Southern California Bioethics Committee
Consortium Newsletter
"The Balance Sheet" Dec.3, 2015
Vol. XXXIX

Meeting Thursday Dec. 3, 2015

Greater Los Angeles Veterans Affairs Medical Center
Wadsworth Bldg (500) 11301 Wilshire Blvd. 90073
6th floor Operator: 310-478-37116400
SW corner San Diego Freeway (405) & Wilshire Blvd. Exit Wilshire Blvd West from 405, right on to campus west of freeway. Free parking in visitor lots
5:30PM free dinner 6:00 meeting (no RSVP needed)

1. Announcements
2. **Embryo Disposition**: An Ethical and Legal Decision – Aliza Grossman, LMU law student
3. **Ethics of Pre-Implantation Genetic Testing** – Andrea Stein, MD, MA, Clinical Prof OBGyn, USC
4. **Ethics of Use of Prognostication in Pediatrics – Case of Hypoplastic Left Ventricle** – Grace Oei, MD, director of Clinical Ethics, Loma Linda U. Health/ Assoc Dir, Center for Christian Bioethics

8:30 adjourn

Upcoming Conferences

UCLA Health Ethics Program
* Ethics Lecture Wed., 2/17/16
Noon-1 lunched served at 11:30 am
"When Patients Make 'Bad' Choices: Complexity in Treatment Decision Making" R. Dresser JD, MS
Washington University School of Law
Tamkin Auditorium RRMC B-130
* Ethics of Caring 2016 Tues.3/15/16
*UCLA **Journal Club -** 2nd Wed of the month
Summer Ethics Fellowship for Medical Students applications due 12/ 22/ 2015
Fellowships at Auschwitz for the Study of Professional Ethics (FASPE) **accepting applications for 6/17-6/30/2016**

Patient-Parent-Pediatrician Relationship: Everyday Ethics in the Office

Lantos, John *Pediatrics in Review* Jan /15
Four scenarios that present potential ethical dilemmas:
*The family that refuses vaccines
*Home births in which Vit K might be refused
*Surreptitious drug testing of a teen
*Parental refusal to disclose an adoption to a child
These are explored using several tenants
1. In depth discussion
2. Assessment of benefits/ burdens of proposed action and alternatives
3. Compromise to preserve relationship
4. Ending the relationship and offering referral if resolution is not possible, realizing such a move might place receiving physician in a compromised position

Digging Deeper

Wall Street Journal Jeanne Marie Laskas 11/ 24, 2015

In 2002 Neuropathologist Bennet Omalu, a native of Nigeria, with multiple degrees from American medical schools examined the body of 50-year-old former Pittsburgh Steelers center Mike Webster in who suffered a" steep mental decline, becoming violent, depressed and forgetful and in chronic pain" during his last years. Dr. Omalu, discovered pathological changes that would" change the medical community's thinking about the effects of head injuries in professional football." Another investigator, Davies, confirmed the findings.

The league commissioned a study, sending researchers at the U of Michigan's Institute for Social Research to survey more than a thousand retired players: inquiring among other things, " if they have ever been diagnosed with dementia, Alzheimer's disease, or other memory-related disease." **The Michigan researchers in 9/2009 noted "Alzheimer's disease, or something very similar, is being diagnosed in former NFL players 19 times more often than in the national population among men ages 30 through 49**." The NFL does not make this information readily public.

"Concussion" (Random House) is a book based on Laskas' interviews and research and is also a soon to be released movie. Highlighted is the question of the lack of credit and involvement of Dr. Omalu in broader discussions regarding safety and prevention of brain injury despite his significant early findings in this important field

Weigh in with the Editor

Ed- in- chief: Kendra Fleagle Gorlitsky, M.D.
kfgorlitsky@gmail.com
Contributors: Ken.Murray, MD., Richard Boudreau,MD, Elvis AmayaConcepts: Edward Lin, MS II KSOM

Fair Play? The Case Against Price Gauging

Commentary Frank David Forbes 9/20
"Turing Pharmaceuticals acquired the rights to an anti-infective medicine used in immune-compromised patients, then hiked the price by more than 50-fold."

