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FROM PERSONALIZED MEDICINE TO CONSUMER-DRIVEN TESTING: AN UPDATE ON DIRECT-TO-CONSUMER GENETIC TESTS

BY MICHELLE KIRTLEY, PHD
BIOETHICS AND PUBLIC POLICY ASSOCIATE

"If it were not for the great variability among individuals, medicine might as well be a science, not an art."
Sir William Osler, 1892

Most experienced medical providers know this all too well. While the majority of patients respond to standard treatments, inevitably a patient will come along who breaks the mold. In the more than 100 years since Canadian biologist Osler made this observation, scientists have been trying to understand and categorize such variability among individuals in order to tailor medical treatments to each person's unique genetic makeup—to turn medicine into a "science," to use Osler's words. Personalized medicine has received a lot of attention in recent years, but as most physicians know, medicine remains an art. Will personalized medicine revolutionize healthcare? Is genetic testing the wave of the future? Should genetic tests be offered directly to consumers?

Two key technological advances have contributed to transforming personalized medicine from science fiction to medical possibility. In the 1970's researchers discovered how to sequence DNA—the key to unraveling the genetic code—and scientists isolated restriction enzymes, special chemicals found in bacteria which cut DNA at particular sequences. These two techniques enabled scientists to begin to isolate single genes, such as the cystic fibrosis gene, identified and sequenced in 1989, and the BRCA1 and 2 genes, implicated in breast cancer. A draft sequence of the human genome was published in 2000, and in subsequent years hundreds of genes associated with a variety of conditions have been identified and sequenced.

Each time a disease gene is identified, patient groups and researchers grow excited about the possibilities for improving diagnosis and developing new treatments. But turning information about the association between a disease and a particular region of the human genome into viable therapies requires additional technology and information.

In many cases, information about which human genes are involved in various diseases and conditions is used in the field of pharmacogenomics. Pharmacogenomics employs genetic tests in "rational drug design": determining which drugs to use to treat a given medical condition, what dosages of those drugs to administer, and how best to reduce adverse effects, in light of underlying genetic differences in disease mechanism or drug metabolism. One of the most successful drugs produced this way, Herceptin® (trastuzumab), is a genetically engineered monoclonal antibody designed to bind to HER-2 (human epidermal growth factor receptor-2 protein), which is overexpressed in 25-30% of breast cancer cells. Herceptin is a multi-million dollar blockbuster drug. Pharmacogenomics also helped researchers learn that individuals vary in their ability to metabolize the anti-clotting drug Coumadin® (warfarin). In 2007, the FDA changed warfarin's package insert to reflect data suggesting that people with certain gene variations need a lower dose.

Despite these significant and lifesaving advances, personalized medicine still faces significant challenges. Genome-wide association studies—the type of study most often used to find particular regions of DNA implicated in certain medical conditions—are limited in terms of the conclusions they can yield. These and other genetic studies are complicated by a factor geneticists call penetrance—the percentage of people with a given genetic variation who actually display the associated disease or condition. Penetrance is affected by environmental conditions and epigenetic factors, non-sequence based structural or chemical changes in the DNA that affect whether a given gene is active or silenced under various circumstances.

Further complicating things, translating information about what causes a disease into viable treatments can be even more technically difficult than identifying relevant genes. Gene therapy, which involves physically modifying genes, is not yet a safe and effective means of treating disease, and drug development is hampered by difficulties in delivering drugs to the appropriate target inside the body, as well as unintended side

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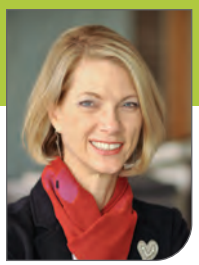

from the director's desk

BY PAIGE COMSTOCK CUNNINGHAM, JD, MA
EXECUTIVE DIRECTOR

"*Did you know there are nanoparticles in our food?*" my husband asked me this morning. "*Oh?*" He added, "*It's used to make the frosting on donuts extra white.*" I might have added, "*and chocolate flavored chewing gum.*"

What Are Nanoparticles?

Why does this matter? Isn't this a debate about taste, not bioethics? Not necessarily. Nanoparticles and nanotechnology exist in the realm of the very small, but the ethical issues loom large.

"Nano" refers to size. Nanoparticles are too small to be detected with a regular microscope, measuring between 1-100 nanometers (nm). (One nanometer is one-billionth of a meter.) The scale is hard to imagine: one human hair is about 80,000 nm wide. Nanotechnology is the engineering of particles at the near-molecular level. At this size, the chemical, biological and physical properties of matter change. For example, aluminum is a safe, nonreactive material for packaging carbonated beverages. At the nanoscale, aluminum is highly reactive, even explosive. In addition to reactivity, nanoscale affects electrical, optical and thermal properties.

The change in properties makes nanoparticles valuable for a variety of applications. "Gold, for example, is inert in bulk but becomes highly reactive at the nanoscale, making it a potentially valuable catalyst."[1] Carbon nanotubes are the strongest fibers known. They are 10-100 times stronger than steel. And, depending on how it is rolled up to make the tube, carbon can act either as a semiconductor or as a metal.

What Should We Do with Them?

Nanotechnology is used to target drugs at specific cells, to eliminate odors in sweat socks, to help sunscreen penetrate better, to make e-paper, to improve packaging materials, to make paint that is scratch resistant, and, yes, to make food.[2] The whitener in the donut frosting is titanium dioxide, which also shows up in candy, gum, pudding, and paint.

We appreciate what nanotechnology gives us. There is the convenience of wrinkle-free clothing. Nanorobots to deliver cancer drugs to only cancerous cells would eliminate the more dreadful side effects of chemotherapy. Nanotechnology is responsible for lengthening battery life and making scratch resistant sunglasses. It may be the key to providing clean and safe drinking water.

With this seemingly limitless cornucopia of benefits, why the concern?

The very qualities that make nanoparticles attractive also render them chaotic and unpredictable. Rather than binding to larger molecules or cells, nanoparticles are able to penetrate the cellular barrier, the blood-brain barrier, and the placental barrier. Their cumulative effect on human tissues is unknown. Environmental and health hazards are nearly impossible to predict.

Let me suggest one of several ethical themes: caution.

Where there is uncertainty about consequences, whether unintended or unknown, and there is potential for significant harm, the *precautionary principle* applies. The risk from nanoparticles escaping from sunglasses, paint or other coatings is unknown. The pollution potential from free-floating nanoparticles is also unknown. Eric Drexler, the father of both the science and neologism "nanotechnology," warned that uncontrolled nanorobots could rapidly replicate, consuming all the carbon atoms in matter, turning the world into a lifeless mass of "gray goo."[3]

Although his specific concern has been refuted by others, the broader need for caution remains. One study of mice has found that inhaled carbon nanotubes are more toxic than silicon particles. Pat Mooney, executive director of the ETC Group, says, "All of these [studies] say there is a yellow light here."[4] Yellow means caution; go slowly.

The Center for Bioethics & Human Dignity (CBHD) is a Christian bioethics research center at Trinity International University.

"Exploring the nexus of biomedicine, biotechnology, and our common humanity."

Dignitas is the quarterly publication of the Center and is a vehicle for the scholarly discussion of bioethical issues from a Judeo-Christian Hippocratic worldview, updates in the fields of bioethics, medicine, and technology, and information regarding the Center's ongoing activities.

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THE CENTER FOR BIOETHICS & HUMAN DIGNITY
TRINITY INTERNATIONAL UNIVERSITY
2065 HALF DAY ROAD | DEERFIELD, IL 60015 USA
V 847.317.8180 | F 847.317.8101
INFO@CBHD.ORG | WWW.CBHD.ORG

Dónal O'Mathúna suggests that the *precautionary principle* "does not try to stop or slow science, but encourages it in certain directions."[5] This means taking moral responsibility for risk assessment and compensation should harm occur. How that can be accomplished is itself uncertain. Risk assessment may be cost prohibitive for the manufacturer and therefore the customer; it takes time for nanoparticles to accumulate; and we lack technology to detect their presence.

