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At the Crossroads of Bioethics and Industry

By Rahul K. Dhanda

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Bioethics and the corporate practice of biotechnology are often characterized as two forces at odds. While representatives from each may recognize the necessity of the other, most from one side of the fence resist the line of reasoning that would engage those on the other. Industry, in the eyes of many bioethicists, is too strongly driven by the profit motive, which may lead to executives relegating bioethics specialists to a silent position within a company—as window dressing at best, or at worst, as credulous corporate stooges brought in to facilitate mechanisms like public relations or marketing. Corporate representatives, on the other hand, may view the field of bioethics as an esoteric hindrance, irrelevant to their 'real world', and unfairly targeting industry for criticism without understanding its intricacies.

There may be some truth to these beliefs, but there is little wisdom in living by them. Ethical problems arise in many areas within a bioscience company, as ImClone has recently reminded the world. When he discovered that the FDA was not going to accept the application for review of ImClone's drug Erbitux, former ImClone CEO Sam Waksal attempted to trade some of his shares in the firm through a relative. His belief was that the insider trading would not be caught if the transaction occurred through his daughter, Alisa. The story took an even greater public turn when a close associate, Martha Stewart, was implicated in the scandal for trading that occurred at about the same time as Waksal's—just days before the company was legally impelled to state the FDA's decision, which was sure to send the stock price plummeting. After the media and judicial dust settled, Waksal received a punishment of seven years in prison for SEC violations. Because Waksal's behavior was egregious, the lines are much easier to draw between ethical and unethical. If companies can break a clearly defined law, one cannot fault a bioethicist for concluding that the gray areas that are addressed by bioethics might be easily violated. Profit and greed, a bioethicist might posit, can sometimes undermine moral deliberation and ethical consideration, and, further, profit and greed may advance business, while ethics may impede it.

Corporate executives take particular offense to this depiction of their motives. Many industry representatives believe that bioethicists are concerned primarily with getting in the way of scientific progress and advances in healthcare. Additionally, controversy often fuels the discipline, and there is no better target for career-minded bioethicists than one painted on companies performing bioscience research. The argument continues that therapies and diagnostics are the business of bioscience firms, and academics whose career paths depend on opposing healthcare have no place outside of the ivory towers that foster this viewpoint. Corporate officials may conclude that they are best served to let the ethicists concern themselves with the esoterica best left to the humanities, while businessmen and scientists will focus on inquiry into scientific knowledge and participation in the global economy.

These are such simplistic characterizations that it may seem unlikely that either group would believe them. Yet, often they do, and clearly both sides are mistaken. The cultural rift between bioethics and biotechnologists has placed each in a position where they would prefer to see the other as one-dimensional. It is often easier for bioethicists to perform their work under the assumption that businesses only concern themselves with making money, making science merely a slave to profit.

Both groups must realize the need for interaction, and perhaps the best way to draw attention to the need is to explain how each field can better serve their respective goals by building a constructive rapport; indeed, there is a clear necessity to do so. Biotechnology, by virtue of its study and manipulation of human, animal and plant biology, has a profound influence on all human beings as well as the entire ecosystem. The leading purveyors of this set of technologies hail from the private sector, and the most advanced thinkers regarding the implications of this technology are situated within the discipline of bioethics. That an open exchange between the two fields does not exist is troubling to say the least, and an adversarial relationship is almost inexcusable, if not embarrassing.

Regrettably, there are only a few on both sides of the fence who have come to this realization. Although it should be enough that their union would lead to more effective and responsible research, the interested parties remain unconvinced. Each group must overcome their misgivings, embrace their common goals, and try to appeal to the sensibilities of the other. Put simply, bioethicists and

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business people need to realize how valuable they can be to each other while still serving the interests of their own professions.

Industry representatives are very aware that to meet the goals of stakeholder satisfaction, sustainability, profit, and continuing productive research, they will need to understand the many intricacies of the life science landscape. This will require understanding patient interests, legal and regulatory trends, market segmentation and international receptivity to products—all components that bioethics can shed light on, even though this may not be the traditional interpretation of the role of bioethicists. In the most general sense, bioethics offers a context for technology—socially, economically and politically—which is critical given the complexities of the biotechnological enterprise.

