ORI NEWSLETTER

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ANNUAL REPORT PUBLISHED FOR 1995

Eighty-four percent of the 38 extramural investigations closed by ORI in 1995 were conducted solely by institutions; 11 percent were conducted by ORI, and 5 percent were conducted by an institution and ORI. Three intramural investigations were also closed by ORI for a total of 41 investigations. ORI became involved in six extramural cases because they were carried over from its predecessor office or they concerned multi-center clinical trials.

The extramural cases resulted in 23 findings of misconduct and 15 findings of no misconduct. The intramural cases resulted in one finding of misconduct and two findings of no misconduct. No finding of misconduct was based solely on the "other practices" clause of the PHS definition of scientific misconduct.

Sixteen of 24 respondents were found to have committed scientific misconduct and were debarred from receiving Federal grants, contracts and cooperative agreements for 2 or 3 years. All but five of the respondents had multiple administrative actions imposed on them by the PHS. Forty-eight percent of the inquiries were completed within the 60-day time frame stipulated in the PHS regulation; 24 percent of the investigations were completed within the stipulated 120-day time frame.

ORI requested policies and procedures for responding to allegations of scientific misconduct from 295 institutions for review in 1995. Institutions were sent the results of the review and asked to submit a revised document when appropriate.

These are some of the facts presented in the *ORI Annual Report - 1995* available on the ORI home page along with summaries and descriptive statistics on 41 closed investigations, legal issues, retaliation complaints, reviews of institutional policies and procedures, and compliance reviews.

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POLICY REVISION REQUESTED FROM 69 INSTITUTIONS IN 1995 SAMPLE

Eighty-one percent of the institutional policies and procedures for responding to allegations of scientific misconduct reviewed by ORI in the 1995 sample were returned to institutions for revision because they failed to incorporate an average of 12 provisions in the PHS regulation (42 C.F.R. Part 50, Subpart A).

Besides fulfilling its monitoring responsibility, ORI conducts

these reviews because it has found that the availability of complete and accurate institutional procedures increases the probability that inquiries and investigations will be effectively and efficiently conducted and that complainants, respondents, witnesses, and the institutional community will be accurately informed about the process for handling allegations of scientific misconduct.

In April 1995, ORI requested policies and procedures from 93 institutions. In response, 5 institutions withdrew their assurances and became ineligible to receive PHS support, 4 submitted small organization agreements, and 84 institutions submitted 85 written policies. Under a small organization agreement, the institution collaborates with ORI in responding to the allegation. A small organization is defined as having less than 10 members.

Sixteen policies and procedures were accepted without revision. The other 69 contained from 3 to 36 deficiencies. There was a median number of 13 deficiencies noted. See Table 1. As of May 1996, ORI has accepted 56 revised documents. Thirteen of the 56 institutions submitting revised documents adopted the ORI Model Policy for Responding to Allegations of Scientific Misconduct with appropriate adaptation.

In April, ORI requested policies and procedures from 82 institutions in the 1996 sample. Review reports will be sent to institutions in this calendar year. Institutions are afforded 90 days to submit a revised document if deficiencies are found.

Table 1: Number of deficiencies found in review of institutional policies and procedures for responding to allegations of scientific misconduct: 1995 sample.

Number of Deficiencies	Number of Policies
30 to 36	6
20 to 29	23
10 to 19	21
Zero to 9	35
Total	85

The deficiencies noted in the policies and procedures reviewed in 1995 covered every provision in the regulation. Each provision was not incorporated by a minimum of 11 institutions and a maximum of 51 institutions.

Thirty-nine policies and procedures did not explicitly cover all persons who are supported by PHS research funding. In many cases the policies covered faculty, and sometimes, staff. However, these terms were not defined so it was not clear whether postdoctoral fellows, technicians, and nurses were covered. Graduate and undergraduate students were not covered in most policies.

The definition of scientific misconduct was not stated or major elements of the PHS definition were not included in 26 policies. Missing elements included falsification, plagiarism and the other practices clause. In addition, falsification and fabrication were frequently limited to data in the policies when no such restriction exists in the regulation. Several policies did not include "proposing" research in their definition.

The overwhelming number of deficiencies occurred because provisions in the regulation that apply to inquiries and investigations were not incorporated at all or were included in the inquiry or the investigation section of the policy, but not in both. Many of these deficiencies could be eliminated by listing the procedures in a general section.

Provisions that apply to inquiries and investigations include: securing appropriate expertise to conduct a thorough evaluation of the evidence, elimination of conflicts of interest, maintaining confidentiality of the proceedings, providing the reports to the respondent for comment, restoring the reputation of the respondent when the allegation is unconfirmed, protecting the position and reputation of the complainant who makes a good faith allegation, and maintaining detailed documentation to substantiate the findings.

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ORI RELOCATED IN OPHS

A departmental reorganization has placed ORI in the Office of Public Health and Science (OPHS) within the Office of the Secretary of Health and Human Services.

The reorganization also merged the Office of the Assistant Secretary for Health (ASH) with the Office of the Secretary and established the eight PHS agencies as operating divisions reporting directly to the Secretary. The ASH heads OPHS and serves as senior advisor for public health and science to the Secretary.