The burden of proof for safety should be on the one introducing nanoparticles or processes, and the entity that introduces the nanoparticles should pay for adverse health and environmental consequences. As consumers we may object to higher prices, but the price of not paying attention to risks is even higher.

Government regulation adds a layer of complexity. Nanotechnologies are so diverse, they cannot be easily categorized and frequently involve multiple disciplines and expertise. There is no single "nanoindustry," and therefore no industry-wide standards. Which agency or agencies should have oversight responsibility? Nanoengineering can enter at a variety of points in the process, and the final manufacturer may not even be aware of nanoparticles in the product. Full disclosure at each step, including labeling of the final product, could help us to notice and take nano more seriously.

Government-sponsored research into environmental impact and the effects on the human body of products that have already entered the market may be warranted. For example, the Food Standards Agency in the UK, which assesses new foods, is researching how "nanomaterials enter the human body and what happens to them once they are there."[6] The agency commissioned an ongoing study that investigates whether titanium dioxide (the donut frosting whitener) is absorbed into the gut.[7]

There is also the ethical matter of personal responsibility. Staying abreast of major "nano-developments" is as close as Google. And, those of us in the various scientific disciplines need to get out of the research labs, and notice what is happening in the lab down the hall or across the ocean.

We cannot rely on science to guide itself. As Eric Cohen writes, "Science is power without wisdom about the uses of power."[8] Wisdom and the wise use of technological power are matters of ethical concern and, when they affect human bodies, matters of bioethics. Whether in our favorite Dunkin' Donuts treat or nanorobot-delivered chemotherapy, nanoparticles matter.

1 Robert Service, "Nanotechnology Grows Up," *Science* 304, no. 5678 (June 18, 2004): 1721.

2 See, for example, Heather Miller, "Nanoparticles Are in Our Food, Clothing and Medicine—And No One Knows for Sure How Dangerous They Might Be: Inside Nanotechnology's Little Universe of Big Unknowns," *AlterNet*, February 23, 2013, http://www.alternet.org/environment/nanoparticles-are-our-food-clothing-and-medicine-and-no-one-knows-sure-how-dangerous?page=0%2C2 (accessed April 4, 2013).

3 K. Eric Drexler, *Engines of Creation: The Coming Era of Nanotechnology* (New York: Random House, 1986), 172-173.

4 Service, 1733.

5 Dónal P. O'Mathúna. *Nanoethics: Big Ethical Issues with Small Technology* (London: Continuum, 2009), 83.

6 "Nanotechnology," *Food Standards Agency*, http://www.food.gov.uk/policy-advice/nano/#.UVIcLRlrQxM (accessed April 4, 2013).

7 "Human In Vivo and In Vitro Studies on Gastrointestinal Absorption of Nanoparticles: The Effect of Size and Surface Properties (Ongoing)," *Food Standards Agency*, February 25, 2010, http://www.food.gov.uk/science/research/gm-research/nano-research/t01061/#.UYK-aILA0sc (accessed April 4, 2013).

8 Eric Cohen, *In the Shadow of Progress: Being Human in the Age of Technology* (New York: Encounter, 2008), 21.

Editors: The CBHD staff welcomes your comments and critical engagement with the articles we publish here in *Dignitas*. While each article is rigorously reviewed for quality, we desire them to initiate broader dialogue and collegial engagement. Sometimes an author may be offering an update on a given issue, highlighting new developments in a field, or raising suggestions for areas of additional inquiry. Other times, authors may argue for a particular perspective or approach that invites response or even disagreement. We are firmly committed to the value of interdisciplinary dialogue done in a charitable, but critical manner. If you desire to offer a critical response to a recent article, please send us a note to get feedback and guidelines for submitting pieces to msleasman@cbhd.org.

In a recent "From the Director's Desk" (*Dignitas* 19:2, Summer 2012, 2-3) Paige raised the question "Who is my neighbor?" in relation to the topic of vaccinations. This commentary initiated several comments, two of which we are including here. They have been edited for length, formatting, and citation style.

THE CASE FOR VACCINATION

FERDINAND D. YATES, JR., MD, MA (BIOETHICS)

Paige Cunningham recently used the parable of the Good Samaritan to call us to action in the protection of our neighbor in the use of vaccinations to the benefit of the community. Her contention was that vaccinations provide benefit both to the person and to the plurality. As a practicing pediatrician, I not only echo the contention, but champion it on the basis of efficacy coupled with a favorable benefit-burden ratio. There is much information regarding this topic that is easily available, and in writing this piece I make use of both the more "standard" medical sites[1] in addition to the less-traditional options.

Why do people refuse to allow vaccinations for themselves, or for the people that they care for?

It is my experience that the greatest resistance to the use of vaccinations has come from young educated parents who have benefited the most from a vaccination program that was implemented many years prior to their birth. These parents' grandparents welcomed the use of vaccinations because they had witnessed the scourge of illness, morbidity, and mortality that ravaged a pre-vaccination population; they had suffered through the use of the iron lung following polio; they had seen death following diphtheria and pertussis; they had even perhaps participated in a quarantine to help isolate infected children and adults to the greater benefit of the local community. These glimpses from recent history may not be relegated only to the past; Ms. Cunningham made reference to the current alarming increase in cases of whooping cough.[2] What she did not mention was the startling rise in the number of cases of acute measles infections in Europe[3] – not the relatively benign course of German Measles, but the substantial disease process of Rubeola which carries a definitive risk of neurologic impairment and mortality. It is astounding to me that the very recipients of the documented benefits of modern-day medical progress refuse to provide the same benefit for their own progeny.

Another reason often given by those refusing vaccinations is anecdotal information: information that is presented but neither adequately proved or studied. Many vaccinations are given during a time period of rapid change and development of the child; children are typically seen many times during this window (birth to 3 years of age) by the medical practitioner, and particular attention is given to the issues of growth and development. In modern medicine, a temporal relationship of a vaccination and an unfortunate neurologic condition does not imply causality. Medical research studies of this venue would not only be difficult, but unethical, and would never be approved by a research guidance board. Which of us, as parents, would allow our unvaccinated child to be a member of the study group that is purposefully and willfully exposed to a child with active and contagious pertussis?

Also, some individuals continue to refer to poor medical studies that are either misleading or – in some cases – entirely discredited. Medical professionals often have an "air" about them and are frequently regarded as experts – even in a medical field that is not their particular area of expertise. And so, it is not surprising to come across medical information such as that provided by Dr. Andrew Wakefeld that was published in 1998.[4] His information alleged a medical causation between MMR (measles, mumps, rubella) vaccination and autism. The non-blinded research 'study' – not approved by the hospital ethics committee – included hand-picked children at a party (who were paid for their participation) who underwent painful procedures – such as spinal taps and colonoscopies – in the attempt to obtain serum and tissue culture samples for viral analysis. Following the publishing of the article, and spread of the "findings," UK vaccination rates for MMR plummeted to

80 % in 2004 and there were reports of measles-related deaths – the first in fourteen years.[5] In 2010, the UK Medical Council pronounced Dr. Wakefeld both dishonest and unethical; *The Lancet* retracted his article (in 2004, 10 of the 12 co-authors issued a "retraction of interpretation",) and Dr. Wakefeld was erased from the medical register in the UK.

Another reason used by individuals opposed to vaccinations is the persistent accusation regarding autism and the use of mercury as a vaccine preservative.[6] Despite the remarkable implementation of 'single-dose' vaccinations (that have either miniscule or no amount of mercury, implying the discontinuation of the multiple-dose vaccine bottle), the immediately-expected decline in the number of cases of autism never occurred. Undoubtedly, much of this accounting is due to the difficulty in diagnosis of the condition as well as the present-day use of reclassification terminology such as "autism spectrum disorder." The courts have ruled[7] regarding the alleged association, but many remain skeptical.

The religious leaders of the day left the injured on the street, while the caring sojourner – with little to gain – provided care for the stranger. Vaccinations give us the same opportunity – to protect the least of these – among others: the very young, the very old, and the medically compromised.

I vaccinated my children, and my daughter has vaccinated my twin grandsons. For this, I am thankful.

