de saúde, notadamente, aos programas que visam cuidado humanizado ao paciente terminal, verifica-se o esquecimento de reflexão sobre a necessidade de suporte também ao profissional que experimenta, a todo momento, por dilemas a respeito da morte e do morrer, sem contudo, haver retaguarda para externar ou amenizar suas aflições. Para que haja um concreto trabalho de humanização, todavia, deve-se englobar todos os atores do sistema, proporcionando retaguarda de acolhimento emocional para que os dilemas internos sobre a morte e o morrer sejam dirimidos e aclarados à medida do possível. Tal medida de enfrentamento se faz necessária, pois em havendo equilíbrio em todos os sentidos dos profissionais que efetivamente abordam o paciente ou os familiares, melhor será a comunicação e o acolhimento para a execução dos cuidados na maneira mais ampla possível.

Key Words: paciente terminal, comunicação, reflexões

Reflexões sobre o dever de informar do médico no consentimento informado

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Abstract

O consentimento informado e o direito à informação são matérias que passaram a ser relevantes com a consagração dos Direitos Humanos e o conseqüente reconhecimento do paciente como ser humano. Anteriormente, imperava o paternalismo clínico, em que o médico era considerado um "sacerdote" ao qual cabia exclusivamente decidir sobre o paciente; este, por sua vez, era considerado praticamente um incapaz, um ente sem vontade que apenas obedecia o médico. Havia um verdadeiro paternalismo clínico, que poderia em última análise ser equiparado à censura imposta pelos médicos ao paciente, era a "ditadura" dos doutores da saúde. A partir do momento em que o homem deixou de ser objeto de estudo da Medicina e passou a ser sua finalidade, a Ciência Médica começou a ser exercida em favor do homem. Só então, se colocaram na sociedade, no Direito e na própria ética médica questões concernentes ao consentimento informado e ao direito à informação sobre a própria saúde. Na atualidade, essas matérias possuem conteúdo extremamente relevante e enseja infinitos estudos a fim de que, na prática, sejam concretizados os direitos de personalidade. O consentimento informado e o direito à informação envolvem, portanto, questões referentes à liberdade individual, à integridade física e moral, ao livre desenvolvimento da personalidade, ao direito à saúde, ao direito à informação em si mesmo considerada e ao direito à autodeterminação. Daí decorre a importância do tema que tem como último escopo respeitar a dignidade humana. A informação a ser transmitida ao paciente sobre a sua própria saúde, não é menos importante do que o estudo do consentimento informado, não se configurando apenas parte dele, mas sim um pressuposto. A informação possui uma importância peculiar porque constitui o primeiro passo, em matéria de saúde, para que a pessoa concretize sua autonomia e desenvolva livremente sua personalidade. A partir de uma primeira informação básica e genérica é que o paciente poderá decidir se quer ou não submeter-se a tratamento, e decidir, inclusive, que não quer tomar conhecimento do seu estado de saúde, exercendo o chamado 'direito a não saber'. Assim, na atualidade as questões pertinentes ao consentimento informado adquiriram um conteúdo muito mais complexo porque nem sempre significam dar o conhecimento de tudo. Ademais, a forma como a informação é passada e sua captação pelo paciente são dignas de teorias jurídicas que merecem uma reflexão dos juristas e médicos da contemporaneidade para que o conteúdo humanístico do consentimento informado seja concretizado.

Key Words: REFLEXÕES, INFORMAR, MÉDICO

REGULATING IRANIAN MEDICAL INSTITUTES: TOWARDS A CLEAR REGULATORY MODEL

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Abstract

Background: Regulation has been considered as a tool of performance improvement and an instrument of social justice. Medical regulation has obsessed Iranian legislator's mind to a great extent but s/he didn't specify a clear regulatory model.

Method: The method is based on the literature review. The author tries to discuss different medical and legal aspects of medical regulation in Iranian statutes. Regulating managers and personnel, clinical governance, internal and external regulatory models with legislative and practical approaches to them are explained. Upgrading public health is also paid attention to.

Results: patients' rights are sometimes breached due to diversified regulatory models. Most of medical institutes are reluctant to make their performance clear. Hybrid regulatory model is suggested to use as an appropriate regulatory model with the most benefits and the least disadvantages. Public health plays a vital role in observing patients' rights in different medical issues.

Key Words: Iranian Acts; medical regulation; clinical governance; internal and external regulation; regulatory model.

RESPONSABILIDADE CIVIL DO CIRURGIÃO-DENTISTA: UM NOVO PARADIGMA.

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Abstract

A Odontologia, assim como outras profissões da área da saúde, vem sendo assolada por questionamentos de origem desconectada de embasamento técnico calcadas, tão somente, com o objetivo de ganho pecuniário desproporcional. Baseadas com linguajar totalmente dissonante ao preconizado pela literatura odontológica se perdem as demandas indenizatórias com conceitos distorcidos, trazendo inescusável banalização ao instituto. Muita vez, impõe-se ao desempenho da atividade, em larga escala, viés de obrigação de resultado a qualquer dos procedimentos, sem se verificar as especificidades e a real impossibilidade de excluir-se o elemento alea inerente a situações em que existe a manipulação de um organismo vivo e as reações dele advindas. A par disso, também se verifica exígua produção doutrinária que gere inovação aos aspectos peculiares referentes à responsabilidade civil do cirurgião-dentista, sendo raros os trabalhos que, de fato, alinhem a realidade científica aos conceitos jurídicos. Ao contrário, majoritariamente, apenas são criados verdadeiros sofismas, aumentando os equívocos e instabilidade entre as relações. Fato é que, pelo estado atual da ciência, conceitos empíricos não mais são cabíveis e nem tampouco devem ser absorvidos de maneira simplista, como verdade absoluta, sem a adequada reflexão. Por outro lado, assim como na Medicina, por ter natureza personalíssima, atuação profissional do cirurgião-dentista não caracteriza relação de consumo, conforme vedado no Código de Ética Profissional que impede a prática de atos que impliquem em comercialização. Deve o cirurgião-dentista, portanto, agir com presteza, prudência e habituais cuidados de conduta adequados às regras técnicas mais atualizadas, fornecendo informação clara ao tratamento proposto e alternativas viáveis, para que o paciente se revista de capacidade de interagir mais amplamente para o sucesso da aplicação terapêutica adotada. É dever imposto, pois, obviamente, pela peculiaridade da atividade o paciente invariavelmente será coparticipe do resultado final, devendo colaborar com alguns deveres, principalmente relativos ao autocuidado. Dessa feita há necessidade de não se desatrelar a conceituação jurídica destituída de elementos essenciais que revestem a relação jurídica cirurgião-dentista/paciente, com mera repetição de teorias aplicáveis a outras categorias profissionais a fim de que não se perpetuem enganos conceituais.

Key Words: RESPONSABILIDADE, CIVIL, CIRURGIÃO-DENTISTA

RESPONSABILIDADE CIVIL DOS CIRURGIÕES PLÁSTICOS NAS CIRURGIAS ESTÉTICAS: UM ESTUDO COMPARATIVO ENTRE ASPECTOSJURÍDICO-CIVIS NO DIREITO ARGENTINO E BRASILEIRO

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Abstract

CONSIDERAÇÕES INICIAIS O desenvolvimento das ciências biomédicas e das tecnologias aplicadas à área da saúde, especialmente no século XX, fizeram com que surgissem novas possibilidades de intervenções nessa área. Juntamente com esse instrumental, emergiram novos conflitos jurídicos jamais antes concebidos, e para os quais não há respostas prontas e estanques. Entretanto, este progresso alterou sobremaneira a relação médico-paciente em razão da dinâmica dos dias atuais, afastando os envolvidos na relação, tornando este contato cada vez mais objetivo e distante. Conforme diz Pereiro de Grigaravicius, “no debemos olvidar, asimismo que cuando se requiere su auxilio profesional, lo que se busca es su ciencia y pericia y sus directivas y opiniones se respetan y cumplen a menudo con una confianza ciega.” Pode-se atribuir a este fato o crescente aumento a cada ano o número de demandas movidas em desfavor de médicos com pedidos ressarcitórios de danos por “erro médico”, principalmente nas denominadas cirurgias estéticas. O presente texto tem como objetivo realizar um estudo comparativo da responsabilidade civil por erro médico nas cirurgias estéticas no direito argentino e brasileiro, já que no meio jurídico restam posicionamentos controvertidos sobre que tipo de obrigação estaria envolvido o médico que atua nesta especialidade, se de meio ou de resultado e quais os requisitos necessários para a responsabilização civil por erro médico. Neste sentido, inicialmente apresentam-se as principais características dogmáticas do direito argentino e, após algumas considerações, passa-se a apresentar os fundamentos legais no Direito brasileiro para buscar, a partir de um estudo comparado verificar qual o enquadramento jurídico da obrigação dos médicos que atuam especificamente em cirurgias estéticas? Há correlação entre os ordenamentos jurídicos? Finalmente, a partir deste estudo comparativo, apresentam-se argumentos de convergência jurídico-civil dos ordenamentos jurídicos.

Key Words: ciências biomédicas , tecnologias aplicadas, século XX

RESPONSABILIDADE LEGAL DO MÉDICO - CIVIL PENAL E ADMINISTRATIVA

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Abstract

O trabalho trata das responsabilidades dos profissionais de saúde em razão de sua conduta profissional. Já está pacificado que a responsabilidade do profissional liberal (médico) é subjetiva, ou seja, há que se provar que o mesmo agiu com culpa. Nesse contexto, a matéria é dividida em três tópicos distintos: implicações do Direito Civil, implicações do Direito Penal e implicações administrativas. No âmbito do Direito Civil, a atividade médica pode gerar a propositura de ações indenizatórias, em razão de uma conduta culposa que tenha gerado danos ao paciente, dependendo a condenação da comprovação de existência do nexo de casualidade. Ao lado da responsabilidade civil dos profissionais de saúde, a atuação médica pode ensejar a instauração de inquéritos policiais e processos penais para apuração de eventual crime. O objetivo, nesse campo, é o de impor ao profissional uma penalidade pelo desvalor da ação ou da omissão. A penalidade pode ser de restrição da liberdade de ir e vir(prisão),monetária(multa) ou de outra natureza, chamada de pena alternativa (como a de prestar gratuitamente serviços à coletividade). O terceiro tópico tratado deriva dos Códigos de Ética Profissional, que regulam as profissões liberais. Ao lado das responsabilidades civil e penal , o profissional da área da saúde pode, em razão de sua conduta (omissiva ou comissiva), sujeitar-se a processo ético. Nesse caso, as penalidades possíveis são: advertência confidencial, em aviso reservado, censura confidencial, em aviso reservado, censura pública, em publicação oficial, suspensão do exercício profissional até 30 dias, ou cassação do exercício profissional. Todas as disciplinas legislativas citadas poderão incidir em razão de um único ato médico, sujeitando-se o profissional a três processos distintos, ação de indenização na esfera civil, visando ao ressarcimento dos danos ocasionados, processo criminal, para a averiguação da prática de determinado crime, e processo ético administrativo, para a apuração de eventual transgressão de norma ética profissional.

