
Professional Ethics Report



ADVANCING SCIENCE, SERVING SOCIETY

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TROUBLED WATERS, PART II: ON THE TRAIL OF THE LOST DATA

In 2004, CDC scientists published a reassuring report about lead contamination in Washington's water even though they knew that thousands of blood lead measurements had been lost. Now Congress wants to know why.

Rebecca Renner

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In the last issue of *Professional Ethics Report*, I described some of the ethical and scientific issues raised about a 2007 peer-reviewed paper on the Washington, DC lead crisis which concluded that record levels of lead in the capital's drinking water did not have an identifiable public health impact [1]. In this essay, I will outline some of the problems and shortcomings identified in the first public health publication about the crisis, a 2004 report from the Centers for Disease Control and Prevention (CDC) [2]. One of the most glaring problems is missing data -- thousands of children's blood lead measurements that went missing from the database CDC uses to evaluate the effects of the contamination. Even though they knew about this major flaw, CDC scientists used the data in a publication to reassure the public without any mention of potential limitations [2].

I first wrote about the lost blood lead measurements in an April 10 story for Salon.com [3]. Last month, Congressional investigators on the trail of the lost data found over 4,000 missing blood test results, which show that almost 500 children, more than twice the number listed in the CDC report, had high levels of lead in their blood during 2003 [4]. As a result of this finding and other concerns, the Subcommittee on Investigations and Oversight of the U.S. House Science and Technology Committee is scheduling a hearing on the issue later this fall [5].

When Salon.com revealed the lost data, subcommittee chairman Brad Miller said, "it's difficult to understand why the loss of so much data didn't merit a caveat or even a footnote in CDC's report." He added, "If the CDC tells parents that they shouldn't worry about their children's health, its evidence had better be rock solid. It's hard to win back lost trust" [3].

Much about the CDC's response to the lead crisis is difficult to understand. Since 2006, I have been trying to get to the bottom of it. Below I'll describe what my own and others' reporting has revealed as the major issues--the sampling gap and the missing data.

Calming the Waters

First, it is important to understand the impact of the CDC report. Just before it was published in March 2004, Washington, DC was a storm of public agitation over lead in drinking water.

The water company had distributed over 20,000 water filters, children under 6 and pregnant women were being advised to drink bottled water, and four official investigations were trying to find out why DC residents had been drinking tap water contaminated with record levels of lead for almost 3 years without being notified. CDC's brief report completely calmed the public when it stated that the public health effect of the water contamination was minimal.

The report was based on nearly 85,000 blood lead measurements reported to the city since 1998. It found that tap water contributed to a small increase in blood lead levels in Washington. But it explicitly ruled out tap water as a major cause of high blood lead levels in children. The authors even cited the worst case exposures -- some 200 residents of all ages in homes with ultra-high levels of lead in tap water who agreed to be screened—and stated that not one of them had blood lead exceeding levels of concern.

DC Councilwoman Carol Schwartz was one of many people who were relieved by the findings. She described the CDC findings as "marvelously, enormously encouraging" [6]. The findings were also extremely influential in and outside the US. The CDC report has been cited by Congress's investigative arm, the Government Accountability Office, and the Congressional Research Service.

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School officials in New York and Seattle have cited the CDC report as justification for not aggressively responding to high levels of lead in their water, and many other cities in the U.S. and worldwide have cited the report to downplay concerns about lead in tap water.

Mind the gap

The finding that even in “worst case” homes there was no evidence that blood lead levels rose as a result of drinking water seemed to be dramatic proof that contaminated tap water had not caused health problems. But in 2006, environmental engineer and McArthur fellow Marc Edwards at Virginia Tech University pointed out that the CDC publication failed to note that the blood samples were taken up to a year after the water samples. Most important, the blood samples were taken after the public knew about the contamination and had largely stopped drinking the tap water [7].

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Missing Data

In 2007, Edwards filed a complaint of scientific misconduct with CDC’s Associate Director of Science, alleging that the authors of the CDC study must have known about serious flaws with the data, but had failed to acknowledge them when writing the 2004 CDC report. Edwards filed the complaint in frustration, after years of trying with no success to discuss his concerns with some of the authors [8].