Ferdinand D. Yates, Jr., MD, MA (Bioethics)
Medical Director, Neighborhood Health Center, Buffalo, New York
Professor of Clinical Pediatrics, State University of New York at Buffalo
Co-Chair Healthcare Ethics Council, CBHD

1 Center for Disease Control and Prevention, "Vaccines & Immunizations," http://www.cdc.gov/vaccines/hcp.htm and American Academy of Pediatrics, http://aap.org (accessed March 19, 2013).

2 Steven Reinberg, "Whooping Cough Cases Reaching Record Highs: CDC," *HealthDay*, July 19, 2012, http://consumer.healthday.com/Article.asp?AID=666879 (accessed March 19, 2013).

3 Makiko Kitamura, "Measles Surge in Europe Raises Risks for Sports Fans," *Bloomberg*, April 4, 2012, http://www.bloomberg.com/news/2012-04-03/measles-surge-in-europe-raises-risks-for-sports-fans.html (accessed March 19, 2013).

4 AJ Wakefield, "Ileal-lymphoid-nodular Hyperplasia, Non-specific Colitis, and Pervasive Developmental Disorder in Children," *The Lancet* 351, no. 9103, February 28, 1998, 637-641. (Retracted, 2010)

5 Brian Deer, "Andrew Wakefield and MMR: The Investigation," http://briandeer.com/mmr-lancet.htm (accessed March 19, 2013).

6 Cf. Lisa Jo Rudy, "Autism, Vaccines and Mercury," *About.com*, http://autism.about.com/od/vaccinesandautism/a/mmrautism.htm (accessed March 19, 2013).

7 Alex Newman, "Court Rules Against Autism-Vaccine Link," *The New Ameri-*

WHAT KIND OF OBLIGATION IS IMMUNIZATION?

ARTHUR J. DYKE, PHD

In this past summer's edition of *Dignitas*, Paige Comstock Cunningham wrote a very thoughtful piece that focused upon our moral obligations to act on behalf of the common good. She is certainly on the mark when she draws upon the parable of the Good Samaritan to remind us that our neighbors include everyone and we should feel obligated, not only to help them in distress, but also to avoid harming them.

As an example of decisions that can harm others, she discusses the growing number of parents who are not giving permission to have their children vaccinated. She cites recent increases in the number contracting certain communicable diseases to illustrate how these decisions have deleterious effects for one's neighbors. Her admonition to those who are making these decisions not to have their children vaccinated, and to all of us more generally, is that our understanding of health and human flourishing not be confined to the personal sphere to the neglect of the communal. Parents, therefore, should feel obligated to have their children vaccinated for communicable diseases in order to increase public health, the health of everyone in our communities.

Now I do not disagree with her contention that we should attend to the common good, and in matters of health, the health of others as well as of ourselves and of our own children. However, the current practices attending vaccination, and the conceptualization of what constitutes immunization against diseases, need to be critically examined.

I begin with a rather extreme example of a practice that should not only be questioned: it should not be permitted to continue. In 2007, parents of 2,300 children who had not provided certificates of immunization, were issued a court order to have their children appear in court to have their children obtain state-mandated vaccinations—up to 17 doses on the spot—or face imprisonment. This occurred in Prince George's County, Maryland at the behest of the State Attorney General and the chairman of the district's school board. The school district stood to lose money from the state unless it complied with the state's vaccine mandate.[1] In response, Katherine Serkes of the Association of American Physicians and Surgeons sounded the alarm:

> This campaign of intimidation to brutally enforce blanket vaccine mandates by the government agencies and the school district gives

> no consideration for the rights of the parents or the individual medical condition of the child. . . . It's not just local now, and parents across the county are ready to fight.[2]

One could argue, however, that mandating certain parental behaviors on behalf of their children is something we do now for generally accepted reasons. For example, we require that children be educated in a public or private school, or in a child's home. Educators are held to certain standards, and also held responsible for not harming in any way those they instruct, whether through what they teach, or how they discipline. This kind of enforcement of the benefits of education is regarded, not only as good for those being educated, but also for the community as a whole. Indeed, properly educated individuals can acquire the knowledge of what helps make a person healthy, a boon to them and our communities as well. However, are vaccinations an individual and communal good like education so that having one's child vaccinated is always clearly a parental obligation? Properly carried out in accord with morally acceptable standards, education is as such beneficial. This is not true of vaccines.

The most disturbing characteristic of vaccines is that they come with risks to one's health and life.

Even if no direct connection exists between autism and receiving multiple doses of vaccine in early life as some might propose, there are nevertheless serious risks to being vaccinated. Pharmaceutical companies knew this when they prevailed upon Congress to pass the aptly named "National Childhood Vaccine Injury Act" in 1986. The purpose of this law is clearly stated: "No vaccine manufacturer shall be liable from vaccine related injury or death." (Public Law 99-660) That vaccines are risky is clearly acknowledged, and these risks include death. On behalf of this law, the argument that prevailed was that manufacturers of vaccines cannot profitably supply them for mass vaccinations of American children if they were to be subjected to lawsuits seeking compensation for the serious injuries and death that vaccinations can and do cause. The law did create an "Office of Special Masters" made up of scientists and others who would determine if a vaccine had harmed someone and whether compensation was warranted. Since 1989, the National Vaccine Injury Compensation Program has handed out over 2 billion dollars to families to compensate for vaccine-related injury or death.[3] For medical interventions generally, parental consent for their children while they are minors is required; why shouldn't this be the case with respect to vaccinations as a general rule?

The most obvious retort to those who refuse vaccinations is that they thereby expose themselves, their children, and others to infectious diseases that can also cause serious illness and sometimes death. However, the quest for personal and communal immunity from diseases should be viewed from a much broader perspective. Some of the dramatic declines in deaths from diseases such as measles, typhoid, and Whooping cough can and should be attributed to improved standards of living, the elimination of water-borne pathogens, cleaner food, and better standards of hygiene. Unsafe water supplies and unsanitary conditions can by themselves and even now do, result in outbreaks of deadly infectious disease—in refugee camps, for example.

Immunity from infectious diseases should not be simply equated with being vaccinated. Immunity from illness is first and foremost very much dependent upon the strength and soundness of an individual's immune system. Ironically one even needs a relatively healthy, well-developed immune system to benefit from vaccines and avoid being seriously harmed by them. A neighbor of mine conscientiously took her flu shot and suffered a near fatal bout with the flu. Knowing her age and lack of healthy habits, her immune system was weak, too weak to cope well with flu shots. It almost took her life.

Where do all of these considerations leave us with respect to how we may best carry out our obligations to prevent infectious diseases that threaten to harm not only ourselves but others as well? All of us have an obligation to obtain the information necessary to engage in suitable physical exercise, consume nutritious food, cultivate hygienic habits, provide for wholesome physical and social environments, and make use of vitamin and mineral supplements appropriate for our ages and needs. As one ages, all of this is even more important. Further supplements may be essential for preventing growing deficiencies. This knowledge and these practices parents should provide for themselves and their children: certainly my wife and I, our adult children, and adolescent grandchildren have benefited immensely from this path. Flu, and many other ailments, are thankfully alien to us. No flu shots for this family so far, and none are contemplated for the future. I would also urge that we not only love our neighbors, but that we also love God: such love is essential to our well-being and that of our neighbors.

What about vaccinations? I would not rule them out. What we should seek in the way of public policy is a very selective use of them when the need for them can be convincingly demonstrated. And, when they are used, those who receive them should be old enough and healthy enough to receive them. Physicians and nurses should be administering vaccinations.

Whether vaccines should ever be mandated depends upon whether the following conditions are met: (1) A compelling need for a particular vaccine or vaccines can be clearly documented. That means that alternatives to vaccines have not or will not work in a timely enough fashion, and the failure to use vaccines involve much greater risks than the particular vaccinations being advocated; (2) A voluntary program that has been set in motion, and extensively publicized, is not working. There are not sufficient number of individuals being immunized to overcome a very dire, immediate threat to public health; (3) Any

mandate should only apply to communicable diseases. Vaccinating people for conditions like shingles should be voluntary; (4) Any mandate for mass vaccinations should be temporary, lasting only as long as necessary. After all, it is only in emergencies that we justifiably risk lives to save lives.