If bioethics offers industry context, then what does industry do to reciprocate? To put it bluntly, industry offers relevance to bioethics. Bioethics, among other things, is concerned with the just development and distribution of medical technologies. The discipline is concerned with policy setting over scientific grant funding, academic research, and private/public healthcare, but when asked to address industry issues, the discipline's goals are eclipsed by debates over the ethical propriety of working with private firms rather than how to engage them. For instance, helping corporations understand their research's ethical context is seemingly less important than hosting endless discussions over conflicts of interest. While the poor decision-making that might arise due to conflicts of interest ought to be avoided, invoking conflict of interest arguments does more to damage the credibility of the field of ethics than any other area. Bioethics is a discipline directed at fostering integrity and fairness—in all areas related to bioscience, not just sensational technologies. At its very core, conduct is a key component of those that claim expertise in the area, and it is the field that vets those experts. If ethicists cannot be trained adequately to behave fairly, then members of the field might do well to spend more time researching themselves, rather than those outside of it. Further, the belief that corporate dollars are inherently corrupting leads to two clearly untrue assumptions: 1) ethicists on the whole lack the integrity to remain true to their discipline, and 2) every corporate employee functions with a conflict of interest. These sweeping claims are exactly the kind of falsehoods that arise when the term 'conflict of interest' is used as an unqualified, debate-ending argument. Indeed, it seems that the label is often applied without constructive effort because it is easier to claim a conflict of interest than it is to offer constructive solutions.

Conflicts of interest are often a concise and handy label that can be applied to decisions that occur in corporations, but with ethics, the label requires considerable review. Such arguments will force the field to become more insular, and evade contact with the sector that popularizes technical innovation: industry. While academic researchers, government scientists, and other not-for-profit entities may discover and invent many of the critical advances in bioscience, it remains industry's role to deliver the technologies to the end users, the consumers, safely and effectively. Failure to engage corporations will eventually lead the discipline of bioethics towards irrelevance, as it constructs artificial boundaries based on fashions that neglect the important and pervasive place of industry.

While it may seem vulgar to couch a discussion over ethics in terms of 'gain', the discourses of democracy, virtue and duty have failed to bring industry representatives and bioethicists together thus far. Indeed, the question of who gains or loses from this interaction is hardly about industry and the field of bioethics. It is about the public affected by the practices of both, and if both do not learn to work together, society stands to lose the most.

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IN THE NEWS

ANIMAL RIGHTS ACTIVISTS: PRO-ANIMAL OR ANTI-HUMAN?

Chris Hall says he will not be forced out of business.[1] However, this vow may be difficult to achieve if animal rights activists have their way. Hall and his family own Darley Oaks Farm in Newchurch, UK where, along with producing traditional farm products such as milk, they breed guinea pigs for laboratory research. The latter is what has the attention of animal rights groups. In fact, the Halls have their very own animal rights group, Save the Newchurch Guinea Pigs (SNGP).

SNGP organizes protests outside the Halls' farm every week and, at times, the Halls have received upwards of 400 calls each day from "animal-loving" individuals instigated to action by the SNGP website. On the more sinister side, bombs have been placed near the homes of employees, electricity to entire villages has been cut off and this past October the Halls lost one of their houses—fortunately, uninhabited—to arson.

However, more insidious are the indirect attacks against the Halls, designed to hurt them by hurting those who do business with them. Any businesses that associate with the Halls are targets, whether they deal in guinea pigs or other farm prod-

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ucts, resulting in significant economic business losses for the farm. Recently, the Halls have lost two dairy contracts for milk they produce when the dairy services companies were targeted by SNGP. The Halls' lawyers have even severed ties with the family due to protests outside their offices.

This strategy of attacking a targeted business by attacking its customers is a growing one among extreme animal rights groups. In September 2003, two U.S. customers of Huntingdon Life Sciences (HLS) were bombed because of their connections with HLS, a British medical testing facility that uses animals for testing. Like the Halls, HLS has its own activist group working against it, Stop Huntingdon Animal Cruelty (SHAC), also very active in Newchurch. Although HLS is still alive and well, and the Halls are far from bowing to the pressure, this strategy will unlikely be abandoned anytime soon. Animal rights groups are being spurred on by recent successful efforts at putting other breeding companies in the UK out of business by targeting their customers. Additionally, there is the overarching philosophy of animal rights activists, as expressed by Ken Kjonaas, leader of SHAC, "We hold the radical line. . . . and we will not relent."[2]

**KS*

[1] Jha, Alok. "Animal rights activists target farmer." *The Guardian*, October 27, 2003. http://www.guardian.co.uk/print/0,3858,4783162-10369,00.html.
[2] Berman, Richard. "Animal groups callous, not cute," *USA Today*, April 15, 2003. http://www.usatoday.com/news/opinion/editorials/2003-04-15-berman_x.htm.