Edwards also noted that thousands of measurements appeared to be missing for 2003, based on CDC’s tabulation of data [9]. Even though my reporting has subsequently shown that at the time Mary Jean Brown, lead author of the report and head of CDC’s Lead Poisoning and Prevention branch, knew about the missing data, Edwards did not receive an answer.

In September 2007, James Stephens, CDC’s associate director of science at the time, wrote to Edwards informing him that “the questions you raised pertained to data collected by others outside of CDC,” and “we have examined CDC’s role in the study and have found no evidence of misconduct.” Stephens advised him to address his remaining concerns to the D.C. inspector general [10].

Eventually, I had the opportunity to ask Brown’s boss, Howard Frumkin, about the missing data. In reply, he sent me Brown’s explanation. She wrote that in 2003, before the CDC report was written, she noticed that data were missing, and questioned DC Health Department staff about the gap. Brown wrote that one of the large commercial laboratories had failed to submit some test results in the last quarter of 2003 (a year when lead levels in the water were high). Specifically, Brown said the lab only omitted results below CDC’s level of concern. Brown claimed that the highest blood lead results in 2003 were reported accurately and that if anything, the error strengthened CDC’s conclusions because the bias would have overestimated incidence of lead poisoning [11].

CDC reiterated this point of view in a press release intended to counter my Salon story [12]. But when Congressional staffers looked for the lost data, they did not just rely on the explanation of DC DOH staff. The Congressional investigators directly contacted all the labs for the data. That is how they found the over 4000 “lost” blood lead measurements. When the lost data are included, the number of children with elevated blood lead levels more than doubles from the CDC report’s previous estimate [4]. Further, a CDC scientist in 2007 gave a talk that revised CDC’s assessment of the lead crisis and estimated that many young children living in D.C. homes with lead pipes were poisoned by drinking water and suffered ill effects [13]. Yet the health agency did not publicize the new findings or alert public health authorities in D.C. or other federal agencies that regulate lead.

CDC scientist Jaime Raymond presented the 2007 results at the American Public Health Association’s 2007 annual meeting in Washington, D.C. The study used data from a total of 22,981 children under 6 years old who lived in Washington from 1998 to 2006. Twenty-nine percent of the children (6670) lived in houses with lead service lines and 16,311 lived in houses without lead pipes. Raymond and colleagues studied how the blood lead levels of these children changed over time, including in their analysis the effects of other factors, such as the age of the house and gender of the child. “The proportion of children tested with blood lead levels greater than or equal to five micrograms/deciliter or 10 micrograms/deciliter was significantly higher” during the crisis they concluded. The most likely cause, they concluded, was the high levels of lead in Washington’s drinking water [13].

Passing the Buck

Even though the lead author on the 2004 CDC report, Mary Jean Brown, is a CDC scientist and manager, and even though experts familiar with the report

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attribute it to CDC, the public health organization has taken a more hands-off attitude, and appears to be unwilling to take responsibility for the scientific integrity of the effort, my reporting indicates.

When I asked Howard Frumkin about the data quality, he noted that some of the data CDC used were controlled by other groups. "Look at the [2004 CDC] report," he said. "At several points in the report it says that WASA reported data that remains in the hands of DOH. It is not our data [sic]," he stressed [14]. Speaking about the database used for CDC's 2004 paper, he said, "The data used was [sic] the best available for a rapid field investigation. No public-health database is perfect. But this database is not so flawed that it fails" [14]. Shortly after he made this statement, Brown e-mailed Frumkin her explanation about the missing data. His response echos science advisor Steven's reply to Edwards, advising him that, "the questions you raised pertained to data collected by others outside of CDC." This position that CDC is not responsible for the data and has no responsibility to publicize the data's shortcomings also appears to be apparent in posts about the Salon story to a blog that covers CDC issues [15].

This apparent unwillingness seems all the more troubling to me as a science writer who covers environmental issues, when you realize that CDC was funding and monitoring the lead poisoning prevention program in Washington. Indeed, CDC is the government organization that funds and monitors the efforts of health departments around the country to reduce and prevent childhood lead poisoning [16].

The Subcommittee hearings certainly should be interesting.

Letters to the Editor: The editors welcome comments from our readers. We reserve the right to edit and abridge the letter as space permits. Please address all correspondence to the deputy editor.