In conclusion, people should be taught immunization is not simply attained by vaccinations. Immunization is best achieved by a healthy lifestyle and environment that supports it. The disciplines of studying nutrition, the environment, and infectious diseases found in Schools of Public Health, aid us in gaining the knowledge and policies that help immunize us.

Arthur J. Dyke, PhD
Research Professor of Ethics, Harvard Divinity School
Mary B. Saltonstall Professor of Population Ethics Emeritus in the School of Public Health, Harvard University
Distinguished Fellow, CBHD

Editor's Note: In the months since Paige's piece originally ran, two publications from the National Academies Press came across our desks that contribute to this conversation: National Research Council. *Adverse Effects of Vaccines: Evidence and Causality*. Washington, DC: The National Academies Press, 2012; and National Research Council. *The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies*. Washington, DC: The National Academies Press, 2013. In February 2011, the U.S. Supreme Court ruled 6-2 upholding the immunity of vaccine manufacturers in *Bruesewitz v. Wyeth*.[4] Additionally, the NIH Department of Bioethics has produced a resource, *Exploring Bioethics* that devotes an entire module to exploring issues related to vaccination (Module 2, "Balancing Individual and Community Claims: Establishing State Vaccination Policies" http://science.education.nih.gov/supplements/nih9/bioethics/guide/teaching_modules.htm).

1 N. Hernandes, "Get Kids Vaccinated or Else, Parents Told," *Washington Post*, November 14, 2007 http://www.washingtonpost.com/wp-dyn/content/article/2007/11/13/AR2007111301408.html (accessed December 20, 2012).

2 Katherine Serkes, "Doctors Oppose Maryland Vaccine Roundups: Expect Dangerous Reactions When Children Are Treated Like Cattle," *Association of American Physicians and Surgeons*, November 16, 2007 http://www.aapsonline.org/index.php/article/doctors_oppose_maryland_vaccine_roundup/ (accessed May 2, 2013).

3 "National Vaccine Injury Compensation Program" *Health Resources and Services Administration* http://www.hrsa.gov/vaccinecompensation/index.html (accessed December 20, 2012).

4 Alicia Gallegos, "Supreme Court Upholds Vaccine Liability Shield," *American Medical News*, March 7, 2011, http://www.amednews.com/article/20110307/government/303079950/7/ (accessed May 2, 2013).

REPORT FROM THE ACADEMY OF FELLOWS

DÓNAL P. O'MATHÚNA, PHD
CHAIR, ACADEMY OF FELLOWS

For the past three years, I have had the humbling privilege of serving as Chair of the CBHD Academy of Fellows. The current celebration of the 20th Anniversary of the Center gives us reason to reflect on the activities of the Academy, which both contributes to and serves as an expression of what CBHD is about.

My first engagement with CBHD was to present a parallel paper at the first conference in 1994. Having just completed an MA in Theology at Ashland Seminary in Ohio, the conference gave me an opportunity to present part of my thesis. My interest in bioethics came after completing graduate school in pharmacy, and in those days training in bioethics was primarily through general philosophy or theology programs. Coming to that first CBHD conference and engaging with others burdened to bring Christian insight to bear in bioethics changed the direction of my academic career. The growing sense I had of a calling to this field was nurtured by the support and encouragement I received at the conference, as well as through the ongoing collaborations that resulted and the friendships that developed. CBHD has played a significant role in helping me find my way through academic bioethics.

The Academy of Fellows aims to provide such support and encouragement to those in academia. CBHD had appointed fellows for many years, but in 2010 the program was completely overhauled and re-launched, and the Academy as such was formed. A grant from an anonymous donor made it possible to focus time and resources on developing the Academy and permitting Fellows to meet occasionally. This investment in Christian bioethics scholarship has been much appreciated by the Fellows and CBHD, and is bearing fruit. The current list of Fellows is available at http://cbhd.org/Academy-of-Fellows.

During its first twenty years, CBHD has focused on many aspects of bioethics. At the same time, bioethics "arrived" as an academic discipline. Universities around the world now have bioethics centers, and a number of academic conferences, journals and societies have developed. In this context, the Academy of Fellows grew out of a desire to support Christian academic bioethicists, especially those in secular settings, and to encourage Christian scholarship to engage more fully with academic bioethics. Part of this involves identifying ways that Christian bioethicists in academia can both be encouraged in their calling and support one another in pursuing similar paths. Another aim is to nurture and support those early in academic careers as they maneuver their way through this challenging field.

An evaluation of the Academy's first three years (2010 - 2012) has recently been completed. A full report is being drawn up, but an overview can be given here. CBHD and the Academy do not claim any credit for the Fellows' impressive achievements – Fellows engage in academic activities because of their individual callings and commitments – but even a brief account illustrates the extent to which members of the Academy of Fellows are actively involved in secular and Christian bioethics, accomplishing many things. This should also serve as a reminder to pray for these men and women.

In compiling the report evaluating the Academy, the diversity of ways in which Fellows contribute to their respective communities stands out. Fellows are involved in everything from national commissions and professional ethics committees to small group meetings in churches and communities. Fellows have written books for the most prestigious academic publishers and articles for peer-reviewed journals, and they have also written for church bulletins and local newspapers. Fellows speak at international conferences one week and Sunday school the next. The list of classes taught by Fellows in universities, hospitals, and churches is too extensive to reproduce. The willingness of Fellows to engage with both international scholars and local communities is impressive; their commitment to share the gifts they have received from the Lord with anyone in need of bioethical counsel is inspiring and humbling.

Shari Falkenheimer, Associate Fellow; Dónal P. O'Mathúna, PhD, Chair, Academy of Fellows; Scott Rae, PhD, Fellow, converse at the first consultation.

One of the aims of the Academy is to "advance scholarship in bioethics." The complete list of academic publications and presentations made by Fellows between 2010 and 2012 extends to over thirty pages. Additionally, several Fellows have received significant funding for bioethics research projects (an important aspect of how contemporary academia works). For example, Mary Adam is the Principal Investigator in the project "Impact of a Perinatal Community Health Project in Kenya." William Cheshire is the Principal Investigator on a funded Mayo Clinic Program in Professionalism & Ethics entitled "Assessment of Empathy in Stroke Telemedicine." Daniel Sulmasy and Farr Curlin have received significant funding from the John Templeton Foundation for research on spirituality and medicine. Curlin is also leading the "Project on the Good Physician," a study on the impact of moral formation on physicians. Gilbert Meilaender has received funding from the Arete Project at the University of Chicago for a research project titled "Acceptance of Decline or Thirst to Live: the Challenge of Anti-Aging Research." Dónal O'Mathúna received funding from the European Union COST agency to establish a network of bioethicists and humanitarian relief workers to investigate ethical dilemmas in disaster medicine and disaster research.

A number of Fellows also received honors and awards between 2010 and 2012. Daniel Sulmasy was appointed to the Presidential Commission for the Study of Bioethical Issues in April 2010. William Cheshire was named a Fellow, Bronze level, of the Mayo Clinic Quality Academy (2011). Farr Curlin was a nominee for the 2011 Arnold P. Gold Foundation Humanism in Medicine Award from the Pritzker School of Medicine student body. Eugene Diamond received the Bartholomew Award, the American Academy of Pediatrics' Annual Award in Bioethics. Gilbert Meilaender received the Dignitatis Humanae Award, bestowed by the University of St. Thomas School of Law. He was also the 2010-11 Remick Fellow at the Center for Ethics and Culture, University of Notre Dame.

"a community of scholars in bioethics who engage in thoughtful discussion, charitable engagement, and mutual support."

The range of ways that Fellows have pursued communication of bioethical issues and ideas is also extensive. Matthew Eppinette has been involved in the production of bioethics films: *Anonymous Father's Day* (2011), a documentary on the ethics of donor conception, was noted at the 2012 Rome International Film Festival in Rome, GA and the 2012 California Independent Film Festival in Orinda, CA. Shari Falkenheimer has taught bioethics topics internationally, including in South, Central and East Asia, the Middle East and the Balkans.

