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Managing Integrity in Research

A summary of a conference co-sponsored

by

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and

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Prepared by the Office of Research Integrity

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The University of Michigan and ORI sponsored a two-day conference, "Managing Integrity in Research," with an associated "Alternative Dispute Resolution Workshop," in Ann Arbor, Michigan, on February 10-11, 1998. The Conference was attended by approximately 150 people, primarily faculty, graduate students, and research administrators with responsibilities at the universities for teaching, demonstrating, and encouraging high standards of integrity in biomedical research.

Dr. Harold Shapiro, President of Princeton University, former President of the University of Michigan, and current Chairman of the President's National Bioethics Advisory Commission, was the keynote speaker. Ms. Judith Nowack, Assistant Vice President for Research, University of Michigan, served as the conference coordinator in collaboration with other Big Ten Universities' Research Officers and with Dr. Alicia Dustira, ORI.

The following summary briefly describes the substantive presentations and includes some of the discussion and question and answer sessions that followed.

Welcome Session

Mr. Chris Pascal, Esq., Acting Director, Office of Research Integrity, outlined ORI's dual roles of responding to misconduct and promoting research integrity. ORI's primary focus since 1992 has included (1) handling 1,500 allegations, (2) reducing the prior backlog of cases, (3) making 80 findings of scientific misconduct, (4) developing model policies and procedures to assist research institutions in conducting allegation assessments, inquiries, and investigations, and (5) providing institutions with education and technical assistance in cases of scientific misconduct. Since 1997 ORI has focused on research integrity, announcing support for regional workshops and conferences, including this one at the University of Michigan as well as others at the University of North Carolina and the University of Arizona later this year. Mr. Pascal suggested the following questions and issues for consideration during this conference: (1) Does the locus of control and responsibility for maintaining integrity in research lie with the individual or the institution? (2) How would an institution design and implement a system to promote research integrity and prevent research misconduct? What elements of such a system are already in place? What additional features are needed? What incentives and disincentives will influence the system? (3) What are the responsibilities of the research institutions to the general public? (4) What are the perceptions of the public with regard to the institutions' commitment to research integrity?

*This summary was prepared by the Office of Research Integrity based on the notes of one of the participants and is not intended to be a complete or official version of the proceedings. It has not been approved by the speakers or the University of Michigan. ORI regrets any errors in reporting or in identifying the participants.

(5) How does the institutions' commitment to research integrity (and the public perception thereof) affect the scientific enterprise?

Session on Design of Research Integrity Programs

Dr. Jane Dutton (University of Michigan, Business and Psychology Professor) was the moderator of this session. Four senior administrators described unique approaches to encouraging integrity in research at their institutions.

Dr. Mark Brenner (University of Minnesota, Vice President for Research) described a mandated program for training three groups: faculty and central administrators, unit administrators and support staff, and graduate students. This program was developed after NIH had designated the University as an "exceptional institution" due to poor financial management of grants and cost reimbursement problems in the Medical School. The program provides core training for principal investigators on their roles and responsibilities, ethics and the conduct of research, regulatory assurances, and fiscal accountability; this training is required for a professor to continue to hold the privilege of being a principal investigator on any grant. Whenever possible, case studies are used to engage the participants; this has proven more effective than lectures. For the administrative group, audiovisual materials were developed at a cost of $20,000. Sponsored project administrators are given a certificate for passing the training. A curriculum is being developed for all graduate students and trainees, not just those on NIH training grants. There is also a two-hour introduction as part of the New Employee Orientation, with brochures and access to training modules, which will be available on the World Wide Web, focused on informed consent for human subjects in research in the areas of health or social sciences, effort certification, and roles and responsibilities (in progress). The total cost of the program will be about $5 million.

Dr. Peter Dunn (Purdue University Assistant Vice President for Research) outlined a more decentralized focus on shared values at the school and departmental level. However, Purdue does offer a centralized orientation to a research program (half-day) conducted by the Office of the Vice President for Research and monthly administrative seminars for department heads under the Office of the Vice President for Academic Affairs. The University also offers a Bioethics Institute workshop each summer for faculty in the life sciences to enrich teaching of their regular courses by including ethical theory, ethics and religion, or ethics and science. The faculty participants receive a $1,500 supply award for use in their courses. The Administrator, Faculty, and Staff Advisory Committee has a regular seminar throughout the year on ethics and case studies in research.

Dr. Nancy Schwartz (University of Chicago Associate Dean for Academic Affairs) detailed a required, graded, four-credit course on Scientific Integrity and the Ethical Conduct of Science included in the 18 units of the Biological Sciences Division for first-year graduate students. This course is used to meet the NIH training grant's requirement for teaching responsible conduct of research. The course successfully used a play by Dr. Robert Martin (NIH) entitled "Stampede of

Zebras." It also used Dr. Frank Macrina's paperback textbook on research ethics, with readings and case studies. The first class had 62 students, in biweekly, two-hour sessions: the first five weeks as small group discussions, then lectures, outside AAAS videotapes, and student presentations; the last lecture was by Dr. David Baltimore (Massachusetts Institute of Technology), who happened to be on campus. The faculty wanted more on research ethics, no outsiders, and avoiding the "big public cases." The students wanted more on ethical problems, big names like Drs. Leon Kass and David Baltimore to speak, and more details on the big public cases as examples.

Dr. David Wright (Michigan State University Assistant Vice President for Research) documented some centrally-fostered, theme-based discussions going beyond the individual professions. He noted that today's universities are much more racially and socially diverse, more team-focused, and cross-disciplinary in research and that there was more concern over getting credit. Michigan State University (MSU) "triages" the 23-24 allegations received each year, only 2-3 of which involve scientific misconduct and only 1 of which leads to an investigation. The distribution of the remainder shows about 40% as authorship disputes and 25% as data issues, mentoring, etc. MSU holds an annual symposium with outside speakers; last year Dr. Marcel LaFollette (George Washington University), Ms. Judy Nowack (University of Michigan), and Dr. Steven Goldstein (University of Michigan Medical School) were featured in a symposium on authorship. MSU assembled a briefing book on (1) data management and (2) preventive ethics. The University has a *Research Integrity Newsletter*, edited by Ms. Julie Reyes, a graduate student in anthropology who works with the Office of the Vice President for Research. This preceded the development of a University default policy on authorship requirements and a policy on data management and retention.

