



ACLM 2017 ANNUAL SCIENTIFIC MEETING

THE LAW AND ETHICS OF THERAPEUTICS: PROGRAM

SATURDAY 21 OCTOBER 2017

8:00 am	<i>Registration opens</i>
8:30 am	President's welcome
8:45 am	MR PAUL YOVICH SC Doctors behaving badly
9:30 am	DR ANDY ROBERTSON State regulation of medicinal cannabis
10:00 am	PROF ROY BERAN Conducting clinical trials in private practice
10:30 am	<i>Morning tea</i>
11:00 am	DR BRENT HYSLOP Dementia, best interests, and non-consensual drug trials
11:30 am	DR ALEXANDER HOLDEN A whiter shade of grey: the professional and legal position of tooth whitening
12:00 pm	PROF VERA LUCIA RAPOSO Off-label prescription and the best standard of care
12:30 pm	<i>Lunch</i>
1:30 pm	DR ANDY ROBERTSON Drug supplies in a disaster response
2:00 pm	MR COLIN PRIDDIS New psychoactive substances: the dynamic legal status
2:30 pm	PROF MIKE O'CONNOR Going to grass in pregnancy
3:15 pm	<i>Afternoon tea / ASM Day 1 close</i>
3:45 pm	ACLM AGM
4:45 pm	<i>AGM close</i>
6:00 pm	Pre-dinner canapes in the courtyard
7:00 pm	COLLEGE DINNER <i>Dress: Cocktail</i> Presentation of awards and speech by Dr Wojciech Chrzanowski

SUNDAY 22 OCTOBER 2017

8:00 am	<i>Registration opens</i>
8:30 am	PROF ERWIN LOH & DR JESSICA DEAN Pharmaceutical industry presence in health services
9:00 am	DR MARIA DUDYCZ The law and ethics of sterilisation of disabled persons
9:45 am	DR MICHAEL CHRISTMASS The problem is crystal... but is the solution clear?
10:30 am	<i>Morning tea</i>
11:00 am	DR WOJCIECH CHRZANOWSKI Nanosafety and therapeutics
12:00 pm	DR SANDRA JOHNSON Ethics of therapeutics in paediatrics
12:30 pm	DR DON BUCHANAN Opiate prescribing and real time reporting
1:00 pm	<i>Lunch / ASM concludes</i>



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AUSTRALASIAN COLLEGE
OF LEGAL MEDICINE

THE LAW AND ETHICS OF THERAPEUTICS: ABSTRACTS

MR PAUL YOVICH SC

DOCTORS BEHAVING BADLY

I will present an outline of the legal principles relating to professional disciplinary sanctions, including reference to the statutory definitions of the various levels of misconduct set out in the Health Practitioner National Law, and to the leading statements in the case law about how disciplinary sanctions are assessed.

I will also talk a little about the apparatus of complaints and their resolution, and particularly about how to approach a professional disciplinary allegation if one is made against you.

I will then discuss issues specifically relating to drugs – touching on abuse of prescription or other medication by health practitioners but focusing more on inappropriate prescribing to patients, with reference to examples from my own legal practice. I will discuss how those sorts of cases are typically dealt with in professional disciplinary cases, and why, and consider the law's part to play in minimising inappropriate prescribing of drugs of dependence. In this context I will compare how the criminal law deals with illicit drug use and distribution.

*Barrister, Francis Burt Chambers
B.Juris (Hons), LLB*



DR ANDY ROBERTSON

STATE REGULATION OF MEDICINAL CANNABIS

In November 2016, the Therapeutic Goods Administration reclassified cannabis-based products (CBP) with tetrahydrocannabinol as Schedule 8 drugs. The Commonwealth Office of Drug Control also opened a license and permit scheme for cultivation and manufacture of medicinal cannabis. As current medical evidence for the safety and efficacy of CBP is still limited for most indications, the Western Australian Department of Health was required to develop the legislation, policy and processes to manage the expected demand for these drugs. This presentation will outline the benefits and challenges of this approach in managing an unregistered drug with limited benefits but significant consumer demand.