Speakers at the 2nd Fellows Consultation

When the Fellows evaluated the Academy itself at the end of 2012, all who responded stated that they greatly valued the experience of being a Fellow. The opportunity to meet and engage with other Christian scholars was meaningful and significant to them. The primary purpose of the Academy is to be "a community of scholars in bioethics who engage in thoughtful discussion, charitable engagement, and mutual support." The anonymous donation mentioned above has funded two Academy meetings, or Consultations. Both were viewed very positively as a way to stimulate discussions and creative thinking. Many of the Fellows work in secular universities and medical settings, often without Christian colleagues with whom they can regularly discuss the bioethical issues they are examining. Simply knowing that other Christian scholars and practitioners are engaging with these issues was a significant encouragement. The Consultations fostered relationships which continued afterwards by email and telephone and have led to some collaborative links on projects, as well as opportunities for Fellows to help one another with teaching and learning activities in their home institutions.

The 2012 Consultation took a new approach in order to develop a concrete collaborative project. The details of this initiative were reported in an earlier *Dignitas*.[1] Written resources on the Consultation topic, "The Ethics and Theology of Synthetic Gametes," are being developed by a team led by Calum MacKellar. At the same time, the Consultation led to collaboration between CBHD, the Anscombe Bioethics Centre in Oxford, UK, and St. Mary's University College, London. This

FELLOWS CONTINUED FROM PAGE 9

is in keeping with the Academy of Fellows' aim to engage in scholarship with the wider Christian bioethics community. As a result of an evaluation of the Consultation, exciting changes were introduced into the structure of the Call for Proposals for the 2013 Consultation, currently being planned.

While the Academy was positively evaluated in many areas, the evaluation also helped provide direction for the next stage of its development. Many Fellows, despite being busy, expressed a desire for more frequent contact and communication with one another to greater enhance the Academy's potential. As Fellows live across the U.S. and in other parts of the world, much of this will need to be electronic. CBHD has recently developed new expertise in hosting virtual meetings, and the Academy is poised to leverage these new opportunities. At the same time, face-to-face meetings continue to be important for fellowship and developing relationships. The 2011 Consultation was highly valued because of the opportunity to brainstorm and engage in open and private conversations. Travel expenses for such meetings can be prohibitive, but CBHD and the Academy are actively pursuing ways to fund such activities. Meanwhile, topics are being identified around which working sub-groups of the Academy can develop to encourage dialogue and development of meaningful collaboration.

The Academy also aims to foster the development of the next generation of Christian bioethicists. The Academy has a range of Fellows, from those who are internationally renowned to those who are just beginning to engage with academic bioethics. A mentoring system exists for Associate Fellows as they begin to engage more actively in academia, and those involved in its preliminary phase have valued it highly, so the Academy also intends to devote attention to advancing this system's practical development.

Over the past twenty years, CBHD has grown and developed. As with any human community led by God, there have been ups and downs. The Academy of Fellows is a relatively new initiative within CBHD. Significant steps have been made towards its vision during its first three years, and many more remain for years to come. Like Paul, we press on toward that to which Christ has called us (Philippians 3:12). As we do, we ask for your prayers for the Academy as a community and for each Fellow individually. Be watchful and thankful, praying that God would open doors for our message, so that we can proclaim it clearly, wisely, and with grace (Colossians 4:2-6).

1. Dónal O'Mathúna, "Academy of Fellows Holds Consultation on Synthetic Gametes," *Dignitas* 19, no. 4 (2012): 12-13.

(FREE) ONLINE COURSE IN CLINICAL ETHICS

BY ROBERT D. ORR, MD, CM
CBHD FELLOW, CO-CHAIR HEALTHCARE ETHICS COUNCIL

Loma Linda University (LLU), a Seventh-day Adventist health sciences institution in southern California, seeks in the mission of the School of Medicine "to continue the healing and teaching ministry of Jesus Christ, 'To make man whole.'" As part of its mission and outreach, the Office of Staff Development is offering a brief online introductory course in clinical ethics for members of ethics committees at healthcare institutions around the world. The content of the course was developed by Dr. Robert Orr, Professor of Medical Ethics at LLU and Professor of Bioethics at Trinity International University (TIU).

Hospital Ethics Committees generally have three functions: (a) education, (b) policy review, and (c) case consultation. This course is designed to address the third function, case consultation. It consists of four sessions that may be undertaken by an entire committee or independently by committee members. There will be discussion of some of the more common issues that lead to requests for consultation in clinical ethics and a procedure that may be used in providing consultations. The titles of the four sessions are:

- Clinical Ethics: What, Why, How & Who?
- Consent, Capacity and Competence
- Surrogacy and Futility; and
- Bedside Consultation.

Each session will include brief readings (provided electronically), a didactic session (PowerPoint slides with voice-over) given by Dr. Orr, and two case studies.

While the course is designed with ethics committee members in mind, it might also be of interest to others in the healthcare fields, or even to students preparing to pursue graduate studies in bioethics at Trinity International University.

The course is presented in a self-contained online format and may be taken at any time; the sessions may be completed at whatever pace suits the participants. It is available through the LLU continuing education webpage (ceonline.llu.edu) at no charge to members of ethics committees. Continuing education credit is available for a modest fee. Questions may be directed to Joy Guy at the Office of Staff Development (909-558-3500).

effects.

In addition to these technical challenges, the cost of both the genetic tests themselves and the associated interventions is prohibitive in many cases. And it is difficult to communicate complicated genetic information about disease risk to patients accurately, such that it actually alters patient behavior.

For these reasons, researchers and physicians have established three criteria for determining whether or not a genetic test is beneficial. First, a test must be analytically valid, meaning that test must accurately identify the presence or absence of a given genetic variation. Second, it must be clinically valid, meaning that the mutation or genetic variation must be associated with a disease or medical condition. Finally, the test must be clinically useful, meaning that it must aid in the treatment or prevention of disease.

As it turns out, these criteria are difficult to meet.

In most cases genetic tests are ordered by a physician, and often the results are interpreted to patients with the help of a genetic counselor. However, because sequencing technology has become increasingly more cost effective, some companies have begun marketing genetic tests directly to consumers. Prior to 2006, most direct-to-consumer (DTC) genetic testing was conducted by companies advertising "nutrigenetic profiles," which marketed genetic testing toward the sale of nutritional supplements. From 2007 to 2008, new DTC companies emerged to market information about ancestry or paternity for "informational" or "entertainment" purposes, rather than "clinical." But after 2009 several companies, including 23andMe, Navigenics, deCode, Pathway, and Lumigenix, began marketing medical information as part of their genetic profiles.

23andMe, whose founder is married to one of the founders of Google, offers a "Personal Genome Service" with the tagline "Get to know your DNA. All it takes is a little bit of spit."[1] Included in this service is a "health report" with information about 241 medical conditions, including carrier risk—the risk that the customer carries a gene for a medical condition they could pass on to their children—as well as disease risk—the risk that the customer will develop a certain disease or condition. The 241 conditions tested range from known single gene diseases such as cystic fibrosis to complex medical conditions such as back pain and asthma.

Advantages and Pitfalls

Looking at a common, complex condition such as Type II diabetes illustrates the advantages and pitfalls of this type of genetic testing. Among leading causes of morbidity and mortality in the U.S., Type II diabetes is particularly amenable to lifestyle interventions such as diet and exercise. Over 20 million Americans have diabetes, making the disease a major contributor to overall health costs. In 2005 researchers at the biotechnology company deCode found that 20% of people with Type II diabetes carry two copies of a high risk allele of the TCF7L2 gene. In fact, researchers found that even one copy of the allele confers significant risk above that of the average population.

So, is the TCF7L2 gene an ideal candidate for genetic testing? In 2007, the private company DNA Direct began to offer this genetic test directly to consumers. At first glance, the argument for offering the test this way is fairly straightforward. As Ryan Phelan, founder and CEO of DNA Direct, said, "If [people] know they're at an increased risk, they will be motivated toward stronger interventions, be it losing weight or quitting smoking."[2] But research shows that patient behavior is more complicated and unpredictable than this.[3] Critics worry that patients who receive a negative result will develop a false sense of security and neglect lifestyle changes, such as exercise and losing weight. Other patients may succumb to genetic fatalism, giving up on lifestyle changes "because they're going to get the disease anyway." And many patients are simply resistant to change. Clinicians are all too familiar with the difficulty of getting patients to change behavior even in the face of known risk factors. How many physicians have warned their patients to stop smoking or lose weight, only to have their advice fall on deaf ears?