Key Words: RESPONSABILIDADE LEGAL, MÉDICO, CIVIL, PENAL, ADMINISTRATIVA

RESPONSABILIDADE PENAL MÉDICA EM PORTUGAL -A CONDUTA NEGLIGENTE NAS EQUIPAS MÉDICAS

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Abstract

O direito penal português reconhece a relevante função social exercida pela classe médica, dedicando um regime diferenciado e privilegiado às intervenções e tratamentos médico-cirúrgicos: o artigo 150.º do Código Penal estabelece que, verificados certos pressupostos, as intervenções e os tratamentos médicos "não se consideram ofensa à integridade física". No entanto, se o médico actuar em violação do seu dever de cuidado, criando um risco não permitido que venha a concretizar-se numa ofensa ao corpo ou à saúde ou mesmo na morte do paciente, poderá a ser punido por ofensa à integridade física por negligência (artigo 148.º do Código Penal) ou por homicídio por negligência (artigo 137.º do Código Penal). Actuando os profissionais de saúde, hoje, predominantemente no âmbito de equipas multidisciplinares, questiona-se se os critérios tradicionais de determinação da conduta negligente, pensados para a actuação individual, serão adequados para a determinação da responsabilidade na actuação em equipa. O princípio da divisão do trabalho e o princípio da confiança apresentam-se como os fundamentos com base nos quais se poderá delimitar o âmbito de responsabilidade de cada elemento da equipa quando da intervenção resultar uma ofensa para o paciente. No decurso de uma intervenção médica estabelece-se uma teia complexa de relações entre os diversos profissionais e o âmbito de actuação do princípio da confiança dependerá da posição que cada profissional assume na equipa médica. No caso de divisão do trabalho horizontal, vale plenamente o princípio da confiança. Nas relações verticais surge para o chefe de equipa o dever de coordenação da actuação da actividade de equipa e, em certas circunstâncias, o dever de controlar a actividade dos membros da equipa. Nas relações verticais também vigora o princípio da confiança – o dever de controlo por parte do superior só surgirá quando circunstâncias concretas o fizerem (ou deverem fazer) duvidar da correcção da actuação do subordinado. Os subordinados podem, por regra, confiar na correcção das instruções recebidas. Delimitando o campo de actuação do princípio da confiança (na divisão do trabalho horizontal e vertical) será possível determinar o dever de cuidado de cada elemento da equipa e, correlativamente, a responsabilidade de cada um quando da intervenção resultar um dano para o paciente.

Key Words: RESPONSABILIDADE, PENAL, MÉDICA

Restored Allograft Transplants After Resection of Renal Cell Carcinoma

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Abstract

Japan has an acute shortage of kidney donations. In 2010, the number of patients receiving kidney dialysis treatment (at a cost of about $50,000 per patient per annum) was 297,126; and by May 2012, 12,359 patients were waiting for transplants. Among patients on dialysis in 2010, kidneys from healthy relatives were donated in 1,276 cases, while 208 kidneys from deceased (146) or brain dead (62) donors were used. With only about 200 kidneys a year available for transplant from deceased sources, waiting lists are up to 16 years, which means most patients die before they can receive a transplant. One problem is that the Guidelines for Practical Use (referred to in the Human Transplant Act) limit the use of restored kidneys to clinical research, and national health insurance cannot be used to fund such transplants. One solution might be that up to half of the 2,000 diseased kidneys removed and abandoned every year could be restored and used for allograft transplants. Currently, patients can take advantage of restored kidneys only if they register within a research scheme. Use of restored kidneys as a standard treatment would help to solve the donor crisis and enable patients to use national health insurance. Patients' best interests would be served and over $50 million in taxes saved on kidney dialysis treatment. This paper will discuss the recognition of restored kidney transplants as a standard procedure, from both the medical and social viewpoints.

Key Words: treatment , Practical , transplants

RIGHT OF CHILDREN WHO ARE IN THE HOSPITAL TO HAVE THEIR LEGAL REPRESENTATIVES WITH THEM

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Abstract

On February 15, 2012 the Committee of Ministers of the Council of Europe adopted the Strategy for the Rights of the Child for 2012-2015. The main goal of this strategy is provision for the execution of the legal instruments and standards in the sphere of children rights worked out by the Council of Europe and other organizations as well as the analysis of how these documents are carried out. Among the objectives of the Strategy it is foreseen to promote a child friendly health care services, securing all children' rights, in particular of those who belong to vulnerable groups, children in detention, migrant children, asylum seeking children, Roma children, to support the right of a child to be heard as well as provide for a serious attitude to children' opinions concerning issues which touch their interests. Of course, among the spectrum of child's resources, of a great importance is the issue of securing children' rights in the sphere of patient care, which has a normative regulation both on national and international levels. According to Article 24 of the 1989 UN Convention on the Rights of the Child (ratified by Ukraine on September 27, 1991) (hereinafter – 1989 Convention), states parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services. Article 6 (Right to life and health care) of the Law of Ukraine "On the Protection of Childhood" foresees that the state guarantees each child a right to health care, free qualified medical care in public and communal health care institutions, promotes the creation of safe life conditions and healthy development of a child, rational nutrition and creation the healthy life style skills. One of the least investigated rights of child, which is usually accompanied by difficulties in realization, is right of a child who is in the hospital to have his/her legal representatives with them. This possibility of a child caused a scientific concern not only because it hasn't been investigated by scholars enough, but first of all, because is stipulated by the problems of law enforcement, which in its turn are caused by loss of a balance in correlation between normative regulation and implementation into practice. Legal regulation of this right has been provided both on international, regional standards and national laws.

RIGHTS OF THE PATIENTS IN THE RUSSIAN LEGISLATION

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Abstract

The constitutional right on health protection belongs to the generation of socio-economic rights, which are the guide for social policy of the state. Therefore, improvement of legislation in healthcare is the guarantee of realization of this right, because its full realization is impossible without developed system of healthcare in the country. It should be noted that until 1917 the public healthcare system in Russia did not exist. There was a heterogeneous combination of manufacturing medical service and insurance medicine (with elements of state regulation), which coexisted with free-of-charge rural medicine, charity medical care in the towns and fees for medical aid in the whole. For these reasons it was not possible to say about the rights of patients in that period of the Russian history. The healthcare system in Russia began creating only since 1917. Nevertheless the right on health protection was not declared in the first Russian Constitutions of 1918 and 1924. The first indirect institutionalization of this right appeared in Russian Constitution of 1936. The creation of healthcare system in Russia was declared in 1977, and after that the right on health protection was introduced in Constitution of 1977 and hereafter in Constitution of 1993. Direct mention about patient's rights initially appeared in legal codified act "Fundamental Principles of Legislation of the Russian Federation on Health Protection"(approved in 1993). In accordance with this document the patients had the right to humane treatment from the part of medical and nursing personnel, choice of doctor and medical facility in accordance with obligatory and voluntary health insurance, relief of pain associated with the disease, informed voluntary consent to medical intervention, information about their health and the others. All of them were further enriched in Federal Law № 323-FZ of 21.11.2011 "On the basis of health protection in the Russian Federation", which emphasized the priority of the interests of the patient in health care and the inadmissibility of denial in medical care providing, as well as the specified rights of certain categories of citizens (of employees in certain types of work; of militaries). Consequently, the process of formation of the healthcare system had begun since 1917. Simultaneously with this process the development of patients' rights has proceeded.

Key Words: constitutional, social policy , Russia

ROL DE LA DOCUMENTACIÓN MÉDICA EN GRAVES DENUNCIAS CONTRA CIRUJANOS Y ANESTESISTAS

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Abstract

ANTECEDENTES: Las distintas comunicaciones científicas que relacionan a los cirujanos y anestesistas con la justicia suelen circunscribirse a los delitos culposos como la Responsabilidad Profesional; sin perjuicio de ello existen denuncias de otros delitos que ensombrecen la práctica quirúrgica, y que también deben ser conocidos para su prevención. OBJETIVO: Difundir la existencia de otras causas de reproches judiciales contra los cirujanos y reafirmar la importancia de la documentación médica como elemento fundamental para el discernimiento de la existencia de un delito. LUGAR DE APLICACION: Fiscalías de Instrucción del Ministerio Público Fiscal de la Provincia de Buenos Aires. DISEÑO: Estudio observacional retrospectivo. POBLACION: 345 pericias complejas desde julio de 2006 a diciembre de 2007. METODO: Selección de 214 peritaciones sobre historias clínicas en una denuncia contra cirujanos y anestesistas por presunta defraudación al Estado. RESULTADOS: De las 214 historias clínicas evaluadas, sólo 71 poseían la documentación médica apta para realizar la peritación ordenada, coincidiendo en todas ellas los criterios de oportunidad quirúrgica asistencial y pericialmente, descartando médico-legalmente el proceder delictivo. Sin embargo, el estudio de la documentación médica-quirúrgica obrante arrojó 6% de H.C. sin fecha y 59% sin hora de ingreso; 6 % sin protocolo quirúrgico, 12 % sin parte anestésico y 93% sin consentimiento informado. Sólo el 33% de los protocolos quirúrgicos consignaban oportunidad de la cirugía (urgencia o programada). CONCLUSIONES: No sólo las tácticas y técnicas quirúrgicas son pasibles de reproches judiciales cuando aparece daño; existen denuncias de conductas delictivas que suponen utilizar la profesión como medio para su concreción. Esta comunicación reafirma la importancia de la documentación médica como único puente entre los procedimientos asistenciales y las evaluaciones periciales en todo tipo de denuncias.

Key Words: cirujanos, defraudación, responsabilidad profesional, documentación médica

ROUBARAM-NOS A CAPACIDADE DE SONHAR? DEVERES DOS PACIENTES EM TEMPOS DE CRISE SISTÉMICA DO CAPITALISMO.