Southern California Bioethics Committee
Consortium Newsletter
"The Balance Sheet" Dec.3, 2015
Vol. XXXIX

Price Gauging cont'd

Set aside "whether this is legal (probably) or good for the company's short-term bottom line (ditto)," or as CEO Martin Shkreli's claim "benefits all of [the company's] stakeholders." and focus on "what the Turing case represents for pharma companies: an opportunity to take an unambiguously pro-patient position in a drug pricing debate."

Pharm "execs haven't been anti-patient on drug pricing"— but have "focused on whether drugs deliver 'value,' how to measure it, how much it's worth, and whether we risk imperiling the entire drug R&D."

He notes, "Annual double-digit percentage price increases on marketed drugs, year after year. Yes, 15% is less than 5,0000%--but…, if pharma's dismal approval rating continues to lie just below that of insurance companies, it's hard to imagine much public sympathy…"

But Pharm execs aren't likely to speak up "fearing that critiquing extreme price hikes like Turing's will make their own practices more vulnerable to scrutiny." The issue isn't whether annual price hikes will be questioned but "what new regulations or business practices will emerge to rein them in.

"And if any pharm execs want to have a seat at table when that happens, their best chance is to take a principled stand against the egregious excesses, and try to establish themselves as credible partners in defining the new shape of the drug pricing landscape." (The author is a physician scientist trained at Columbia, and Harvard, Managing Director of Pharmagellan, biotechnical consultant)

Murray's Musings

Evidence-Based Death? by **Ken Murray MD**
retired Family physician and author of
"How Doctors Die," contributor to several national news magazines and medical journals

On Nov 19 the NEJM published an opinion piece titled: "Toward Evidence-Based End-of-Life Care." I thought it was a shot across the bow of efforts of those who work in the field, including Bioethicists. For example: "The public and private sectors are now engaged in an unprecedented array of virtuous efforts to improve end-of-life care. But these efforts are generally not evidence based." Wow!

It goes on to name specific programs, such as Gunderson's Respecting Wishes program, which has the town of LaCrosse demonstrating a 98% rate of adults with AD's, and the lowest cost of Medicare expenditures per person in the last year of life—in the entire US.

This article is worth reading for all in the field. You get the sense that they want placebo-controlled death studies on everything. It also seems that the only endpoint that matters, is financial. I hope all ethics issues do not come to be measured in money.

On the other hand, they perhaps make a good point that there is insufficient sharing of best practices via referred literature. I think for many in the field, it is challenging enough to get home at a decent hour, and have a weekend off!

Of course, this is what SCBCC is all about. I doubt that there are many who attend who have not learned very interesting approaches from colleagues. But it is unfortunate that there is not a wider audience for these great discussions.

The Challenge of Orphan Diseases

Expensive Proposition:

Case in point:

Enzyme replacement therapy for Fabry disease: A systematic review and meta-analysis Genet Mol Biol. 2012 Dec; 35(4 Suppl): 947–954. Published online 2012 Dec 18. PMCID: PMC3571424Taciane Alegra,[1] et al

The specific treatment available for Fabry disease (FD) a debilitating condition affecting multiple organ systems, beginning as early as 5 years of age and progressing well into adulthood, shortening the lifespan by over a decade, is enzyme replacement therapy (ERT) with agalsidase. Response is variable across subgroups. Agalsidase may slow progression of FD, with slight improvement. "Uncertainties remain with further studies required…"

Because FD is rare there are few patients available for clinical trials, restricting the statistical power of assessment. The principle behind treatment of diseases of exceedingly low incidence often referred to as "orphan diseases," runs into bioethical issues involving questions: **equity, scarcity of resources** (ed. note: some estimates as high as $200,000 a year per patient which does not provide a cure),

Southern California Bioethics Committee
Consortium Newsletter
"The Balance Sheet" Dec.3, 2015
Vol. XXXIX

and the **legal concept of the "proviso of possibility."**

Orphan diseases and their treating agents, "orphan drugs," require specific ways of assessing efficacy and safety. The limitation of available RCTs creates difficulties in the decision making process for drug approval and reimbursement. This article suggests the decision about reimbursement for agalsidase should "take into account the fact that there is no other specific treatment for these diseases, as well as the public opinion."