In the case of Type II diabetes, it turns out that other factors, such as increased body mass index (BMI), increased blood pressure, and increased serum levels of triglycerides, apolipoprotein A-1, and liver enzymes, are better predictors of the onset of Type II diabetes than this genetic test, despite the apparent predictive power of the presence of the mutant allele. Genetic tests are expensive, and as Harvard researcher and diabetes physician David Altshuler points out, "There is no evidence that this genetic test does result in an improved health outcome."[4]

Proprietary barriers further complicate the issue. Because the US Patent and Trademark Office offers patents not only on specific human genes, but also on specific variations of those genes, each genetic testing company offers unique genetic tests. For example, 23andMe offers a diabetes panel as part of its genetic profile, but it does not include TCF7L2 because deCode owns the patent on TCF7L2. This further hinders the patient's ability to interpret a negative result.

So, are genetic tests offered directly to consumers medically beneficial? Maybe. But if as a patient you order a report from a DTC genetic testing company and see that you have a 30% increased risk of Type II diabetes, what does it really mean?

Interpreting the Data

Genetic data are complex and can be difficult to interpret and translate into meaningful information that will actually improve health outcomes. Interpreting odds ratios can be challenging for the average patient. Having your risk of a disease increase by 50% sounds ominous, but if it is a 50% increase over an already low risk (say 1% in the average population), then your increased risk is relatively minor. Making matters more

complex, genetic markers vary widely in their specificity (the number of individuals correctly identified as low risk among those who will not get the disease) and sensitivity (the number correctly identified as high risk who will get the disease). Furthermore, because the odds ratios (or percentages) from genome-wide association studies are population averages, individual family history is often a better indicator of an individual's risk.[5]

Ethical Concerns

In addition to these technical concerns, there are several ethical considerations which must be weighed as our society decides how to handle technological advances in genetic testing. Do people have a moral right to know the information in their own DNA? Should family members of individuals affected by relevant conditions be tested? Should genetic tests be performed for incurable, fatal illnesses? What do people *DO* with the information they receive? Can or should the government require medical oversight of genetic testing? How are gene patents helping or hurting patient interests? Should payers (insurance companies) reimburse for genetic tests? Under what circumstances?

Some of these questions are being addressed by professional associations, such as medical specialty societies. For instance, studies are currently underway to assess the value of including testing for a heart disease-linked allele in standard risk assessment profiles for aggressive cholesterol intervention. And in 2011, the American College of Cardiology and the American Heart Association issued guidelines regarding hypertrophic cardiomyopathy (HCM), which can be caused by an autosomal dominant mutation. When patients are diagnosed with HCM, the guidelines recommend that family members be tested and appropriate interventions be applied. These guidelines, however, do not address the issue of over-the-counter availability of genetic testing.

The federal government has tasked several agencies with oversight of one aspect of genetic testing or another. As is often the case with emerging technologies, multiple agencies have dabbled in regulating the DTC genetic testing market, but the federal government has not yet developed a uniform approach to regulating the industry.

Regulation of Genetic Testing

Earlier this year, the National Institutes of Health launched a voluntary registry for genetic tests. The Food and Drug Administration (FDA) has the authority to regulate—through premarket submissions and postmarket controls—medical devices, a category defined broadly enough so as to include many genetic tests. According to the FDA, genetic tests directed toward ancestry, forensics, or other non-medical information do not qualify as medical devices subject to its oversight, but tests providing information on pharmacogenomic profiles, Mendelian (genetic) disease mutations, or risk assessments for medical conditions do qualify as such. Those genetic tests falling into this latter category, thus, are subject to FDA oversight. Since 2010, the FDA has been evaluating

> (1) the risks and benefits of making clinical genetic tests available for direct access by a consumer without the involvement of a clinician, (2) the risks of and possible mitigations for incorrect, miscommunicated, or misunderstood test results for clinical genetic tests that might be beneficial if offered through direct access testing and (3) the level and type of scientific evidence appropriate for supporting direct-to-consumer genetic testing claims.[6]

The Federal Trade Commission (FTC) has the authority to regulate claims of false advertising. In 2006 the FTC released "At-Home Genetic Tests: A Healthy Dose of Skepticism May Be the Best Prescription"—a fact sheet for consumers, warning about the limitations of DTC genetic tests.[7] Although the FTC has been only minimally involved in DTC genetic testing regulation since then, some have proposed requiring companies that offer DTC genetic tests to register with the Genetic Testing Registry at the NIH, which might enable the FTC to better police spurious advertising claims.

The Center for Medicare and Medicaid Services (CMS) regulates medical laboratory testing through the Clinical Laboratories Improvement Amendments (CLIA). CLIA standards cover how tests are performed, the qualifications of laboratory personnel, and quality control and testing procedures for each laboratory. CLIA certification evaluates the analytic validity of genetic testing—that is whether or not the test accurately determines the presence or absence of a specific genetic variation. Not all DTC genetic testing companies are CLIA certified, and CLIA certification does not include standards specific to DNA-based genetic tests.

Between 2000 and 2004 the Centers for Disease Control and Prevention (CDC) piloted a project to provide a publicly available tool for "evaluating scientific data on emerging genetic tests." In 2004 this was replaced by the Evaluation of Genomic Applications in Practice and Prevention (EGAPP™) project, which provides "objective, timely, and credible information that is clearly linked to available scientific evidence. This information will allow health care providers and payers, consumers, policymakers, and others to distinguish genetic tests that are safe and useful."[8] To the extent that patients are aware of this tool, and to the extent that the project maintains enough funding to continue its work, the EGAPP table provides a useful place for consumers to check whether a given genetic test has the opportunity to provide any medical benefit.

In the absence of a federal response to the DTC genetic testing market, state governments have begun to take action. California and New York require companies to have state licenses and regulate DTC genetic testing companies as laboratories, and California prohibits companies from offering DTC genetic tests without a physician's order.

In certain cases, personalized medicine has improved diagnosis, transformed certain procedures, and extended the length and quality of life for patients. As more professional associations make determinations about the best practices for the introduction of genetic testing into their specialties, these tests and treatments will benefit more and more people.

Nevertheless, though the individualism and autonomy so highly prized in our culture may incline us toward self-directed health care, consumers should recognize the inherent complexity of genetic information and discuss results ordered over the internet with their physicians. And at the cultural and governmental levels, we should continue to grapple with how to ensure that the vast and rapid availability of information, medical and otherwise, actually serves the common good.

1 "23andMe: How It Works," *23andMe*, https://www.23andme.com/howitworks/ (accessed July 1, 2012).

2 Emily Singer, "A Genetic Test for Diabetes Risk: Will It Help Make People Healthier?" *MIT Technology Review*, October 15, 2007, http://www.technologyreview.com/review/408873/a-genetic-test-for-diabetes-risk/ (accessed December 3, 2012).

3 David J. Kaufman, Juli M. Bollinger, Rachel L. Dvoskin, and Joan A. Scott, "Risky Business: Risk Perception and the Use of Medical Services among Customers of DTC Personal Genetic Testing," *Journal of Genetic Counseling* 21, no. 3 (June 2012): 413-422, http://www.dnapolicy.org/resources/Riskybusiness.pdf (accessed December 3, 2012).

4 Singer.

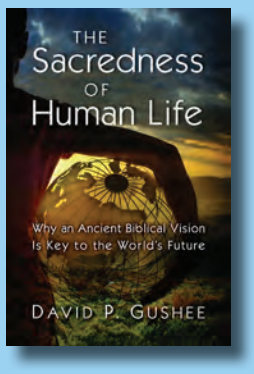
5 See Emma J. Spaulding, "Interpreting Risk: Direct-to-Consumer Genetic Testing," *NCI Cancer Bulletin* 8, no. 23 (November 29, 2011): http://www.cancer.gov/ncicancerbulletin/112911/page7 (accessed on December 3, 2012).