[1] Renner, R. 2009. "Troubled Waters: Controversy over Public Health Impact of Tap Water Contaminated with Lead Takes on an Ethical Dimension," *Professional Ethics Report*, Number 2. <http://www.aaas.org/spp/sfrr/per/newper>

[2] Stokes, L. et al. "Blood Lead Levels in Residents of Homes with Elevated Lead in Tap Water --- District of Columbia, v2004," *Morbidity and Mortality Weekly Report, MMWR Dispatch*, Vol. 53 / March 30, 2004, Department of Health and Human Services, Centers for Disease Control and Prevention. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5312a6.htm>

[3] Renner, R. 2009. "Health agency covered up lead harm," April 10, 2009, Salon.com. http://www.salon.com/env/feature/2009/04/10/cdc_lead_report/

[4] Leonnig, C. "More D.C. Kids Had Elevated Lead Than Stated," *The Washington Post*, August 4, 2009. <http://www.washingtonpost.com/wp-dyn/content/article/2009/08/03/AR2009080303003.html>

[5] Living on Earth, "Lead in Water Underreported," August 7, 2009, interview with Congressman Brad Miller. <http://www.loe.org/shows/segments.htm?programID=09-P13-00032&segmentID=1>

[6] Lambrinidou, Y. "A New Congressional Inquiry into Scientific Integrity Highlights Lead in DC Drinking Water," WASAwatch, March 22, 2009. video excerpt of Carol Schwartz. <http://dcwasawatch.blogspot.com/2009/03/new-congressional-inquiry-into.html>

[7] Renner, R. "Mis-lead," *Environ. Sci. Technol.*, 2006, 40 (14), pp 4326-4334 Publication Date (Web): July 15, 2006 DOI: 10.1021/es062989g. <http://pubs.acs.org/doi/pdf/10.1021/es062989g>

[8] E-mail from Marc Edwards to James Stephens, August 6, 2007. On file with author.

[9] Centers for Disease Control and Prevention, Tested and Confirmed Elevated Blood Lead Levels by State, Year, and Blood Lead Level Group for Children < 72 months, CDC National Surveillance Data. <http://www.cdc.gov/nceh/lead/data/national.htm>

[10] Letter from James Stephens to Marc Edwards, September 18, 2007. On file with author.

[11] E-mail from Mary Jean Brown to Howard Frumkin, July 14, 2008. On file with author.

[12] "CDC Responds to Salon.com Article," April 10, 2009. CDC press release. <http://www.cdc.gov/media/pressrel/2009/s090410.htm>

[13] Raymond, J. "Association between lead poisoning among children less than six years old and lead service pipes in Washington DC," Abstract #166176, American Public Health Association, Annual Meeting, November 3-7, 2007, Washington, DC. http://apha.confex.com/apha/135am/techprogram/paper_166176.htm

[14] Renner, R. 2009. "Mapping Out Lead's Legacy," *Environmental Science & Technology*, 43, 1655-1658. <http://pubs.acs.org/doi/full/10.1021/es8037017>

[15] Topic: "Health agency covered up lead harm," 2009. CDC Chatter - A blog to discuss issues at CDC. <http://www.cdchatter.net/index.php?name=News&file=article&sid=713>

[16] CDC's Childhood Lead Poisoning Prevention Program. <http://www.cdc.gov/nceh/lead/about/program.htm>

To the Editor

Tee L. Guidotti, MD, MPH, DABT, of Washington, DC, wrote this letter in response to the cover story in Professional Ethics Report, Volume XXII, Number 2, Spring 2009, by Rebecca Renner titled, "Troubled Waters: Controversy over Public Health Impact of Tap Water Contaminated with Lead Takes on an Ethical Dimension."

The item by Rebecca Renner published in the Spring 2009 AAAS Professional Ethics Report has come to my attention. It is incorrect and irresponsible. Renner insists on repeating allegations that a review by the journal Environmental Health Perspectives found to be unsupported by the facts. Repetition does not make them true.

From 2004 to 2008, I led a team at the George Washington University (GW) to assist the District of Columbia Water and Sewer Authority (WASA) in dealing with public health and risk management issues. Together with my colleagues at the DC Department of Health (DOH), we published in 2007 the findings of a lead screening program at the height of the water lead levels.