DRUG SUPPLIES IN A DISASTER RESPONSE

Disaster planning requires an understanding of the requirements in any major incident, whether that be an earthquake or a bioterrorism attack. Disaster responses may require the stockpiling and use of large quantities of pharmaceuticals, the rapid supply of these drugs, administration of drugs by other health professionals, and the rapid distribution and the use of unregistered novel pharmaceuticals to manage emerging chemical or infectious threats. In this presentation, the legislative options for rapidly supplying the required therapeutic agents, the issues with these approaches, and the strategies designed to address these, including the National Medical Stockpile, will be discussed.

*Deputy Chief Health Officer and Director of Disaster Management, Office of the Chief Health Officer,
Public Health Division, Department of Health WA
CSC, PSM, MBBC, MHSM, MPH, FAFPHM, FRACMA*



PROFESSOR ROY BERAN

CONDUCTING CLINICAL TRIALS IN PRIVATE PRACTICE

Clinical trials of new agents enhance treatment options. Such trials are usually conducted in large tertiary referral centres, rather than the private practice setting. This paper reports the experiences of a private outpatient neurological clinic, which conducts such trials as part of its commitment to improve patient care.

Trials conducted in private practice give those patients access to novel treatments. They do not require referral to a tertiary institution, thereby maintaining continuity of care. The recruitment base is broader and may better reflect 'real world' practice. The private practice setting generates different pressures and ethical expectations. This paper discusses these demands and how they are addressed and offers concepts which should be transposable and transportable to other private clinics and clinical environments. This should allow clinicians to offer their patients additional options and contribute to greater satisfaction by ensuring that those doctors remain at the forefront of therapeutics.

*ACLM Council Member | Consultant Neurologist | Conjoint Associate Professor of Medicine,
University of NSW | Professor, School of Medicine, Griffith University, Gold Coast QLD
MBBS, MD, FRACP, FRACGP, Grad. Dip. Tertiary Ed., Grad. Dip. Further Ed., FAFPHM, FACLM, FRCP,
FACBS, B Leg. S, MHL and FFFLM (Hon)*



DR BRENT HYSLOP

DEMENTIA, BEST INTERESTS, AND NON-CONSENSUAL DRUG TRIALS

People with advanced dementia (and some other conditions) may be unable to consent to enrollment in clinical drug trials (CDTs). It is important, though, that dementia research continues and non-consensual CDTs may be proposed. Under New Zealand law, non-consensual CDTs (and other research) may only proceed if it is deemed to be in participants' "best interests". It has been argued, however, that non-consensual CDTs cannot be known to be in participants' best interests and so are not currently permissible, leading to a 2017 Health and Disability Commissioner review.

In this paper, I argue that non-consensual CDTs are in some cases permissible under a best interests standard. Firstly, assuming clinical equipoise, enrollment in a trial offers participants a chance of receiving a superior treatment. The concept of best interests is inherently probabilistic and may be satisfied on this basis. Secondly, there may be an objective medical benefit from simply being enrolled in a clinical trial, regardless of which treatment is received ('the inclusion benefit'). Thirdly, based on Right 7(4) and common law, a determination of best interests should include a subjective element. A best interests standard may be satisfied based on a person's known wishes about participation in research. I conclude that, in some cases, non-consensual CDTs may be in a person with dementia's "best interests", although more clarity is still required on this issue.

*Geriatrician, Southern District Health Board | Clinical Senior Lecturer, Dunedin School of Medicine, University of Otago
FRACP, MBChB, ClinDipPallMed, PGDipBHL, and have completed requirements for MBHL*



DR ALEXANDER HOLDEN

A WHITER SHADE OF GREY: THE PROFESSIONAL AND LEGAL POSITION OF TOOTH WHITENING

Tooth whitening or bleaching is a divisive and controversial intervention with regards to professional remit and scope of practice. The dental profession is of the belief that the intervention is a professional procedure whilst non-qualified practitioners feel it is a legitimate addition to a cosmetic, beautifying armamentarium. This presentation will begin by considering and contrasting the differing legislative pharmaceutical frameworks relating to tooth whitening/bleaching within the jurisdictions of the United Kingdom, Australia and New Zealand. The consequences of these differing positions on dentistry's professionalism and the social contract will then be examined.