6 Elizabeth Mansfield, "Why Are We Here? The History and Landscape of DTC Genetic Tests" (presentation, OIVD/CDRH/FDA, Holiday Inn, Gaithersburg, MD, March 8, 2011). Transcript of this presentation is available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/MolecularandClinicalGeneticsPanel/UCM249857.pdf.

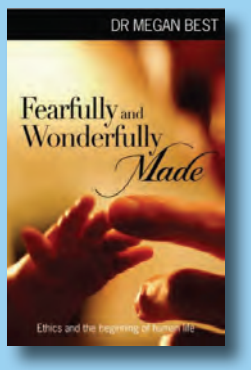
7 "At-Home Genetic Tests: A Healthy Dose of Skepticism May be the Best Prescription" *FDA*, June 2006, http://www.consumer.ftc.gov/articles/0166-home-genetic-tests (accessed December 3, 2012).

8 "Genomics Translation," *Centers for Disease Control and Prevention*, http://www.cdc.gov/genomics/gtesting/EGAPP/index.htm (accessed January 30, 2013).

BOOK HIGHLIGHTS



David P. Gushee, PhD, published *The Sacredness of Human Life: Why an Ancient Biblical Vision Is Key to the World's Future* (Eerdmans, 2013). CBHD provided early support for the book, and Dr. Gushee presented portions of his research at the Center's 2009 summer conference and in various essays published on cbhd.org.



Megan Best, MAAE, BMed (Hons), ThA, published the volume *Fearfully and Wonderfully Made: Ethics and the Beginning of Human Life* (Matthias Media, 2012). Portions of the research were completed during Dr. Best's time with CBHD as a 2009 Global Bioethics Education Scholar, and additional research was made possible through one of our GBEI grants.

TOP BIOETHICS STORIES: JANUARY - MARCH 2013

COMPILED BY HEATHER ZEIGER, MS, MA
RESEARCH ANALYST

"In the Flesh: The Embedded Dangers of Untested Stem Cell Cosmetics" by Ferris Jabr, *Scientific American*, December 17, 2012.

> When cosmetic surgeon Allan Wu first heard the woman's complaint, he wondered if she was imagining things or making it up. A resident of Los Angeles in her late sixties, she explained that she could not open her right eye without considerable pain and that every time she forced it open, she heard a strange click—a sharp sound, like a tiny castanet snapping shut. (http://tinyurl.com/d76mh8q)

The latest rage in cosmetic procedures is to inject the client's stem cells, retrieved from fat cells, into his or her face for their supposed rejuvenation effects, a procedure that has not been approved by the FDA. A woman in California received stem cell treatments at an anti-aging center. Several weeks later she experienced "considerable pain" opening her eye. Surgical investigation revealed that the stem cells injected into her eye had reacted with the dermal filler the doctors used, causing tiny bone fragments to form within her eyelid.

"Female Vaccination Workers, Essential in Pakistan, Become Prey" by Declan Walsh and Donald G. McNeil, Jr., *New York Times*, December 20, 2012.

> The front-line heroes of Pakistan's war on polio are its volunteers: young women who tread fearlessly from door to door, in slums and highland villages, administering precious drops of vaccine to children in places where their immunization campaign is often viewed with suspicion. (http://tinyurl.com/bef8mzj)

Door-to-door polio vaccinations for children in impoverished parts of Pakistan are one of the country's key public health initiatives. Often the people administering the vaccine are female volunteers. Last December, militant groups in Pakistan stalked and gunned down nine volunteers due to suspicion that the vaccination effort was either a plot to sterilize Muslim children or a front for American clandestine activities.

"Experts Aim to Redefine Healthcare and Research Ethics" *Science Daily*, January 11, 2013.

> In what they acknowledge as a seismic shift in the ethical foundation of medical research, practice and policy, a prominent group of interdisciplinary healthcare experts, led by bioethicists at Johns Hopkins, rejects an ethical paradigm that has guided the American system since the 1970s and calls for morally obligatory participation in a 'learning healthcare system' more in step with the digital age. (http://tinyurl.com/bzhmaod)

Several leading bioethicists recently published a new set of guidelines for patient research in *The Hastings Center Report*. These guidelines, if accepted, would relax the ethical distinction between doctor/patient and scientist/subject, as they call for integrating clinical research with clinical practice. Additionally, the report prescribes obligations on both the doctor's and the patient's part for improving health for all by learning from patient care.

"Belgian Twins Had First Request to Die Refused" by Bruno Waterfield, *The Telegraph*, January 14, 2013.

> The two men, 45, from the village of Putte, near the city of Mechelen outside Brussels, were both born deaf and sought euthanasia after finding that they would also soon go blind. (http://tinyurl.com/czytmdk)

With some U.S. states, as well as countries such as France and Ireland, considering new euthanasia laws, the story of 45-year-old deaf Belgian twins who sought euthanasia because they were going to lose their vision as well was a hot topic in the media. Belgian law allows for euthanasia if a person is experiencing "unbearable suffering," but the brothers' request was rejected by doctors at their local hospital because they were not terminally ill or in physical pain. They eventually found a doctor to honor their request and died by lethal injection in December, 2012.

"IVF on Steroids: The Dangerous Off-Label Use of 'Dex' During Pregnancy" by Alice Dreger, *The Atlantic,* January 16, 2013.

> When Susan Manning, a 39-year-old woman just a few weeks into her first pregnancy, wrote to tell me she had been put on the steroid dexamethasone to prevent a miscarriage—and to ask whether she should be worried about taking this drug—at first I could not even process what she was saying. Dexamethasone is known to cross the placental barrier and impact fetal development, so the very idea of first trimester exposure sets off warning bells. Besides, dexamethasone is not known to help in preventing miscarriage. Susan's story sounded too crazy to be true. (http://tinyurl.com/a2h6cx4)

Dex is a steroid that is known to suppress the immune system. Some IVF clinicians routinely prescribe Dex, believing that suppressing the woman's immune system will help prevent a miscarriage; however, the data for this is scant. Furthermore, clinical trial data does show that Dex passes the placental barrier, raising questions about certain off-label use. Animal trials yield concerning data about fetal development under Dex exposure, but there is no definitive data on the safety of using Dex during human fetal development.

"Controversial Stem Cell Company Moves Treatment Outside of the United States" by David Cyranoski, *Nature,* January 30, 2013.

> US citizens who had pinned their

> hopes on a company being able to offer stem-cell treatments close to home will now need to travel a little farther. Celltex Therapeutics of Houston, Texas, stopped treating patients in the United States last year following a warning from regulators. A 25 January e-mail to Celltex customers indicates that the firm will now follow in the footsteps of many other companies offering unproven stem-cell therapies and send its patients abroad for treatment — but only to Mexico. (http://tinyurl.com/bwaplpr)

Celltex is just one of many stem cell companies that have relocated outside the U.S. in order to avoid FDA restrictions. Celltex offers therapeutic stem cell treatments that have not been approved by the FDA; upon threat of being shut down, the company decided to move its business to Mexico where there are fewer restrictions.

"A Miami Clinic Supplies Drugs to Sports' Biggest Names" by Tim Elfrink, *The Miami New Times*, January 31, 2013.

> Then check out the main column, where their real names flash like an all-star roster of professional athletes with Miami ties: San Francisco Giants outfielder Melky Cabrera, Oakland A's hurler Bartolo Colón, pro tennis player Wayne Odesnik, budding Cuban superstar boxer Yuriorkis Gamboa, and Texas Rangers slugger Nelson Cruz. There's even the New York Yankees' $275 million man himself, Alex Rodriguez, who has sworn he stopped juicing a decade ago. (http://tinyurl.com/bamocn5)

An article published in *The Miami New Times* revealed the results of a several-month investigation into Biogenesis, an anti-aging clinic in Miami that allegedly supplied performance enhancing drugs to high-profile athletes. The clinic closed one month before this article was published and the owner was nowhere to be found.

"Gene Therapy Cures Diabetes in Dogs" by Amy Coghlan, *New Scientist*, February 12, 2013.

