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REAL TIME MACROETHICAL ASSESSMENT

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It is increasingly apparent that the past several centuries have seen a fundamental change in the relationship of the human species to the Earth as a whole, in that a principal result of the Industrial Revolution and concomitant demographic, economic and cultural changes is a planet where the dynamics of most major natural systems are increasingly shaped by human activity [1]. The climate change debates, for example, reflect not a temporary aberration but the fact that for the foreseeable future climate dynamics will continue to be shaped in significant ways by the activities of our species – and that the climate system and human economic activity are integrated and co-evolving. Some note that with synthetic biology the essence of biodiversity is shifting from a "naturally evolved" basis to a designed basis, with only dimly perceived implications. Meanwhile, the rate of technological evolution is accelerating rapidly, a phenomenon that is particularly evident in the literature discussing the implications of converging nanotechnology, biotechnology, robotics, information and communication technology, and cognitive science fields (NBRIC) [2], especially in the area of "transhumanism," where the human is increasingly understood as design space [3]. In short, as *Nature* put it in a 2003 editorial, "Welcome to the Anthropocene," to the human earth [4].

Three important characteristics of the Anthropocene differentiate it from the traditional human systems within which existing ethical structures have developed. The first is that the earth systems characteristics of the Anthropocene are neither "human" nor "natural," but highly integrated composites of both [5]. Second, and perhaps most important for ethical analysis, the dynamics of such Anthropocenic systems include the reflexivity and, thus, unpredictability of human systems. Third, these systems are highly interconnected: managing global climate change is difficult precisely because the climate system is tightly coupled to human economic and technological systems and their future paths, to powerful cultural and ideological systems, and to other natural systems such as the carbon and nitrogen cycles. In short, the future paths of these complex adaptive systems (CASs) are highly uncertain and unpredictable.

CASs thus pose a challenge to the existing ethical approaches most familiar to scientists and technologists. These approaches include explicit professional ethics, such as those common in engineering [6], which are in turn only part of the overall ethical structure that individuals bring with them. These in turn can reflect many different ethical frameworks: duty (Kant), rights, a utilitarian calculus (Bentham), revealed universals (religions), varying emphases on outcome or intent (the basis of many legal systems), and the like [7]; [8]. At a somewhat higher level, the idea of "social ethics" has been advanced to cover the important intersection between the practice of individual ethics and the institutional context within which those ethics are to be practiced or, in some cases, undermined [9].

These ethical structures, generally bounded by culture and underlain by unitary ontologies, are adequate because under most circumstances ethical issues arise in systems that don't extend beyond these boundaries. Thus, a scientist may resolve her ethical dilemma simply by referring back to the accepted standards of scientific behavior, or an engineer may refer to her professional organization's ethical cannons. Accordingly, although ethical conflicts are not uncommon, their analysis and resolution in general occurs within a settled cultural and ontological context.

Alternative Ethical Principles

The highly complex integrated human/natural/built systems that characterize the anthropogenic Earth do not necessarily respect the boundaries which traditional ethical systems assume, and within which they are valid. This has led to efforts to generate alternative ethical precepts. These include formulations based on sustainability, such as the Precautionary Principle so popular in Europe (as stated in the UN's World Charter for Nature [10]: "where potential adverse effects are not fully understood, the activities should not proceed."). Another sustainability example is the Aldo Leopold ecoethic: "A thing is right when it tends to preserve the integrity, stability and beauty of the biotic community. It is wrong otherwise"

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(Leopold, quoted in Sagoff, 1996, at 154 [11]). They also include over-emphasis of particular religious traditions or worldviews in complex ethical environments, a situation some have alleged exists with the Bush Administration's Council on Bioethics [12], or efforts to extend existing ethical systems into broader regimes (e.g., the movement to make individual scientists responsible for the behavior of the larger systems, such as biotechnology or nanotechnology, on which they work, leading some to claim, for example, that "nanoethics" are necessary to deal with issues raised by nanotechnology [13]).

