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Cover Story

Complexity Simulations, and Ethics

By Carl Mitcham and Sanyin Siang

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Advances in science and technology often introduce ethical challenges. After all, everything that can be done is not necessarily something that should be done. Hence, as technology expands the realm of the possible, it requires us to extend our critical assessment regarding the ethical limitations to human action and what should not be done. This has been true with the development of nuclear weapons, biomedical engineering, computers, biotechnology, and more. It is thus to be expected that new developments in the simulation and design of complexity should in their turn raise ethical issues. To put the point another way, ethical problems have always been considered complex. They become even more so when we are dealing with the science and engineering of complexity. This article will explore this new region of interaction between science, technology, and ethics by reporting on a symposium that we organized at the 2001 AAAS annual meeting in San Francisco, and then discussing current ethical trends in the field.

The symposium, titled *Complexity, Simulations, and Ethics*, examined the ways that we can take lessons learned from existing approaches to research ethics and apply them specifically to complexity simulations. The ensuing discussion included questions regarding whether this relatively new field of scientific inquiry might raise new and special ethical issues or responsibilities and whether ethical issues should be included in complexity simulations. The symposium included representatives from the sciences, engineering, the social sciences, and the humanities.

Sergio Sismondo (Queen's University, Canada), a philosopher and social scientist, began by noting how computer simulations cut across traditional scientific boundaries. As he puts it, "simulations occupy an ill-defined space between experiment and theory." Whereas experiments produce either reliable or unreliable data, and theories are judged as true or false, simulations tend to be thought of in more pragmatic terms as more or less useful. At the same time, because of their complexity - especially insofar as they model complexities - the computer programs on which simulations rest contain a multitude of unclarified assumptions and often unrecognized bugs, the adequacies and inadequacies of which are exceptionally difficult to discern. "Complex science is nothing new. But computer simulation is novel in having some of the local and idiosyncratic features of experimentation even while its looks like theory." What this means is that our trust in a simulation must in fact rely on "trust in the skills of people who have created it" more than any comprehensively tested program.

Aerospace engineer Stephen M. Batill (University of Notre Dame) continued the discussion by distinguishing three interrelated complexities: the complexities of "large, collaborative groups representing many disciplines" that design complex systems; the complex systems themselves; and the complexities of interactions between these systems and the world. Complexity in the design process is the result of "the curse of dimensionality," which grows with the level of detail used to describe a system. Using the aeronautics industry as an example, he describes the complexity and uncertainties posed in the design of a plane. In the design process, engineers try to predict the behavior of systems prior to their realization. To achieve this end they commonly use "computer-based models and simulations intended to represent some of the most complex phenomena that science can describe." But there is always a degree of

uncertainty associated with the information provided by such simulations.

Characterizing and quantifying the uncertainty of simulations "is a key element in developing information of value to the engineer in the design decision-making process." On the one hand, this very characterization has its limitations. On the other, social expectations regarding the powers of technology have increased at the same time that tolerance for failure has decreased. "This introduces new ethical issues into the design process related to the engineer's ability to use uncertain information to provide an assessment of the risk/cost versus the benefit to society for new technology development."

Biologist Joseph Berry (Stanford University) extended the questioning by considering some of these issues in relation to what might be termed a live-in simulation, Biosphere 2. For him, "models are powerful tools for dealing with complex systems" that run the "danger of misinforming or misleading if the input data, parameterizations or model structure have important errors." As a result, modelers have special responsibilities "to use the best available science and to be candid about the limitations of any particular model."

But another problem is that precisely because of their complexity, simulations are easily criticized or dismissed when their results turn out to be counter-intuitive or contrary to strong economic interests - a phenomenon that has been well illustrated by reactions to climate change models. This is where Biosphere 2 offers a new approach. A large-scale model or simulation such as Biosphere 2 can serve not only as a testbed in which scientists can assess the adequacy of models for various earth system processes, but also as a demonstration site through which the non-scientific public may come to have more confidence in the models and thus not so easily dismiss unpalatable implications. With 40,000 visitors a year touring Biosphere 2, this simulation presents real opportunities for scientific education of the general public.

Finally, Carl Mitcham (Colorado School of Mines), representing the interdisciplinary field of science, technology, and society studies, argued that although simulations of complexity may not require the development of any new ethics, they do call for deeper integration than have heretofore been achieved of research ethics and engineering ethics . Research ethics in science is primarily concerned with process: doing research in the right ways. Engineering ethics, by contrast, is primarily concerned with product: designing efficient or safe products, processes, or systems. Simulations of complexity bridge the traditional science/engineering divide by serving as large-scale virtual experiments (simulations) mounted on complex engineering products (computers). As with the case of Biosphere 2, these simulations also may have important policy implications for the society at large; the questions they address are not simply issues of knowledge for its own sake. As such, they engage not only research and engineering ethical issues, but even the politics of science.

Critical reflection on the ethical dimensions of complex computer modeling and simulations of complexity is something about which some members of the computer professional community have also become aware. As a member of the symposium audience, Billy Grassie (editor of the "Meta" Listserve on science and religion, http://www.meta-list.org), commented on the listserv: "Scientists, engineers, economists, and policy makers often take... simulations too literally, committing what A.N. Whitehead once labeled `the fallacy of misplaced concreteness.' ... Forget the debate about utilitarian ethics, deonotological ethics, or virtue ethics, we are losing moral agency in our growing collective inability to predict the consequences of complex systems."