*Dental Surgeon - Lecturer in Dental Ethics, Law and Professionalism
BDS MDPH LLM MJDF RCS (Eng) MA CLM FRSA*



PROFESSOR VERA LUCIA RAPOSO

OFF-LABEL PRESCRIPTION AND THE BEST STANDARD OF CARE: DO THEY GO TOGETHER?

Off-label prescription refers to the use of an approved drug, but in different circumstances than the ones stated in its marketing authorization (MA) and in its label. Therefore, the drug may be used for clinical situations not envisaged in the MA, in groups of patients not included in the MA or by using a different delivery method. This is a common practice all around the world, since frequently there is no specifically approved drug for certain medical conditions, while there are good scientific evidences that a drug originally approved for another medical condition can also have good results for that first one.

Freedom of prescription is a defining note of the medical profession; therefore, the doctor has the power to choose which drug to use, even disregarding the content of the MA, provided it complies with the medical *leges artis*. However, when a drug is prescribed off-label this means that it is being used in a medical scenario for which it has not been specifically authorized (i.e., the drug was not submitted to clinical trials concerning that particular medical situation). Because of the lack of scientific evidences regarding the efficiency and safety of the drug the patient can suffer serious injuries and, consequently, the doctor faces an increased risk of medical liability. In most countries the law is not clear regarding the legitimacy of this practice, so, in the absence of express prohibition, doctors continue to prescribe off-label, even though its legitimacy is still discussed.

This presentation will demonstrate that off-label prescription is not necessarily illegal. However, it depends on the fulfilment of certain requirements related with the medical decision to prescribe off-label: preference of the duly approved drug for the medical condition, patient's informed consent, sound scientific grounds, monitoring and follow up of the patient. The decision must be taken by the doctor, having exclusively in consideration the patient's well being and disregarding economic or pharmaceutical motivations. Under these circumstance off-label prescription is not against *leges artis*; quite the opposite, frequently corresponds to the best standard of care.

*Professor at the Faculty of Law of Macau University, China | Professor at the Faculty of Law of Coimbra University, Portugal
Bachelor in Law, Post-Graduation in Medical Law, Master in Public Law, Doctorate in Public Law*



MR COLIN PRIDDIS

NEW PSYCHOACTIVE SUBSTANCES (NPS) – THE DYNAMIC LEGAL STATUS OF SUBSTANCES DERIVED FROM LICIT AND ILLICIT SOURCES

Typically NPS find their way into our community through an individual's importations of substances via internet sources or organized crime syndicate importations. They challenge law enforcement at both the national and state levels. NPS are usually chemical derivatives of known licit or illicit drugs however can also, whilst bearing seemingly little chemical structure similarity, exert a strong interaction on specific receptor sites. Impact on public health can be dramatic from elevated incidents of unusual and unexplained behavior through to road trauma, criminal activity and fatalities. The emergency departments, police and forensic scientists are left scrambling to understand the health, legal and analytical issues that arise from the diversity of NPS. This paper will discuss these issues and some of the solutions used in WA to counter the impact of NPS.

Director, Forensic Science Laboratory, ChemCentre WA

Qualifications in Organic Chemistry, Pharmacology and IT with additional training in QA, Clandestine Laboratory Investigation, CBRN, Management and Leadership. A member of RACI, ANZFSS and TIAFT and a NATA technical assessor. Chair of the Former Senior Managers of ANZ Forensic Laboratories and a foundation member of the National Institute of Forensic Science (NIFS) Forensic Executive Committee. Mentor to the NIFS Chemical Criminalistics Specialist Advisory Group(SAG), past mentor to the Toxicology and Illicit Drugs SAGs and a member of the Standards Australia Forensic Standards Committee.