These efforts are doomed to be unsuccessful because they fail to understand the profound difference in systems behavior between the usual bounded ethical situation, and the much different ethical demands generated by CASs. Thus, both the Precautionary Principle and the requirement that individual scientists be responsible for systems effects require a knowledge of future paths which is simply not possible with CASs: such proposals are thus either naïve or backdoor attempts to halt technological and scientific advance. Most other approaches, such as the ecoethic, implicitly assume that single ontologies are adequate to ethically frame CASs in the Anthropocene. But this critical assumption is mistaken. The behavior of these systems at scale is of an order of complexity that cannot be captured by any single worldview [14]; [15]. Moreover, the related assumption that decisions about ethics by individuals or even specific political entities are controlling is questionable: neither the strong European Union reaction against genetically modified organisms (GMOs), nor the Bush Administration's efforts to limit federal funding of biomedical research in certain areas for religious reasons has prevented the rapid advance of the relevant science and technology.

Real Time Assessments

Several years ago, Guston and Sarewitz [16] wrote an influential article about "real time technology assessment." They understood technology as a complex phenomenon combining elements of engineering, economics, and social science, demanding an appropriately flexible approach. It is increasingly apparent that a similar approach needs to be developed to be able to work rationally, responsibly and ethically with the CASs that increasingly characterize the anthropogenic world – in short, we also need a "real time macroethical assessment" capability, or RTMA.

RTMA entails several requirements. First, macroethical frameworks must be able to accept, respect, and work with mutually exclusive but equally valid ontologies. This is not a recipe for mere relativism, for the systems state, and the goals of the relevant decisionmakers and designers, will in individual cases rely far more heavily on certain ontologies than on others – but at the level of the CAS itself, multiple ontologies will be engaged. Similarly, as the GMO and stem cell cases indicate, any reasonable macroethical system must also be global in scope, and thus truly multicultural.

Second, macroethical systems must not rely on assumptions about outcomes, for the future behavior of CASs is highly uncertain; among other things, this means that the utilitarian calculus which often underlies scientific and technological ontologies is inadequate since utility can not be known beforehand. Thus, in practice, macroethics will need to rely on continued real-time dialog with the systems in question, rather than one off snapshots. In other words, given the inherent unpredictability of these systems, RTMA requires that institutions and individuals remain engaged with them as they evolve, as otherwise it will be difficult to react in real time to system changes as they implicate ethical - or for that matter design or operational - concerns.

Thirdly, many of the systems of interest – the climate system, carbon cycle, or designed biodiversity, for example – will extend long enough so that the cultural models and assumptions that ethical systems are built on will themselves evolve and change. Thus, RTMA will not only focus on process rather than specific outcome, but it must be able to function in an environment where norms, teleologies and ontologies are understood to be contingent. Ethics at this level of flexibility is a new and, for many people, challenging concept [7] – but it is systems structure, not choice, that imposes these requirements. And again flexibility is not relativism, for if CASs are uncertain, they also display local order. Thus, rules that are contingent when the system is taken as a whole may well be valid within bounded subsystems that remain locally stable.

For those used to rule-based and simplistic ethical frameworks, developing and relying on RTMA is no doubt challenging. But it is a necessary response to the complexity of the anthropogenic Earth which, far from being hypothetical, is already upon us.

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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.

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In the News

HOW RSEARCHERS CAN PROPERLY ADDRESS NSF'S BRODAER IMPACTS CRITERION

In April 2008, the National Science Foundation (NSF) published a "Dear Colleague Letter on Broader Impacts Proposal Requirements." The Letter informed researchers about the two criteria-intellectual merit and broader impacts-that apply to research proposal evaluations. The letter focused on broader impacts and ways that it might be addressed.

The NSF recommended that, "proposers should carefully consider ways to incorporate rigorous, meaningful, and innovative broader impacts activities that integrate with the research being proposed." They also cautioned researchers that, "a simple listing of outreach activities, or reference to inclusion of research personnel who are members of underrepresented groups, falls short of the rigor required to satisfactorily address this criteria."

In response to the many requests from the community, NSF included in its letter the ways in which one would address the broader impacts criteria, offering questions to address, relevant information to include, and additional links for further assistance.
As researchers prepare their proposals, particular attention to the broader impacts criterion should be given for the *Project Summary*, the *Project Description*, and the *Results of Prior Support* section.

Included in the *Project Summary*, two separate statements addressing intellectual merit and broader impacts of the proposed activity must be presented. The NSF also provided guidance for researchers who must complete a *Results of Prior Support* section of the proposal.