Marc Edwards, in his 2009 paper, erroneously suggested that our paper was wrong on several points. Publication of his paper was followed by extensive, highly prejudicial coverage in the *Washington Post*, which Renner chooses to emphasize without telling the reader that the *Post* subsequently reported a more balanced and accurate view of the story. (See, for example, "Lead study not tainted by utility, panel says," 16 June 2009, and "Clarification," 23 July 2009.) The *Post* also reported that a \$200 million class-action lawsuit was filed against WASA, alleging that WASA covered up and failed to remedy the effects of the elevated water lead levels, shortly after appearance of the Edwards article.

Renner persists in describing me as a "paid consultant" to WASA, which implies that I had a direct financial relationship with WASA that

enriched me personally. In fact, the contract was between WASA and GW. It covered many other drinking water-related activities and supported partial FTE for several faculty, staff, and students. I did not depend on this contract for my income or position, and received no more than my salary as a tenured professor and department chair.

I have never been granted the courtesy of receiving a copy of Edwards's letter, and so do not know what it actually says. I can only respond to Renner in reiterating that only subjects who participated in the expanded screening program, from February through July, constituted the base population for our study, as is clearly stated in the *EHP* article. The 65 children were identified from the database of the expanded screening program and, as are all such cases, were investigated by the DC DOH. For comparison, approximately 150 to 200 cases of blood lead >10 µg/dl were being observed every year in DC during those years.

I first joined AAAS decades ago, as a junior scientist, and my membership is important to me. It saddens me that a publication of this great Association would be the vehicle for such unwarranted allegations.

This letter arrived just as PER went to press, allowing neither time nor space for Rebecca Renner's response, which will be published in PER's December issue—Ed.

In the News

HOUSE OF LORDS SCIENCE COMMITTEE CALLS FOR GENOMIC MEDICINE IN HEALTH CARE

On July 7, 2009, the House of Lords Science and Technology Committee published a report on advancements in genomic medicine and how they could lead to improvement of medical care in the United Kingdom. The report charges the Office of the Strategic Coordination of Health Research (OSCHR) with the task of developing an overarching strategy to incorporate genomic research into clinical practice.

The result of their task would be a new government White Paper, which includes suggestions for integrating the new genomic medicine infrastructure into the National Health Service (NHS) and obtaining funding to support these new genomic medicine activities. *Our Inheritance, Our Future*, a 2003 White Paper, addressed several genomic medicine issues in the diagnosis and treatment of single-gene disorders. The newly proposed White Paper would address scientific advances made since that time, such as the discovery of complex genomic links to common diseases, and what policy changes should be made to accommodate these advances.

To facilitate the translation of genomic research into clinical practice, the report suggests that funding be guaranteed for "research into the clinical utility and validity of genetic and genomic tests." It also recommends a more rigorous pre-market review for the tests. The government plans to use clinical genomic research to develop pharmacogenetic tests that will 'stratify' medicinal usage, a methodology where treatments and therapies are "matched" with populations possessing certain clinical biomarkers to maximize beneficial health outcomes and minimize adverse effects [1].

The report clarifies that the NHS and the National Institute of Health Research should have oversight over the implementation of the proposed changes to the genomic medicine infrastructure in the UK. The National Institute for Health and Clinical Excellence (NICE) should provide guidance to non-genetic specialty fields on the usage of genetic testing as a decision-making aid for treatment in order to facilitate the seamless integration of genomics into mainstream clinical care. An Institute of Biomedical Informatics should be established to fill gaps in expertise, interface electronic genetic information with electronic health records, and develop a national center for training biomedical informatics professionals.

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The report acknowledges the necessity of public engagement and the importance of considering ethical, social, and legal implications related to genomic medicine's expansion in the health care system. The government should increase public awareness of genetic testing for complex diseases, improve public understanding of genetic risk, and collaborate with the Association of British Insurers to set standards for when personal genetic data can be used for insurance purposes. The Information Commissioner should also set professional guidelines for researchers who handle genetic data.

With respect to the consumer, the report recommends increased regulation for "direct to consumer" tests (DCT). The voluntary code of practice for the DCT industry, which is currently being developed by the Human Genetics Commission, should include guidelines for declaring standards, accreditation status, and the clinical utility and validity of the tests offered by the company, in addition to provisions for counseling services and an ethical code of conduct. Additionally, the report urges the Department of Health to disseminate information on the accreditation and quality assurance standards of the DCT laboratories, and the predictive value of the biomarkers used by their tests.