DR MIKE O'CONNOR AM

GOING TO GRASS IN PREGNANCY

In the United States the use of marijuana for the control of nausea has been legalised in 29 States and Washington DC. One consequence of that is the increasing use of cannabis to control hyperemesis gravidarum especially in the first trimester of pregnancy. Although deemed by many as harmless in terms of adverse fetal effects there is evidence that the use of marijuana in pregnancy is associated with maternal anaemia, low fetal birthweights and an increased risk of neonatal intensive care requirements. In the longer term there is evidence that cognitive function in the offspring is impaired: in particular reduced attention span, poorer visual memory and reduced impulse control. These may impact on a child's learning and behaviour during school years. In Australia we are facing a growing demand for medical marijuana to be legalised nationwide. The Federal Government has already enacted enabling legislation for chronically and seriously ill patients to access marijuana for the control of pain and nausea from chemotherapy [Narcotics Drugs Amendment Act 2016 (C'th)]. Children with drug-resistant epilepsy may also be eligible e.g. Access to Medicinal Cannabis Act 2016 (Vic) Victoria. This will require a doctor's certificate as well as an import licence from the Therapeutic Goods Administration (where the drug is provided by overseas manufacturers). Local cultivation will also be facilitated by amendments to the Narcotics Drugs Act 1967 (C'th). In NSW marijuana will only be available for 'end of life' adult patients whereas in Queensland there will be no age restrictions but a doctor will need to certify its beneficial properties for conditions such as multiple sclerosis epilepsy, cancer and HIV/AIDS (Public Health (Medicinal Cannabis) Act 2016 (Qld)). In Western Australia MM has been available from pharmacies under strict condition since November 2016. If Australia follows in the wake of the US then it is possible that we will see the widespread use of cannabis as an anti-nauseant for pregnancy. The fetal consequences of that might be regrettable.

*ACLM Council Member | Chair Obstetrics & Gynaecology, School Of Medicine, Western Sydney University
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PROFESSOR ERWIN LOH & DR JESSICA DEAN

PHARMACEUTICAL INDUSTRY PRESENCE IN HEALTH SERVICES – MORE THAN JUST FREE PENS

Despite recent changes in attitudes, most hospitals continue to experience pharmaceutical industry presence. Despite evidence to the contrary, doctors believe they are able to effectively manage pharmaceutical sales representative interactions such that their own prescribing is not adversely impacted. Doctors also share a belief that small gifts and benefits are harmless. There may be significant financial burden associated with divestment of such sponsorship by hospitals. Change requires education and effective policies to manage industry relationships and conflicts of interest. Health services need to be proactive in transitioning financial and cultural reliance on industry sponsorship to other potentially less harmful sources.

Professor Erwin Loh – ACLM Vice President Administration | Chief Medical Officer, Monash Health | Clinical Professor, Monash University, MBBS, LLB (Hons), MBA, MHS (PhD) FRACMA, FACLM

Dr Jessica Dean – Basic Physician Trainee at Monash Health, MBBS(Hons) BMedSci(Hons)



DR MARIA DUDYCZ

THE LAW AND ETHICS OF STERILISATION OF DISABLED PERSONS - CHALLENGES IN ADOPTING A THERAPEUTIC APPROACH CONSISTENT WITH HUMAN RIGHTS LEGISLATION

In the early 20th Century and underlying some thinking today is the Eugenics programs to forcibly sterilise "undesirable" populations. Shifting views to enshrine international Human Rights treaties, supporting the protection of disabled persons from inappropriate medical treatment, into Australian legislation, has seen a prohibition on sterilisation of disabled persons unless it is in their "best interests"; essentially for therapeutic purposes. In Victoria, sterilisation only occurs with the authority of VCAT. However, ethical challenges arise regarding what amounts to "best interest". While therapeutic reasons for sterilisation should be the paramount consideration enabling disabled persons to receive equal treatment to all others in society, applications pursuant to the Guardianship Act 1986 (Vic) often arise from carers for convenience in managing menstrual cycles, to prevent pregnancy, to prevent sexual assault, etc. Does the persistence of historical eugenic thinking permeate ongoing applications and "ethical" decision making to sterilise disabled persons in Australia?