GUIDING THE INDUSTRY: PHARMACOGENOMICS

On November 4, 2003, The Food and Drug Administration (FDA) posted in the *Federal Register* (Vol. 68, No. 213) references to the draft document, "Guidance for Industry – Pharmacogenomic Data Submissions." The draft guidelines identify what pharmacogenomic data to submit to the FDA during their drug development process to sponsors holding investigational new drug applications (INDs), new drug applications (NDAs), and biologics license applications (BLAs). The guidelines also describe how the FDA may use pharmacogenomic data for regulatory decision making and policy making.

Although the study of pharmacogenomics may lead to significant advances in scientific progress, pharmaceutical sponsors and researchers have been reluctant to devote resources to this emerging field due to uncertainties about the kinds of data the FDA will require and how it might react to it. There is little public policy that responds to pharmacogenomics due to the field's infancy, the lack of validation and accuracy of the necessary laboratory techniques and test procedures used therein, and the lack of available scientific studies reporting on pharmacogenomic experimental results. These draft guidelines represent the FDA's acknowledgement of these concerns and an attempt to communicate more clearly its objectives and interests in pharmacogenomics, thus allowing the field to develop in a more structured environment. The FDA defines pharmacogenomics in the guidelines as "the use of a pharmacogenomic or pharmacogenetic test in conjunction with drug therapy. Pharmacogenomics does not include the use of genetic or genomic techniques for the purposes of biological product characterization or quality control (e.g., cell bank characterization, bioassays)."

The draft guidelines are available online at www.fda.gov/cder/guidance/5900dft.doc or www.fda.gov/cder/guidance/5900dft.pdf. Written or electronic comments on the draft guidelines are due by February 2, 2004. Further information on submitting comments is available at http://www.gpoaccess.gov/index.html.

For more information, see the following: HHS. (2003) Draft Guidance for Industry on Pharmacogenomic Data Submissions; Availability. *Federal Register*, 68 (213): 62461-62463. **CB*

ORAL HISTORY EXEMPT FROM IRBS

In a letter dated September 22, 2003, the Department of Health and Human Services issued a response to members of the American Historical Association and the Oral History Association agreeing that "oral history interviewing activities, in general, are not designed to contribute to generalizable knowledge and, therefore, do not involve research as defined by Department of Health and Human Services (HHS) regulations […] and do not need to be reviewed by an institutional review board."[1] This declaration came after oral historians and other social scientists had for years voiced concerns that institutional review boards, whose job is to review and approve all federally funded research involving human subjects, had gone too far in regulating their research. Though many researchers may make this complaint when faced with any type of regulation that threatens to hinder their work, social scientists and oral historians may be more warranted in their objections because "much if not most social and behavioral research presents no more than minimal risk."[2]

The original regulations for human subjects research in the U.S. arose to prevent medical studies from physically or mentally injuring the persons studied. The American Association of University Professors concluded that as a result, "IRBs, in carrying out their responsibilities, too often mistakenly apply standards of clinical and biomedical research to social science research."[3] Despite the fact that under the Common Rule,[4] certain low-risk social science research should have already been exempt from review, past events (i.e., the deaths of human subjects in studies at the University of Pennsylvania in 1999 and John Hopkins University in 2001) have led IRBs to prefer hypersensitive regulation and review.

The clarification that oral history is not subject to regulation by IRBs is an example of a government agency seeking to respond to the concerns of the research community. Implementation may, however, be limited, as the declaration is "made only on behalf of HHS and does not represent concurrence by any other

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Federal department or agency that has adopted the Common Rule."[5] **CL*

[1] Michael A. Carome, letter to Linda Shopes and Donald A. Ritchie, Office for Human Research Protections, 22 September 2003. Available online at: http://www.theaha.org/PRESS/IRBLetter.pdf
[2] Sieber, Joan E., Stuart Plattner, and Philip Rubin. "How (Not) to Regulate Social and Behavioral Research." *Professional Ethics Report*. Vol. XV, No. 2, Spring 2002.
[3] "Protecting Human Beings: Institutional Review Boards and Social Science Research." American Association of University Professors. Available online at: http://www.theaha.org/perspectives/issues/2000/0009/0009vie1.cfm
[4] The Common Rule refers to the 1991 revised regulations for protecting the rights and welfare of human-research subjects, subscribed to by seventeen federal departments and agencies. Available online at: http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.109
[5] Michael A. Carome, *op. cit.*[e]