In the question period, it was asked how an institution could transmit to foreign faculty and students who come to work in the United States our values in this area. Dr. Irwin Goldstein (Michigan Medical School Associate Dean for Research) noted the growing number of cases going to their conflict of interest review board that involve foreign faculty and students. Dr. Stuart Offenbach (Purdue University Professor) asked what disciplinary actions for faculty could be considered short of dismissal or tenure termination. Dr. Nicholas Steneck (History Professor, Michigan) asked what the main motive was for their programs and whether program support was secure or a worry for the future. In response, Dr. Dunn cited public accountability, and Dr. Brenner noted the effort toward an environment of integrity as the motive.

Session on How to Use Existing Organizational Mechanisms to Better Manage Integrity

Dr. Nicholas Steneck (University of Michigan Professor of History) was the moderator of this session.

Dr. John Birge (University of Michigan Industrial Engineering Chairman) talked about solving as an editor a dispute in which he had to "slice" up a paper three ways between the three coauthors who were arguing about its use. He noted that he had, as an engineering professional society

member, discussed the ABM debate in 1978, and more recently the SDI effort and the Bell Curve (IQ). There was a question about a member not using his professional background and responsibilities as an engineer, but rather addressing an issue from a personal, moral perspective.

Dr. Don Brown (University of Michigan Psychology Professor emeritus) reviewed difficulties in his Institutional Review Board's consideration of behavioral research. It often includes some manipulation and deception of the human subjects.

Dr. Michael Loui (University of Illinois Engineering Professor and Graduate Associate Dean) related several cases he had encountered, which were seldom of the falsification/fabrication/ plagiarism variety, but instead involved unprofessional behavior between faculty and students, including student moon-lighting jobs, student competing with faculty mentor for a grant, student accusing the mentor of plagiarism on the World Wide Web, etc. The University has a decentralized administration, with solutions unique to the disciplines. The Graduate School encourages in depth ethical training--one session required per year, expanded to all graduate students (not just for NIH trainees).

Mr. James Randolph (University of Michigan Research Administration Assistant Director) addressed the role of university grants administrators in assisting faculty to understand and meet regulatory and reporting requirements to federal agencies. He noted that his role is to foster compliance, to remind faculty and staff what is expected of them and why, and to ensure that institutional responsibilities are met on NIH grants. He reflected on how the skills in this area appear to be concentrated in a few seasoned administrators. He noted that they cannot just enforce more and more rules, but they need to assume that the principal investigators want to do the right thing, even if they grumble over the paperwork. Investigators should have easy access to all existing policies (as on the Web), be given straight-forward interpretations of rules along with implementation plans in useable language (he has an NIH Email group, tracking the *NIH Guide* and a U-M Policy Implementation Guide), and receive appropriate education. The University is preparing a course in Fundamentals of Research Project Administration--he noted that most research project administrators like himself received no formal training, just on the job experience.

In the question session, Dr. Kenneth Pimple (Indiana University Poynter Center Scientist) stated that the key role is educating the faculty on what limited regulations they need to know, but perhaps the institutions often do it too formally, as "regulations" rather than "help." Dr. Pimple served on the Institutional Animal Care and Use Committee and the Misconduct Committee of the University. Dr. Howard Rush (University of Michigan Animal Medicine Professor) noted that the IACUC is generally staffed by a professional administrator, not a veterinarian, and the committee has people trained in research methods with animals. He added that the University often "recruits" faculty members to the IACUC who have been "recalcitrant" in the past as a form of education. Dr. Fred Bookstein (University of Michigan Distinguished Research Scientist and Member of the University Conflict of Interest Committee) stated that "casuistry wins hands-down," that reviewing case studies is most effective. Mr. Marvin Parnes (University of Michigan

Assistant Vice President for Research) asked about scientific norms versus rules imposed by authority. Dr. Brown cited the Federal Government as the origin of the regulatory authority. Dr. Steneck added that we would like to have the authority come from the professional community and society, not the Government. Dr. Birge noted that how to define any "standard" is tough.

Session on The Ethical Climate in the Academy

Dr. David Smith (Indiana University Poynter Center Director) served as the moderator for this session.

Ms. Veronica Barcelona (University of Michigan nursing student), gave an undergraduate's view, noting the full dependence of an undergraduate on their faculty mentor in research.

Ms. Julie Reyes (Michigan State University graduate student in Anthropology and editor of the University's *Research Integrity Newsletter*) reported that the semiannual newsletter is available on the World Wide Web (http://www.msu.edu/user/gradschl/gradstudy/newslett/Research/ri2.htm). She commented on her survey of graduate student attitudes, wherein 52% found satisfactory and 48% found unsatisfactory the communication between graduate students and faculty--the departments with the most defined policy on integrity and coverage of "gray areas" have the most satisfied students. Mentors need to explain rules, regulations, and policies from the beginning of the research effort to avoid conflicts and misconduct. This is especially important on IRB and human rights issues for foreign nationals.

Dr. Joshua Margolis (Visiting Assistant Professor in Business at the University of Michigan) cited a survey on dignity inside a corporate organization; one person felt humiliated enough to quit. He said there is a tension between audiences for research results, rigor versus relevance in research, but it actually contributes to research integrity to satisfy both the academic and the practical (professional) standards.

Dr. Karen Muskavitch (University of Indiana Biology Researcher) reported on faculty or graduate and postdoctoral student attitudes on ethical issues. She believed things had improved; no longer were those persons interested in research ethics considered to be "outside science" or "defectors," although such efforts are still viewed as "extra," beyond the usual public and career development work. Faculty are willing to support ethics training of their students, and more case studies are being used to do so. Postdoctoral fellows are more interested in the "news" items on misconduct, as it is seen as more "personal." But most students are still looking for "Yes/No" answers, seeking people to "sit in judgment." There are high feelings about credit disputes, since career advancement requires individual recognition (numbers of papers and talks), yet more research today is conducted by teams. There are conflicts of interest in academic-industrial research interactions, which is a growing concern. The problem is how to get people to talk and express their feelings to each others (scientists tend to be too introverted).

Dr. Steven Kunkel (University of Michigan Graduate School Associate Dean) outlined the need to address integrity in research at many levels (laboratory manager, postdoctoral, research scientist, graduate, undergraduate, technician, and high school volunteer). He demonstrated the ease by which digital images of immunofluorescent protein gels could be changed and falsified with a computer.