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Abstract

Partindo da noção de dever (jurídico), em contraponto com a de ónus jurídico, o Autor analisa os tradicionais "deveres" dos pacientes. Se é correcto afirmar a existência do dever de pagar os honorários, já se levantam dúvidas acerca da qualificação jurídica do "dever" de contar com verdade a história clínica e o "dever" de cumprir a prescrição. Em segundo lugar serão perspectivados os seis deveres apregoados pela Carta dos Direitos e Deveres do Doente (em Portugal): 1. o doente tem o dever de zelar pelo seu estado de saúde, por forma a garantir o seu bem-estar e o seu restabelecimento; 2. o doente tem o dever de fornecer aos profissionais de saúde todas as informações relevantes para a obtenção de um correcto diagnóstico e adequada terapêutica; 3. o doente tem o dever de respeitar os direitos dos outros doentes; 4. o doente tem o dever de colaborar com os profissionais de saúde, respeitando as indicações que lhe são recomendadas e, por si, livremente aceites; 5. o doente tem o dever de respeitar as regras de funcionamento dos serviços de saúde; 6. o doente tem o dever de utilizar os serviços de saúde de forma apropriada e de colaborar activamente na redução de gastos desnecessários. Esta Carta não tem valor vinculativo, mas constitui uma base importante da relação médico-paciente. Serão ainda equacionados outros deveres dos pacientes, como o dever de participar em ensaios clínicos (justiça inter-geracional (H M Evans); o dever de revelar a utilização de plantas medicinais; revelar ser portador de um Testamento de Paciente e revelar algum evento adverso de que o doente se aperceba. Se a construção de um modelo humanístico de cuidados do doente-cidadão impõe estas condutas (positivas e negativas) por parte do paciente, não é menos verdade que a narrativa que se tem vindo a instalar no sentido de uma quase discriminatória responsabilização do doente e da imposição de deveres àqueles que estão mais vulneráveis merece ser denunciada como um processo de contra-reforma e de opressão do livre desenvolvimento da personalidade.

Key Words: Carta dos Direitos, Deveres do Doente, Diagnóstico

SAÚDE PÚBLICA E ESCASSEZ DE RECURSOS PÚBLICOS: A QUEM CABEM AS ESCOLHAS TRÁGICAS?

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Abstract

Desde o advento da Constituição da República de 1988, o direito à saúde foi erigido à categoria de direito fundamental, catalogando-o como autêntico direito social. A sua garantia pelo Estado àquele desprovido dos recursos necessários a custeá-lo visa a garantir a dignidade da pessoa humana e, em último fim, a própria liberdade material do indivíduo, uma vez que, prejudicadas as condições mínimas de sobrevivência do ser humano, não é possível afirmá-lo enquanto pessoa livre . Em uma visão liberal, a dignidade da pessoa humana está intrinsecamente associada à satisfação das parcelas mínimas materiais que são protegidas pelos direitos sociais capitulados no art. 6º da Carta Magna brasileira, dentre eles o direito à saúde. No entanto, o direito a medicamentos e a tratamentos médicos vem sendo negado pelo Estado a pessoas economicamente hipossuficientes, ao argumento principal da falta de recursos públicos, alegando, ainda, a falta de legitimação democrática ao Poder Judiciário para decidir acerca da alocação dos recursos públicos. As decisões judiciais, majoritariamente, vêm decidindo pela obrigatoriedade do Poder Público em implementar o direito à saúde das pessoas que necessitem. Mas pode o Poder Judiciário interferir nas escolhas trágicas, decidindo acerca da alocação de recursos públicos? O direito a medicamentos e a tratamentos médicos deve ser garantido a todos os indivíduos, ainda que não se encontrem em situação econômica desfavorável? Através da análise de casos serão propostas indagações se o direito a medicamentos e a tratamento médico deve ser garantido a todos os indivíduos, independentemente da situação econômica, e se é legítimo ao Poder Judiciário interferir em matéria orçamentária a fim de implementar o direito à saúde.

Key Words: Saúde pública, Recursos Públicos, Reserva do Possível, Estudo de casos

SEXUAL AND PSHYCOLOGICAL ABUSE IN ITALY: VICTIMS, CASES, SOCIAL AND LEGAL ASPECTS.

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Abstract

In Italy during the last years there is an increasing in the number of cases of children and femals as victims of sexual and / or psycological abuse. The lack of specific and professional centers inside the Universities or in the main health care centers, apart from the main cities, the low sensibility of the legal system and the “false” punishment for the abuser sometimes makes these crimes falling down into the shadow. In Italy for instance there are differences between the approach of the families in the north and in the center – south of the country. Infact, the concept of the “clan”, and the concept of the family as a closed circle make these cases more difficult to examine and to prevent. The authors would like to present the Italian reality throught cases and the give a presentationof the juridical system and what is done toward the victims.

Key Words: In Italy, number of cases, or psycological abuse.

Sharing genetic biobanks : which protection for rights of French patients ?

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Abstract

Sharing samples and genetic data in Europe Within European Union members states, the Directive 2004/23/EC organizes standards of quality and safety for exchanges and sales of human tissues and cells. Although elements of the human body are out of trade, the free movement of goods within the European Union is possible in order to facilitate access to biobanks for research and the exchange of samples and data between researchers. For personal data, the implementation of the Directive 95/46/EC ensures an equivalent level of protection in all countries of the European Community. The transmission of data outside the community is possible only if the state recipient provides an adequate level of protection of privacy, respect of freedoms and the fundamental rights of individuals. Otherwise, it is necessary provide information on this difference of standard of privacy to the person concerned and to obtain an express consent to the transfer. The Commission of the European Communities determines if the level of protection is adequate in terms of the provisions in force in the state, regarding the characteristics of treatment, and the security measures to apply. There is a controller of the European Data Protection www.edps.europa.eu Protection of the rights of French citizens In France, the human body is protected by the law. A person is not allowed to sell products or parts of his or her body (article 16-1 of the Civil Code).The person has only the right to authorize their use for care or research. Regarding the analysis of the genetic characteristics, the art 16-10 of the civil code allows it only for medical or scientific purposes, and required a specific informed written consent. Since the law 2004-800 (August 6, 2004) all collections of human material are regulated by the article 1243-3 of Public Health Code. The law allows the secondary use for biomedical researches of material collected during the care. Indeed, if the subject implicitly consent to the use of biological material from his body for medical diagnosis and treatment, it is necessary to inform the patient about storage in a collection for research purposes, so that he or she possibly could exercise her or his right of opposition to the conservation (article L.1211-2 of the Public Health Code). For international research projects that require to pool biological samples with clinical data and share the results from different countries, the ethical guidelines of the Declaration of Helsinki are applicable and it is important that foreign partners outside the European Union, are well informed of the requirements imposed by the French and European legislation in order to organise an equivalent protection of the rights of persons and privacy that allows transfers.

Key Words: genetic, biobanks, protection for rights, patients

SITUACION JURIDICA DEL ABORTO EN EL PARAGUAY

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Abstract

Históricamente, a lo largo del desarrollo de la humanidad, el aborto provocado ha sido utilizado como recurso para la regulación de la fecundidad, aún en culturas en las cuales las pautas de valores vigentes eran contrarias a esta práctica. En el Paraguay los datos sobre el aborto es insuficiente y poco confiable, debido a un sub registro, la muerte materna frecuentemente es encubierto debido a la penalidad de la práctica debido a ello tanto la historia clínica como los certificados de defunción no figura el aborto, solo la consecuencia sus complicaciones como la hemorragia y la sepsis. El aborto inseguro es probablemente la primera causa de muerte materna, según datos proporcionados por el departamento de bioestadística del Ministerio de Salud, los departamentos, con más casos de abortos son Alto Paraná y Central. El 25% de las muertes en menores de 19 años ocurre a causa de abortos clandestinos. La Constitución Nacional promulgada y sancionada, el 20 de junio de 1992, en concordancia con disposiciones establecidas en convenios internacionales como el Art. 4o. de la Convención Americana sobre Derechos Humanos, ratificada como Ley No. 1/89 e inspirada en el Pacto de Derechos Civiles y Políticos de San José de Costa Rica, incorpora una modificación al Art. 4o: Del derecho a la vida, El derecho a la vida es inherente a la persona humana. Se garantiza su protección, en general, desde la concepción. Queda abolida la pena de muerte. Toda persona será protegida por el Estado en su integridad física y psíquica, así como en su honor y en su reputación. La ley reglamentará la liberta de las personas para disponer de su propio cuerpo, sólo con fines científicos o médicos. Ley Nº 836/80 Código Sanitario Artículo 15.- Las personas por nacer tienen derecho a ser protegidas por el Estado, en su vida y en su salud, desde su concepción. .Artículo 17.- El aborto en su calificación y sanción quedará sujeto a las disposiciones de la legislación penal común. Código Penal Ley Nº 1160/97 modificado ley N° 3440/08 Art. 81 – Prohibición del ejercicio de profesión u oficio 1º Al que haya realizado un hecho antijurídico grave abusando de su profesión u oficio o violando gravemente los deberes inherentes a ellos, se le prohibirá el ejercicio de dicha profesión u oficio cuando el hecho y la personalidad demuestren que el autor previsiblemente volverá a delinquir a través de la práctica. 2º La prohibición no será menor de un año ni mayor de cinco. En casos excepcionales, de alta peligrosidad del autor, se podrá ordenar una duración de hasta diez años con revisiones periódicas. Durante el periodo de prohibición, el autor tampoco podrá ejercer la actividad para otro ni por interpósita persona. Capítulo I Hechos punibles contra la Vida Artículo 105.- Homicidio doloso 3º Se aplicará una pena privativa de libertad de hasta cinco años y se castigará también la tentativa, cuando: 2. una mujer matara a su hijo durante o inmediatamente después del parto.

Key Words: ABORTO, PARAGUAY, SITUACION, JURIDICA

STUDIES ON THE ALTERNATIVE DISPUTE RESSOLUTION OF PHYSICIAN-PATIENT RELATIONSHIP

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Abstract

Qiao Shiming, Minzu University of China Law School, ADR (Alternative Dispute Resolution) as a medical dispute solution is very necessary when the number of medical disputes increases quickly and Physician-patient relationship is intense now in china. ADR is not only conducive to control “medical litigation arising” but also to protect the interests of patients and medical staff to avoid time-consuming litigations, and it will also promote social harmony. Specific measures includes to apply “People's Mediation Act of the people's Republic of China” to mediation before litigation or to apply “Arbitration law of the people's Republic of China” to solve the problem.