SMALL SCIENCE TAKES BIG LEAP
On December 3, 2003 President Bush signed "The 21st Century Nanotechnology Research and Development Act" (S.189) into law. S.189 represents a compromise between an earlier Senate version of the bill and the House Nanotechnology Research and Development Act (H.R. 776). S.189 was passed by the Senate on November 18, 2003 and by the House two days later.

Nanotechnology is the study of materials on the subatomic scale. One nanometer is a billionth of a meter. Proponents envision nanotechnology as a field with tremendous potential, including applications in a diverse array of areas such as electronics, medicine, and environmental technology. The National Science Foundation has recently estimated that nanotechnology applications could be worth more than $1 trillion globally in a little more than a decade. As such, nanotechnology is seen as important both economically and scientifically.

The law authorizes $3.7 billion in funding for nanotechnology over the next four years and directs President Bush to create a National Nanotechnology Research Program that will establish goals, priorities, and challenges; invest in research and development programs; and provide coordination of federal research and development in nanotechnology.

The program must also establish long-term basic research priorities; interdisciplinary nanotechnology research centers; and a center to analyze the ethical, societal, educational, legal, and workforce issues related to nanotechnology. The National Science and Technology Council will manage the program and report annually on its progress to Congress.

Critics of nanotechnology are concerned that breakthroughs in research will initiate a new series of health and environmental hazards that society is unequipped to handle. The provision within the bill for the creation of a center to analyze ethical, legal, and societal issues (ELSI) is an attempt to address those fears. A previous version of the bill included a proposed amendment to the House Nanotechnology Research and Development Act (HR. 776) by Representative Brad Sherman (D-Calif.) and Chris Bell (D-Tex.) that proposed allocating 5% of the federal nanotechnology budget to research on ethical, legal, and societal issues, much like a similar policy established in 1988 for the Human Genome Project. However, their amendment failed, and the new law fails to allocate any specific funds for the new center.

For More Information
Library of Congress, Thomas Legislative Information, S.189 http://thomas.loc.gov/cgi-bin/bdquery/z?d108:s.00189:

"Congress Considers Ethical, Social Impact of Nanotechnology Research" Issues in Science and Technology. Fall, 2003

New, William "Science: Nanotechnology Bill Heralds New Era in Science, Backers Say". National Journal's Technology Daily December 1, 2003

"Nanotech R&D Bill Headed to White House" Center for Science Technology and Congress, AAAS, December 2, 2003 http://www.aaas.org/spp/cstc/news/articles2003/031202_nano.shtml
**BL*

TASTES GREAT, LESS FILLING
The Executive Summary of "Animal Cloning – A Risk Assessment," conducted by the Center for Veterinary Medicine (CVM) at the Food and Drug Administration (FDA), was released on October 31, 2003. The document states the agency's conclusion that milk and meat from cloned animals and their progeny is safe for human consumption. The report's release came in advance of the FDA's November 4, 2003 Veterinary Medicine Advisory Committee meeting, during which a preliminary review and discussion of the risk assessment took place.

In the fall of 2000, the CVM contracted with the National Academy of Sciences (NAS) to conduct an independent review of available safety data on cloned animals. The project, *Process to Identify Hazards and Assess the Unintended Effects of Genetically Engineered Foods on Human Health* (further information available at http://www4.nas.edu/cp.nsf/Projects%20_by%20_PIN/BBXX-K-00-02-A?OpenDocument), reviewed the safety of cloning to animals and to the environment, and of food derived from cloned animals. At the time CVM contracted with NAS, agriculturalists and scientists were expressing commercial and economic interest in ventures to utilize somatic cell nuclear transfer (SCNT) for breeding food production animals. The CVM requested that cloning companies not introduce cloned animals, their progeny, or their food products to the human or animal food market until further scientific inquiry had been completed regarding the safety of the cloning procedures. CVM also requested that cloning companies supply scientific data on the safety of cloned animals, and that this data be made publicly available.