In the question session, Dr. Steneck (University of Michigan History Professor) asked, "Given the ethical 'climate' in academia, how is the 'weather'?" Dr. Muskavitch stated that more people are now worried about integrity matters. Mr. Randolph added that the questions and courses appear to be discipline-specific. A chemistry professor cited the conflict of interests in drug-testing trials and access to data. Another professor noted the general public discord over ethical foundations or philosophy; he believed there was a failure to recognize the fundamental dignity of the human being as a person. Dr. Smith agreed that students are most interested in the "Pandora's Box" of current issues, which could be used to "hook" them into a discussion of ethics with an enlarged focus. Another person stated that the Executive Branch of Government appears to be in a "mess," lacking principles and guidelines. Dr. Offenbach (Purdue University) stated that it is a matter of being honest with each other, reporting honestly and accurately. Dr. Smith noted moralists writing about casuistry see the sweeping morality statements as the most detrimental thing, that one may sweep out all ethics, given the questions raised. Dr. Pimple (Indiana University) asked about institutional pressures and whether there was a way to avoid a pressure to "cheat." Dr. Steneck summarized his belief that we still do not know what the "weather" is in the laboratory (i.e., what the incidence of misconduct is), that there may be "too much trust" in science, and that we still do not know who to "focus" on. He added that the reported incidence of misconduct by scientists of 1% or less may be far less than the actual number. The Panel members were asked what the one biggest issue in ethics was for them now. Ms. Barcelona cited the genome mapping and human cloning issue; Dr. Kunkel, the expected size of a bibliography for success; Dr. Margolis, the real or imagined pressures to produce; Dr. Muskavitch, the pressure to publish and to get (versus give) credit; Mr. Randolph, the lack of accountability in the gray areas, with too little faculty and student interest; and Dr. Brenner, whether we are using the right measures of performance, counting publications and talks versus assessing their quality.

Keynote Address

Dr. Harold Shapiro (Princeton University President) noted that "managing research integrity" is a very difficult issue, especially given that we are not really sure what it is. His remarks were focused on his role as Chair of the National Bioethics Advisory Commission and on the intersection of bioethical issues and public policy. He noted that he had taken the appointment on the condition that the Commission not have to handle any controversial issues (like the use of fetal tissue) in its first year, but a controversy quickly arose.

Dr. Shapiro described one of the charges from President William J. Clinton to the Commission, to quickly make recommendations upon the ethics of the possible cloning of human beings, given press reports of an apparent success in cloning a newborn sheep ("Dolly") from an adult nucleus

(although other scientists have recently questioned the proof of a specialized adult-cell-origin). The President had asked for an answer in 90 days to questions about the ethics of somatic cell nuclear transplantation and cloning. Dr. Shapiro said he almost turned down the request, as being outside their earlier agreement; however, he determined that there was an important need to give public service in this area, and there were several scary Congressional bills already introduced to ban such research.

Dr. Shapiro recalled the public's feelings of fear, concern, and anxiety when the Dolly report appeared in *Nature*, including what it meant for our concept of human identity. The scientific community had been surprised by the results of this experiment (which had not worked previously, and perhaps since). The "science fiction" nature of the reporting fed the public's psychic fears. Thus, the Commission first accessed and assessed the available information and public predictions of possible next steps in this area of science and related legal issues, such as the constitutional question of whether cloning is procreation, which is a private matter not subject to governmental regulation, and who is the father or mother of such a clone. He also invited comments from philosophers and religious leaders; although some critics questioned its constitutionality, he found it inspirational to hear from Catholic bishops and Jewish rabbis. Both traced to *Genesis* in *The Bible* the idea of the moral superiority of humans to animals ("dominion"), a delegation from God to Mankind. While the Catholics felt cloning humans would be an attempt to "be God," and thus a "sin," the Jews felt there was an unlimited covenant, the key issue being the "motivation" of what to do or not to do with that dominion. Philosophers took positions on ethical systems but did not provide a guide to practical decision-making, so their ideas were not usable directly.

The academics on the Commission wrestled with the issues. They chose to redefine the problem: (1) leaving legal issues to the courts, noting that it will be hard to develop a compelling "state interest" in the matter; (2) believing that the animal rights issues were not different from the general consideration of experimentation; and (3) noting it was already illegal to use Federal funds for research on embryos (the President had already rejected a committee report suggesting that embryo research go forward, and Congress had prevented use of Federal funds for such work in its two-year appropriation). Thus, the Commission focused, as a strategic judgment, only on whether there should be attempts in cloning "to carry a fetus to term" for human reproduction, to create infants. Dr. Shapiro indicated that the concerns were largely speculative, how cloning a baby would affect its "identity" and how the baby would be treated by its "relatives." While there was information about twins, the Commission did not have time to consider the literature in depth.

Dr. Shapiro stated that in the end the Commission recommended that it was unsafe, scientifically premature, and thus unethical to clone a human at this time--thus, it was reasonable to ban such work for a fixed period. Of course, science already does some "unsafe" research, with reasons. But the Commission felt that a ban would not distort the scientific agenda for some time, and it would allow some debate and development of a rationale for going forward. While he was personally against any legislation, feeling that a voluntary moratorium would be sufficient (as it

was in the Recombinant DNA debates in the 1970's), the rest of the 17 Commissioners believed that there should be a ban on privately-supported attempts at human cloning as well. Thus, the Commission asked for Congressional legislation to ban the practice, with a three to five year sunset clause; the President chose three years. Since then, legislation has been introduced (and Dr. Richard Seed has indicated publicly his readiness to begin private work).

On another ethical issue, the use in research of human subjects whose decision-making capacity and ability to give informed consent for themselves is impaired, Dr. Shapiro noted that since World War II, we have dramatically increased the level of protection of subjects (especially since the Nazi experiments, the Tuskegee Experiment, and the DOD Radiation Testing work). We now have in place special provisions in the Federal regulations for protection of children, but none for the "decisionally-impaired." Yet there is a huge need for research on new medications for patients who really cannot give informed consent alone. He indicated that he was not sure where to go on this issue. It is sometimes unclear which subjects are impaired, in Alzheimer's Disease, bipolar disorder, emergency medicine, etc. Recommendations exist on giving parents the right to consent for children in cases with minor increases over minimal risk or advance designation of a decision-maker for a time when one becomes incapable of making decisions. Perhaps there is a need for a "special IRB" for such matters. He added that the United States needs to "graduate" from having specialized commissions to deal with such difficult matters; most countries have standing committees for such issues.