Current work is conducted by John Illgen (Illgen Simulation Technology, Inc, a Santa Barbara firm that focuses on modeling and simulations and receives direct contracts from government agencies and companies such as the FAA, NASA, Raytheon, and SAAB. He is developing a code of ethics for simulations and modeling that can be used throughout the industry in the US and globally. He maintains the importance of the community delivering what it practices, and not pressured by customers wanting more than what is possible beyond the technical standpoint. Already, military offices of modeling and simulations - army, airforce, navy, and marines- have been pressing for solid verification, validation, and accreditation (VVA) policies and cookbooks on how to perform such efforts. " We want to make sure what's produced is done in a quality fashion, meaning the architecture that the models and simulations reside on, have all been properly tested - strict quality control, including verification, validation and accreditation. There are VVA processes that have been developed by the defense and modeling and simulation office. We should leverage off the excellent work that that group has done," Ilgen has stated.

The code in development will strongly urge industry to cost programs in a realistic fashion. It is just as important not to underbid programs beyond the capabilities of what a company is able to deliver as it is not to have profits that are too high. The code will also stress the necessity to assign appropriate personnel, in terms of proper experience and academic level, to achieve the task. It will also require simulation modelers, when encountering unforseen problems, to inform those for whom they work and present the solutions in an honest fashion. Illgen believes that in parallel

with a code of ethics, the computer simulation community needs certification in modeling simulation. Currently, the Society for Computer Simulation is working on such a certification process with the idea those doing computer simulations would have to be certified in order to receive public funding. He anticipates completing the code by November 2001.

In the News

AAA Investigates Allegations of Improper Behavior

The American Anthropological Association (AAA) announced in February that it would formally investigate recent accusations of misconduct by two researchers studying the Yanomami people of the Amazon Basin. As reported previously in PER (Fall 2000, http://www.aaas.org/spp/sfrl/per/per23.htm#News), Patrick Tierney alleged in his book, *Darkness in El Dorado: How Scientists and Journalists Devastated the Amazon*, that over the course of several decades, beginning in the 1960s, anthropologist Napoleon Chagnon and geneticist James Neal seriously deviated from the ethical norms of research in ways that caused harm to the Yanomami. In November 2000, the AAA Executive Board appointed a Special Ad Hoc Task Force to investigate whether the organization should launch a formal inquiry into these allegations, and in February 2001 the Executive Board met again to hear the Task Force's recommendations.

Based on those recommendations, the Board approved a formal investigation by AAA. An El Dorado Task Force, made up of five AAA members appointed by the AAA President, will seek to establish the veracity of the allegations and develop recommendations for how the alleged incidents and issues they raise can be used to improve ethical guidelines for all anthropologists and others working with indigenous populations.

The Task Force will investigate several areas of controversy. The fieldwork practices of researchers studying the Yanomami will be examined, as will the possible negative impact of organizations established to assist or protect the Yanomami. The negative impact on the Yanomami of their characterization by researchers as a "fierce people" will also be assessed. Additionally, the extent to which the activities of researchers and journalists led to increased sickness, malnutrition or "disorganization" among the Yanomami will be investigated, and the role of personal gain-financial, professional, or other-for researchers and journalists studying the Yanomami in motivating these activities will be considered. The Executive Board chose not to direct the Task Force to consider some of the medical treatment allegations made, instead leaving it up to the Task Force to decide whether it would include this area of inquiry in its investigation. In conducting its inquiry, the Task Force was instructed to keep in mind the research and human subject protection conventions of the time period (principally the 1960s and 1970s), and to draw upon a diversity of sources. Communications between the AAA Task Force and groups conducting similar investigations in Brazil and Venezuela was also stipulated.

The Task Force will deliver a final report to the Executive Board at the AAA Annual Meeting in November 2001.

For more information, see http://www.aaanet.org/press/press.htm. **MI*

Stem Cell Research is Hot Again

Proponents and opponents of using federal funding for embryonic stem cell research are gearing up for battle again (See PER XIII No. 3 http://www.aaas.org/spp/sfrl/per/per22.htm#Stem). Last August, a set of guidelines allowing the government to finance researchers working with embryonic stem cells was approved by the Clinton Administration. However, President Bush has instructed the Deparment of Health and Human Services to undertake a review of the guidelines to determine whether they are based on solid legal grounds.

A key player in the issue will be newly appointed Health and Human Services Secretary, Tommy Thompson. Although an opponent of abortion, Thompson has been a strong proponent of embryonic stem cell research. Both sides are watching developments carefully, with the review expected to be completed by this summer.

On the proponents side, key groups such as the American Society of Cell Biology, the American Association of Medical Colleges, University of Wisconsin-Madison, Harvard University, and Parkinson's Action Network joined forces to form the Coalition for the Advancement of Medical Research (CAMR) in March. That same month, Congressman Jim McDermott (D-WA) sent a letter signed by 95 House members (including five Republicans) to Bush and HHS Secretary Thompson, urging them to maintain federal funding for embryonic stem cell research.

Presidents of more than 112 colleges and universities also released a letter to Thompson on March 26, 2001 with a similar message. The letter cites human pluripotent stem cells as one of the "most promising biomedical developments in years," holding "exceptional promise for developing cures or treatments for many dread diseases,

including Alzheimer's diabetes, Parkinson's, spinal cord injury, cancer, and heart disease." They wrote that the NIH guidelines would provide appropriate federal oversight and standards for ethical progression of the research.

AAAS, the world's largest federation of scientific and engineering societies, also released a letter to the President, urging careful review of the policy and offering the use of its resources. The letter lists the benefits of public oversight and the necessity for transparency of research as reasons for federal funding.