Although a public dialog about the future of SCNT in agriculture may lead people to

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to believe that scientists are close to having perfected cloning animals, they remain far from it. Most clones continue to die before birth or are born with serious and life threatening birth defects. The FDA has made clear that apparently abnormal clones are not considered safe for consumption or further breeding. The question remains, however, to define what a "normal" clone is. One biological implication of cloning is that absent the traditional fertilization process involving sperm and egg, the process of embryonic development called imprinting does not occur. Imprinting allows certain genes to be turned "on" or "off" to ensure healthy growth and development of a fetus. Scientists have noticed that clones often have genes turned "on" that are normally turned "off," or vice versa. While these changes are not necessarily life threatening to the clone, scientists are as yet unable to determine the long-term consequences of abnormal gene expression.

The FDA has maintained that the process and progress of this risk assessment should be as transparent as possible. To that end, a condition of the risk assessment was that all data used by CVM be made publicly available. Moreover, the FDA opened the November 4, 2003 meeting to the public, and plans to provide the opportunity for public comment on the risk assessment prior to its finalization. The FDA expects the final assessment, to include guidelines for if and how clone food products should be regulated and labeled, will be completed in spring 2004. In a time when more and more people appear to be questioning the legitimacy and purpose of scientific progress in genetic engineering, and struggling with the "yuck factor" associated with genetically modified organisms, the FDA's final decision may have a significant impact on the public's acceptance of progress in the field of genetic engineering as we know it today.

For more information, see the following:

Barbaro, Michael, Gillis, Justin. FDA Panel Backs Cloning In Agriculture. *Washington Post*, November 5, 2003. http://www.washingtonpost.com/wp-dyn/articles/A544-2003Nov4.html.

Food and Drug Administration. (2003) Cloning: Revolution or Evolution in Animal Production? *FDA Consumer Magazine*, May-June 2003. http://www.fda.gov/fdac/features/2003/303_clone.html.

Food and Drug Administration. (2003) FDA Issues Draft Executive Summary of its Assessment of Safety of Animal Cloning; Current Voluntary Moratorium on Releasing Animal Clones Remains in Effect. *FDA News*, October 31, 2003. http://www.fda.gov/bbs/topics/NEWS/2003/NEW00968.html.

Gillis, Justin. FDA Says Cloned Animals Are Safe as Food. *Washington Post*, October 31, 2003. http://www.washingtonpost.com/wp-dyn/articles/A44602-2003Oct30.html.

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UN (NON)VOTE ON HUMAN CLONING

Since the creation of the Ad Hoc Committee on an International Convention against the Reproductive Cloning of Human Beings in December of 2001, the world has been anticipating an official declaration by the United Nations regarding this very controversial subject. The expectation by many was that a declaration would be made this year at the 58th session of the General Assembly. However, in early November, by a vote of 80 to 79, the Legal Committee recommended that the General Assembly delay the vote on a cloning ban until its 60th session, putting a moratorium on the issue until September 2005.[1] The move to adjourn the debate and vote for a two-year delay was proposed by Iran, on behalf of the nations of the Organization of the Islamic Conference.

The UN is currently split on the issue of therapeutic cloning. While the resolution sponsored by Costa Rica advocates a complete ban on all forms of human cloning, the rival resolution would have only banned human reproductive cloning. Costa Rica, immediately following (and despite) the early November vote by the Legal Committee for a two year delay, began lobbying the General Assembly to vote on its resolution. Given the division of the UN on this issue, Costa Rica and supporting countries were unable to secure enough votes for a complete ban on human cloning. Instead, the General Assembly has agreed to raise this issue again next year - effectively overturning the decision by the Legal Committee and replacing the two-year delay with a one-year delay.[2]

The next year will be critical. If research shows that there is great potential for the use of therapeutic cloning in medical treatments, the case for a partial ban on human cloning will be bolstered. On the other hand, in the absence of any type of ban, there is the risk of a cloned baby being born. Given the fact that "governments have almost universally agreed to prohibit the reproductive cloning of human beings,"[3] the General Assembly could have approached the cloning debate in two stages: first passing a resolution banning cloning for reproductive purposes and then turning to the question of therapeutic cloning. In defense, the UN then may have faced the risk that a ban solely on reproductive cloning would be viewed as an endorsement for therapeutic cloning rather than one stage of a two-step process. **CL*

[1] "Ad Hoc Committee on an International Convention against the Reproductive Cloning of Human Beings." 18 November 2003. Available online at: http://www.un.organization/law/cloning/

[2] Lederer, Edith. "UN delays anti-cloning treaty discussion." *CNEWS Science*. 9 December 2003.