Dr. Gilbert Omenn (University of Michigan Executive Vice President for Medical Affairs) was the moderator of the panel. He noted that he helped set up the President's Commission for Bioethics in 1980.

Ms. Diane Baker (University of Michigan Human Genetics Counseling Director) reported that in North America there are only about 1,500 practitioners in her field. As an example of a "disease" about which potential ethical problems might arise, she cited achondroplasia (short stature, under 5 foot height) being found in all subjects to be due to one mutation; however, she observed that the possible genetic testing for the gene has never been used by parents who possibly might want to bear only such genetically short children.

Dr. Thomas Gelehrter (University of Michigan Human Genetics Chairman) stated that the Commission report is remarkable. Scientists reaction to the Dolly report was that it was "cool," a possible first step in understanding how inactive adult genes might be turned on again for fetal development. But he noted that society has a fear reaction and will continue to have it without continuing education on the potential benefits. He also feared legislation, noting the current Congressional bills have no "sunset" clause and could slow research of potential value. He also recalled the fears of the 1970's, that cloned *E. coli* would run rampant over the Earth, but it did not come to pass. He believed that we could deal with the child-and-family issues that arise and that we should do so now.

Dr. Paul Courant (University of Michigan Economics and Public Policy Professor) said that we do

have academic experts, paid well to do policy research; society should get the benefit of their knowledge, as they are (sometimes) right. While recognizing the economic potential of Dolly for livestock cloning, he believed that human cloning might save a sick child and thus be a value to those who may be affected--as well as an economic profit to those who do the work.

Dr. J. David Velleman (University of Michigan Philosophy Professor) believed the Commission report was not "neutral" on the ethical issues, although it was not stated to be the basis for the recommendations (which was based on biosafety problems). He was not sure that education to overcome ignorance would dispel the worries about ethical issues. The "private" matter of a transaction between a nucleus donor, a recipient cell/mother, and a physician is not a "neutral" one, but tendentious, leading to questions about what it means to be a human being. We tend to "finesse" the moral issues by leaving the matter to the participants, which is a "cop-out."

Dr. Janet Weiss (University of Michigan Business and Public Policy Professor) addressed the politics of Presidential commissions, which she said were created to serve the President's needs in carrying out difficult tasks, although that may not be identical to the purposes of the members of commissions. Often commissions are created when there is angst in the land, a real need to address the issue, or a need to have a cooling off period. However, the recommendations of commissions are often not followed by the President or Congress. Nonetheless, an "issue network" of knowledgeable experts can be built upon a commission's reports.

In the question session, Dr. Omenn (Michigan) cited a bill in the Michigan Legislature to ban nuclear transplantation in humans. In Congress, bills have been initiated, with provisions to protect key research. In addition to commissions, he noted there are NIH consensus panels, which reach in two days a consensus on the state of a field (recently on the benefits of mammography tests). Dr. Offenbach (Purdue) stated that he was not sure public education was the answer, since "the public doesn't trust science" since the time of the Nazis, atomic bomb, etc. Dr. Shapiro indicated that the "crest of the wave" of public concern and Presidential reaction went by the Commission. Dr. Omenn regretted that the "maverick" Dr. Seed had raised the fear again over cloning when it would have remained quiet without him. Dr. Shapiro added that the issue of having someone else decide and consent for another person is scary to him. Dr. Omenn, citing the thousands of consents he had obtained for trials, stated that it was not hard to avoid legalistic language therein; he added that it was an imposition on other countries for the U.S. to impose our ethical standards and requirements.

Dr. Shapiro summarized his thoughts. He said he had not meant in the Commission's report to avoid the informed consent issue. The problems are when cloning becomes a social practice (he cited the "clones are us" Web page, with a price list favoring celebrities like Mother Theresa and Albert Einstein for cloning); it would be less a problem if there were only 1,000 or so each year. He thought the harms imposed on others should be considered. He also believed we should be delighted with the possible genetic benefits, assuming the Dolly cloning was authentic. He said he had been surprised about the impact of the Commission report worldwide, with followup seminars in academia, journal issues, etc. When professional societies reacted that, if our motivation is

right then the act is right to do, he found it stunning; he felt scientists should talk more to philosophers. There's a chasm between the Public and Science, or the Public and Philosophy; we are all to blame. There is nothing in cloning that does not come up in the assisted reproduction and genetic engineering debates, but cloning became a focus. But we also need to decide how to deal with genetic tests, commercialization, and use of long-stored tissue.

Session on Public and Media Perceptions of Academic Approaches to Integrity in Research

Dr. Charles Eisendrath (University of Michigan, Communication Studies Professor and Michigan Journalism Fellows Program Director) served as the moderator for this session.

Mr. Chris Pascal (ORI) stated that while the media is a public obsession, the media has a major role in setting public perceptions. ORI has been a "body bag" for the media, taking blows or negative press. He said he was not speaking as an academic, but focusing on cases and policy related to the media. He said ORI has made mistakes and perhaps overreacted to earlier cases. He argued that there should not be routine disclosure of a respondent's name; privacy is paramount in most cases.

Mr. Pascal described the history of ORI's interactions with editors, the press, and Congressmen in several public cases. At St. Luc's Hospital in Montreal, ORI was not able to require correction or retraction of the literature; it was up to the institutions or funding agencies to do so. The *Chicago Tribune* reported the case after ORI's investigation was complete. At the Memorial Research Foundation of Southern California, the *Chicago Tribune* reported the case before the investigation, which found problems mostly on human subject issues; there was no finding of scientific misconduct, and ORI issued a press release clearing the respondent. In the Tufts/MIT case, Dr. David Baltimore was never the accused, rather was a big-name coworker who became a focus for the media, and there was a lot of negative publicity for ORI. The 1986 allegation against Dr. Imanishi-Kari was handled at the institution and then NIH, followed by Congressional hearings as well as Secret Service forensic testing that found apparent evidence of scientific misconduct. ORI inherited the case, and there was a long lag in resolving it; ORI's 1994 report was overturned at a Departmental Appeals Board hearing in 1996. ORI's side of the case did not get much press coverage. ORI decided not to respond to the media but published some comments on the process issues in the *ORI Newsletter*.