Key Words: medical litigation arising, medical disputes , Physician-patient

"SYSTEMS OF PATIENTS' RIGHTS PROTECTION – A COMPARATIVE VIEW"

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Abstract

The aim of the present article is to create a comparative insight into the systems of patients' rights protection in four neighboring countries – Serbia, Croatia, Bosnia and Herzegovina and Slovenia. Even though in the recent past all four were a part of the same federative country, with one of them being a member of the EU, their own paths of development differ significantly from each other, which can also be seen in their health care systems. In the area of patients' rights, institutes of protection in each system vary in structure, effectiveness and quality, level of independence and compliance with the accepted European standards and tendencies.Therefore, a critical overview is to be made with a purpose of concluding on the matter of progressiveness and development in the area of patients' rights protection in one EU member state and three countries on their way to accession.

Key Words: systems of patients, member state , standards and tendencies

Task shifting and patient rights. Experiences from the Netherlands

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Abstract

Under the Dutch Individual Healthcare Professions Act (IHCP Act) a limited number of perceived high risk health procedures (the so called 'reserved procedures') can only be carried out by physicians, or be delegated by physicians. This systems seeks to protect the patient's right to high quality care. On 1 January 2012 an amendment to the IHCP Act came into force. Since that moment, specialized nurses and physician assistants are, on a limited trial basis, also authorized to perform some specific reserved procedures, so far exclusively assigned to physicians. The new act results from the ongoing discussion in the Netherlands about task shifting from physicians to nurses and other healthcare workers. According to the Dutch government task shifting is one of the ways in which the capacity problem in Dutch healthcare could be solved. It is uncertain whether the conditions under which task shifting is introduced, provides enough clarity about its scope and limits and if the quality of care is sufficiently guaranteed in order comply with patient rights. Task shifting thus touches upon such patient rights as the right to accessible and affordable healthcare, the right to quality care, the right to choose one's own physician and the right to informed consent. In this presentation I will focus on task shifting in the Netherlands and the potential conficts with the Dutch and internationally guaranteed patient rights.

Key Words: Healthcare, Professions, physicians

TESTAMENTO VITAL ENTRE O NEOCONSTITUCIONALISMO E O CONSTITUCIONALISMO ANDINO

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Abstract

Sempre foi delicado entender o funcionamento cerebral na antecâmara da morte, o que tradicionalmente se incumbia à psiquiatria. Prevalecia a tese contrária à tomada de declarações de vontade, como o testamento, próximo à morte. Ocorreria a incapacidade testamentária ativa, diante de um estado de delírio/ofuscação mental. Competiria ao médico se pronunciar, antes de um testamento. Uma humanização do Direito atingiu o texto das constituições, configurando o Neoconstitucionalismo, levado o Direito Constitucional ao triunfo,sendo exigível a leitura dos fenômenos jurídicos conforme a Constitucionalização/Internacionalização do Direito A Constitucionalização do Direito Brasileiro integra o Constitucionalismo Andino, nascido junto aos países latino-americanos.Para compreender instituições/institutos jurídicos brasileiros,torna-se necessário um exame constitucionalizado/comparativo. Destarte, o tema das decisões sobre o fim da vida ganha novas cores. De um lado, no Brasil, o exercício da autonomia sobre a própria morte,seria inadmissível, de outro, novos posicionamentos doutrinários surgem.Em nome da dignidade humana, defende-se um direito constitucional de morrer dignamente,em oposição às prorrogações infindáveis da agonia da morte, decorrentes dos avanços tecnológicos. Propõe-se um estudo constitucionalizado e sob o viés latino-americano do 'testamento vital',estipulação escrita, para os casos de eventual e futura incapacitação, estado terminal ou doença incurável,em prejuízo da manifestação do querer

Key Words: Testamento Vital, Neoconstitucionalismo, Constitucionalismo Andino

TESTAMENTO VITAL: DIGNIDADE DA PESSOA HUMANA VERSUS INVIOLABILIDADE À VIDA

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Abstract

O presente artigo visa a discussão a respeito do direito do indivíduo expressar sua vontade de forma livre e lúcida, dispondo sobre sua vida até momento final. A abordagem destaca os princípios referentes à vida, dignidade e direitos do indivíduo, revelando a viabilidade de ser inserido no pátrio ordenamento o direito ao testamento vital. Apresentaremos os motivos que ensejam este direito ao indivíduo em estado terminal, visam a dignidade, integridade física, psíquica e moral, violados por um princípio que dispõe que o ser humano não terá direito sobre a vida, vez que vivem para cumprir sua função social. Será exposto e discutido os escopos da recusa terapêutica realizada antecipadamente de forma consciente e livre de um paciente que posteriormente poderá se encontrar com patologia irreversível, incurável, a qual o tratamento apenas prolongaria seu tempo de vida, deteriorando a qualidade de sua existência. Após extensa revisão bibliográfica fica demonstrado que os direitos do enfermo não são respeitados em sua totalidade, vez que tais direitos não afrontam o princípio da inviolabilidade do direito à vida, apenas buscam uma morte com dignidade e respeito à sua integridade.

Key Words: testamento vital, documento de vontade antecipada, consentimento informado, dignidade da pessoa humana

TESTAMENTO VITAL: UMA POSSIBILIDADE NO DIREITO BRASILEIRO?

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Abstract

O Direito brasileiro reconhece, classicamente, o testamento como ato unilateral e personalíssimo de última vontade pelo qual se dispõem direitos (patrimoniais ou não) para depois da morte. Trata-se, portanto, de uma das formas de manifestação da autonomia privada. Destacam-se como principais características dos testamentos: são negócios jurídicos unilaterais sempre revogáveis (a qualquer tempo), gratuitos (ou benéficos) e formais cujos efeitos só podem ser produzidos após a morte do testador. É, sem dúvida, um dos atos mais solenes do Direito Civil brasileiro e poderá adotar as seguintes formas: a) ordinárias: público; cerrado; particular (art. 1.862, CC; b) especiais: marítimo; aeronáutico; militar (art. 1.886, CC). O legislador brasileiro aponta diversas limitações à autonomia do testador, no entanto, nada prevê quanto a impossibilidade de disposição de última vontade sobre direitos de personalidade, sendo portanto, plenamente aceitável testamentos com conteúdos destinados a sobre estes direitos dispor. Tem este trabalho por objetivo analisar a possibilidade de utilização do denominado testamento vital (biológico, testamento em vida, 'testament de vie', ou 'living will') à luz dor ordenamento jurídico brasileiro e se sua categorização como testamento é correta. Afirma-se que o testamento vital é negócio jurídico unilateral pelo qual a pessoa determina a que tipos de tratamento pretende ou não se submeter no caso de doença incurável ou terminal ou emergências ou urgências que lhe impeçam de manifestar sua vontade. No entanto, questiona-se até que ponto se pode admitir, à luz do ordenamento brasileiro, manifestações de última vontade sobre liberdades pessoais decorrentes de direitos fundamentais como vida, integridade física epsíquica e saúde, uma vez que expressamente o art. 11, do Código Civil, determina serem estes direitos irrenunciáveis e intransmissíveis, não podendo sofrer limitações voluntárias. Pergunta-se, então: pode o testamento dispor sobre eventual tratamento médico do autor da herança? É correto denominá-lo testamento uma vez que possui forma livre e produz efeitos para antes da morte? Tem o presente trabalho por objetivo analisar a possibilidade de negócios jurídicos unilaterais no Brasil que disponham sobre eventual tratamento médico do titular do direito de personalidade. Seria esta disposição de última vontade capaz de compatibilizar direito à dignidade da pessoa humana, regras de existência e validade dos negócios jurídicos e o art. 15, do Código Civil? Em tempos de alto desenvolvimento das tecnologias diagnósticas e terapêuticas médicas, trata-se de tema relevante, que exige discussões imediatas, a fim de garantir ao disponente segurança de que sua vontade será respeitada em uma situação clínica na qual já não possa mais manifestar expressamente sua vontade.

Key Words: testamento, validade, direitos fundamentais

THE (LIMITED) ROLE OF AUTONOMY IN THE CONTEXT OF THE LEGALISATION OF EUTHANASIA AND ASSISTED SUICIDE

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Abstract

In Western countries, patient autonomy is an important concept in medical law and medical decision-making. In the context of the debate on whether and how to legalise active euthanasia and assisted suicide, patient autonomy is often invoked as a principle that justifies, and in fact might even require, the legalisation of these practices under certain circumstances. However, when looking more closely at how the debate is framed, and how legalisation is proposed and implemented, it becomes clear that autonomy is an important, but never the decisive reason behind legalisation. Drawing on previous comparative research, this paper will examine some of the factors besides autonomy that influence the debate on the legalisation of euthanasia and assisted suicide, such as compassion; human dignity; the medical condition of the patient; and public interest considerations. Different approaches to the partial legalisation or decriminalisation of euthanasia and/or assisted suicide (in particular the Netherlands, Switzerland, Colombia and the UK) will be compared in order to analyse how they address the interplay of the different rights and interests that are at stake, and what role is given to the principle of autonomy. It will be shown that substantial variations exist with regard to the main reasons motivating the legalisation or decriminalisation in the different legal systems under examination. They equally differ in respect of the importance they attach to the principle of autonomy in this context. However, it will be argued that they all have in common that autonomy is only protected as long as the individual's choices are perceived to be in line with the prevailing social attitude towards euthanasia and/or assisted suicide. This leads to a discussion of whether the approaches to euthanasia and assisted suicide are out of synch with the focus on patient autonomy that pervades Western medical law, or whether, in a less obvious way, patient autonomy is always limited by the predominant views of society with regard to the acceptability of a patient's decisions.

Key Words: medical condition , assisted suicide , patient's decisions

The Application of International Health Regulation（2005） and International Travelers Rights in China

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Abstract

We should analyze the application pattern of international treaties in China and legal basis of the International Health Regulation (IHR) (2005) the in China. The Application of IHR(2005) in China goes by a kind of mixed mode that fuses such modes “adoption”, “transformation” and others. The Chinese government has clearly IHR (2005)" in the domestic legal force, And legislative form in order to provide for the corresponding legal laws and regulations, the administrative and judicial organs for the specific implementation. The Chinese government adopted a series of measures to implement the IHR(2005) To further safeguard and clear international travelers rights in China.