Finally, the report recommends that genomic medicine be integrated into the standard training of medical students, general practitioners, primary and secondary caregivers, and nurses. Furthermore, support for the field of genetic pathology should be reinstated, and training programs for genetic counselors expanded.

To read the full report, visit: <http://www.publications.parliament.uk/pa/ld200809/ldselect/ldsctech/107/107i.pdf>

[1] Trusheim, M. R., Berndt, E. R. and Douglas, F. L. "Stratified medicine: strategic and economic implications of

combining drugs and clinical biomarkers," *Nature Reviews Drug Discovery* 6, 287-293 (2007).

*EL

INTERNATIONAL BIOETHICS COMMITTEE ADDRESSES HUMAN CLONING AND INTERNATIONAL GOVERNANCE

Currently, international governance for human cloning is constituted by Article 11 of the UNESCO Universal Declaration of Human Genome and Human Rights (1997), a World Health Organization Resolution (1998), and the UN Declaration on Human Cloning (2005). All three urge the prohibition of cloning for the purpose of human reproduction, stating it is contrary to human dignity.

In 2008-2009, UNESCO's International Bioethics Committee (IBC) assessed the value of beginning an initiative to update the international governance framework for human cloning. Its conclusions were published in the June *Report of IBC on Human Cloning and International Governance*. In 2007, the United Nations University Institute of Advanced Studies (UNU-IAC) report, *Is Human Reproductive Cloning Inevitable: Future Options for UN Governance*, also attempted to describe the state of international governance on human cloning. However, according to the IBC report, the work of the UNU-IAC was limited in that it was based on previous discussions about human cloning—such as the four-year debate that preceded the passage of the UN Declaration on Human Cloning in 2005—and did not consider the effects of any recent developments in the field. Alternatively, IBC made an effort to identify and include in its analysis new scientific, legal, and social developments that have affected or could affect the ethical discussion on human cloning and its governance by working with experts, national bioethics committees, international scientific organizations, and the international governance bioethics committee (IGBC). IBC concluded that an initiative for a binding normative instrument should be postponed until

after the international community has a discussion about the recent scientific, legal, and social changes in the field, including those identified by the IBC's preliminary analysis. For example, the report states that research on induced pluripotent stem cells has the potential to alter drastically the debate on human cloning, as iPS cells may enable the creation of germ cell lines from somatic cells rather than embryos. IBC also advises international discussion on the merits of human cloning for research. As demonstrated in the report's annex, titled *Study on National Legislation Concerning Human Cloning*, while the majority of UN Member States have banned human cloning for reproductive purposes, they have also developed a variety of opinions on the acceptability of human cloning for research.

In conclusion, IBC recommends that UNESCO develop methods for facilitating the dissemination of opinions on the recent scientific, legal, and social developments associated with human cloning and their ethical implications by coordinating efforts with relevant bioethics groups and UN bodies, such as the World Health Organization.

To read the full report, visit: http://portal.unesco.org/shs/en/files/12828/12446291141IBC_Report_Human_Cloning_en.pdf/IBC%2BReport%2BHuman%2BCloning_en.pdf

*KA

FDA ISSUES FINAL RULES FOR PATIENTS SEEKING ACCESS TO INVESTIGATIONAL DRUGS

On August 12, 2009 the U.S. Food and Drug Administration published two rules clarifying the methods available to seriously ill patients seeking to obtain access to investigational drugs even though they do not qualify for participation in the clinical trials. Patients seek these drugs due to a dearth of satisfactory alternative treatment options.

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The first rule, “Expanded Access to Investigational Drugs for Treatment Use,” clarifies procedures and standards relating to the availability of investigational drugs. The second rule, “Charging for Investigational Drugs Under an Investigational New Drug Application,” clarifies the circumstances and types of costs associated with an investigational drug when used either as a part of or outside the scope of a clinical trial.

According to Janet Woodcock, M.D., director of the FDA’s Center for Drug Evaluation and Research, these final rules established by the FDA “balance access to new therapies against the need to protect patient safety and seek to ensure that expanded access does not discourage participation in clinical trials or otherwise interfere with the drug development process” [1]. The FDA has also launched a new website in conjunction with these new rules to help patients and health care professionals learn about their options regarding investigational drugs.