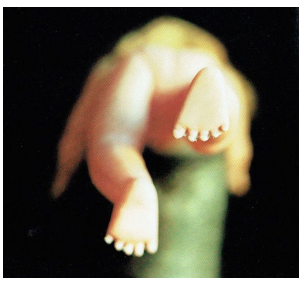
TO THE RESCUE: (from the FDA website)

Office of Orphan Products Development (OOPD) Missions: to advance the evaluation and development of products that demonstrate promise for the diagnosis and/or treatment of rare diseases. It evaluates scientific and clinical data submissions from sponsors to identify products as promising for rare diseases and to further advance scientific development of such. The office works with "the medical and research communities, professional organizations, academia, governmental agencies, industry, and patient groups."

OOPD provides incentives for sponsors to develop products for rare diseases. The program has enabled the development and marketing of more than 400 drugs and biologic products for rare diseases since 1983. The Orphan Drug designation program provides orphan status to drugs and biologics defined as "intended for the safe and effective treatment, diagnosis or prevention of rare disease and/disorder that affect fewer than 200,000 people in the US or that affect more than 200,000 people but are not expected to recover the costs of developing and marketing a treatment drug."

UNDERGRAD Corner

An Homage to Small Boats by Elvis Amaya , student at Santa Monica College



Beyond the circle of the sea,
When voyaging is past,
We seek our final port in thee;
Oh! Bring us home at last.
In thee we trust, whate'er befalls; The sea is great, our boat is small. -*Henry van Dy*

Some may stick up their nose at nuclear transfer cells. Others might even say that it is unethical to do research with cells obtained this way. But there has been a large leap forward with the use of embryotic stem cells which has opened many doors for creating more effective medicines. Those exploring the sea of data and research with their small boats, enable a much clearer understanding of the beginning of life and what it means to be working on medicines that use ES cells and the ethical concerns surrounding that use.

There will be children born in future generations who will not know the researchers or bioethicists who were on this journey, protecting their early growth. Only the sea will know with which small brave boats such areas were discovered.

A Matter of Conscience

The Editor of Canadian Medical Association Journal, John Fletcher, makes the case for permitting physicians who have conscientious objections to response to Physician Aid in Dying measures to follow that conviction. In Nov 23 edition of that journal, he states his concern that the same rights granted physicians who object to abortion be afforded physicians who refuse to assist patient's in their efforts die.

He points out that the medical profession has defined itself since the time of Hippocrates as one that "will not administer poison to anyone, and this trust forms an essential backdrop to the doctor–patient relationship during end-of-life care. Canadian society may soon allow some doctors to redefine their role, but this should not compel the majority of physicians who are not comfortable with this to abandon their convictions" and participate even indirectly, in an act "that they see as wrong."

"Canada has a tradition of respecting conscientious objection, and we should be wary of compelling anyone, including doctors, to act against their own moral compass." The Canadian Medical Association's draft framework document on medical aid in dying supports conscientious objection, but also suggests physicians should refer patients for medical aid in dying if they are not willing to provide the service themselves.