Key Words: international, health, regulation, travelers, rights

THE COMMERCIAL USE OF HUMAN MATERIAL

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Abstract

Over the course of history, the use of human materials has been cause for debate and controversy. The human has been regarded as sacred, a gift (or rather, a loan) from God. The subject's corpse represented and still represents the memory of the deceased, and is usually treated with the utmost respect by the relatives. Nevertheless, human material has also been used for scientific study, to train aspiring medical professionals, for therapeutic purposes and, in some cases, purely for profit. The human body has thus lost its "sacred" aspect in favour of a more practical one. As a result, a semi-commercial market in human material is on the rise. A double duality arises, as will be discussed in this paper. The first duality appears on this level, in Europe. Whereas pharmaceutical companies and biobanks are usually allowed to sell the material, the donor is not. As such, the donor is excluded from any profits that might be gained. Some believe that this is not fair towards the donor. However, switching to a fullblown commercial system might not be the right solution either. Commercial donors often face social isolation, a lower self-esteem, etc. The Iranian and Indian experience has shown us that these effects cannot be so easily circumvented. To do so would be to abandon the reasoning behind Titmus' "The Gift Relationship" and to embrace a respectful, yet commercial market system. This would also require a substantial reinterpretation of "human dignity" and basic human rights. Another duality presents itself. Whereas the commercial enterprises usually maintain property rights in the acquired materials, the donors tend to maintain a certain right of control as well. The donor's right of control seems to stem from basic human rights, such as the right to physical integrity, the right to self-determination, etc. This control does not have to impede the creation of a (continental law) property right. However, it would be logical for the donor to be the first proprietor, by right of acquisition. The material becomes a good as soon as it is separated from the person and is acquired by the donor, who may then relinquish the property right to a third party. Both dualities combine to create a feasible system. A higher level of transparency and consistency, however, is required.

Key Words: commercial use, human material, transplant

THE DUTY TO PERFORM A PATIENT RECALL

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Abstract

In my contribution, I will discuss the so-called patient recall. The relevance of this topic has recently been demonstrated by some topical cases. I can refer to the PIP breast implants-case1 and the worldwide recall of some Johnson & Johnson hip replacements in 20102. Besides some problems concerning product recall and product liability, the question arises what the obligations of the physician are in those cases. More specifically, it must be determined when the physician should inform his patient about dangers regarding the treatment or the resources used when those dangers are only discovered after the relationship between the physician and his patient is terminated. In other words: when should a physician carry out a patient recall? In my point of view, a physician is obliged to perform a patient recall in some cases, depending on the factual circumstances. When the physician fails to do so, he will be liable for breach of his obligation to inform the patient. In my opinion, three fundamental criteria should be taken into account in order to assess when the physician is obliged to carry out a patient recall, namely: the severity of the potential harm, the probability of the potential harm and the foreseeability of the potential harm. In my contribution, these criteria will be analyzed on the basis of some concrete examples.

Key Words: PATIENT RECALL, DUTY, PERFORM

THE ETHICS OR NON ETHICS OF AN EXPERT: THE HIRED GUN.

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Abstract

It has been said that there are three kinds of liars; the common liar; the damned liar and the scientific expert. That being said, one must look at the experts, the testimony, the methodology for selecting experts, as well as the influences and pressures surrounding an expert and the opinions of an expert. In addition, one must look at various state and federal rules designed to prevent bias, prejudice, pressures, and influences on an expert and whether or not any rules will ever enforce ethics upon an expert. In other words, when an expert testifies is the expert testifying as an expert who has been able to come to his or her own conclusions or opinions or is testifying as an expert draped in the mantle of either the plaintiff or defendant. It is a well known fact that attorneys “shop” to find an expert who will say what he or she wants. It is a well known fact that many attorneys draft either some or all of the written reports of experts, especially those that have to be disclosed to the opposite party. It is a well known fact that many experts charge exceeding high fees knowing that they will be paid “anything” to get a favorable opinion. This paper will explore the problems with the current expert system and whether or not the “hired gun” will ever be killed.

Key Words: written reports, methodology, defendant

the Euthanasia in East-Asia region: Based on observations of culture and experience

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Abstract

The Euthanasia is not only a legal or technological issue, but also a culture one. Based on the cases and discussions from P.R.China,Japan and Taiwan, which once are influenced by the Confucian culture, the author tries to find out that to what extent the culture functions in this issue.When we talk about series of the legislation on Euthanasia, we may take into account cultural characteristic.

Key Words: Euthanasia, East-Asia region, Culture

THE IMPACT OF PRESUMED CONSENT LAW ON ORGAN DONATION: AN EMPIRICAL ANALYSIS FROM QUANTILE REGRESSION FOR LONGITUDINAL DATA

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Abstract

Human organs for transplantation are extremely valuable goods and their shortage is a problem that has been verified in most countries around the world, generating a long waiting list for organ transplants. This is one of the most pressing health policy issues for governments. To deal with this problem, some researchers have suggested a change in organ donation law, from informed consent to presumed consent. However, few empirical works have been done to measure the relationship between presumed consent and the number of organ donations. The aim of this paper is to estimate that impact, using a new method proposed by Koenker (2004): quantile regression for longitudinal data, for a panel of 34 countries in the period 1998-2002. The results suggest that presumed consent has a positive effect on organ donation, which varies in the interval 21-26% for the quartiles {0.25; 0.5; 0.75}, the impact being stronger in the left tail of the distribution. Health expenditure has an important role on the response variable as well, the coefficient estimate varying between 42-52%.

Key Words: Human organs for transplantation , organ transplants, estimate that impact

The Information rights of the patient in the European Patients Rights Directive.

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Abstract

On 9 March 2011 the European Parliament and the Council adopted Directive 2001/24/EU on the application of patients' rights in cross-border healthcare (hereinafter: Patients' Rights Directive – PRD). It entered into force on 24 April 2011 and will have to be implemented by the Member States by 25 October 2013. The Directive imposes informational responsibilities upon both the Member State of affiliation (MSA) and the Member State of treatment (MST). The MSA shall ensure that there are mechanisms in place to provide patients on request with information on their rights and entitlements in that Member State relating to receiving cross-border healthcare, in particular as regards the terms and conditions for reimbursement of costs and procedures for accessing and determining those entitlements and for appeal and redress if patients consider that their rights have not been respected (article 5 b). The informational responsibilities imposed upon the MST and the healthcare providers in this state clarify the healthcare and the circumstances in which it is provided. These responsibilities can easily be read as rights to information of patients. They may be distinguished in 2 categories: information upon request of the patient by the national contact point for cross-border healthcare of the MST on the hand and information to be provided by healthcare providers of the MST on their initiative on the other hand. In this paper these information rights will be critically analyzed and compared to the 'classic' patients' rights to information and informed consent.

Key Words: rights, patient, European Patients Rights

THE LEGISLATIVE AND REGULATORY ACTS OF THE CIRCUMPOLAR REGION OF RUSSIA IN THE FIELD OF PUBLIC HEALTH

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Abstract

The method of continuous monitoring of the analysis work, the structure and dynamics of the 2159 legislation and regulations in the field of health care prepared by the staff of the Legal department of the Ministry of Health of the Republic of Komi (LD MH RK) and accepted for execution in 2007-2011. Among them: 40 Laws of RK, 9 Decisions of the State Council of RK, 18 decrees of the Head of RK Government Resolution 111, 97 Orders of the Government of the RK, 1884 Orders of the RK Ministry of Health (Table 1). Table 1. Dynamics of legislative and regulatory acts in the field of Health of the Republic of Komi by month and weekdays in 2007-2011. (In absolute numbers and P ± m%)

Key Words: method, continuous, monitoring

THE MARKET INTRODUCTION OF INNOVATIVE HIGH RISK MEDICAL DEVICES

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Abstract

The European Conformity (CE) marking grants early market introduction to innovative high risk medical devices based on safety and device performance only, without any requirement to demonstrate clinical efficacy or effectiveness. Hence healthcare providers, patients and payers are informed neither about the added clinical value compared to an existing medical device nor about the risks incurred by using such innovations. In addition there is a lack of coherence and uniformity of approach in the assessment of high risk medical devices. These gaps may put the health and safety of patients in danger. In contrast with Europe, the US system requires the demonstration of clinical safety and efficacy in a controlled way. The European Commission, in concert with Competent Authorities, industry, Notified Bodies, and other stakeholders, is working on a "recast" of the directives, with an anticipated date of implementation before the end of 2015. The target is the creation of a transparent system that supports the managed entry of new, safe and effective high-risk medical devices in the healthcare systems of EU Member States and at the same time stimulates innovation.

Key Words: patients in danger, patients and payers , healthcare providers

THE MEDICO-LEGAL DILEMMAS AND PITFALLS OF THE MEDICAL EXPERT WITNESS

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Abstract

The fastest growing field of law is undoubtedly that of Medical Law with the civil and disciplinary cases flowing from it. Globalization, international communication, development and evolution of Law as well as Medicine, cause this worldwide rising medical litigation. Humanitarian rights, post-modern scepticism and even iconoclastic attitudes contribute to this phenomenon. Medico-legal litigation and disciplinary complaints rise (in South Africa) up to 10 per cent per year. To assist the courts and legal profession, in medico-legal issues, helping the parties where the plaintiff has the burden of proof and the defendant for rebuttal, a medical expert witness must be used. The dilemmas and pitfalls arise,in that althoughknowledgeable medical experts could be used to guide the courts to the correct decision, the lack of a legal mind setting, court procedure and legal knowledge could affect the relevance, credibility and reliability, making the medical evidence of poor quality. The legal profession, deliberately, could “abuse” medical expert witnesses with demanding and coercion of results, which have unrealistic and unreasonable expectations. “Case building” occurs, especially in the adversarial systems of law, making the medical expert vulnerable under cross-examination, when it is shown that the witness has turned into a “hired gun” or is unfair. Thus,lacunae develop, making reasonable cases difficult and a quagmire of facts have to be evaluated for unreasonableness, credibility and appropriate-ness, compounded by the fact that seldom, cases are comparable.. The danger is that the presiding officer could be misled and with limited medical knowledge and misplaced values, could reach the wrong findings. Several cases arguably show that this has led to wrongful outcome and even unacceptable jurisprudence. The desire to “win” a case, can make a medical witness lose credibility and reasonableness with loss of objectivity, realism and relevance. With personality traits and subjectivity, the case becomes argumentative, obstinate and could even lead to lies. The miasmatic, hostile witness emerges, leading to embarrassing, unnecessary prolongation of court procedures. Medical expert witness should be well guided by the legal profession and well informed of the issues. Medical witness should have legal training and insight into the legal and court procedures. At the time of discovery of documents, via arbitration or mediation, medical experts should strive to reach consensus and then present their unified finding, helping the parties fairly and expediting the legal procedure and processes.