[3] Pisik, Betsy. "U.N. delays human cloning vote." *The Washington Times*. 7 November 2003.

UNIFORM FEDERAL CONFLICT OF INTEREST POLICY

Senator Richard C. Shelby of Alabama requested the General Accounting Office (GAO) to examine federal agencies' policies to ensure against financial conflict of interest in university research that is federally funded. With enactment of the Bayh-Dole Act in 1980, universities and small businesses were given the rights to any patents based on federally funded innovation. Senator Shelby's concern is based on the premise that without a specific conflict of interest policy, the government may not be able to safeguard against federally funding

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research that is biased due to financial conflict of interest. For instance, a researcher may own stock in a business that would directly profit from his/her federally funded university innovation.

In response to Senator Shelby's request, GAO examined eight federal agencies' policies on conflict of interest and on publication of results (Departments of Agriculture, Defense, Education, Energy; EPA; NASA; NIH; and NSF) and conducted a Web-based survey of the 200 universities in the country that received the most federal funding for research and development in fiscal year 2000. All of the federal agencies examined rely on university researchers to make the results of their research public, and encourage publication in peer-reviewed scientific journals. Five of the agencies, Agriculture, Defense, Energy, EPA, and NASA, post the results of funded research to their Web sites. The department of Education is currently determining the best method for disseminating research results. The NIH does not post researchers' results to its Web site because NIH believes results of biomedical research should be peer-reviewed and analyzed before being released to the public. The NSF does not post results to its Web site because some scientific journals reject manuscripts that have already been posted to the Web. Of the eight agencies, the NIH and NSF are the only two that require universities to implement policies to mitigate financial conflict of interest for the research they fund. GAO reported that some of the other six agencies do not require such policies because they believe it to be the university's responsibility to identify and manage financial conflict of interest issues.

The GAO survey asked universities to explain how they determine and address financial conflict of interest for the principal investigators conducting federally funded research and development projects, and their policies on publication of results from those federally funded projects. GAO received responses from 171 universities (86% response rate). One hundred and forty eight of the respondents reported having financial conflict of interest policies that are consistent with those of NIH and NSF. However, 17 of the respondents said they do not enforce their financial conflict of interest policies to research funded by agencies other than NIH or NSF.

The GAO concluded from its examination that the federal "government can not properly safeguard against conflicts of interest that might bias federally funded research" without creating and implementing a universal financial conflict of interest policy applicable to universities. (GAO report, 2003) The "GAO recommended that the National Science and Technology Council coordinate the development of a uniform federal requirement for identifying and resolving financial conflicts of interest in federally funded research." (GAO report, 2003)

The universities' responses to the GAO Web survey are available at http://www.gao.gov/special.pubs/gao-04-223sp.

For more information, see the following:
GAO-04-31. November 14, 2003.
Borrego, Anne Marie. (2003) Federal Agencies Should Provide Better Protections Against Conflicts of Interest, Report Says. *The Chronicle of Higher Education*. November 19, 2003. Retrieved from: http://chronicle.com/prm/daily/2003/11/2003111902n.htm **CB*

WELLCOME TRUST CALLS FOR AN INTERNATIONAL SCIENTIFIC CODE OF ETHICS

On November 6, 2003, Wellcome Trust issued a position statement addressing the conundrum involving the degree of regulation necessary in biotechnology research to allay fears of bioterrorism. Underlying the position statement is the belief that regulations must always attempt to balance an experiment's potential benefit against its potential risk. For many experiments, such as research regarding biological pathogens, results could be indispensable for either bioterrorism or bioterrorism response.

The statement agrees with the National Academies of Science's (NAS) position in its *Biotechnology Research in an Age of Terrorism: Confronting the Dual Use Dilemma* (October, 2003) report that certain types of biotechnology experiments should be reviewed by external experts before the experiment is approved. The category includes experiments that the NAS believes contain the greatest risk of weaponisation: experiments that render vaccines ineffective, discovering resistance to antibiotics, and increasing transmissibility of a pathogen.

In addition, the Wellcome Trust statement emphasizes the need for free international collaboration and communication between scientists in order to maintain a vital international research community. It places the onus of regulation on scientific self regulation, calling for the creation of an international scientific "code of conduct."