At the CMA General Council meeting in August, 2015 a motion to support conscientious objectors who refuse to refer their patients for medical aid in dying was defeated by a 79% vote against, but Fletcher maintains, "If doctors are to be compelled to aid their patients to access medical aid in dying, then they are not being allowed to follow their consciences at all." He grants that ""Doctors have no business denying patients their newly recognized right, no matter how strongly they may feel …. But where does this leave

Southern California Bioethics Committee
Consortium Newsletter
"The Balance Sheet" Dec.3, 2015
Vol. XXXIX

physicians who, for whatever reason, do not wish to be involved with helping their patients to gain access to medical aid in dying? Those who would refuse, not only to offer medical aid in dying themselves, but also to refer a patient to another doctor for such a service, argue that referral would make them guilty by association of an act that they see as wrong."

A possible solution might be found in the form of public health measures informing patients of their end of life options which would include, when appropriate, Aid in Dying. Physicians personally objecting to AID would at least know that referring to a general information program would not directly imply they are in favor of that option.

From the Halls

Richard Boudreau, MA, MBA, DDS, MD, JD, PHD, **Faculty LMU** Bioethics Institute Dept. of Theological Studies . **Ethics of Informing Patients of Resident Role in Their Surgery**

We vividly recall early July when most hospital based residency programs begin. Each year newly minted physicians enter their period of graduate medical education ready to obtain advanced clinical education and be taught and refine patient care skills. Each year the trainee moves up a rung on the training ladder taking on ever-increasing responsibilities for patient care. Surgical programs are by nature heavily procedurally oriented involving invasive procedures. The methods used to teach another person how to do surgery certainly vary. As the resident's experience progresses, he or she is given an increasingly greater role in performing the procedure. Eventually, the surgeon in training is allowed to do the entire procedure while the teacher plays the role of first assistant, but with continued ultimate command of the procedure.

The common tactic of having the experienced surgeon teach the neophyte includes one other critical player – that being the patient. Today's patients commonly want to feel more empowered to participate in their health care; in some cases, they demand this. This brings us to the important question of whether patients have a right to know exactly who will be conducting their surgery, using the word "conducting" in the way most people would, namely, the person who is doing the cutting, sawing, suturing, etc.

I'll call up what I'll term the 'golden rule' applied to informed consent; namely, the surgeon should inform patients about the same risks and alternatives to the procedure that the surgeon himself or herself would want to know if the surgeon himself or herself required the procedure, including who will be performing the surgery.

Most of us want to know who will be in charge of our procedure and what role residents will play. Should this information always be shared with patients? This is where informing the patient can enter a gray area. Patients coming to academic health centers might rightfully be assumed to be aware that trainees will be involved in their care. But do patients think that 'helping' involves just holding retractors and suctioning? Or is it fair to assume patients know that some or all of their operation will be done by a trainee? Here is where it gets sticky.

Is it right for the surgeon to assume the patient is on board with trainees doing the surgery while the attending assists and guides the resident? Or would it be more appropriate to not make any assumptions and to clearly inform the patient of who will be involved in the procedure and the role played by each individual. The 'golden rule' should guide us toward full transparency.

Is it not hypocritical to permit residents to operate on one's patients while requesting special treatment from other surgeons by asking that the surgeon himself or herself do all the procedures needed by the requesting surgeon or their family member?

On the other hand, one must question the wisdom of potentially undermining patient confidence with overwhelming information and balance the benefits/burdens of comprehensive disclosure for each patient.

Academicians are producing competent surgeons while delivering excellent care. An ethical approach is to let patients know how this occurs and how the patients' help makes it possible.

SCBCC Steering Committee

Paul Schneider, MD Paul.Schneider@med.va.gov
Jim Hornstein, MD jimfamdoc@sbcglobal.net
Neil Wenger, MD NWenger@mednet.ucla.edu
Kendra Gorlitsky, MD kfgorlitsky@gmail.com
Kenneth Landis, MD kwlsccrdoc@aol.com
Theresa Drought Theresa.s.drought@kp.org
Ronald B. Miller, M.D .rbmiller@uci.edu
Roberto Dell'Oro rdelloro@lmu.edu
Stuart Finder **Webmaster** Stuart.Finder@cshs.org