[1] FDA News Release, 8/12/2009. FDA website explaining the options for investigational drugs:
<http://www.fda.gov/Safety/Recalls/ucm177114.htm>

“Final Rules for Expanded Access to Investigational Drugs for Treatment Use and Charging for Investigational Drugs” can be found at:
<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm172492.htm>

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WHITE HOUSE S&T PRIORITIES FOR 2011 INCLUDE SCIENTIFIC INTEGRITY

On August 4, 2009, the White Office of Management and Budget and the Office of Science and Technology Policy issued a joint memo to the heads of all executive departments and agencies

requesting that they “explain in their budget submissions [for FY 2011] how they will redirect available resources, as appropriate, from lower-priority areas to science and technology activities that address four practical challenges:

- Applying science and technology strategies to drive economic recovery, job creation, and economic growth;
- Promoting innovative energy technologies to reduce dependence on energy imports and mitigate the impact of climate-change while creating green jobs and new businesses;
- Applying biomedical science and information technology to help Americans live longer, healthier lives while reducing health care costs; and
- Assuring we have the technologies needed to protect our troops, citizens, and national interests, including those needed to verify arms control and nonproliferation agreements essential to our security.

While such memos are routine well in advance of the FY budget request, what is not routine are explicit instructions to the agencies regarding scientific integrity.

The final paragraph of the memo includes the following admonition: “Finally, agencies are expected to conduct programs in accordance with the highest standards of ethical and scientific integrity and to have clear principles, guidelines, and policies on issues such as scientific openness, scientific misconduct, conflicts of interest, protection of privacy, and the appropriate treatment of human subjects.”

The entire memo can be viewed at:
http://www.whitehouse.gov/omb/assets/memoranda_fy2009/m09-27.pdf

*MSF

SECURITIES AND EXCHANGE COMMISSION CHARGES CELLCYTE WITH FRAUD

On September 8, 2009, following a year-long investigation, the Securities and Exchange Commission (SEC) charged CellCyte Genetics Corporation, a biotechnology company based in Bothell, Washington, with fraud for falsely representing an experimental stem cell therapy as being close to human clinical trials. The SEC also charged the company’s former CEO, Gary Reys, and Chief Scientific Officer, Ronald Berninger, for their participation in the fraudulent activities.

CellCyte was formed in 2005 as a private company in order to acquire to rights to a scientist’s stem cell-related research. The company signed a licensing agreement requiring them to demonstrate the capacity to conduct active research and development of technology within one year. At the time of the licensing agreement, CellCyte was aware that the scientist’s research was only preliminary and produced no data showing that the stem cells could repair injured organs or that it was safe to administer in human trials.

In 2006, CellCyte performed a reverse merger with a public shell company controlled by a Canadian stock promoter, making CellCyte a public company. The stock promoter allegedly received 15 million “freely tradable” CellCyte shares, of which there is no record of the required registration statement. The following year, the company began attempts to formulate the compound the scientist had previously used, failing to produce the results necessary to apply for clinical trials. Despite these results, CellCyte and the stock promoter began a marketing campaign releasing millions of spam emails, faxes, and newsletters claiming that the company had received approval from the Food and Drug Administration (FDA) to move forward with human clinical trials.

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During this time, CellCyte's stock price grew to \$7.50 a share, giving the company a market capitalization of almost \$450 million. In January 2008, the marking campaign ended and the stock dropped to under one dollar, now selling for \$0.07 per share.

The SEC reports that CellCyte's filings between 2007 and 2008 contained "false and misleading" material, including omissions about status of the research and falsely reporting FDA clinical trial approval. Though CellCyte claims it has not shut down, it has placed all employees on unpaid leave. Berninger has reached a settlement agreement with the SEC, but there have been no reports of a settlement for Reys.

View details of the SEC charges at: <http://www.sec.gov/litigation/complaints/2009/comp21200-berninger.pdf>

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CHINA-UK RESEARCH ETHICS REPORT

The UK Medical Research Council (MRC), in partnership with the Foreign and Commonwealth Office and China National Center for Biotechnology Development convened the China-UK Research Ethics (CURE) committee in response to the rapid development of science and technology in China and the resultant increase in collaborations between China and the UK. The task of CURE was to examine the ethical issues raised by the recent China-UK human subject research collaborations, and to make recommendations to maintain a high standard of ethics throughout the research collaborations. CURE issued its report on August 14, 2009.