The *Project Description* must describe "broader impacts resulting from the proposed activities," addressing how well the activity "advances discovery and understanding, broadens the participation of underrepresented groups, enhances the infrastructure of research and education," along with other issues addressed in the Letter. Additional educational materials on the broader impacts criterion are available in the American Chemical Society Broader Impacts Showcase.

Although NSF identifies several ideal foci, they urge researchers "to be creative in their approaches and to discuss ideas with their NSF program officer."

"Dear Colleague Letter on Broader Impacts Proposal Requirements"
http://www.nsf.gov/pubs/2008/nsf08044/nsf08044.pdf
American Chemical Society Broader Impacts Showcase
http://www.nsf.gov/pubs/2005/nsf0540/nsf0540.jsp

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PLAGUED PUBLISHERS' PLANS ON PREVENTING PLAGIARISM

In response to the many plagiarism concerns plaguing publishers, CrossRef will launched new plagiarism detection service, CrossCheck, on June 19th of this year. Access to CrossRef will allow "users from one publisher to link citations and references to the primary source material of another publisher, to check content and accuracy," explained Caroline White of the *British Medical Journal*.

According to Geoffrey Bilder, director of strategic initiatives at CrossRef, "the system contains 30 million DOIs (digital object identifier) for articles, theses, and conference proceedings, 19,000 journals and material dating back to the 1600s." CrossCheck will work by creating "text fingerprints" from small chunks of the original document, "which are then checked against databases for evidence of similar matches," and an "originality report" is produced. The report is then "interpreted by a human being" to identify legitimate matches such as: references, formulas, and quotes, said Mr. Bilder.

The BMJ Publishing Group Ltd., Elsevier, Wiley-Blackwell, Taylor and

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Francis, and the *New England Journal of Medicine*, the Institute of Electrical and Electronics Engineers, IUCr, and the Association for Computing Machinery have agreed to participate in the CrossCheck pilot.

There are, however, several limits in the system. CrossCheck cannot identify plagiarized images or graphics, nor does it feed from a universal database. Only CrossRef articles will be assigned a DOI, so it will not apply to those articles without a digital object identifier. http://www.crossref.org/crosscheck.html

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NIH'S EFFORTS TO PROTECT DATA

On February 23, 2008, a government laptop computer with information on human study subjects was stolen from the trunk of an NIH employee's vehicle. Initially believed to contain only patients' medical records, it was later found that the computer also had a file with the Social Security numbers for approximately 1200 of the 3000 patients enrolled in the study. Contrary to federal policy, the data were not encrypted. The NIH Office of Extramural Research issued a statement on April 11, 2008, on the importance of protecting electronic and hard copies of federal data. The notice recommends not storing sensitive information on portable electronic devices. If using a portable electronic device is unavoidable, it should be encrypted. Password protection should also be implemented to control data access, and the security of the recipient's systems should be verified when transmitting sensitive information. The original statement can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-066.html.

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CLINICAL TRIALS IN DEVELOPING NATIONS: ARE EUROPEAN OFFICIALS ENCOURAGING UNETHICAL DRUG TESTING?

In February 2008, SOMO (*Stichting Onderzoek Multinationale Ondernemingen*, translated as "Centre for Research on Multinational Corporations") published a report on "Ethics for Drug Testing in Low and Middle Income Countries: Considerations for European Market Authorization" by Irene Schipper and Francis Weyzig. SOMO is a Dutch non-profit research organization that focuses on the effects of Multinational Enterprise policies and activities on developing countries resulting from the internationalization of business. The study analyzes phase III clinical trials conducted in low- and middle-income countries using publicly available information, and focuses on three drugs: Abilify (aripiprazole), Olmetec (olmesartan medoxomil, also marketed as Benicar), and Seroquel (quetiapine fumarate). The report concludes that European authorities are complicit in unethically conducted clinical trials by drug companies in developing countries. Authorities encourage the "offshoring" of trials by allowing companies to conduct trials in developing countries that have been rejected by ethics committees in Western Europe and by granting European Union ("EU") marketing authorization based on these trials. Furthermore, the report criticizes governments and the pharmaceutical industry for lack of transparency in the general clinical trial process, and calls for more publicly available information.