On the opponents side, the Christian Medical Association and others have joined to file a lawsuit in the DC District Courts. The suit alleges that the current guidelines violate the ban on federal funding for research involving embryos because the stem cell research "requires and depends upon the destruction of living human embryos." The lawsuit also claims that guidelines are "arbitrary and capricious" because HHS and the NIH "improperly dismissed or ignored substantial scientific research that demonstrate the availability of other sources of stem cells for research, most notably from adult bone marrow and other tissue, that renders unnecessary the harvesting of stem cells from human embryos." **SS*

First International Protocol to Ban Human Cloning

Prompted by successful attempts to clone mammals, particularly by embryo splitting and nuclear transfer, the Council of Europe (COE) has set out to prevent any use of such techniques on humans. The Prohibition of Cloning Human Beings is an additional protocol to the COE Convention on Human Rights and Biomedicine. Effective March 1, 2001, the protocol is the first and only international agreement banning human cloning. The COE claims that the absolute prohibition of cloning is designed to protect the identity of human beings, to preserve the random character of naturally occurring genetic recombination (to ensure genetic freedom and uniqueness), and to prevent their instrumentalization through artificial cloning.

Article 1 of the protocol prohibits "any intervention seeking to create a human being genetically identical to another human being, whether living or dead," and the responsibility to define the term human being is to be determined by the countries' domestic laws. Next, Article 2 states that no exceptions will be made for "reasons of public safety, to prevent criminal offenses, to protect public health or to protect the rights or freedoms of others."

The protocol does not take a position on the ethical admissibility of cloning cells and tissue for research purposes. Cloning cells and tissues for research purposes includes: 1) cloning cells as a technique; 2) use of embryonic cells in cloning techniques; and 3) cloning human beings. Under the protocol, the first area of research is considered ethically sound, the second would need to be examined against the COE's protocol on embryo research, and the third is prohibited.

What the protocol means in terms of the prospects of a worldwide ban on cloning is not clear. So far, twenty-four of the forty-three COE countries have signed the protocol and the legislatures of Slovakia, Slovenia, Greece, Spain and Georgia have ratified the text. Some commentators believe that the United Stated should follow suit, while opponents are concerned that it restricts individual's reproductive choice.

Other countries not included in the COE that have banned cloning include Japan, Portugal, Germany and Denmark. It is rumored that France's Prime Minister has made statements suggesting his country may be next.

For more information on the COE protocol prohibiting the cloning of a human being see: http://press.coe.int/press2/press.asp?B=62,0,0,1,0&M=http://press.coe.int/files/topics/e-clonage.htm. **RJG*

Proposed New Rule for Gene Therapy and Xenotransplantation

On January 17th, 2001, the Food and Drug Administration (FDA) released a proposed new rule that would make information on all new or ongoing clinical trials involving either gene therapy or xenotransplantation publicly available. This rule would provide public access to most of the study design and safety information related to these studies, putting the regulations more in line with those imposed by the National Institutes of Health, which traditionally makes such information publicly available.

Xenotransplantation and gene therapy have stirred controversy for years because of their potential to spread disease-causing viruses to patients and, subsequently, the rest of the population. In particular, the proposed rule is part of an overhaul of gene therapy regulations that followed in the wake of the death of 18-year-old Jesse Gelsinger in a 1999 gene therapy experiment. This tragedy illustrated the shortcomings in the regulatory framework.

Specifically, the rule calls for the FDA to release full descriptions of all clinical studies in the two fields. Among the

information that will be made publicly available are the following: the investigational new drug (IND) form; copies of informed-consent forms signed by participants: the procedures by which volunteers are to be monitored; a constantly updated record of safety problems in humans; and a record of any disciplinary actions by the FDA regarding each study. However, the names of participants would remain confidential and companies would be able to edit out company trade secrets. The proposal will also make certain that the FDA's policies for public access to this information are compatible with those of other government agencies that oversee similar types of research.

The proposed rule is praised by many patient advocates and gene therapy researchers as a significant step in ensuring greater public confidence in these technologies. However, many industry representatives oppose the disclosures put forth in the proposed rule, claiming that they might be misleading since most of the adverse events reported during a clinical trial are not related to the experimental therapy. They also maintain that the proposed rule has the potential to violate patients' rights if sensitive information were unintentionally released. The FDA says the proposed rule would have little practical impact on the biotech industry since much of the information is already divulged by companies to the NIH and the Securities and Exchange Commission. Comments on the proposal will be accepted for 90 days and can be e-mailed to the FDA at FDADOCKETS@OC.FDA.GOV. **MH*

New Data Quality Law Implemented

The Office of Management and Budget (OMB) will begin implementing a new data quality law by September 30, 2001. With public and federal agency involvement, OMB is charged with providing "policy and procedural guidance to Federal agencies to ensure and maximize the quality, objectivity, utility and integrity of information (including statistical information) disseminated by Federal agencies." Impetus for the law is based on obtaining the greatest possible public benefits and the maximum utility from information disseminated by or for the federal government.

In developing the government-wide data quality law OMB must define four key terms - quality, objectivity, utility and integrity - and how these terms are defined will likely determine the scope of the law. Guidelines and regulation on issues surrounding the sharing of and access to data are also to be covered. Additionally, the OMB guidelines will contain a mechanism through which "the public can petition agencies to correct information that does not meet the standards" of the OMB data quality law and "seek agency correction of information." Once the law and guidelines are developed and implemented, all federal agencies must issue their own conforming guidelines within one year of the finalized data quality law.

Congress has called for broad public input in developing the data quality standards. The Center for Regulatory Effectiveness (CRE) has developed its own draft data quality rule to "provide a strawman for [OMB] discussion." The CRE believes that the new data quality provisions will "advance good government principles" and "promote transparency [of data], the use of sound science, and the formulation of national regulatory policy." CRE has stated that it will be involved throughout the OMB data quality law development and implementation process.