The Wellcome Trust is a British biomedical research funding charity that seeks to foster and promote research aimed at improving human and animal health, especially with regard to infection and immunity. Recently, it has been a source of funding for genome sequencing and functional genomics.

For More Information:

Wellcome Trust Position Statement on Bioterrorism and Biomedical Research
http://www.wellcome.ac.uk/en/1/awtvispolter.html

Biotechnology Research in an Age of Terrorism: Confronting the Dual use Dilemma
http://books.nap.edu/catalog/10827.html

**BL*

IN THE SOCIETIES

AAUP ISSUES REPORT ON ACADEMIC FREEDOM POST 9/11

In November, the American Association of University Professors (AAUP) published the report of its Special Committee on Academic Freedom and National Security in a Time of Crisis. The committee was formed in September 2002 to assess the risks to academic freedom posed by the federal government's response to the terrorist attacks of

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September 11. The crux of the report is that freedom of inquiry and freedom to exchange ideas are essential to national security and that efforts to curb these activities ultimately impair the nation's security and well-being.

The report examines specific developments that may impact academic freedom, including the USA Patriot Act, with special emphasis on the Act's provisions regarding federal agents' ability to obtain warrants for information about book-borrowers and purchasers from libraries and bookstores. Another focus is restrictions on information and how this may impact the circulation of research results, as well as the uncertainty caused by the federal government's emphasis on information that is "sensitive but unclassified," a phrase whose meaning is unclear. Finally, the report focuses on the impact of legislation and regulation on college campuses, from the barriers to foreign students wishing to enter the U.S., to the more subtle impact on professorial lecturing and discourse and lectures by controversial speakers.

The committee concludes the report with cautions and recommendations, noting that the effect of September 11 on academic freedom is not fully realized and that the committee will continue to monitor the situation. The recommendations are aimed at different groups. A few of the recommendations aimed at the national policy level are:

- Acknowledge realistically the threat of terrorism and measures needed to deal with it;
- Remind those outside the academic world of the imperative values of academic freedom and free inquiry;
- Resist further government regulations or intrusions until and unless current measures have proved clearly inadequate;
- Limit the classification of research to those grants and contracts for which the interests of national security clearly require secrecy.

At the campus and institutional level, recommendations include:

- Assume a major role in the review and shaping of institutional policies, especially those that should protect academic freedom and may affect it in a such vital areas as the freedom to invite and hear controversial speakers;
- Assume a major role on reviewing and developing institutional policies to protect academic freedom against governmental constraints and threats in such vital areas as sharing of library and student records with external agencies;
- Determine precisely what information is collected and maintained about faculty and students, by whom (on and off the campus) and for what purposes.

The report was published in the November-December 2003 issue of *Academe*, Volume 89, Number 6, and is available online at http://www.aaup.org/statements/REPORTS/911report.htm. **KS*

RESOURCES

THERAPY OR ENHANCEMENT?

by Kevin Alleman

William Blake once said, "What is now proved was once only imagined." We live in an unprecedented age of science, which was largely enabled by the transformation of nature, hitherto thought of by the Ancients as perfect in form and essence, to an object of manipulation. Modern science has enabled new and momentous powers over our biology that questions the very boundaries of human nature and the meaning of humanness. One of more powerful means by which we give expression to the uniquely human desire of self-modification is biotechnology.

But what is biotechnology for? What should it be for? And what ends does it serve? These and other pressing questions have been raised by the President's Council on Bioethics in its new report entitled, *Beyond Therapy: Biotechnology and the Pursuit of Happiness*, which was publicly released on October 16. The report is an inquiry into the scientific possibilities of biotechnology, and explores the ethical and societal implications of using these enabling powers for purposes beyond therapy.