First, CURE analyzed the guidelines for research ethics in China by investigating the principles, methods and frameworks of regulation applied to biomedical research in China. Next, CURE examined the implementation of these guidelines for research ethics in China (focusing primarily on the regions of Beijing and Shanghai) by examining how the mechanisms of ethics review operate in specific

research environments. CURE also compared these mechanisms of review to their UK equivalents. Finally, CURE made recommendations to the MRC for future policy, and also suggestions about ways of maintaining communication and exchange between China and the UK.

The research guidelines in China were found to draw heavily on international regulations, the UK in particular with regards to embryonic stem cell research. The implementation of regulation is less strict in China than in the UK. Although in the regions of China that were studied, scientists and institutions were committed to implementing national standards, CURE recommended a close review of any potential research collaborations. There are also significant differences between review board processes in the UK and in China. China currently has no equivalent to the UK's National Research Ethics Service (NRES). Additionally, while UK law dictates Research Ethics Committees (RECs) include members independent of the research teams, China has no such requirement. CURE also produced more detailed analyses of three areas. In the area of stem cell research, CURE recommended attention be paid to the source of research tissue (including, but not limited to, embryos) as well ensuring that procedures for obtaining consent are compatible in both China and the UK.

For clinical trials, CURE suggested that MRC ensure that there are adequate monitoring systems in place to carefully review the protocol, procedures for approval, recruitment and consent, and the issue of post-trial benefits. Finally, in the area of Traditional Chinese Medicine, CURE noted that attention must be paid to the quality, purity, and standardization of the products used, the selection of participants, and the use of placebo and control groups.

Read the full report at: <http://www.mrc.ac.uk/Utilities/DocumentRecord/index.htm?d=MRC006303>

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Resources

NEW NIH "EXPLORING BIOETHICS" CURRICULUM SUPPLEMENT

A partnership between the National Institutes of Health (NIH) Office of Science Education and Department of Bioethics and, the Education Development Center (EDC) and its Center for Applied Ethics and the Center for Science Education has produced a high school curriculum supplement, "Exploring Bioethics." The supplement provides guidelines that teachers can use to engage students in acknowledging and discussing bioethical issues. Students learn to approach ethical dilemmas using four core questions that guide them to identify the ethical question, significant facts, potential outcomes, and relevant ethical considerations.

The supplement is geared toward promoting critical thinking, communication, problem-solving, and teamwork. It is broken down into six three-day lessons covering six topics. The lesson series begins with basic bioethical concepts and skills, extending to more specific issues, such as genetic testing, steroid use by athletes, organ donation for transplants, human experimentation, animal modification for human benefit, and vaccination policies.

"Exploring Bioethics" joins the NIH's 16 other school curriculum programs, which cover a variety of topics for elementary, middle, and high school students. These supplements are in accordance with National Science Education Standards as well as state education standards, and offer guidance to teachers on how to help their students achieve specific learning objectives.

HTML and PDF versions of the material are available online. For more information visit: <http://science.education.nih.gov/supplements>.

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RCR FOR ENGINEERS

Jason Borenstein

Jason Borenstein is the Director of Graduate Research Ethics Programs at Georgia Tech and the Editor of the *Journal of Philosophy, Science & Law* at: www.miami.edu/ethics/jpsl

Many researchers and their respective institutions are seeking to develop strategies regarding how they are going to address Responsible Conduct of Research (RCR) training. A resource that may assist in this effort is the CITI* RCR for Engineers Program.

The RCR for Engineers Program is a collection of online educational modules. Each module contains background text, case studies, a quiz, and information about additional resources. The modules were written by prominent scholars in realm of engineering and ethics, including Caroline Whitbeck, Charles Fleddermann, Michael Loui, and Steven Nichols.

The Program covers the traditional nine core RCR subject areas, including authorship, conflicts of interest, and peer review. In addition, the Program contains a module on environmental and social aspects of engineering research and a module on whistleblowing. A forthcoming module will focus on export control and “dual use” considerations. The RCR for Engineers Program can be customized depending on an institution’s or instructor’s needs. For example, a subset of the most relevant modules could be used to train a particular type of engineering researcher.