Further information on the OMB Data Quality Law can be found at: http://www.thecre.com/quality/OMB_Implements_New_DataQualityLaw.html and CRE's Data Quality Rule can be found at: http://www.thecre.com/quality/dqdraft.html. **RJG*

Genetic Testing in the Works

Since the Human Genome Project began over ten years ago, there has been concern that the resulting information could be used in negative ways. For example, an employer who used genetic tests to avoid hiring employees at risk for certain diseases that could result in higher insurance costs.

Although this possibility was mostly theoretical for a long time, an instance of such use by an employer was reported in February 2001. The Burlington Northern Santa Fe Railroad was sued for performing genetic tests on employees who submitted claims for work injuries related to carpal tunnel syndrome.

The U.S. Equal Employment Opportunity Commission (EEOC) is representing the employees of the railroad in the suit before the U.S. District Court in the Northern District of Iowa. EEOC believes that it is a violation of the Americans with Disabilities Act for companies to make employment decisions based on an employee's genetic make-up. EEOC also alleges that the employees did not realize that their blood was being used to conduct genetic tests.

Railroad president Richard Russack said the tests were recommended by the company's medical experts. In response to the court case, Burlington agreed to stop performing the tests for the next 60 days to evaluate the situation. On April 18, the suit filed against the Burlington Northern Santa Fe Railroad Company was settled with the EEOC. The EEOC believes that this settlement will send a message to employers that the use of genetic testing to

discriminate against workers will not be tolerated.

Twenty-two states have enacted laws that ban the use of genetic screening for employment decisions. At the federal level, Sen. Thomas A. Daschle (D-S.D.) and Rep. Louise M. Slaughter (D-N.Y.) both introduced bills in Congress on February 13, 2001, to prohibit the use of genetic information as a basis for discrimination in employment and health insurance (S.19 and H.R. 602 http://thomas.loc.gov/bss/d107query.html). Last year, former President Bill Clinton signed an Executive Order prohibiting federal departments from making employment decisions based on an employee's genetic information. **JS*

Final PHS Guideline on Infectious Disease Issues in Xenotransplantation

On January 19, 2001, the Department of Health and Human Services (DHHS) published the final Public Health Service (PHS) Guideline on Infectious Disease Issues in Xenotransplantation. The guideline contains few substantive changes from the revised guideline released on May 25th, 2000 (see PER, Volume XIII (3), Summer 2000). It reflects comments received on the draft guideline offered in 1996 (see PER, Volume IX (4), Fall 1996), advances in science, international policy discussions, and two DHHS sponsored workshops on xenotransplantation that took place in 1997 and 1998.

The guideline recommends procedures for the prevention and control of infectious diseases associated with xenotransplantation that may pose a public health risk. Among the many issues addressed are the following: source of animal care, screening, and selection; informed consent and patient education; health monitoring; infection control practices; and maintenance of records and samples.

All other scientific, medical, public health, social, ethical, and legal issues will be addressed by the Secretary's Advisory Committee on Xenotransplantation (SACX), which met for the first time February 20-21, 2001, to focus on issue identification. The Committee's mandate is to recommend to the DHHS Secretary policies and procedures for oversight and conduct of xenotransplantation.

Information on the Secretary's Advisory Committee on Xenotransplantation can be found at http://www4.od.nih.gov/oba/sacx.htm.

The final guideline is available at http://www.fda.gov/cber/gdlns/xenophs0101.pdf. **MH*

ORI Suspends Policy to Train University Researchers in Ethics

In an effort to improve responsible conduct in research, the Office of Research Integrity (ORI) proposed a policy in July 2000 to train university researchers about ethics and research misconduct. However, the HHS suspended this policy indefinitely on February 21, 2001. The policy is aimed at universities that receive HHS health research grants. Areas in which researchers would be educated include conflicts of interest, publishing of findings, and the proper reporting of data.

The policy has been under consideration some seven months already. After the ORI initially published a *Federal Register* notice of its intent and where the draft policy can be found, the next two months were set aside to get public input on the issues involved. This included a meeting in August where representatives from twenty-five scientific societies, associations, and research institutions were able to give their opinions on the draft policy. The ORI believed that this was a sufficient period of time for the public to give feedback on the policy. Revisions were made to the original draft, including the ability for universities to decide which of its researchers needed to receive the education.

There was no shortage of criticism of the policy. Many university officials complained that it would be far too cumbersome and expensive to carry out all of the requirements outlined in the policy. For example, the policy requires universities to document that they have provided education to researchers. But many people argue that education often takes place in informal discussions that are difficult to document.

Rep. W.J. Tauzin (R-LA) wrote a letter to Chris Pascal, Director of ORI, in which he raised a point of administrative procedure about the way in which the policy was formulated. Tauzin argued that the policy appeared to be a final substantive rule, meaning that the ORI should have gone through a more formal process before issuing it. This would have required HHS to publish the full text of the policy in the *Federal Register* for public comment. Pascal responded saying that the ORI believed it had the authority to issue the policy under its power to impose reasonable conditions on grant funds it awards.

The result for the present time is that ORI has suspended the implementation of the policy to permit additional review of both the substance of the policy and the means for adopting it. *JS

Conflict of Interest Guidelines Proposed For Medical Schools

The Office for Human Research Protections (OHRP), in the Department of Health and Human Services recently released a "draft interim guidance" for medical schools to deal with issues involved in conflict of interest cases. The main concern is financial relationships in clinical research that could impair the objectivity of researchers and possibly harm patients.

The guidance was spurred by the 1999 Jesse Gelsinger incident, where a subject died in a University of Pennsylvania gene therapy experiment. The lead clinician in the research, as well as the University of Pennsylvania, had equity in a company that stood to benefit from the study.