Mr. Pascal indicated that the HHS Commission on Research Integrity recommended an expanded definition of research misconduct in the Fall 1995. The scientific community reacted negatively; it wanted a narrow and clear definition. The scientific establishment identified almost uniformly with the accused in cases, not the whistleblower, and believed that ORI should have a narrow authority. The scientific community was concerned about issues of fairness, and ORI responded by addressing due process early on. Mr. Pascal suggested that institutions should not just say "No comment" when questioned by the press; rather the institutions should talk about the process of investigation and the need for confidentiality and then disclose the facts when they can. Institutions should "own the problem" and not just deny misconduct.

Mr. Daniel Sharphorn, Esq. (University of Michigan Co-General Counsel) explained the role of institutional lawyers; they try to ensure that the institution, if sued, does not lose a law suit. They do not want institutional officials saying anything on the record, as doing so may aggravate the suit or lead to claims about defamation, invasion of privacy, negative effect on careers, etc. Plaintiff's lawyers see public and media pressure as a tool to force an institutional settlement or to get larger amounts of damages. State Freedom of Information Acts (FOIA) allow media to obtain information, but only a small part of a file; however, states differ on FOIA. Jurors tend not to understand or appreciate science and the academic perspective. The adversary system may limit what information jurors get. He noted the goal of law is "justice," that of lawyers is "winning the case," and that of Science is "determining the Truth," which are not always the same. He asked whether decisions about falsification and fabrication of scientific results should be made by scientists. He added that due process is a variable standard, especially in areas of personal liberty and freedom. Standards of proof also vary, from 95% certain in beyond-a-reasonable-doubt, to 70% certain in clear-and-convincing, to 51% certain in preponderance-of-the-evidence. Research misconduct is not a criminal issue, but to a scientist, it is more significant than a misdemeanor crime in terms of its impact on the reputation and career. However, going to the highest standard would imply that "you have to accept" that only 5% of the time the results reported may be correct!

Mr. Daniel Greenberg (former editor of *Science and Government Report* newsletter, now a visiting fellow at Johns Hopkins University) gave a compressed political history of scientific misconduct as a public policy issue. He said he started as a police reporter. Misconduct arrived on the national scene in the early 1980's, with the case of Dr. John Darsee, a cardiologist at Harvard Medical School, who adjusted the tapes in the laboratory and wrote many, many papers. There were three investigations at Harvard and NIH, which turned the case over to Pittsburgh; the scientist was defrocked but returned to medical practice. A book by William Broad and Nicholas Wade, *Betrayers of the Truth*, suggested that university reports of a few high profile cases were just the "tip of the iceberg." The scientific community put out a "spin story" that science was self-policing and the literature self-correcting.

Mr. Greenberg cited the followup paper in *Nature* on Darsee's coauthors by Mr. Walter Stewart and Dr. Ned Feder at NIH, who turned from a study of lucifer yellow dye on snail nerves to research fraud. Their paper questioned whether the peer review system should have rejected Darsee's papers, as they contained mathematical errors, mistakes, and contradictions. Both *Science* and *Cell* declined the Stewart and Feder manuscript, but *Nature* published it, despite legal threats by Harvard Medical School faculty. Other complainants also came to them, and they took several cases to Congressman Dingell: (1) Dr. Robert Sprague at Illinois accused Dr. Stephen Bruening at Pittsburgh; after Pittsburgh, Illinois, and NIMH turned Dr. Sprague away, *Science* considered and *Science and Government Report* publicized the matter; (2) Dr. Margot O'Toole questioned the results of Dr. Theresa Imanishi-Kari at MIT; (3) Mr. John Crewdson questioned Dr. Robert Gallo's work at NCI. Then in 1989 NIH created the Office of Scientific Integrity, which later became the Office of Research Integrity ("an odd name that says nothing"). NIH's new Director fired some people; a retired microbiologist, who did not fit at NIH, asked as new

OSI Director for a "hold" on cases for a year to organize the office, but Congress would not wait. Leaks occurred on cases, especially from Congressman Dingell's staff (who routinely said to the press, "Remember, you didn't get this from me.").

Mr. Greenberg noted that two years ago the HHS Commission on Research Integrity worked hard and made recommendations, including a proposed whistleblowers' bill of rights (which was opposed by FASEB). Although we have not heard much in this area in recent times, there is still a lot going on--just no high profile cases (like Gallo and Baltimore) and no Congressman Dingell in power (since 1995 when the Republicans took over). Mr. Greenberg thought likely this is a "hiatus for political reasons" but an issue that "will break out again" sometime in the future.

Mr. Karl Bates (*Detroit News* reporter, now a Michigan Journalism Fellow) noted that the general public does not have research integrity on its "radar," but it does care about controversial issues involving bioethics (cloning humans, the Tuskegee Experiments, radiation of human subjects, and research related to fetal tissue and production of embryos). If there is a law suit, it gets attention, but reporters generally do not understand the rights of the accused. He noted that a few years ago there was a "he said, she said" suit at the University of Michigan over the ideas for a grant.

Mr. Bates thought that the press was doing a lousy job on issues of education, tenure, peer review, science policy, the role of journals, etc., and that the public (including juries) and policy makers were left "out of the loop," still retaining a "mad scientist" image. Similarly, editors do not understand science and these issues. It is a "tough sell" to get people to distinguish between recommendations of "ban human cloning" but "allow genetic research." He encouraged universities to "tell all, the good and the bad"; to come out with stories about scientific misconduct (shielding names if necessary). Do not try to "sweep it under a rug," which will "kill you like a cancer" if it becomes public. Your employees and the press will hear about it, and you will look like an accomplice in a "cover-up." He believed that a university should use its faculty and public relations staff, even bringing in real people (such as patients, with anonymity) to tell the story. The "human dimension sells," especially to print-reporters. Researchers are "human beings subject to the same evil attributes as the rest of us." Policies alone will not prevent the problems, and the media does not know the truth. It takes deliberate, careful work to provide the media with the university's side of the story.

In the panel discussion period, Dr. Eisendrath related that he had been asked by the tobacco companies to talk to them about dealing with the press over their problems of alleged data manipulation for decades. The companies had their public relations (P-R) people under the legal staff, which was hopeless for P-R staff to get anything out. Mr. Greenberg felt that the press acts as a "court of last resort," after complainants have gone to the university, the funding agency, Congress, etc. But the press does not know them--while they have to be given a good hearing, he related a personal case in which one whistleblower tried to use him to counter-attack an agency OIG investigation, having committed fraud himself.