According to the report, the number of clinical trials conducted in low- and middle-income countries has increased significantly in the last five years because of lower costs and faster enrollment. Conducting trials in these areas presents ethical concerns associated with the vulnerable participant population, the conflict of interest experienced by medical professionals with relatively low salaries, questionable ethics review committees, and the lack of regulatory enforcement. Contract Research Organizations ("CROs") are of particular concern because they are hired by the pharmaceutical company to perform a broad range of tasks, including locating research sites, recruiting patients, creating study designs, and working with healthcare facilities. In 2002, pharmaceutical companies employed CROs in at least 60% of their clinical research projects. To the authors, the prevalent use of CROs is an example of the ethically murky waters in which pharmaceutical companies swim.

The researchers used the Declaration of Helsinki ("DoH") as a benchmark of ethically appropriate behavior. The study depends on five DoH provisions: ¶14 (instructing that research protocols should include a statement of ethical considerations), ¶19 (mandating that the population from which the participants come must benefit from the results of the research), ¶30 (asserting that every trial participant must have post-trial access to healthcare), ¶29 (requiring justification for use of a placebo control if safe, standard treatment for the condition is available), and ¶8 (emphasizing the need for caution when participants belong to a vulnerable population).

The authors offer Abilify as an example of available public information deficiency and regulation enforcement inadequacy. The study could not locate the original trial protocol, information regarding post-trial treatment, or justification for the use of a placebo control given to approximately 300 acutely relapsed schizophrenics. Furthermore, the European Medicines Agency ("EMEA") accepted the results of trials despite expressing concerns regarding the predominant use of vulnerable psychiatric populations in countries where Good Clinical Practice ("GCP") inspections were not conducted.

The information available for Olmetec trials was sparser. The drug marketing, developer, and sponsor websites offered little information. Similar to the Abilify trials, there was no justification for the use of a placebo and no information regarding post-trial access to healthcare, or precautions taken because of the vulnerability of the population, which included children as young as one-year old. The authors consider the possibility of adequate justification for testing a treatment for hypertension in a vulnerable group, but stress that companies invite suspicion when no explanation is offered.

Unlike for Abilify or Olmetec, a

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considerable amount of information on the Seroquel trials was available, including trials intended to prove additional uses and improved efficacy of new formulations. However, the Dutch regulatory agency that granted the EU marketing authorization has not published its assessment report. The research protocols for individual studies were uniform, but there were notable differences in the types of studies partially performed in high-income countries and those performed exclusively in low- or middle-income countries. For example, while placebo trials were conducted worldwide, trials for schizophrenia, acute mania, and elderly individuals were limited to low- or middle-income countries. Furthermore, a statement of ethical considerations was unavailable. The informed consent procedure and the use of a placebo in schizophrenic populations to prove the efficacy of a new formulation need clear explanation because the health of the acutely ill patients is exacerbated by poverty, illiteracy, language barriers, and the unequal dominance position between doctor and patient.

The report also addresses a November 2007 European Parliamentary meeting and provides recommendations, including: (1) there should be no discrepancy between the ethical criteria used to approve trials in developed and low- or middle-income countries; (2) pharmaceutical companies should take more responsibility and develop research methods to replace ethically questionable protocols; (3) registration of all clinical trials in public registries should be legally required and include the locations of the trials; and (4) trial sponsors should make it possible for external actors to check the ethical considerations and precautions taken to protect vulnerable trial subjects.

Report available at: http://somo.nl/html/paginas/pdf/Ethics_for_Drug_Testing_feb08_EN.pdf

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INDUSTRY MUST ABSTAIN FROM INFLUENCING ALCOHOL RESEARCH, INTERNATIONAL EXPERTS DECLARE

Torn between protecting public health and maximizing profits, large corporations, like the tobacco industry, often choose the latter. The alcoholic beverage industry is no exception, and the first guideline regarding its influence over alcohol research was recently issued, declaring that the alcohol industry must not fund alcohol research in order to avoid conflict of interest. This conclusion was decided upon by public health experts, alcohol policy researchers, and non-governmental organization specialists who met in Dublin, Ireland, on May 15 & 16, 2008, for an international expert meeting in relation to this issue.