DR MICHAEL CHRISTMASS

THE PROBLEM IS CRYSTAL... BUT IS THE SOLUTION CLEAR?

Methamphetamine is a synthetic chemical with structural similarity to endogenous amines. Crystal methamphetamine is a highly potent form of methamphetamine that can be smoked or injected intravenously. Methamphetamine is not a new chemical and problematic use of this substance is not a new issue. Methamphetamine differs from common illicit substances (e.g. heroin) in that organic cultivation is unnecessary. Methamphetamine administration causes excess accumulation of the monoamines (nor-epinephrine, dopamine, serotonin) in the brain. Sympathetic outflow is increased markedly and psychological outcomes include euphoria, disinhibition, psychosis and hypersexuality. The evidence base for treatment is poor. Options include cognitive behavioural therapy with a limited, but potential, role for pharmacotherapy.

Fellow in Addiction Medicine | Next Step East Metropolitan Community Alcohol and Drug Service, East Perth, Mental Health Commission WA | MBBS, MSc, PhD, FRACGP, FACHAM



DR WOJCIECH CHRZANOWSKI

NANOSAFETY – FROM SAFETY OF NANOPARTICLES TO THEIR THERAPEUTIC APPLICATIONS

Nanoparticles are ubiquitous in foods, baby formulas, medicines and the environment. Therefore, human and environmental exposure to nanomaterials is inevitable, and as the use of these nano-enabled products become more widespread, so too will concerns around their safety and impact on human and environmental health. However, progress in the development of nanoparticles and the steep increase in their applications do not match the progress in the evaluation of the possible environmental health and safety impacts across their life cycle. Thus, detailed data on nanoparticle safety is critically needed both to protect health and to protect the sustainability and benefits of nanomaterials. The author will present progress in nanoparticle toxicity screening using the state-of-art and ultrasensitive techniques that allow evaluation of toxicity of individual nanoparticles with resolution ~10 nm and 3D liver models. Generate methodological are aimed to form a framework for nanotoxicity testing that can be used in the future to guide safer-by-design drug formulations, food products and cosmeceuticals.

SOAR Fellow | Senior Lecturer, Australian Institute for Nanoscale Science and Technology (Health and Medicine Theme Leader) | Charles Perkins Centre | Faculty of Pharmacy, the University of Sydney | PhD, DSc



DR SANDRA JOHNSON

ETHICS OF THERAPEUTICS IN PAEDIATRICS

Paediatric practice demands that therapy, treatment and intervention performed in children be done in the best interests of the child. The discipline aims to provide a high standard of care that is child-centred and that takes the mental, social, emotional and physical needs of the child into account. Clear communication using child-specific language that is appropriate to the child's developmental level of understanding is essential when instituting therapy and treatment. Paediatricians have a prime responsibility to promote and protect the well-being of children. This presentation will focus on ethical considerations when new drugs and therapies are being considered for use in children and when research is being done with children.

ACLM Vice President Academic | Consultant Developmental Paediatrician | M.Bch.B, D.(Paed), FRACP, FACLM, FRCPC



DR DON BUCHANAN

OPIATE PRESCRIBING AND REAL-TIME REPORTING

In recent years there has been a significant increase in the therapeutic use of orally ingested, longer acting opioids in many developed countries, including Australia. These longer acting and sustained release preparations result in less fluctuation of blood concentrations, leading to better control of chronic pain. A role that has emerged for these opioid preparations is the treatment of chronic non-malignant pain. In the USA, 95% of these preparations are prescribed for this purpose. A strong correlation exists between the extent of misuse of opioid medications and their licit availability. One such manifestation is 'prescription shopping.' Real time electronic monitoring and reporting of opioid prescriptions dispensed is an important tool to assist prescribers and pharmacists to meet their professional and legal obligations by providing real time information regarding a patient's prescription history. This paper will review four cases where real time opioid prescription monitoring would have assisted in the effective management these patients' chronic non-malignant pain.

ACLM President | Forensic Physician and Legal Practitioner | MBBS, FRACGP, FACLM, MPH, JD