Key Words: Medical Law, Globalization, medical expert

THE MYTH OF INFORMED CONSENT. HOW INFORMATION AND CHOICE CAN REVEAL THE TRUE FACE OF AUTONOMY

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Abstract

This paper aims to demonstrate that there is a gap in the way patient´s autonomy is being discussed. All attention is focused on informed consent, and this approach is essentially wrong. Consenting is just a part of the process of choosing, and is not enough to allow patients to exercise their right to autonomy. This can only be accomplished through the complete and understandable disclosure of all information regarding treatment, their options and possible consequences. Among the numerous challenges facing health care providers today, few experiences are as ubiquitous as treatment refusal. Tragically, it is often the case that the very patients who are most inclined to refuse treatment are the ones who are in most need of it. Further complicating this matter, the dilemma pits two of the highest ethical principles in direct confrontation: respect for patient autonomy and beneficence. This situation often forces clinicians to navigate a treacherous path between the need to protect the patient and those around him or her while steering clear of any failure to respect the person. Consent to care and treatment is at the core of this relationship. Today, however, the increasing complexity of therapeutic options and a greater degree of autonomy of decision granted to patients as regards medical care, have led to a situation where the patient's consent is no longer simply implicit. It must be explicit with, as a consequence, more attention being devoted to what the patient has to say, even when it is in opposition to medical purposes. The most important right that a patient possesses is the right of self-determination, the right to make the ultimate decision concerning what will or will not be done to his body. This right, embodied in the informed consent doctrine, has a critical and essential corollary: the right to refuse treatment. Adequate disclosure of information, comprehension of information by the patient, free and voluntary choices, and competency must all be fully satisfied before any decision to refuse treatment can be considered valid. Particular emphasis should be placed on the information factor and the options available to the patient. In this respect, the physician should attempt to enhance the patient's ability to make decisions on his own behalf and to promote an understanding of the available options. This enables the competent patient to know the full range of options from which an informed refusal of treatment may be made. It should be emphasized that although competent patients generally are entitled to choose to forgo any treatments, including those that sustain life, physicians serve patients best by maintaining a presumption in favor of sustaining life and rendering optimum treatment until an effective informed refusal of treatment has been received from the patient or the patient's surrogate in those cases involving an incompetent patient. A patient's right to refuse medical care and treatment is protected by law. While improper handling of patient refusal is unlikely to give rise to a claim by itself, consent and refusal issues can complicate the defense of malpractice allegations when they do arise. The informed refusal obligation requires physicians to take a great deal of responsibility in communicating with patients about the need for specific treatment or tests, the risks involved, and the consequences of noncompliance. Proving that this communication has taken place, and that a patient's refusal is an "informed" one, hinges greatly on proper follow-up and documentation practices. Policy and procedure development can assist with establishing solid follow-up and documentation systems, but physician diligence and commitment to good record keeping is requisite for such systems to work. The paradox of contemporary medicine is that a constant expansion of therapeutic options makes decoding these options increasingly difficult. In legal terms, this new situation has been transposed into a growing demand for patient participation in decision making which seems to express the notion that anxiety caused by being subjected to some kind of medical dictatorship creates the need to even out a relationship which is by essence asymmetrical. To this recent culture is added a growing trend to judiciarization (although this is less prevalent than is generally thought to be the case) which challenges medicine to respond to contradictory imperatives: give the best possible care, but within mandatory limits and constraints, or confronted with hostility.

Key Words: Informed Consent, Information, Choice, Autonomy

THE NATURE OF MEDICAL OBLIGATIONS IN THE LIGHT OF COMPARATIVE STUDY

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Abstract

One find out by scrutinizing in the obligations of medical professionals that although the jurists have not explicitly mentioned the performance obligation or best efforts obligation of the medical professionals, but this is obviously evident from the tenor of their words and statements. In the Shiite jurisprudence the majority of jurists hold that the obligations of the permitted proficient physician are performance obligations and the physician's responsibility might be waived only in case of obtaining clearance before the operation. In the Sunnite jurisprudence, however the majority of jurists oppose the opinion of Shiite jurists and they consider the physician's obligation as the best efforts obligation in principle. In the laws of Islamic countries, France and common law the physician's obligation is basically regarded as the best efforts obligation too. It also seems in the statutory law of Iran that contrary to the legislature's view that has apparently deemed the physician's obligation a performance obligation following the majority of jurists, the physician's obligation is in principle the best efforts obligation in case of obtaining permission and enjoying proficiency; but in some particular cases and based on reasonable grounds, the nature of medical professions' obligations has been introduced as a performance obligation. Therefore, the nature of medical obligations and its manifestations are studied in this paper with a comparative view. For this purpose, the analytical discussion of the obligations of the medical professionals and affiliates in some of their disputed, common and involved applications such as prostheses, blood transfusion, medical trials, anesthesia process, guarantee of the patients' health and beauty surgeries have been addressed.

Key Words: Nature of Obligation; Performance Obligation; Best efforts Obligation; Medical Professionals

THE OFF-LABEL USE OF MEDICATION: STILL NOT THE FINAL WORD ON THE AVASTIN-LUCENTIS DEBACLE.

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Abstract

Off-label use of medication has become an important part of mainstream, legitimate medical practice worldwide and accounts for an estimated 21 per cent of drug use overall. It however remains a problematic area, with heightened risks for patients and medical practitioners. The Avastin – Lucentis debacle illustrates the ethical, policy and legal dilemmas encountered with such use. Avastin is authorized for the systemic treatment of metastatic colorectal and breast cancer by intravenous infusion. Ophthalmologists are using intra-ocular injections of Avastin (off-label) to treat age-related macular degeneration (AMD), which led to impressive results. AMD is a chronic disease of the elderly and is the leading cause of blindness in people over 50 years of age. The off-label use of Avastin is controversial because there are anti-VEGF drugs on the market, authorized for AMD, such as Lucentis. Lucentis is however extremely expensive and costs approximately 50 times more than Avastin. Many patients cannot afford Lucentis. In 2010 in the USA Lucentis accounted for 10% of the entire Medicare Part B drug budget, its single largest expenditure. Ophthalmologists did not have the backing of randomised controlled trials, or the blessing of the manufacturer of Avastin. However, in May 2011 the results from the first year of CATT, a large, randomized clinical trial comparing Lucentis and Avastin, were released. On efficacy the results for the drugs were the same. The study was not statistically powerful enough to identify meaningful differences in systemic drug-related adverse events and long term safety. In April 2012 the eagerly awaited final results were released. CATT was still not capable of determining an association between a particular adverse event and treatment. Ongoing trials in other parts of the world might or might not bring clarity in future. Currently there is conflict on the Avastin-issue between cost-conscious health authorities in EU Member States and the EU drug regulators which ensure that medicines are safe and effective. There are examples of cost-cutting solutions by health authorities which risk undermining the fundamental principles of the regulatory framework. Issues such as possible registration initiated by health authorities and product liability will be discussed. In the meantime risk is being shouldered by patients and doctors.

Key Words: OFF-LABEL USE, MEDICATION, AVASTIN-LUCENTIS DEBACLE

The Patients Obligations and Liabilities as the Condition Precedent for… the Protection of Their Rights

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Abstract

Legislations of many countries of the world are primarily aimed at the protection of patients' rights. This is natural and certainly justified. In the meantime, even a considerable number of legal norms envisaging patients' rights (especially without proper mechanisms for their implementation), with the insufficient legislative protection of health care professionals, is incapable of providing the effective protection of patients' rights. Indeed, if the legislation in force does not provide for a set of norms establishing the obligations of patients and protections for medical professionals or if it fails to do this in a clear way, the medical professionals start inventing the tools to protect their interests placed at risk in equivocal situations, by themselves. In most cases those tools do not directly stand in contrast with the legislation. However, medical professionals and health care institutions often resort to the use of legal shifts which are sometimes controversial from the ethical viewpoint. Although said tools are normally created to be doctors' remedies in ambiguous situations occurring because of the lack of proper legislative regulation, in practice they are from time to time used for avoidance of their liability for medical malpractice. When a patient's right is really infringed, sophisticated legal measures designed to protect medical professionals can make it problematic for the patient to defend his / her right, irrespective of the fact that it is envisaged by the legislation. Needless to say, that the state of affairs when doctors are more concerned about their protection than about the help to the patient is hardly acceptable. At the same time, when patients' obligations and liabilities are set force by the legislation, and when it is done in a clear way thus allowing both parties to determine what is expected from them, there is no need for medical professionals to think of the use of legally intricate protective measures instead of concentrating on helping the patient to manage a disease. The experience of many countries, including the newly emerged ones, shows that the better rights and obligations of patients and medical professionals are balanced and the more clearly they are stated in relevant laws, - the higher level of patients' protection and satisfaction is achieved.

Key Words: International Health Law, Bioinformation Society, New Dimensions

THE PRINCIPLE OF "EQUIVALENCE OF CARE" IN PRISON SETTINGS - EXPERIENCE OF INTERNATIONAL MONITORING BODIES FOR THE PREVENTION OF TORTURE

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Abstract

One of the international norms guiding prison health service is the principle of equivalence by which persons detained are entitled to have service of a quality equivalent to that provided to the general public in the same country. Although many countries have adopted that principle in their legal documents relating to care in prison settings, the principle of equivalence is far from being achieved and applied worldwide. The experience of international monitoring bodies for the prevention of torture and other forms of ill-treatment (United Nations Subcommittee on Prevention and European Committee for the Prevention) shows that it is time to think more on what we really mean by this principle and how to apply such care to prison population having in mind the fact that detainees are the most vulnerable group in the society, with all their specificity. A new step forward for prison medicine will be to admit that the principle of equivalence is often insufficient and that prison health service would need to be higher in many aspects.