Alcohol research significantly affects the development of alcohol policy. Research findings are employed to alert public policy makers of the harms caused by alcohol consumption. Furthermore, it plays an integral role in the development of alcohol prevention and alcohol use reduction programs. Funding research gives the industry unfair control over policies that may otherwise negatively impact its profits.

Experts from Europe, the United States, and the South agreed that industry-supported research is often biased and directly conflicts with the interest of public health. According to the Alcohol, Drugs and Development (ADD) report by Dag Endal, the industry appears to get involved in alcohol research only to challenge social policy on the limitation of alcohol consumption and to deter initiatives for preventing alcohol problems. The industry directs alcohol politics towards its commercial interests while feigning "corporate citizenship."

The ADD report asserted that the industry's obligation to produce maximum earnings for its shareholders pressures it to undermine research that may compromise its profits. In the past, the alcohol industry has: (1) assaulted the scientific integrity of rival researchers; (2) paid their own scientists to attack conflicting research; (3) attempted to discontinue or diminish researchers' funding; (4) promoted unsuccessful forms of alcohol abuse help; and (5) taken advantage of their research involvement to gain credibility to weaken opposing research.

The alcohol industry's actions affect not only public health, but also the public's perception of research in general. Eliminating financial ties between researchers and alcoholic beverage corporations may restore the rectitude of alcohol research and protect the public's health.

A report on this meeting is posted at: http://www.add-resources.org/international-expert-meeting-alcohol-research-must-be-protected-from-industry-influence.4484336-76188.html.

*VC

ETHICAL STANDARDS TO PROTECT SUBJECTS OF WHOLE-GENOME RESEARCH

A committee of experts has produced a consensus statement on ethics related to research of individual genomes [1] that offers "ethically rigorous and practical guidance for investigators and research ethics boards." Although numerous issues may develop from whole-genome research, the committee chose to focus on four specific areas: consent, withdrawal from research, return of research results, and public data release.

Informed consent is pivotal to achieving an ethical research environment when working with human subjects. Researching whole-genomes has created new obstacles to achieving fully informed participants. One major hurdle is the unpredictability of how the data gathered will be used in the future. To overcome this and other concerns, the committee recommends that research participants be provided thorough details regarding potential future use of their information as well as the possibility of reconsent when a project significantly differs from what the person originally agreed to.

Withdrawal from research without repercussion is another of the

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cornerstones of ethical human subject research. While this right must be upheld in whole-genome research, it may be more difficult to apply because the nature of this research calls for broad and quick distribution of results, and there may be no recourse for withdrawal of an individual's information. To this end, the committee's third and fourth recommendations support the individual's right to withdraw, which may include destroying tissue samples and written information. The subject must also be advised during the original consent process that this right may be limited due to the nature of the research. Experiments should be designed with the subject's ability to withdraw in mind.

Results from whole-genome experiments may produce a range of information about individual participants, even if that is not the primary function of the study. The committee recommends that a process be in place to determine what findings will be shared with the individual. The individual's right to know or not know certain information should be covered in the initial informed consent process. The results offered to participants should be "scientifically valid, confirmed, and have significant implications for the subject's health and well being."

Finally, whole-genome studies rapidly disseminate their data in order to benefit worldwide science. This dissemination needs to be carefully balanced with subjects' privacy rights. In order to achieve this balance the committee recommends policies that consider both access to information and privacy interests of participants. Subjects must be thoroughly informed of the implications of the release of their data, and issues regarding the potential impact on family members and certain populations should be weighed.

[1] Caufield T, McGuire AL, Cho M, Buchanan JA, Burgess MM, et al. (2008) Research ethics recommendations for whole-genome research: Consensus statement. *PLoS Biol* 6(3): e73.

The original article can be found at: http://biology.plosjournals.org/perlserv/?request=get-document&doi=10.1371%2Fjournal.pbio.0060073

*CK

UNIVERSITY OF TORNOTO PROMOTES MORAL RESPONSIBILITY THROUGH GRADUATE STUDENT OATH

In response to increased concerns regarding the social impact of technology, the Institute of Medical Studies ("IMS") at the University of Toronto created a graduate student oath to promote professionalism and ethical conduct. IMS instituted the oath to encourage awareness and discussion of the social and moral responsibilities of biomedical students. The declarations, voluntarily recited at the first meeting of each new graduate student body, are part of a program aimed at combating academic misconduct. Each student is provided a booklet of information and a personal copy of the oath. In addition, students are required to attend a seminar course, which includes material on scientific misconduct, and complete an online ethics course. IMS encourages other life science programs to develop similar ethics educational programs, oaths, and faculty–trainee relationships that address community, professionalism, and ethical conduct.