Mr. Pascal stated that, in general, the whistleblower has gotten a "bum rap" in press coverage.

Most cases consider questions of whistleblower bias, their integrity, the reasons they came forward, etc. (which may involve a personal or scientific dispute), and ignore the strong motive the accused has for presenting a one-sided or distorted view. The whistleblowers feel "left out in the cold" by the legitimate fear of retaliation and the negative publicity they have received. There is even a separate "whistleblower community" that sometimes says they do not want to bring cases to institutions or ORI, given a lack of trust. ORI does take confidential or anonymous calls and discusses the allegations with the caller and may refer them back to the institution if the allegations do not fall under the PHS definition. While ORI recognizes the difficulties whistleblowers have, it has to be balanced in handling allegations. Whistleblowers, do not "drive" the case in ORI. He said ORI is trying to issue a new policy in this area; he encouraged institutions to handle them in the same way (remaining neutral, not becoming their advocate). He added a plea to the research institutions to create "an environment of trust" where scientists can feel safe to question research and, where appropriate, make allegations of wrongdoing. The expectation should be that legitimate criticism is honorable, and those who speak up will not be punished but protected from harm.

Mr. Sharphorn added that the institutional officials do care about whistleblowers, but tend to know the accused better or to have known him/her for a longer period of time, as many are senior persons at the university. While there are laws protecting whistleblowers, you have to handle them sensitively and set aside their emotional response and anger. He stated that it is serious to come forward with an allegation, and it should be honorable to do so, a good thing, which we really need.

In the question period, Mr. Lynn Early (consumer rights advocate, retired) stated that FDA and NCI evidence is compromised by intense corporate lobbying. He objected to this Conference not including a "public representative," since "the public have a perception [of research integrity] and need to be heard." He noted three University of Michigan cases picked up by the national press (Ms. Carolyn Phinney won her case in court, in contrast to three university panels' decisions). He cited a recent *New England Journal of Medicine* article on corporate attempts to change research on channel antagonists and a book on *Media Monopoly* by Ben Bednade of the *Washington Post*. Mr. Bates stated that he had not had such experiences, even working at the university--there was no university/corporate influence on his reporting. Mr. Early claimed that "managing integrity" is a misnomer, and he gave a list of topics and apparent conflicts of interest. Dr. Joy Skeel (Medical College of Ohio) believed the word "whistleblower" has a pejorative edge to it. Mr. Sharphorn agreed but noted the statutes used that word; Mr. Pascal added that ORI's statute and the Federal Whistleblower Protection Act did too, as did an official of the Government Accountability Project who served on the HHS Commission. A student asked about lesser cases, noting graduate students' fear of damage to their careers if they become a whistleblower. Mr. Bates confirmed that one can be "marked" by being a plaintiff, making it less likely to be hired in the future. Mr. Sharphorn said that institutions should do as much as they can to protect complainants; in the area of sexual harassment and assault, the university has a center to help such persons. Mr. Jeffrey Knowles (Ohio Office of Criminal Justice Services) asked how they could get press interest in coverage of the police court matters (they do research on victimology and justice).

Dr. Eisendrath stated that the fastest way is from the top of one's bureaucracy direct to the media (the media prefers to use "the great person" to tell its story).

To a question from a Wisconsin staffer about where a reporter's "objective criteria" starts, Mr. Bates replied that it is in the eye of the beholder," that "sin" in the media exists, and that reporters and scientists are biased from their own viewpoint. Mr. Greenberg added that "no one is happy about a newspaper story about which they have knowledge," but if elements are "twisted," one can document it, can complain, and will be heard. He thought that newspapers do cover science, but the public may not read it. Ms. Jennifer Walters (Michigan Ombuds) stated that "The X Files" is one of the few science shows on television, but it also features a "government conspiracy." Noting that institutions and scientists are supposed to be self-policing, she asked how trust can be rebuilt. Mr. Bates noted that trust in the press is usually polled at below that of used-car salesmen. Dr. Eisendrath noted that after World War II, reporters were at the top of the trust polls, but now the media fall below even lawyers. Mr. Greenberg recalled that the National Science Foundation (NSF) supports a Public Opinion Research Center at the University of Chicago, which surveys public attitudes about science every two years, finding the public still puts scientists and physicians at the top, Congressmen and journalists at the bottom. He believed the idea that "the public does not appreciate science" has been fomented by the scientific community to generate pity for itself. Mr. Greenberg observed that, despite scientists' public statements, the NIH budget has not been cut but rather has increased enormously over 15 years. Mr. Bates stated that the public today is willing to readily accept allegations against scientists and institutions and that there is no longer a blind faith in science but rather an acceptance of the possibility of fraud.

Dr. Kimberley Quaid (Indiana University) said it scares the public to see corporate cultures taking scientists' discoveries for profit and makes it suspicious of the use of technology. Dr. Steneck (Michigan) believed that Congressman Dingell had a lot to gain from his attacks on science. Mr. Greenberg said Congressman Dingell had a very large agenda that went far beyond scientific misconduct--an issue he took on only grudgingly on the advice of his staff. He held only three or four days of hearings over five years on the topic, not as a thug or ruffian, but because he wanted NIH to clean up its own act and make good use of the taxpayers' money. Dr. Eisendrath closed by stating that every reporter knows from his editor that they should not overestimate the amount of data the public needs and their ability to make a decision. He recalled that former Secretary of State Henry Kissinger once said, "What will be said ultimately should be said immediately."

Session on Emerging Issues

Dr. Lawrence Rhoades (ORI) indicated that all the issues in scientific misconduct are still "emerging," but some are "on the horizon." He outlined the problems of (1) potential liability of institutional committee members (Baylor College of Medicine officials, committee members, and witnesses have been privately sued by a respondent for defamation in their reporting to ORI); (2) prevention of misconduct; (3) promotion of integrity; (4) expansion of the knowledge base on the incidence of misconduct; (5) detecting misconduct (it is almost always dependent upon the

whistleblower or a reviewer--one professor has suggested conducting data audits of papers); (6) under-reporting of misconduct and cultural taboos to "snitching;" and (7) rehabilitation of respondents.