The proposal recommends that medical schools require researchers to disclose any financial interests they might have to Institutional Review Boards (IRBs) and to journal editors before publication of the results. Currently, one third of publicly funded IRBs are considering looking at the issue, according to the March 16, 2001 issue of *Science*. The guidance seeks to harmonize various federal and university policies related to conflicts of interest.

Most research institutions are in favor of monitoring the financial interests of researchers. Yet a number of these institutions have requested that the guidance be reconsidered. They believe that it is difficult to define an institutional conflict of interest and that there may not be enough evidence to support the present concerns.

The American Association of Medical Colleges (AAMC) is scheduled to begin discussions on the issue in the near future. Its goal is for its members to voluntarily follow a set of guidelines on conflict of interest issues.

It is important to note that HHS has not implemented the guidance. It was only proposed to spark discussion of this important topic. *JS

Ethics, Policy & Law Column

Privacy By Compliance?

By Alexander Fowler

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An earlier version of this article first appeared in the ZeroKnowledge newsletter, Private Sector Issue 2.1, March 2001.

As the Internet bubble continues to deflate, those engrossed with counting pink slips and bankruptcy filings have probably missed a coming catalyst of dot-com angst: lost business due to failed compliance with privacy laws. When two high-tech companies recently announced that they were scaling back their businesses, it was not due to poor revenues or dwindling investor confidence; it was the result of a new children's online privacy regulation. Zeeks.com and eCrush, which had hoped to commodify interactive sections of their sites and email lists through advertising and marketing for wired kids, found they were unable to comply with the requirements set forth by the recently passed Children's Online Privacy Protection Act (COPPA), and closed down parts of their operations. With both the financial and health care sectors facing costly new privacy regulations in the US, as well as the -pending enforcement of data protection laws in Europe, Canada, and other countries, the experience of these two kids' sites may be an important harbinger of the future.

The Privacy Landscape

There are around 600 federal and state laws addressing the confidentiality of personal information within the US. These laws form a patchwork of sectoral protections that, when combined with various self-regulatory provisions and case law, loosely cover American citizens' bank records, cable television subscriptions, children's online activities, credit reports, video rental records, library loans, medical records, tax records, and telephone services. And the number of privacy laws is increasing. In 2000, US state legislatures reportedly debated approximately 4,000 legislative privacy proposals, resulting in over 300 new laws. Furthermore, two federal laws were passed that include privacy protections for financial and medical information. This year, privacy is expected to be one of the hottest issues addressed during the new US Congressional session.

The US privacy landscape is unique when compared with the picture of the rest of the world. Most of the 40 to 50 countries that protect privacy through national regulation, including those in Europe, Asia, and Canada, have opted for comprehensive data protection laws. These laws establish government data protection agencies, require registration of databases, and call for institutions to seek consent before processing personal data. For instance, the European Union passed a data protection directive in 1995 that sets the standard for the national law of all its member countries. The directive is currently implemented by all but a few of the EU member countries. It protects the fundamental rights and freedoms of individuals and ensures the free flow of personal data between member states.

Beginning this year, Canada has a new comprehensive privacy law that covers all private sector organizations engaged in commercial activity. The first phase of the law extends to federally regulated industries such as banking and telecommunications, and went into effect January 1, 2001.

A Cross-Jurisdictional Compliance Challenge

The sectoral approach places a significant compliance burden on US companies. As opposed to addressing a single standard, US companies have to carefully consider laws at both the state and federal levels. For example, a survey of mid-size children's sites estimated an annual compliance cost of between $115,000 and $290,000 for meeting the provisions under COPPA(1). A research group at George Mason University expects the Financial Modernization Act (or Gramm- Leach-Bliley) to cost business in excess of $223 million annually (2), while compliance with the privacy provisions under the Health Insurance Portability and Accountability Act is estimated to cost upwards of $22 billion over the next five years (3).

Furthermore, depending on the industry sector, most US companies will be subject to various state laws, which are not at all harmonized. Marc Brailov, spokesperson for the AeA asked, "Have you seen the mind-boggling number of possible solutions there are to regulating the industry?" The AeA, the nation's largest high-tech trade group formerly known as the American Electronics Association, recently recommended that federal Internet privacy legislation be passed to preempt state laws and reduce the cost of compliance. "We need a [federal Internet privacy] law that is in the interest of everybody to ensure consumer confidence online," said Brailov (4).

The cross-jurisdictional impact of these privacy laws is beginning to hamper global commerce. The Daimler-Chrysler merger has resulted in trans-Atlantic data sharing problems such that the new company is unable to transfer customer information between Europe and the US (5). For similar reasons, Dun & Bradstreet has reportedly had to put on hold a data-warehousing deal with a multinational's European division (6). And just last December, Privacy International filed a formal complaint against Amazon.com with the UK Data Protection Commissioner for failing to comply with the UK's data protection Laws (7).

Anticipating precisely these types of problems led the US and Europe to enact the Safe Harbor Privacy Provisions. To comply with the provisions under Safe Harbor, a US company must put in place some of the privacy protections required under the European Data Protection Directive, and make public commitments about its compliance. This process is intended to facilitate the oversight of the Federal Trade Commission (FTC) under its authority to investigate deceptive trade practices.

However, Safe Harbor does not appear to be a viable solution. It is unclear whether this qualifies as self-regulation, and if it does, it is highly questionable how it is less expensive than complying with one national law. While Safe Harbor has created a bridge between two very different approaches to privacy protection, it does little to protect the privacy of US citizens. Yet another shortcoming of Safe Harbor is that it does nothing to encompass laws in Canada and elsewhere worldwide. Finally, it should be noted that very few companies have joined the program.

Long Live Self-Regulation?

Most consumer advocates will tell you privacy self-regulation is dead. They reject the notion that US companies spanning dozens of different sectors, with thousands of disparate products and services could effectively establish a common set of voluntary fair information practices and then be trusted to enforce them.