The text of the Institute of Medical Science Graduate Student Oath follows:

> *"I, [NAME], have entered the serious pursuit of new knowledge as a member of the community of graduate students at the University of Toronto.*
>
> *"I declare the following:*
>
> *"Pride: I solemnly declare my pride in belonging to the international community of research scholars.*
>
> *"Integrity: I promise never to allow financial gain, competitiveness, or ambition cloud my judgment in the conduct of ethical research and scholarship.*
>
> *"Pursuit: I will pursue knowledge and create knowledge for the greater good, but never to the detriment of colleagues, supervisors, research subjects or the international community of scholars of which I am now a member.*
>
> *"By pronouncing this Graduate Student Oath, I affirm my commitment to professional conduct and to abide by the principles of ethical conduct and research policies as set out by the University of Toronto."*

Visit: http://sandwalk.blogspot.com/2008/06/graduate-student-oath.html

*JD

In the Societies

NASULGC RESPONDS TO VIOLENCE STEMMING FROM ANIMAL TESTING OPPOSITION

The National Association of State Universities and Land-Grant Colleges (NASULGC) reaffirmed its support for the use of animals in research on 23 May 2008. The organization issued a statement in response to incidents of harassment, violence against researchers and their families, and destruction of facilities at the University of California at Los Angeles, University of California at Berkeley, University of California at Santa Cruz, and the University of Utah.

NASULGC, a higher education association dedicated to supporting excellence in teaching, research, and public service, endorses the use of animals to advance medicine and science when it conforms to ethical, legal, and safety regulations because of the benefits of research: "The use of animals in scientific research continues to provide the basis for critical innovations that have

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benefited our country and the global community. Through research involving animals, scientists at NASULGC institutions have advanced biomedicine, human nutrition and health, food production, food safety, biodefense, and animal health and welfare. Scientific research also has provided the basis for federal guidelines for the welfare, feeding and housing of animals." However, NASULGC remains committed to refining, reducing, and replacing the use of animals in research, where appropriate.

While the NASULGC continues to support the use of animals in research, it also encourages open discourse and free expression so long as individuals do not resort to harassment, intimidation, or violence. It wishes to "ensure a safe work and learning environment" for all members of its community and activities.

Visit:
http://www.nasulgc.org/NetCommunity/Page.aspx?pid=955&srcid=236

*JD

2008 ABPI ADOPTS NEW REQUIREMENTS FOR WORKING WITH HEALTH PROFESSIONALS AND PATIENT GROUPS

The Association of the British Pharmaceutical Industry (ABPI) will put its newly revised "Code of Practice for the Pharmaceutical Industry" and "Constitution and Procedure for the Prescription Medicines Code of Practice Authority" in effect on July 1, 2008. The focal point of the amendments is greater pharmaceutical company transparency. These alterations are implemented to adjust to the provisions of the code administered by the European Federation of Pharmaceutical Industries and Associations (EFPIA). More than 75 prescription medicine-producing companies included in the ABPI will abide by the changes.

In promoting greater transparency, the companies will make short descriptions of all their significant support – both financial and indirect – for patient organizations publicly available. They are also encouraged to disclose information about donations and grants to institutions that support healthcare and research. Furthermore, sponsorship declarations must be revised to reflect accurately the degree of the company's current involvement. Companies that employ health professionals as consultants are expected to require them to declare this as an interest.

Several changes to the Code focus on increased identification of side effects. Pharmaceutical companies must "prominently" state that "adverse events should be reported" and include contact information for further concerns. The ABPI is also obliging their companies to use the black triangle warning system for high risk drugs. For the first time, details of all clinical trials on experimental drugs conducted by ABPI companies must be made publicly available. These strong suggestions and requirements are made in hopes of ensuring "maximum confidence in the standards set for ethical and responsible behavior of companies and staff," says Chris Brinsmead, President of the ABPI.