> Five diabetic beagles no longer needed insulin injections after being given two extra genes, with two of them still alive more than four years later. Several attempts have been made to treat diabetes with gene therapy but this study is 'the first to show a long-term cure for diabetes in a large animal,' says Fàtima Bosch, who treated the dogs at the Autonomous University of Barcelona, Spain. (http://tinyurl.com/bzdkkho)

Type 1 diabetes, while controllable, is not curable at this point. The media has devoted considerable attention to preliminary studies using gene therapy in beagles that indicate a potential treatment for the disease. Scientists inserted two genes into beagles whose pancreases did not produce the insulin needed to regulate blood sugar. Five of the dogs did not require insulin injections after treatment.

"Why Death Is Not the End of Your Social Media Life" by Will Coldwell, *The Guardian*, February 18, 2013.

> Launching in March is a new Twitter app called LivesOn. The service uses Twitter bots powered by algorithms that analyse your online behaviour and learn how you speak, so it can keep on scouring the internet, favouriting tweets and posting the sort of links you like, creating a personal digital afterlife. As its tagline explains: 'When your heart stops beating, you'll keep tweeting.' (http://tinyurl.com/apkwm2c)

One can hardly over-estimate the impact that social media has had on our culture. It changes how, with whom, and when we communicate. Never before has communication been so instantaneous to such a broad base of people. LivesOn seeks to take this development to a new level with an app which will allow a Twitter profile to keep sending updates even after its owner has died based on past "likes," links, and updates, raising questions that push the limits of our concepts of personal identity, agency, and our mortality.

"Organ Trafficking, a New Crime of the 21st Century" by Andrea Hayley, *The Epoch Times,* February 18, 2013.

> Organ transplant medicine is an incredible life-saving technology, under the right circumstances. Unfortunately, due to a shortage of available organs, a new crime of the 21st century, organ trafficking, is supplying organs to people with the money to pay big dollars for a new life. (http://tinyurl.com/ax2topy)

There are more people in need of an organ transplant than there are organs available. In desperation, some seek underground organ donations. Underground organ donation (also referred to as black market organ trafficking or the 'red market') typically involves exploiting the poor or the imprisoned by offering money in exchange for an organ (usually a kidney). This article describes particularly glaring abuses in which organs were illegally obtained from prisoners in China in exchange for money from wealthy clientele.

"Stem Cells Cruise to the Clinic" by David Cyranoski, *Nature*, February 27, 2013.

> In the seven years since their discovery, induced pluripotent stem (iPS) cells have transformed basic research and won a Nobel prize. Now, a Japanese study is about to test the medical potential of these cells for the first time. Made by reprogramming adult cells into an embryo-like state that can form any cell type in the body, the cells will be transplanted into patients who have a debilitating eye disease. (http://tinyurl.com/d2fjp6b)

Induced pluripotent stem cells (iPSc) have been hailed as a potential solution to the ethical hurdles presented by embryonic stem cells. They also avoid the risk of auto-immune rejection of donor stem cells, since they are harvested from the patients themselves. Now scientists are ready to take induced pluripotent stem cells to human subject trial stages. Scientists in Japan intend to use iPSc treatments for macular degeneration.

EVENTS

Her Dignity Network

On March 7-8, 2013, coinciding with International Women's Day, CBHD held several events in Washington, DC in tandem with the launch of the network and our newest website HerDignity.net devoted to promoting the engagement of global women's health issues. The events featured Dr. Jameela George, a physician with Emmanuel Hospital Association, India. She was a Global Bioethics Education Initiative Scholar with CBHD in 2009.

On March 7, CBHD held a briefing with Congressional staffers on Capitol Hill. Dr. George introduced staffers to global women's health issues with a presentation on "Health Implications of Female Dignity across the Life Span."

On March 8, CBHD held the launch event for Her Dignity Network in the Van Andel Center at the Heritage Foundation. The morning event featured Dr. George and an expert panel, as well as presentations from CBHD staff Paige Cunningham, Jennifer McVey, and Michelle Kirtley. Additionally the Center officially launched HerDignity.net through the release of a video tour on our YouTube channel and social media.

STAFF

PAIGE CUNNINGHAM, JD

- In March Paige introduced Her Dignity Network at the launch event held at the Heritage Foundation in Washington, DC.
- Paige wrote "She's a Person, Not a Uterus," for Her.Meneutics, one of *Christianity Today*'s most popular blogs that provides news and analysis from the perspective of evangelical women.

MICHAEL SLEASMAN, PHD

- Interviewed in early March by Alyssa Ashton for a freelance article on "The Ethics and Risks of Social Egg Freezing."
- Completed an article with CBHD Fellow Gregory Rutecki, MD on "Christian Physicians: Reclaiming Integrity through Conscience, Philanthropia, and Vocation." The article has been submitted to a peer-review journal for consideration.
- Continued teaching ID 5002 Foundations for Cultural Engagement in the Spring semester for Trinity Graduate School.

JENNIFER MCVEY, MDIV

- In late February, represented the Center at the Justice Conference in Philadelphia with CBHD Bioethics & Public Policy Associate, Michelle Kirtley, PhD.
- Co-authored an article with Michelle Kirtley, PhD, in early March for *Relevant Magazine* "Waking Up to the Women's Health Crisis."

JESSICA WILSON, MDIV, THM

- Facilitated the final theological bioethics roundtable discussion with graduate students and CBHD staff on Jeffrey P. Bishop's recent book, *The Anticipatory Corpse: Medicine, Power, and the Care of the Dying* (University of Notre Dame, 2011).
- Successfully defended dissertation proposal: "One Person, Two Wills: Dyothelletism and the Metaphysics of Mind and Volition."
- Was awarded an analytic theology research stipend by the Center for Philosophy of Religion at Notre Dame.

ON THE CBHD BOOKSHELF

ARTICLES OF NOTE: For those interested in knowing what books and articles the Center staff have been reading

Auerbach, David, Douglas Taiger, Ulrike Muench, and Peter Buerhaus. "The Nursing Workforce in an Era of Health Care Reform." *New England Journal of Medicine* 368, no. 16 (2013): 1470-1472.

Bartlett, Virginia. "Knowing (or Not): Distinctions in 'Bioethics' and 'Clinical Ethics.'" *Atrium: The Report of the Northwestern Medical Humanities and Bioethics Program* 11 (Winter 2013): 43, 45.

Belgrave, Kevin and Pablo Requena. "A Primer on Palliative Sedation." *The National Catholic Bioethics Quarterly* 12, no. 2 (2012): 263-281.

Deane-Drummond, Celia. "A Recovery of Wisdom as Virtue for an Ethics of Genetics." *Perspectives on Science and Christian Faith* 59, no. 1 (2007): 19-27.

Delmonico, Francis. "The Concept of Death and Deceased Organ Donation." *The National Catholic Bioethics Quarterly* 10, no. 3 (2010): 451-458.

Guinan, Patrick. "Is Assisted Nutrition and Hydration Always Mandated? The Persistent Vegetative State Differs from Dementia and Frailty." *The National Catholic Bioethics Quarterly* 10, no. 3 (2010): 481-488.

Jost, Timothy. "Religious Freedom and Women's Health – The Litigation on Contraception." *New England Journal of Medicine* 368, no. 1 (2013): 4-6.

Lebacqz, Karen. "Pandemic Justice." *Perspectives on Science and Christian Faith* 59, no. 1 (2007): 10-18.

Luke, Barbara, et al. "Cumulative Birth Rates with Linked Assisted Reproductive Technology Cycles." *New England Journal of Medicine* 366, no. 26 (2012): 2483-2491.

Lynch, Holly. "Ethical Evasion or Happenstance and Hubris? The U.S. Public Health Service STD Inoculation Study." *Hastings Center Report* 42, no. 2 (2012): 30-38.

MEDIA RESOURCES

CBHD.org on Twitter: @bioethicscenter

Bioethics.com on Twitter: @bioethicsdotcom

The Bioethics Podcast at thebioethicspodcast.com

Facebook Cause at causes.com/cbhd

Facebook Page at facebook.com/bioethicscenter

Linked-In Group at linkd.in/thecbhd

YouTube at youtube.com/bioethicscenter

The Christian BioWiki christianbiowiki.org

COMING SOON: RECAP OF THE MARCH LAUNCH OF HER DIGNITY NETWORK