For many in industry, however, self-regulation never really existed. Much like complying with Safe Harbor, publishing a privacy policy brings a US institution under the purview of the FTC, which regulates deviations from a stated policy as deceptive trade practices. In either case, one of the weaknesses of self-regulatory approaches is that a higher standard is applied to those institutions that act responsibly, while the rest of the industry tries to avoid public scrutiny. In the US, the controversy surrounding the now defunct Toysmart.com further illustrates this point. The FTC and all 50 state attorneys general had to sue to prevent the company from selling personal customer information as one of its assets, even though the company's privacy policy stated that it would never share this data with a third

party. Worse yet, self-regulation is silent on how to handle those sites that post non-privacy policies that say, "We collect personal information, deal with it, or go elsewhere."

Self- regulatory practices have not resulted in increased consumer trust. This is the conclusion of major Internet research firms, including Forrester Research, which estimates that online retailers lost $12.4 billion in sales in 2000 because of consumer concerns around online privacy.(8) And for those consumers who didn't leave a site due to privacy concerns, other studies (9) found what the Pew Internet and American Life Project described as "guerrilla tactics": people providing fake personal information to protect their identities. In either case, self-regulation has not resolved the largely adversarial climate that exists between consumers and companies online.

As consumers worldwide are concerned about privacy these days, those who might not like the idea of some government regulation will find it difficult to oppose it outright. Fortunately, with the advent of privacy-enhancing technologies and new, innovative techniques for automating compliance, businesses are now in a better position to consider ways to address the issue. Also, there is growing industry support for legislative approaches to privacy in the US, as illustrated by recent announcements (10) by the AeA, AOL, and Hewlett-Packard. Whether these approaches constitute viable solutions to the compliance challenge in the US and abroad remains to be seen. However, these approaches indicate that the American business community has taken an important first step away from self-regulation.

If you can't take the cost, don't open up shop.
Returning to Zeeks.com and eCrush, which were forced to scale back their businesses due to COPPA, consumers did not appear to lose much sleep over their situation. As one parent wrote on a popular news site, "I guess we're supposed to feel sorry for the Web sites that get closed down because it's too expensive to comply with the law. Sorry, I'm not buying it. Would anyone care if a business had to close down because they couldn't comply with the Americans with Disabilities Act? If you can't take the cost, don't open up shop."

In fact, survey after survey finds that consumers see privacy as a cost of doing business, and expect companies to be open, transparent, and ultimately responsible with their personal information. Thus, companies should not wait until there are laws to begin addressing privacy, and, in fact, investing in a privacy infrastructure now will help defray future compliance costs. This means reviewing data collection practices, hiring an internal privacy ombudsman, incorporating privacy-enhancing technologies, and establishing policies to manage the divergent regulations in different markets.

Finally, some of the most exciting initiatives underway to address the complexity of cross jurisdictional compliance may not come in the form of new laws, but rather in the form of new international standards. During the last few years several standards groups have been founded to tackle challenges related to privacy and anonymity, including the World Wide Web Consortium's Platform for Privacy Preferences, the Personalization Consortium, CPExchange, NymIP, and the Initiative for Privacy Standardization in Europe. Representing roughly 150 different companies and organizations including advertisers, marketers, software and hardware manufacturers, ISPs, auditors, telecommunications and wireless companies, academics, policy makers, lawyers, and consumer advocates, these groups seek to find technical and business solutions that mesh market needs, regulatory requirements, and self-regulatory approaches. While they still have significant work ahead, standards may ultimately represent the best hope of bringing together key stakeholders to address important consumer concerns, preserve the positive elements of self-regulation, and rationalize compliance with privacy and data protection regimes around the world.

Endnotes
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(2) Cochran, III, Jay, Public Interest Comment on The Proposed Rules to Protect the Privacy of Consumer Financial Information, Regulatory Studies Program, the Mercatus Center at George Mason University, March 31, 2000; http://www.mercatus.org/research/RSP20008.html

(3) Pear, Robert, "New Privacy Rules Are Challenged," *New York Times*, December 21, 2000; http://www.nytimes.com/2000/12/21/national/21PRIV.html

(4) DeLong, Daniel,"Internet Law Picks up Steam," Newsfactor.com, January 22, 2001.

(5) Rothfeder, Jeffrey, "Privacy War: The Europe-US Struggle Over Consumer Data," *strategy+business*, Q3, 2000; http://www.strategy-business.com/policy/00305/

(6) *Ibid.*

(7) See http://www.privacyinternational.org/issues/compliance/

(8) Kirby, Carrie, "Spotlight on Privacy," *San Francisco Chronicle*, January 29, 2001

(9)Trust and Privacy Online: Why Americans Want to Rewrite the Rules, Pew Internet & American Life, August 20, 2000: http://www.pewinternet.org/reports/toc.asp?Report=19

(10) "AeA Unveils Federal Privacy Principles," AeA Press Release, January 18, 2001: http://www.aeanet.org/public/press/index.html

Resources
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European Commission, Media, Information Society and Data Protection, Handbook on Cost Effective Compliance with Directive 95/46/EC (Masons Study), August 1998;
http://europa.eu.int/comm/internal_market/en/media/dataprot/studies/masons.htm

European Commission, Media, Information Society and Data Protection, Application of a Methodology Designed to Assess the Adequacy of the Level of Protection of Individuals With Regard to Processing Personal Data: Test of the Method on Several Categories of Transfer , September 1998;
http://europa.eu.int/comm/internal_market/en/media/dataprot/studies/adequat.htm

Smith, Robert Ellis, Compilation of State and Federal Privacy Laws, 1997 (with 2000 Supplement);
http://www.epic.org/privacy/consumer/states.html

AAAS Scientific Freedom and Responsibility Award
The Scientific Freedom and Responsibility Award was established in 1981 and is presented annually by the AAAS. It seeks to honor laudable scientists and engineers and/or their organization for actions that encourage scientific freedom and responsibility. Past awardees have been recognized for a great variety of efforts, ranging from scientists and engineers who have acted to protect the public's health and safety to those who have promoted social responsibility. The award consists of a plaque and $2,500.