Brinsmead also stated that ABPI "made further amendments to reflect experience, comments, and suggestions received since the introduction of the 2006 code." These changes include: more direction about meetings and hospitality; limitations on the supply of samples; publications of interim case reports when final reports are delayed; and placing advertisements for the outcome of certain cases in nursing media in addition to medical and pharmaceutical journals.

The Code is regularly updated every two to three years. A transition period will continue through October 31, 2008.

The 2008 Code is available at:
http://www.pmcpa.org.uk/files/sitecontent/ABPI_Code_of_Practice_2008.pdf.

*VC

PANELISTS PONDER USHERING IN AN ERA OF PERSONALIZED MEDICINE

On June 20 at its headquarters, AAAS, in collaboration with the Food and Drug Law Institute (FDLI), hosted a national conference on personalized medicine. The AAAS presented a morning roundtable that focused on a hypothetical case study, while FDLI hosted an afternoon session highlighted by Dr. Mark McClellan's keynote address and a series of speakers on the legal, regulatory and policy aspects of implementing personalized medicine.

Nine speakers participated in the AAAS roundtable each representing a different sector: industry (Finley Austin of Hoffman-La Roche), ethics (Carol Isaacson Barash from Genetics, Ethics and Policy Consulting), government (Greg Downing on behalf of Health and Human Services' Personalized Health Care Office), patient/consumer advocacy (Annette Bar-Cohen representing the National Breast Cancer Coalition in the District), physician (Dr. Howard P. Levy from the McKusick-Nathans Institute of Genetic Medicine at JHU), legislature (Dr. Kavita Patel representing the Senate Health, Education, Labor and Pensions Committee), scientific research (Charles Rotimi of the NIH Intramural Center for Genomics and Health Disparities), law (Grail Sipes from Covington & Burling LLP), and insurance (Joanne Armstrong on behalf of Aetna). Susan Dentzer, editor-in-chief of *Health Affairs* and on-air health analyst for the *PBS NewsHour*, moderated the discussion, which explored the hypothetical stories of four women, each diagnosed with breast cancer, in the context of very different financial, medical and personal circumstances. The scenario presented a biomarker that could hypothetically predict the cancer's recurrence and thus better dictate the respective courses of treatment for the four women.

Dentzer asked the panelists to advise the patients' physician on how to proceed in light of the newly found biomarker, and personalized medicine more broadly. For example, she asked how employers and insurers ought to provide coverage for treatments based on potentially uncertain information, what legislation Congress should consider and, ultimately, how doctors should educate patients. The discussion expanded beyond the case study, as each panelist shared his or her unique insight on the larger issues surrounding personalized medicine. They

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(**Societies** continued from page 7)

explored the complexities of patient education, data management, privacy, the true meaning of the term "personalized medicine," and other concepts.

Drs. Rotimi and Levy discussed the definition of personalized medicine in the context of race and ethnicity. Dr. Rotimi suggested that personalized medicine could not be limited to ethnic categories, but rather should be applied to any characteristic, from age to gender or even height, which could aid in identifying trends in genomic data. On the subject of education, Ms. Bar-Cohen spoke about the dramatically differing levels of involvement in their own treatments that breast cancer patients desire even today, without the array of options that knowledge of a biomarker might provide. She observed that if personalized medicine allows patients to know more about themselves, they deserve the right to know more about their conditions, diagnoses, and treatment options. Her remarks led others to consider the potential pitfalls of increasingly complex roles for doctors as educators and advisers. Dr. Kavita Patel shared her experience as a more recent graduate of medical training, which she believed prepared her, and increasingly will prepare others, for the new relationships that doctors are likely to have with patients in an era of personalized medicine.

While several of the panelists differed in their opinions of the patient and doctor's respective roles in personalized care, there was consensus that one or all of the following three actions would be crucial first steps toward realizing the potential of personalized medicine: increased funding for basic and biomedical research, improved data management, and protection of patient privacy. As the push continues toward making personalized medicine an attainable, tangible health tool, AAAS and FDLI will continue to foster conversations about the potential and formidable challenges that lie ahead.

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Announcements

Award – The Association for Practical and Professional Ethics will award the Squire Family Foundation Award and a check for $1000 for the best paper submitted on pre-college ethics. Papers may address pedagogy, extracurricular activities, school-based ethics centers, or collaborative efforts with other centers and the community. Visit: http://www.squirefoundation.org/news.appe_2009.html.