Mr. Edward Goldman, Esq. (University of Michigan Medical Center Counsel) summarized the legal issues surrounding protection of human subjects and institutional review boards: (1) Congressional questions about the independence of and self-interest of IRBs; (2) whether one could obtain and use insider-information from serving on IRBs, such as research information that may affect whether a stock may rise in the future; (3) developing-countries and standards of health care; (4) pursuing emergency room research, on heart attack and stroke or accident victims; and (5) the managed health care market.

Dr. Howard Rush (University of Michigan Unit for Laboratory Animal Medicine Professor) described the established principles of humane use of animals in research. He noted the responsibilities of scientists to the animals, to the public (laws, standards, public health, and safety), and to science (to facilitate research; good science includes humane care). There is a need to balance animal welfare and research needs. While one can now design mice to study specific diseases, genetic engineering experiments leave a large number of failures. Xenotransplantation of organs from animals to humans is possible, with the prospect of "organ farms." Limited use of certain animal species remains an issue, with fewer dogs and cats used in recent years. He felt that the public does not trust animal researchers and does not know about IACUCs and the tight controls on animal research.

Ms. Elaine Brock, Esq. (University of Michigan Research Administration) delineated some principles of dealing with apparent conflicts of interest in technology transfer from the universities. She believed that (1) there "should be a line somewhere" that should not be crossed, but she recognized that the "beholder phenomenon" affects the placement of that line; (2) the line moves, depending on who the players are and what appears to be their motivation; (3) a lot of the responsibility for monitoring conflicts rests in the department chairs; (4) a management plan requires management, including disclosure and review by the chair and the conflict of interest faculty committee--and many faculty ask the chair if the effort is worth it; and (5) someone at the institution needs to define the motivation of the institution itself. At the University of Michigan, there is a long-existing conflict of interest review board. This board used to meet only on demand; now it meets twice weekly for two hours, some items taking over a year to resolve.

Ms. Katharina Phillips (Vice President, Council on Government Relations [COGR] in D.C.) summarized the advocacy role that COGR takes in reminding university officials of their responsibilities in meeting the federal regulatory requirements. COGR also advises federal agencies on their rule-making, trying to ensure the rules fit the institutions. She noted the danger that paperwork burdens may impede sharing research materials, and she noted the questions and concerns regarding restrictions that are imposed on materials received, such as those on the later publication of results. She asked if agreement to restrictions on the use of research materials also amounts to giving up control of one's research. She stated that patent protection is not an

obstruction to publication; typically there is a policy of allowing 60 to 90 days for industrial review of sponsored research findings prior to publication. Recently a major company asked universities to sign license agreements, restricting the use of materials in future research (referred to as prelocks). She cited a paper coauthored by Dr. Omenn in the *New England Journal of Medicine* on three case studies where special interest groups tried to manipulate university research and make accusations of misconduct. She also mentioned proposed new federal rules where NIH declared that, under exceptional circumstances, NIH (specifically NCI) could keep title to university inventions. However, given the objections, they may move back to giving inventors the rights and allowing exclusive licenses to be granted to industrial firms.

Closing Luncheon Comments

Dr. Alan Price (ORI) recalled his 17 years as a former member of the University of Michigan faculty and administration and his observation upon coming to Washington in the late 1980's that there was no community of scholars in the area of research integrity, unlike one which had developed in the area of protection of human and animal subjects. But today, as reflected in the speakers and audience of this U-M/ORI Conference, there is now a communal sharing of interests between scientists, historians, ethicists, philosophers, lawyers, engineers, business administrators, and students. He noted the strong role that Dr. Nicholas Steneck had played in this regard for two decades at the University of Michigan as well as in the Public Health Service's original Advisory Committee on Research Integrity. Dr. Price also reminded the group that research and the related misconduct issues go beyond faculty and graduate students to postdoctoral fellows, undergraduate students, technical staff, and survey or clinical study coordinators, all of whom have been respondents investigated and debarred from federal funding by ORI. He further noted that "whistleblower" was seen by some complainants as an unwanted designation; they wished to be recognized as members of the scientific community who were raising legitimate questions about data and conclusions in the normal conduct of research, and their role should be recognized as an appropriate one by scientists and research institutions.

Dr. Stuart Offenbach (Purdue University) asked how we could have an investigation but avoid the negative "tarring" of the reputation of those whose laboratories were involved, like Dr. David Baltimore. He also asked for more thought on how we should implement our ideas for education of researchers and instilling principles of integrity. He cited the 1993 ORI conference on plagiarism, organized by Dr. Price at ORI with AAAS, as his personal motivation for going forward as a professor at his own university to encourage ongoing development of solutions to research integrity issues.

Dr. Nicholas Steneck (University of Michigan) agreed that there has been an "amazing leap" since the 1980's, but he asked: (1) What are we talking about? (2) What are the ethical issues that arise out of the context of research? (3) What is misconduct (falsification, fabrication, plagiarism) in carrying out research? (4) What about the rest of the unprofessional behaviors, which fall around the gray line or questionable areas, of which there are many more than PHS-type "misconduct"? He also asked: (1) Are we talking too much? (2) Are we duplicating efforts (or

can we share, as in the University of Minnesota programs on its World Wide Web site)? (3) What resources are being spent, and are they spent rationally? Finally, he asked: Who cares? He said he knew Chris Pascal and Alan Price at ORI cared, but what of the larger Federal Establishment? The 1992 PHS Advisory Committee's recommendations remain unacted upon, despite a followup HHS Commission.

In the discussion period, Dr. Mark Brenner (University of Minnesota) remarked that one needs to get true "ownership" of these matters by academic administrators; a central administration effort alone will not be successful. A member of the audience noted that in history, since the Age of Enlightenment, many scientists have believed in an absolute right to do research as they chose, but he believed that the Public needs to have a voice as well. Dr. Steneck agreed, noting the Recombinant DNA debates of the 1970's in Ann Arbor and elsewhere, in which committees discussed the issues at public meetings with input from the local communities. While they were not able to decide on the ethical issues, they did assist in explaining and resolving the public safety issues. Dr. Rush (University of Michigan) also noted that the University's animal care committee includes two public citizens, providing valuable advice on local and personal concerns.

Ms. Judith Nowack (University of Michigan Assistant Vice President and the Conference organizer) thanked all the speakers, participants, and staff. She indicated that a evaluative questionnaire and all of the speakers' slides would be mailed to everyone who had registered for the meeting.