This year's winner of the award is Howard Schachman, Professor Emeritus of the Graduate School, Department of Molecular and Cell Biology, at the University of California, Berkeley. Dr. Schachman has been at the vanguard of efforts to eliminate research misconduct in federally funded research while ensuring the preservation of the freedoms that allow scientists to be creative in their pursuit of knowledge. He has served on the advisory boards of numerous national and international professional organizations and has been Chair of the Department of Molecular Biology and the Director of the Virus Laboratory at Berkeley.

More information about the Scientific Freedom and Responsibility Award and previous winners is available at:
http://www.aaas.org/aaas/sncfre.html **MH*

Book Review

The Rum Affair: A True Story of Botanical Fraud, by Karl Sabbagh (Farrar, Straus and Giroux, 1999, $24.00, 276 pp.)

Why do some scientists fabricate their data? What motivates these scientists? And why does it seem like often they are able to get away with it? In his book, *The Rum Affair: A True Story of Botanical Fraud*, science journalist Karl Sabbagh explores these questions through the reconstruction of one episode of fraud that took place within the British botanical community during the first half of the 20th century.

Sabbagh's book focuses on the efforts of one amateur botanist, John Raven, a classics scholar at Cambridge, to uncover evidence proving that a series of discoveries was faked by John Heslop Harrison, a prominent professor of botany at Newcastle University. Raven and others had begun to suspect in the 1930s that Heslop Harrison was faking his unusual discoveries by transporting and secretly planting the very plants he later claimed to find. His

sightings of plant species previously not believed to be native to the Hebrides Islands were suspicious because they frequently were made in locations inaccessible to other botanists and thus could not be independently verified. (The name of the book refers to the Island of Rum, a privately owned island where Heslop Harrison made many of these discoveries). And Heslop Harrison had reason to fake these discoveries, in the sense that he used them to lend support to his own controversial biogeographical theory of perglacial survival, which explained the presence of certain plants in the Hebrides by their survival through the most recent Ice Age. This theory was not accepted by most of his contemporaries, who believed that these plants could be explained by migration from other climates. The book charts Raven's increasing suspicions, the detective work he undertakes to find proof of fraud, and his subsequent efforts to confront Heslop Harrison and the rest of the botanical community with his findings. Despite widespread suspicions and Raven's compelling evidence, the scientific community never denounced Heslop Harrison directly.

The Rum Affair is written in a breezy, engaging style aimed at the general interest reader, and no previous exposure to botany is presumed. Readers interested in scientific misconduct will find this book especially interesting because of Sabbagh's focus on the motivations of both those committing fraud and those investigating it, and for his exploration of the reluctant response of a scientific community. A chapter that compares the "Rum affair" to three other instances of apparent fraud in the history of science lends context to the discussion. The book also offers an introduction to the development of botany as a scientific field, and explores some of the tensions that existed at the time between the amateur naturalists, who had historically dominated British botany, and the increasing number of professional scientists who were reshaping it. Although some may be frustrated by a lack of many footnotes, the author draws convincingly on evidence from interviews, personal letters, and archived documents, as well as from letters and reports published in scientific journals, to support his historical account. **MI*

Announcements

CORRECTION FROM FALL-The web address given in the Fall 2000 announcement for the new website (http://rcr.usd.edu) offering resource materials for fulfilling the new Responsible Conduct of Research (RCR) requirements was incorrect. The correct URL is http://rcr.ucsd.edu

Conference-The conference, **"Legal Issues and Strategies for Responding to Allegations of Research Misconduct,"** will be held in Washington, DC, on May 30-31, 2001. This conference will help improve understanding of policies, procedures and methods for responding to allegations of research misconduct and of the rights and responsibilities of all parties involved. Topics to be covered include the regulatory framework and interactive relationship between government and institutional policies, legal issues embedded in the inquiry, investigation and appeals process, and issues surrounding litigation. The conference is intended for an audience of federal officials, university and medical school administrators and counsel, researchers, private attorneys, law professors and others interested in examining key legal issues associated with allegations of research misconduct and identifying strategies for effectively responding. It is being sponsored by the American Association for the Advancement of Science and the US Office of Research Integrity and co-sponsored with Howard University and Johns Hopkins University. Contact Rachel Gray, AAAS, 1200 New York Ave., NW, Washington, DC 20005, (202)326-7016, Fax (202)289-4950, Email rgray@aaas.org. WWW http://www.aaas.org/spp/legal

Fellowship--Applications are now being accepted for **Brandeis International Fellowships in Human Rights**, Intervention, and International Law. The Brandeis International Fellows will participate in a cycle of three conferences and create new works of scholarship or teaching materials for international judges. Fellows will be selected from a broad range of professional groups, including: judges or former judges; human rights activists; legal professionals; current or former diplomats or military officers; and scholars. Applications from individuals with experience outside the United States, particularly those who work in or with developing nations, are particularly encouraged. This program is sponsored by the International Center for Ethics, Justice, and Public Life at Brandeis University. Complete applications from individuals must be received by June 1, 2001. Contact Jennifer A. Rouse, (781)736-8577, Fax (781)736-8561, Email jrouse@brandeis.edu. WWW http://www.brandeis.edu/ethics