*The Collaborative Institutional Training Initiative (CITI) began in 2000, and is administered in the Office of Research at the University of Miami. CITI offers a collection of ethics training courses on a broad range of topics. The website for the RCR for Engineers Program or CITI’s other courses can be found at: <http://www.citiprogram.org/>

Summer 2009

Announcements

Workshop - Indiana University’s Poynter Center for the Study of Ethics and American Institutions and the Association for Practical and Professional Ethics are sponsoring a 2-day workshop on “Ethical Guidance for Research and Application of Pervasive and Autonomous Information Technology (PAIT)”. The workshop will be held March 3-4, 2010 in Cincinnati, OH. For more information, visit: <http://poynter.indiana.edu/pait/>

Call for Papers - *Neuroethics* is requesting research submissions on the ethical implications of deep brain stimulation for their special spring issue. Submission deadline is May 1, 2010. For more information, visit: http://www.iegm.uni-tuebingen.de/images/pdf/cfp_ethics_of_dbs.pdf

Commission - The Republic of El Salvador has established a National Bioethics Commission. UNESCO will sign a Memorandum of Understanding with the National Bioethics Commission of El Salvador to assure cooperation for the next three years. The Republic of El Salvador is the seventh country to join the UNESCO project on Assisting Bioethics Committees (ABC). For more information visit: <http://www.unesco.org/shs/ethics/abc>

Fellowship - The Center for Ethics at the University of Toronto has issued a call for applications for its Visiting Faculty Fellowships for the academic year 2010-2011. Two fellowships will be awarded to outstanding scholars and teachers interested in writing and conducting research about ethics during a year in residence at the University of Toronto. Applications are due November 16, 2009.

Call for Papers - The Ethical Issues of Emerging ICT Applications (ETICA) will hold its 1st International Conference at Rovira and Virgili University in Tarragona, Catalonia, Spain on April 13, 2010 and is encouraging the submission of original position papers (3500 words) on trends in emerging technologies and related ethical issues. Submissions may be published in the *Journal of Information, Communication & Ethics in Society*. The deadline for submissions is September 25, 2009. For instructions, see: <http://moriarty.tech.dmu.ac.uk/webapps/conf/index.php/ETICA/E2010>

Symposium - The Brocher Foundation and the Universities of Oxford and Geneva are

hosting a symposium titled *Human Enhancement: What Should Be Permitted?* at the Brocher Centre in Geneva, Switzerland on October 20-21, 2009. Register by October 5, 2009. For a registration form, contact: scientificprog@brocher.ch

Session - The 16th (ordinary) session of the International Bioethics Committee of UNESCO (IBC), initially scheduled in May 2009 but postponed due to the H1N1 epidemic, will now be held in Mexico City, from November 23 to 25, 2009. Register before November 18, 2009 at: www.unesco.org/bioethics

Grant - The Wellcome Trust has issued a call for applications for research into the ethical and social aspects of biomedical research and healthcare in developing and restructuring countries through their Biomedical Ethics in Developing Countries funding program. For application information, visit: <http://www.wellcome.ac.uk/Funding/Medical-humanities/Grants/Biomedical-ethics/Developing-countries-schemes/index.htm>

Fellowship - The Cleveland Clinic, in partnership with Case Western Reserve University, University Hospitals Case Medical Center, MetroHealth Medical Center and the Louis Stokes Cleveland Veterans Administration Medical Center, is calling for applications to the Cleveland Fellowship in Advanced Bioethics. Applications will be considered from professionals with terminal post-graduate degrees in medicine, philosophy, nursing, social work, religious studies, law, or other fields related to the practice of clinical and academic bioethics. Application deadline is December 15, 2009. To apply, visit: www.clevelandclinic.org/bioethics/fellowship

Conference - the Federal Trade Commission is hosting a series of three day-long roundtable discussions on the challenges that new technology pose to consumer privacy. The first will be held on December 7, 2009 at the FTC Conference Center in Washington, DC. Comments to be included in the discussion as well as requests to participate as a panelist are being accepted until November 6 and October 30, respectively. See: <http://www.ftc.gov/bcp/workshops/privacyroundtables/>

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