Key Words: international, experience, ill-treatment

THE PROBLEMS OF MEDICAL MALPRACTICE IN CRIMINAL LAW IN JAPAN

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Abstract

Key Words: PROBLEMS, MEDICAL, CRIMINAL

THE PROTECTION OF THE PHYSICAL INTEGRITY AND THE PRINCIPLE OF INVIOLABILITY OF THE HUMAN BODY REGARDING COMPULSORY VACCINATIONS

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Abstract

The Belgian law of 22 August 2002 on patients' rights introduced the requirement of prior informed consent to all medical procedures including vaccination. The right to physical integrity is an absolute right guaranteed by Article 3 of the Convention for the Protection of Human Rights and Fundamental Freedoms. The Charter of Fundamental Rights of the European Union also established in 2010 the right to the integrity of the person, in order that everyone has the right to respect for his or her physical and mental integrity. Article 3 of the Charter also established that in the fields of medicine and biology, this right must be respected, in particular where the free and informed consent of the person is concerned, according to the procedures laid down by law. Under Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms is the right to respect for private and family life protected with no interference by a public authority, with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests for the protection of health. In such circumstances which could be the limits to prior informed consent in the field of compulsory and/or pandemic vaccinations? How do we legally apply the proportionality examination considering the protection of the health in its individual and collective dimensions? To which extent will individual medical contraindications and the therapeutical freedom of physicians be respected? In which circumstances could a medical treatment like vaccination be imposed? What about the responsibilities about the damages caused by the heavy metals which are components of some vaccines? Where the efficacy of a given vaccination is either partial or not guaranteed, could the medical act of vaccination be legally requalified as "medical experimentation"? All these complex questions will be examined through Belgian and European jurisprudence and the application of the constitutional and international law provisions, against the backdrop of the fundamental principle "Primum non noccere".

Key Words: PROTECTION, PHYSICAL INTEGRITY, PHYSICAL INTEGRITY, COMPULSORY VACCINATIONS

THE REFORM OF LIABILITY FOR MEDICAL MALPRACTICE IN THE TORT LAW OF THE PEOPLE'S REPUBLIC OF CHINA:ITS SUCCESS AND SHORTAGES

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Abstract

The amount of medical disputes in China is increasing continually. The main reason is that the legal provisions are conflicting or lacking. In order to clarify the tort liability, promote the social stability, The Tort Law of China implemented in 2010 and set up a chapter on liability for medical malpractice. It provides for diagnosis and treatment behavior for fault liability. It specifies special circumstances that healthcare staff shall be at fault or not assume compensatory liability. The object and content of obligation to disclose and healthcare staff's behavior is regulated and patient's behavior is ordered. The Law maintains both healthcare staff and patient's benefit, promote medicine development and improve the relationship between them. However, there are some shortages in The Law and should be remedied by judicial interpretation. For instance, on models of remedy, we should establish arbitration institution on medical disputes. On legal provisions for remedy, we should give authoritative provisions on cognizance of medical malpractice, demonstration of causal relation. On origin of compensation fund, we can take experiences of medical liability insurance as reference and establish social compensation mechanism, and so on. In this article, how to correctly understand and use The Law will be discused.

Key Words: compensatory liability, healthcare staff , medical malpractice

THE RISE OF STEM CELL IN MEXICO: INEFFECTIVE ENFORCEMENT OF BIOMEDICAL LAW

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Abstract

The rapid pace of stem cell science poses significant challenges, particularly in countries where such novel biomedical activity is ethically controversial. Mexico has not adopted nationwide legislation for stem cell research activities. Lately, it has emerged as one of the favoured places for medical tourists to obtain unregulated stem cell therapies, which are commonly untested and hazardous, yet easily available. This paper explores the regulatory landscape under which these therapies have emerged, which has led to the flourishing of a stem cell tourism phenomenon in the country. This paper illustrates that even though there are a few relevant regulatory provisions and governmental agencies to oversee biomedical research, so far, the ineffective enforcement of these legal mechanisms has allowed the expansion of stem cell therapies, which lack enough evidence of quality, safety and efficacy. Three stem cell therapy providers are scrutinised as case studies in order to illustrate these failings and highlight the main challenges represented by their operation. This informs the answers to the questions of whether and why there is a need to perform a fundamental review of the existing legal scheme to identify improvements that can be performed in terms of scope and enforcement of the regulatory system. It is suggested that the absence of targeted legal provisions for stem cell research and its clinical application may jeopardise the establishment of public trust in this emerging field. It is crucial to strengthen the regulatory regime and agencies to effectively oversee the clinical application of stem cell science seeking to protect those pursuing untested therapies.

Key Words: stem cell tourism, stem cell therapies, ethical oversight, regulation, Mexico

THE ROLE OF THE EXPERT WITNESS IN LEGAL MEDICINE

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Abstract

Legal medicine deals with the interface of medicine and law from the perspective of the health professional, rather than that of the legal practitioner. The expert witness, within the legal medicine domain, provides expert medical testimony, limited to his/her domain of speciality and expertise. This is designed to allow those within the legal system to better understand and to interpret the effect, or influence, exerted upon the issue(s) in question by the medical circumstances that prevail within the context of a given case. There is no need for expert testimony if the information to be considered is freely available and comprehensible to a 'lay' audience – not requiring an expert to explain its intricacies. The expert provides the missing link to the legal deliberations to assist the adjudicators, be they judge or jury, to understand the matters under review and hence allow interpretation and subsequent apportionment of relevant responsibility within any given scenario. The expert must appreciate the absolute expectation for an unbiased evaluation but this does not equate to failing to provide a well constructed and clearly defined opinion, either for or against a given set of presumptions and circumstances. The expert must examine all material provided and, where this is in conjunction with a medical consultation, conduct the consultation without prejudice or favour. The final conclusion should rely on all available information and be prepared in such a way as to ignore which party sought the expertise, as the overarching responsibility is to the court, not the protagonists within any given case. The ultimate responsibility, for the legal medicine expert, is to maintain his/her own integrity, a virtue more important than any other responsibility. The role of the expert witness in legal medicine is to provide truthful medical answers to questions posed and largely ignore the legality of those responses so long as they are true and honest. It is the role of the lawyers to review legality and admissibility – not the legal medicine expert.

Key Words: Legal Medicine, Expert Witness, Duty, Responsibility, Role

The state of medical law and bioethics teaching as a curricular essential in medical training in Nigeria: A case for Africa and the developing world

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Abstract

Medical law and ethics became central to the medical profession since autonomy supplanted medical paternalism following outcry from inhumane practices by the middle of the 20th century. This has been principally to ensure safety of patients while in the hands of healthcare personnel and researchers. While this has not completely exterminated medical malpractice, it has, to a significant degree, brought sanity to the medical profession. Central to this achievement is the integration of medical law and ethics into the medical curriculum in most developed countries; thus equipping the future doctor with the fundamentals of medical law and ethics he would require for his medical career. In these countries the result has been a great departure from medical paternalism with its potential for exploitation and inhumane practices; to the current autonomy model of healthcare that counters such practices. However, while medical law and ethics has significantly developed in most developed countries to facilitate, inter alia, accountability in medical practice, it is not the case in Nigeria and most developing countries thus leaving the future doctor ill prepared for the legal and ethical dilemmas of his career. Not surprising, in such countries medical practice is still largely paternalistic with great potential for malpractices. This paper highlights the current state of medical law and ethics in medical training in Nigeria, thereby raising the case for the developed world to carry along Africa and other developing countries to match in step on strategic integration of medical law and ethics into medical education as deterrent to medical malpractice.

Key Words: autonomy, safety, medical law

THE STUDY OF THE RIGHT TO HEALTH IN INTERNATIONAL MEDICAL LAW

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Abstract

Key Words:

Torture by Introducing Foreign Object in Rectum - A Case Report

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Abstract

Foreign body in rectum has been reported frequently, attributed to whatever may be the cause. If the cause for it is assault or torture, then to quantify the trauma / pain either local or mental cannot be ascertained since it is a subjective matter although it is highly painful and embarassing for the person who sustains the assault. A unique case of assault for the purpose of torture given to a man about 30 years of age male resident of Kashiram Nagar of Uttar Pradesh (India) reported to the emergency department of JNMCH, AMU, Aligarh with severe pain in lower abdomen and bleeding from anus. He was brought at 2:00 PM on 28th of Jan 2012 with alleged history of forced insertion of ceramic tea cup in his rectum that is a forceful insertion of a ceramic tea cup in the rectum by a group of people the reason being defecating in their field. Such a painful situation and also embarassing and awkward position in society is not addressed in societies in developing countries in any terms of compensation, social rehabilitation or mental rehabilitation. Laws are to be stringent enough for prohibiting the assailants from daring such activities

Key Words: Foreign, Frequently, Assault

TRANSFUSÕES DE SANGUE CONTRA A VONTADE DE PACIENTE DA RELIGIÃO TESTEMUNHAS DE JEOVÁ: UMA GRAVÍSSIMA VIOLAÇÃO DOS DIREITOS HUMANOS

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Abstract

A recusa dos pacientes da religião Testemunhas de Jeová em receber transfusões de sangue em situações de iminente risco de vida tem suscitado debates nos meios médicos e jurídicos. O presente artigo tem a pretensão de demonstrar que essa recusa tem apoio na Constituição Brasileira e também na legislação infraconstitucional. Os seguidores da religião Testemunhas de Jeová, diante, basicamente, da interpretação que fazem das passagens bíblicas dos Livros de Gênesis, 9:3-4[1]; Levítico, 17:10[2] e Atos 15:19-21[3], recusam-se a se submeter a tratamentos médicos ou cirúrgicos que incluam transfusões de sangue[4]. Na impossibilidade de se valerem de tratamentos alternativos (sem sangue), negam-se a receber transfusões, mesmo que isso possa levá-las à morte.Esta postura das Testemunhas de Jeová periodicamente desperta a atenção dos meios de comunicação social, que, por ignorância ou má-fé, acabam dando uma conotação de que os adeptos dessa religião são pessoas fanáticas e suicidas. Entretanto, nada poderia ser mais equivocado, pois elas apenas buscam tratamentos e alternativas médicas que reputam seguros (sem sangue) e aceitáveis sob o prisma de suas convicções religiosas. É inegável que a postura firme das Testemunhas de Jeová em rechaçar as transfusões de sangue tem alavancado o progresso científico de descoberta e aprimoramento de tratamentos alternativos[5]. Ademais, elas organizaram uma rede, de âmbito internacional, de Comissões de Ligações com Hospitais (COLIH), existentes em 230 países e territórios, que auxiliam na transferência de pacientes para hospitais ou equipes médicas que usam alternativas às transfusões de sangue. Também fazem trabalho de esclarecimento junto aos profissionais de saúde quanto a esses tratamentos alternativos, bem como em relação aos riscos das transfusões de sangue.