Seminar Series--The **AAAS Program of Dialogue on Science, Ethics, and Religion (DoSER) Program** announces a new evening seminar series. Seminars will bring together ethicists, scientists, and members of the religious community to share their perspectives and discuss scientific developments that raise issues of concern. Seminars will be held once a month, except for July & August. The April seminar will take place on April 26, 2001, and will be on "Evolution & the Quest for Purpose." Dr. John Haught, Landegger Distinguished Professor of Theology at Georgetown University, is the keynote speaker. Participation is free and all events are held as the AAAS auditorium at 1200 NW Avenue NW, Washington DC 20005. Reception begins at 5:15 p.m. Keynote address begins at 6:00 p.m. URL http://www.aaas.org/spp/dser/seminar.htm

Conference--The **"National Conference on Science and the Law"** will take place October 4-6, 2001, in Miami, Florida. The annual conference was developed to address the issues that arise when scientific evidence is introduced in the court system and to improve understanding between scientists, attorneys, and judges. The conference will focus on varied topics such as scientific and demonstrative evidence, admissibility of scientific evidence, jury's comprehension of scientific evidence and qualifications of expert testimony, funding for validation of emerging technologies, research to improve the foundational basis of scientific techniques, ethical questions and concerns about the role scientific evidence may play in the future, and ensuring adequate training for judges so they can perform their role as gatekeepers. The conference is sponsored by the Investigative and Forensic Sciences Division of the Office of Science and Technology, National Institute of Justice. The conference is co-sponsored by the American Academy of Forensic Sciences, the American Bar Association-Criminal Justice Section, and the National Center for State Courts, and is held in collaboration with the American Association for the Advancement of Science and the National Academies. The conference is designed for all criminal justice professionals, as well as members of the academic community and the expert witness community who are interested in learning more about the current impact of science on the law. Contact Institute for Law and Justice, (703)684-5300, Fax (703)739-5533, Email nijpcs@ilj.org. WWW http://www.ojp.usdoj.gov/nij/

Symposium--**"Ethical and Social Issues Criteria in Academic Accreditation"** will be the focus of the International Symposium on Technology and Society 2001 (ISTAS), July 6-7, 2001, held at the University of Connecticut at Stamford. ISTAS 2001 will explore the implications of the increased attention to social and ethical issues as they apply to the curriculum, to the profession, and to society. The symposium is sponsored by IEEE Society on Social Implications of Technology and co-sponsored by IEEE Computer Society. Contact Gerald L. Engel, University of Connecticut, Stamford,1 University Place, Stamford, CT 06091-2315. (203)251-8431 Email g.engel@computer.org. WWW http://chortle.ccsu.ctstateu.edu/istas01/

Call for Papers--The 3rd annual conference of the **Society for Ethics Across the Curriculum (SEAC)**, to be held at University of Florida-Gainesville from January 30-February 3, 2002, will focus on the philosophical and pedagogical issues raised by the use of cases and codes when teaching ethics across the curriculum. Papers are welcomed regarding any question about teaching ethics across the curriculum, but especially questions regarding the selection and evaluation of cases and codes. Teaching methods to best utilize them, confidentiality, legal liability, copyrights, and the general question of whether they are an effective vehicle for ethics across the curriculum. Abstracts or papers are due September 1, 2001. Contact Stephen Scales, Dept. of Philosophy and Religious Studies, Towson University, (410)704-2752, Fax (410)704-4398, Email sscales@towson.edu. WWW http://www.rit.edu/ethics/seac

Conference-**Public Responsibility in Medicine and Research (PRIM&R)** will convene "Promoting the Responsible Conduct of Research: New Policies, Opportunities, and Chalenges" on May 18-19, 2001, in Arlington, Virginia. The conference will provide concrete guidance and specific teaching tools to those institutional officials and faculty members charged with developing or strengthening RCR courses. It will also afford attendees the opportunity to hear from and network with peers who are leaders in the research ethics field, and will include sessions on current controversies including conflicts of interest and commitment. The primary audience for the PRIM&R conference will be individuals who are responsible for the development and teaching of RCR courses. Scientists, bioethicists, administrators, educators, and the lay public who have a professional or personal interest in issues of research integrity, as well as the trainees and fellows who are the focus of this instruction, will all benefit from attending the conference. In conjunction with the conference, a one-day course, "RCR 101 - Teaching Responsible Conduct of Research: Tools and Methods" will be held on May 17, 2001, and will assist institutions as they develop educational programs in this area. The conference is co-sponsored by the Applied Research Ethics National Association, the U.S. Office of Research Integrity, the Association of American Medical Colleges, and Tufts University School of Medicine. Contact PRIM&R, (617)423-4112, Fax (617)423-1185, Email info@primr.org. WWW http://www.primr.org

Conference-The **Fourth International Congress on Peer Review in Biomedical Publication** will be held September 14-16, 2001, in Barcelona Spain. This 3-day congress will feature the presentation of more than 100 reports of new research in peer review and other processes used to evaluate the quality in scientific publication. The Congress is organized by JAMA and the BMJ Publishing Group. Contact: Annette Flanagin, (312)464-2432, Fax (312) 464-5824, Email jama-peer@ama-assn.org. WWW http://www.jama-peer.org.

Seminar-The **Center for Ethics at Emory University** invites registrants for its faculty seminar on "Teaching Ethics." The seminar will occur over alternating mornings and afternoons on May 16-19 and May 23-25. Topics are expected to include the challenge of postmodernism, classroom strategies and techniques, teaching ethics in the midst of professional socialization, and teaching decisional models versus nurturing moral agency. Contact John Banja, Emory University, (404)712-4804, Email jbanja@emory.edu. WWW http://www.emory.edu/ETHICS/