Award –Council of Graduate Schools (CGS) proposals from CGS member institutions who can to develop institutional models for expanding and embedding research integrity and responsible conduct of research education programs. Five $50,000 grants will be awarded. Deadline for project proposals: July 30, 2008. Visit: http://www.cgsnet.org/portals/0/pdf/PSI_RFP.pdf.

Call for Papers – Papers are invited for a conference on *Ethics in Intelligence and Immigration* held on November 20-22, 2008 at the University of Texas-Pan American in Edinburg, Texas. Papers should focus on ethics in fields of intelligence gathering, global security, and immigration. Deadline: September 2008. Contact: pace@utpa.edu.

Conference – Scientists will discuss their collaborative experiences, obstacles encountered with international collaborations, and avenues for collaborative success in the conference, *Challenges and Tensions in International Research Collaborations,* on October 2-3, 2008 in Minneapolis, MN. Organization, funding, cultural expectations, laws, regulations, and graduate and postdoctoral systems abroad will be addressed. Visit: http://www.international.umn.edu/oriconf. Contact: Dr. Melissa S. Anderson, mand@umn.edu; (612) 624-5717.

Conference – Scholars from an array of disciplines will discuss the impact of 21st century genetics at an event called, *Mendel in the 21st Century: The Scientific, Social, and Ethical Impact of Genetics in Our World,* on September 21-23, 2008 at Villanova University. Visit: http://www.villanova.edu/events/yearofmendel/mendelsymposium/.

Conference – On September 15-18, 2008 in St. Louis, MO, PRIM&R is hosting its regional programs: IRB 101sm, IRB Administrator 101, IBC Basics, and Essentials of IACUC Administration. The programs are aimed at educating IRB/HRPP, IACUC, and IBC administrators, coordinators, members, and research staff. Visit: http://www.primr.org/Conferences.aspx?id=3913&ekmensel=297ded8b_327_0_3.

Course – The 2008 Environmental Ethics Institute at the University of Montana will offer a course on Environmental Ethics and Policy (registration ends June 27th, class begins July 1st) and a course on Women, Health and the Environment (registration ends July 25th, class begins August 1st). Public lectures and discussion forums will also be available to students. Visit: http://umt.edu/ethics/programs/EEI.html. Contact: Dane Scott, Director of the Center for Ethics, dane.scott@mso.umt.edu; (406) 243-6632.

Course – UNESCO is hosting an Ethics Teacher Training Course in Minsk, Belarus on November 17-21, 2008. The course is particularly aimed for the younger generation of university teachers to expand and improve ethics courses in all Member States of UNESCO. Deadline: August 1, 2008. Visit: http://portal.unesco.org/shs/en/ev.php-URL_ID=11968&URL_DO=DO_TOPIC&URL_SECTION=201.html.

Course – PRIM&R and the American Society of Law, Medicine and Ethics (ASLME) will sponsor a webinar entitled, *Handling Incidental Findings in Human Subjects Research: Legal and Ethical Perspectives,* on July 15th from 1:00-2:30 PM. The webinar is designed to help participants respond to questions arising from incidental findings in new and complex areas of medical research. Visit: http://www.primr.org/Conferences.aspx?id=4391.

Fellowship – Teachers and scholars with a PhD in philosophy, political theory, theology or related discipline, or an advanced degree, with no more than ten years of academic experience, are invited to apply for a Faculty Fellowship in Ethics at Harvard University. Moral choice in the professions and public life will be explored throughout the 2009-2010 academic year. Deadline: October 31, 2008. Visit: http://www.ethics.harvard.edu. Contact: (617) 495-1336.

Public Consultation – The National Advisory Board for Biosecurity (NSABB) is asking for public input on July 15, 2008 at the National Institutes of Health (NIH) Campus in Bethesda, MD on a proposed framework for the oversight of dual use research. The federal government specifically wishes to address the clarity of the criterion proposed by NSABB for identifying dual use research of concern; institutional oversight responsibilities; and approaches to education to enhance awareness of the issue. Register at: http://www.capconcorp.com/meeting/lifesciences2008/.

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