Key Words: Transfusões de sangue, Liberdade religiosa, Testemunhas de Jeová, Princípios constitucionais, Direitos dos pacientes

Trauma Masking Sudden Natural Death: A Case Report

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Abstract

Major component of forensic pathologists is their ability to recognize and interpret injuries and determine its role in causing death. It becomes more complicated in sudden natural deaths, wherein there are significant external mechanical injuries. Meticulous investigation plays an important role in unravelling such deaths. We here by present a case of sudden death of 75 years old lady who was brought dead to hospital with external injuries to head after fall in bathroom. But after autopsy we were able to attribute cause of death due to rupture of left ventricular wall and not due to head injury.

Key Words: Sudden deaths, myocardial Infarction, trauma

UN ESTUDIO DE DERECHO COMPARADO. LA EXIGENCIA DE RESPONSABILIDAD PENAL POR IMPRUDENCIAS MÉDICAS EN INGLATERRA, GALES Y ESPAÑA.

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Abstract

Pudiera parecer que en los países miembros de la Unión Europea, la respuesta jurídica ante las imprudencias sanitarias que terminan con el fallecimiento o con el menoscabo de la salud del paciente fuese uniforme. Sin embargo, un estudio de Derecho comparado entre ciertos países pone de manifiesto que las diferencias existentes no son menores. El trabajo que ahora se presenta trata de comparar, desde el punto de vista del Derecho penal, la realidad jurídica a la que los profesionales de la salud se pueden ver enfrentados por presuntas negligencias médicas en, de una parte, Inglaterra y Gales, y, de otra, España. Con el objetivo de identificar y explicar estas diferencias, el trabajo se divide en las siguientes partes. (1) A modo de introducción, hay que señalar que lejos de lo que pudiera parecer, la exigencia de responsabilidad al profesional sanitario no cuenta con más tradición en el Reino Unido que en España. (2) La exigencia de responsabilidad en vía penal es casi inexistente en Inglaterra y Gales, a diferencia de España donde, a pesar de que el número de demandas civiles es mayor que el de penales, la cifra de estas últimas no es nada despreciable. (3) Como razón principal de lo anterior hay que señalar las diferencias existentes entre el Derecho positivo de un país y los otros en materia penal. Mientras que en España se tipifican como delito no sólo el 2 homicidio imprudente (incluyendo además la imprudencia profesional), sino también las lesiones por imprudencia, añadiéndose además las faltas por imprudencia grave e incluso leve, en Inglaterra y Gales sólo se contempla el delito de homicidio imprudente como delito potencialmente. (4) En Inglaterra y Gales existe una mayor tradición en lo que al desarrollo de sistemas de notificación de eventos adversos se refiere, enmarcados dentro de la cultura del error (frente a la cultura de la punición), que la existente en España. (5) Todo ello nos lleva a concluir que es necesario estudiar en profundidad cada uno de los sistemas legales para comprender dónde radican las diferencias y, a partir de aquí, sentar las bases para tender hacia la unificación de respuestas jurídicas en un sector, el sanitario, en el que sí existe movilidad de trabajadores en el seno de la Unión (especialmente importante es la migración de profesionales de la salud desde España al Reino Unido en la última década).

Key Words: errores médicos, responsabilidad penal, Derecho comparado

UNFORESEEN ETHICAL/LEGAL COMPLICATIONS WITH SCREENING TESTS IN THE CAPITATION MODEL OF MEDICAL AID SCHEMES

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Abstract

In South Africa, the health care funding industry is under pressure to fund delivery of medical care to its beneficiaries. The sector is divided into those who can afford private care and those who rely on state medical assistance. This discussion aims to determine the effects different funding models have on medico-legal liability of health professionals serving the private sector. Ideally, purely medical reasons should determine the service rendered. However, financial implications of services rendered and defensive practice of medicine due to the threat of litigation, also contribute to what is done to a patient and the remuneration therefore. Where the practitioner commits to delivering a predetermined set of services within a particular time for a predetermined "lump sum", such as an ophthalmologist screening patients for diabetic eye disease, he/she is only paid for the service specifically requested. Should he/she find any other disease than those contracted for, would inaction in regard to that disease be deemed negligent or unethical? This paper argues that according to legal and ethical considerations the practitioner will act unethically and negligently.

Key Words: ETHICAL/LEGAL COMPLICATIONS, SCREENING TESTS, MEDICAL AID SCHEMES

Valor do diálogo enfermeiro/paciente para o cuidado ético e humanizado

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Abstract

Tem havido em nosso meio uma excessiva profissionalização da comunicação enfermeiro-paciente. Em outros termos, na atuação do enfermeiro não se percebe, ou não se explicita, a presença de sua pessoa,mas só de seu papel. Esta situação determina uma identidade de atos comunicativos que, por sua vez, delineia uma relação profissional mecanizada e despersonalizada. Esta situação se contrapõe aos valores que fundamentam a profissão. A Enfermagem é basicamente um processo de interação humana e o diálogo é parte essencial desse processo,constituindo-se em um dos recursos mais significativos do agir do enfermeiro.O propósito deste estudo é discutir o diálogo entre enfermeiro e paciente, com base nas proposições de Barros-Filho,que apontam que do diálogo podem ser derivados:-união de elementos, visão de mundo , formalidade/efetividade e conduta. Tais proposições podem contribuir para o fortalecimento da prática profissional da enfermagem , de tal modo que revele maior humanização no processo e na gestão do cuidado.,bem como maior aproximação entre enfermeiro e paciente.

Key Words: diálogo, ético, enfermeiro

WHAT DOSE TELLING A CHILD ABOUT HIS CANCER TO THE ADLT SURVIVOR?

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Abstract

Objectives: The study was designed to provide research-based evidence of the common procedure of communicating 'information' (i.e., the content, timing and source of information) to a child diagnosed with cancer. The goal was to investigate the psycho-social (quality of life and mental pain) impact of the procedure in adult cancer survivors. It was hypothesized that 'good information' (structured information, given at the time of diagnosis or soon after, by a team and/or parent) provided to the child would contribute positively to the survivor's quality of life, whereas non-constructive information would impact it negatively. Design: Descriptive, correlational prospective study. Setting: A clinic for follow-up of childhood cancer survivors in a major children's' medical center in central Israel. Sample: A convenience sample of 99 healthy adult Israeli survivors of childhood cancer (mean age 25- years; mean time since diagnosis and treatment- 13 years; the mean age of the child at diagnosis was 11.47 years). Main research variables: 'Information', 'constructive information', 'non-constructive information', the meaning of childhood cancer, quality of life, mental pain and mental pain tolerance. Methods: Structured questionnaires about the provided information, quality of life and mental pain were administered to participants while waiting in the course of the annual follow-up visit.

Key Words: Mental pain, a multidimensional operationalization, a multidimensional operationalization

WHEN THE VICTIM IS A CHILD: PEDOFILY, PORNOGRAPHY AND CYBERBULLISM IN THE ITALIAN REALITY.

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Abstract

Italy the problem of child abuse or neglect is coming out during the last 10 years when, very often, different cases of abuse or homicide with these little victims have started to be present. The diffusion of internet and the accessibility also to children or young people, the different education of children aged 8-15 ys old and the lack of the family, especially of the father, represent a source where people with deviated behaviour find the “humus” in which they can find special victims for their crimes, both physical and psycological. The authors present the Italian reality, they make the analysis of cases they have followed both as consultant for the Court tant from cases observed inside specific research made in the University Department of Social Medicine.

Key Words: Italy the problem, abuse or neglect, 10 years when,

WHO NEEDS PALLIATIVE CARE IN AZERBAIJAN?

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Abstract

As it follows from WHO definition, provision of palliative care to patients should start from the moment of diagnosed progressing irreversible illness, when possibilities of specialized treatment are limited or confined, that inevitably leads to death of patients in the near future. Early and correct organization and provision of care makes it more probable that we may carry out set up task – that is achieving of maximally possible quality of life for patient and his family. On this stage palliative care, as a rule, is provided by the physicians that participate in the process of patient's diagnosis and treatment. To speak about selection criteria mainly for palliative care, however, is especially necessary when the issue relates to patients who already received radical treatment, but whose illness is still progressing and passing to terminal stage, or no more treatment due to late examination. That is the group of patients, to whom medicine usually says "we may no more do anything". On this stage we say about "end-of-life care", as a part of palliative care, defined in certain time frames and targeted on provision of support to patients (and his family) in the end of life. However, this care is showed for those patients that experience physical and other types of sufferings and require active intervention. Patients may be divided into three main groups, requiring specialized palliative care in the end of life: • patients with malignant neoplasms on the 4th stage; • patients with AIDS in terminal stage; • patients with non oncologic chronic progressing illnesses on terminal stage of development (including decompensation stage of cardiac, lung, hepatic and renal failure, disseminated sclerosis, grave consequences of dysfunction of cerebral circulation and others). Palliative care specialists consider that selection criteria concern patients with expected limited continuation of life for not more than as well as evidence of the fact that further attempts of treatment are unreasonable (including firm confidence of specialists in accuracy of diagnosis); presence of complains and other symptoms (discomfort), which require special knowledge and skills for conducting symptomatic therapy and care. There are a lot of palliative care models all over the world and Azerbaijan health managers and specialists should think which is best to help thousands patients belonging to mentioned above groups.

Key Words: WHO definition, palliative care to patients , selection criteria

WHY AND HOW TO MAKE AN INTERNATIONAL CRIME OF MEDICINE FALSIFICATION

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Abstract

Although intentionally falsified medicines are a global problem, which sicken or kill at least thousands of people a year, currently international law does not even attempt to criminalize this public health outrage, which is perfectly legal. The international law on intellectual property is not well suited to address the problem, because falsification causes injury to human health and not just property, and should be punished more severely. In this presentation, we summarize the current medical and public health evidence that counterfeit medicines are a serious danger to human well-being, and review legal doctrines from treaties on other subjects and from the jurisprudence on crimes against humanity to argue that a treaty to criminalize the falsified medicine trade is both timely and possible. We couple the proposal to criminalize falsified medicines with other regulatory measures, not of a criminal nature, to improve the quality of accidentally substandard medicines, so as to improve the quality of medicines globally. The proposals that will be presented correspond to a consensus of the leading global institutions of the health professions, such as the World Federation of Public Health Associations and the International Pharmaceutical Federation, with whom these ideas have been co-developed.

Key Words: International Pharmaceutical Federation, medicines, intellectual property