Alternative Dispute Resolution Workshop

Mr. Donald Perigo (Ombudsman in the Michigan Office of Consultation and Conciliation) described the range of mechanisms for settling disputes through "Alternative Dispute Resolution" (ADR): (1) preventative or preemptive (joint problem-solving and consensus building, for disputes that you know will arise); (2) negotiated (principled win/win, positional win/lose, or problem solving); (3) facilitated (third party negotiation, conciliation, use of an ombudsperson); (4) fact-finding (neutral expert or master involvement); (5) advisory (nonbinding arbitration); (6) imposed (binding arbitration); or (7) judicial (resolution in a court of law). He summarized the roles played: (1) complaint handler to listen in confidence, but it remains the complainant's prerogative as to whether to go forward at all; (2) advice off the record, even anonymously, but information may flow up to management on real problems with employees; (3) coaching of employees or managers on performance plans and evaluation; and (4) confidential counseling for groups. He showed a matrix of a system, with different roles of the players.

Ms. Sally Johnson, (Director of the Michigan Office of Consultation and Conciliation) said her office, a service of the human resources and affirmative actions areas, catches the "outfall." However, in the future, the office hopes to do more in preventing disputes between faculty and staff and other employees (persons who are only students, not paid by the university, are handled in a separate office). She noted that her office is constrained from going forward without the permission of the complainant/employee. Most research-related complaints deal with poor use of

grant resources and funds and authorship or credit disputes. Her office does not deal with scientific misconduct allegations, which they refer to the Vice President for Research. Only if there is serious criminal activity or serious legal harassment in a case will her office go forward itself. Conciliation is a voluntary dispute resolution between two parties, with one or two mediators who do not act as judges nor impose sanctions but play a neutral role in clarifying issues and trying to find some agreement through mutual understanding. There is no "penalty for trying" this system.

Mr. Chris Pascal (ORI) stated that ORI encourages alternative dispute resolution in appropriate circumstances and has included this mechanism in the existing ORI guidelines on whistleblower protection. Alternatives are for an institution to conduct an investigation, resolve the matter through negotiation, or go to binding arbitration when there are allegations of retaliation by the whistleblower. One ORI case of alleged retaliation was taken to binding arbitration by the institution and complainant, but it was settled privately before the formal ADR activity took place. ADR techniques are also available to resolve allegations that fall outside the PHS definition of misconduct or to resolve lingering disputes that remain after a misconduct investigation is closed without a finding of misconduct. He noted that ORI does not consider disputes over authorship or credit between collaborators to be plagiarism or other scientific misconduct. ORI is not competent to deal with such disputes, and there is too great a volume of them for ORI to do so.

Dr. Robert Bell (NSF Office of Inspector General) indicated that NSF is different and does not follow ORI's policy definition. NSF will consider some disputes between mentors and their students, for example, as serious deviations from commonly accepted practices.

Dr. Alan Price (ORI) described two cases that probably could have used ADR techniques at the start, but they did not; one tried ADR at the end, while the other went to trial. In one case, an intramural federal postdoctoral employee complained that her data should have been used and that she should have been first author on a manuscript submitted for publication; the PHS agency conducted an inquiry and referred the matter to ORI for investigation. ORI resolved a peripheral question about the origin of the data used in the submitted manuscript but returned to the PHS agency the issue of authorship and use of the complainant's data as falling outside the PHS definition of scientific misconduct. The agency then attempted to resolve the dispute in hopes of resubmitting a paper; however, the complainant had gone public with the dispute early in the case, making any agreement very difficult.

In the second case, a visiting graduate student claimed that she should get credit in all future grant applications and publications from her host institution for her efforts in developing a data base; this credit dispute fell outside the PHS definition. Nonetheless, the institution conducted an inquiry; it found no evidence of misconduct by her former collaborators to warrant further investigation. However, the complainant brought a *qui tam* suit and won a court decision; a later federal appeals court threw out the decision, finding instead on the side of the faculty and institution. Dr. Price stressed the importance of having an institutional official ensure at the start of a case whether or not the matter falls under the definition of scientific misconduct and merits

initiation of the elaborate inquiry/investigation process--or whether an ADR approach would be more appropriate.

Mr. Perigo (Michigan) noted in one case that the faculty senate wanted to require an ADR process be undertaken before the faculty grievance system process was initiated. Dr. Peggie Fischer (NSF OIG) asked how his office would handle a case that involved allegations of both plagiarism and other "nasty" acts. In other words, can the scientific misconduct and ADR processes really run simultaneously? Mr. Pascal (ORI) asked how many institutions represented among the 20 people in the audience had a formal ADR or ombudsperson process--only one so indicated, beyond the normal faculty grievance process.

Mr. Perigo (Michigan) described one case he had handled involving a postdoctoral fellow who felt he was being exploited by his mentor. The fellow had contributed ideas for a new grant application to support work in the mentor's laboratory, but the fellow really felt that he had to find an academic job and continue his career outside the institution for the sake of his family and himself. After sending numerous applications for positions for which he was very qualified and getting no positive expressions of interest, he mentioned his problem to the unit's secretary. She told him that she was leaving the office shortly, but she was discarding a draft letter in the wastebasket that might be of interest. The fellow returned later and read the draft, which was a slanderous letter of "recommendation" for him by the mentor. Unsure of what to do, he called the ombudsman, saying he felt trapped, suicidal, and in fear for his future if he stayed or objected to the mentor. Mr. Perigo said he agreed to help and contacted his ADR colleague at the institution to which the letter was addressed (in a state which made all such letters of recommendation available to the subject), asking that his colleague check the incoming letter to confirm that it contained the slanderous language (which it did, so the draft was not a "joke"). Mr. Perigo and the fellow then met with the department chair, who agreed to remove the mentor from this function and to write positive letters of recommendation for the fellow based on the Chair's knowledge of him. The fellow then got a good job.

In the comment period, one faculty member commented that he feared their advisors were not bringing forward allegations that should be handled as scientific misconduct, instead trying inappropriately to resolve them through ADR. Mr. Pascal, ORI, and Ms. Fischer, NSF OIG, stressed that although ADR techniques can be an appropriate way to resolve scientific and personal disputes, it is not appropriate to use them to deflect or mediate legitimate allegations of scientific misconduct. At the end, Ms. Nowack (University of Michigan) thanked the participants and closed the meeting.