The thrust of the report is to educate and inform the public by reflecting on the unintended consequences that may result from our desire to push beyond the natural boundaries of "normal" human functioning. By examining the concepts of therapy and enhancement, the report attempts to illuminate, in part, the underlying reasons behind the drive to make individuals better than well by focusing on four widespread human desires: better children, superior performance, ageless bodies, and happy souls. Some view biotechnological enhancement as a means of empowerment—to allow one a greater sense of control over the randomness and imperfections of nature. Others, while acknowledging the sense of empowerment, view the path of biological modification with grave concern, as an estrangement from the world in which we were born into and inhabit. The authors recognize that these concerns are not merely academic—that in fact some of these concerns are already upon us. For instance, there already exist techniques to screen early human embryos for the presence or absence of genes that may cause cystic fibrosis, and techniques that allow for the selection of the sex of the child-to-be. There exist techniques for boosting muscle strength and performance in athletes to gain what some consider an unfair advantage over competitors, thus demeaning the spirit of sports. Furthermore, scientists continue to make advancements in understanding biological senescence, which may someday retard or control the biological processes of aging, i.e., life extension. And scientists are also acquiring new techniques for altering memory and mood, beyond selective serotonin reuptake

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Professional Ethics Report

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inhibitors like Prozac and Zoloft (which are prescribed increasingly to children in order to modify their behavior to a more desirable temperament).

The authors address the impact of biotechnology on issues of safety, fairness, identity and individuality, equality and freedom, and ponder whether the degree of perfectibility to which we aspire to manipulate mind, body, and nature could create a biological aristocracy, which would widen the stratification of social classes.

Immoderate human desires and aspirations tend to make us impatient with the frailties of human nature and the contingencies of social institutions. The authors prompt readers to think about the realization of overcoming these imperfections through biotechnological self-modification and the consequences that may ensue—the result of which may establish the creation and transmogrification of a new human, which will reflect a new society, a new polity, and a new paradigm in the course of human history.

The report can be downloaded at: www.bioethics.gov/reports/.

ANNOUNCEMENTS

Call for articles – Business Ethics Quarterly is soliciting articles for a special issue on the ethics of organizational ethics initiatives. Topics of concern include, among others, the ethical assumptions built into the initiatives and the scope of ethical issues and perspectives built into the initiatives. The deadline for submissions is January 31, 2003. For more information on the special issue and subject matter of articles, contact the editor, Gary R. Weaver, at weaverg@lerner.udel.edu. Submission guidelines are available at http://www.societyforbusinessethics.org/info_contrib.htm.

Seminar – Indiana University will offer an Internet-based seminar, Scientists and Subjects: An Online Seminar on the Ethics of Research with Human Subjects, from January 19-March 4. The seminar is open to junior and senior researchers, members of Institutional Review Boards and other administrators, and faculty members who teach future researchers. The fee is $100. More information is available at http://www.poynter.indiana.edu/sas.

Funding – The **Office of Research Integrity** is accepting applications for funding for the creation of advanced instructional materials on the responsible conduct of research (RCR), that will be available to the research community receiving funds from the Public Health Service (PHS). The program will fund up to 10 projects in fiscal year 2004. Applications must be submitted by February 27, 2004. More information is available at http://ori.hhs.gov/html/programs/rfa.asp.

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American Anthropological Association
American Association of University Professors
American Political Science Association
American Psychological Association
American Psychological Society
American Society for Engineering Education
American Sociological Association
Botanical Society of America

Conference – On August 25-28, 2004, the conference "Ethical, Legal and Social Aspects of Human Genetic Databases" will be held together with the 18th European Conference on Philosophy of Medicine and Health Care, "Genetics and Health Care." The conference is organized by **Elsagen**, the **Centre for Ethics at the University of Iceland**, and the **European Society for Philosophy of Medicine and Healthcare (ESPMH)**. The deadline for paper submissions is February 29, 2004. For more information and registration visit http://www.hi.is/~elsagen/conference.

Conference – On March 25-27, 2004 the Conference on Ethics and Epidemics: An International Conference on the Ethical Dimensions of Epidemic Control will be held at **Union University** and **Albany Medical College.** For more information, visit http://www.bioethics.union.edu.

Conference – On June 10-13, 2004, the Communication Ethics Center in the Department of Communication & Rhetorical Studies at **Duquesne University** will host the National Communication Ethics Conference. The conference promotes the research, teaching, academic program development, and collaboration among colleagues in all aspects of human communication and communication ethics. More information on the conference is available at http://www.gradcomm.duq.edu/conference/ethics.html.

Institute – The Ethics Institute at **Dartmouth College** will hold a Summer Institute for faculty who are interested in developing a course on the ethical legal and social implications (ELSI) of the Human Genome Project. Offered in partnership with **Howard University**, the Institute's five-day teaching programs will be offered three times over the summer: June 13-18 at Howard and July 18-23 and July 25-30 at Dartmouth. For further information and online application, visit http://www.dartmouth.edu/~ethics.