Other OPHS offices are women's health, minority health, emergency preparedness, population affairs, international and refugee

health, disease prevention and health promotion, surgeon general, HIV/AIDS policy, and the President's Council on Physical Fitness and Sports.

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CASE SUMMARIES

James H. Abbs, Ph.D., University of Wisconsin-Madison. Based on an investigation conducted by its Division of Research Investigations (DRI), ORI found that Dr. Abbs engaged in scientific misconduct by falsifying and fabricating certain figures and research results supported by Public Health Service (PHS) grants and reported in "Orofacial motor control impairment in Parkinson's disease" (*Neurology* 37:394-398, 1987).

ORI found that Dr. Abbs falsified Figure 1 in the Neurology paper, which displays orofacial motor control instability in a Parkinson's disease patient reported as non-tremorous, by (1) tracing the waveforms from those of a tremorous patient that had previously been published as Figure 6 in the *Journal of Speech and Hearing Research* (26:616-621, 1983); (2) eliminating the apparent tremors from the waveforms depicted in Figure 6; (3) falsifying the standard force levels and structures from those of Figure 6; and (4) misrepresenting the identity of the actual subject reported in Figure 1. ORI also found that Dr. Abbs falsified and fabricated the data for Figures 2 and 4 in the *Neurology* paper by (1) falsifying the number of trials run on each subject; (2) misrepresenting the number of measurements made on each of the waveforms; and (3) fabricating the numbers used to calculate the force instability results presented for Figure 2. Dr. Abbs used the same fabricated numbers in Figure 4.

To avoid the uncertainty and expense of litigation, Dr. Abbs and ORI agreed to resolve the case through a negotiated settlement agreement, which the parties agreed shall not be construed as an admission of liability or wrongdoing on the part of Dr. Abbs. As part of the agreement, Dr. Abbs submitted a letter to ORI in which he addresses each of ORI's findings and explains in more detail the reasons for his decision to settle this matter on these terms. Dr. Abbs has agreed not to appeal ORI's jurisdiction or its findings and has further voluntarily agreed: (1) to exclude himself voluntarily from serving in any advisory capacity to PHS, including but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of 3 years beginning on March 28, 1996; (2) that any institution which submits an application for PHS support for a research project that proposes Dr. Abbs' participation or that uses Dr. Abbs in any capacity on

PHS-supported research, or that submits a report of PHS funded research in which Dr. Abbs is involved, must concurrently submit a plan for supervision of Dr. Abbs' duties, designed to ensure the scientific integrity of Dr. Abbs' research, for a period of 3 years beginning on March 28, 1996; (3) that any institution employing Dr. Abbs be required to submit, in conjunction with each application for PHS funds or report of PHS funded research in which Dr. Abbs is involved, a certification that the data provided by Dr. Abbs are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application or research report for a period of 3 years beginning on March 28, 1996; and (4) to submit a letter to the journal *Neurology* advising it of ORI's request to retract the *Neurology* paper.

Gail L. Daubert, R.N., Northwestern University. Based on an investigation conducted by DRI, ORI found that Ms. Daubert while serving as clinic coordinator for the Collaborative Ocular Melanoma Study (COMS) at Northwestern University, committed scientific misconduct by falsifying clinical trial data. The multicenter COMS involves research on the treatment of choroidal melanoma, a rare form of eye cancer and is supported by NIH. The study is still ongoing, and no results have been published.

ORI found that Ms. Daubert falsified 211 data items, including falsely stating that a radiation oncologist had evaluated patients prior to randomization, falsely reporting laboratory blood test results were normal when they were abnormal, falsely reporting that dates for patient visits or procedures had been performed within the specified protocol window when the actual date was outside the protocol window, and falsely reporting that a COMS certified examiner had performed an evaluation or procedure when a non-certified examiner had performed the task.

Ms. Daubert has entered into a Voluntary Exclusion Agreement with ORI in which she does not admit to any acts of scientific misconduct, but she has agreed to exclude herself voluntarily for the 3-year period beginning March 4, 1996, from: (1) contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in grants and cooperative agreements of the United States Government; and (2) serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

The voluntary exclusion, however, shall not apply to Ms. Daubert's future training or practice of clinical medicine as a

nurse, unless that practice involves research or research training, or to Ms. Daubert's participation in or eligibility for any Federal program relating to student loans, education grants, or educational assistance of any type or kind, for which she would otherwise be qualified to receive or be considered to receive educational assistance, unless that educational assistance involves research or research training.

Jamal Z. Farooqui, Ph.D., University of Cincinnati College of Medicine (UCCM). Based on an investigation conducted by the institution as well as information obtained during its oversight review, ORI found that Dr. Farooqui, Research Associate Professor, Department of Dermatology at UCCM, committed scientific misconduct by plagiarizing material in a PHS grant application from an application another researcher had submitted to the National Science Foundation (NSF). Dr. Farooqui received the NSF application from another faculty member at UCCM while that application was undergoing confidential peer review. Dr. Farooqui included the plagiarized material in the "Prospective Significance" and "Methodology" sections of his application entitled "Proopimelanocortin expression in human epidermis," submitted to the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

Dr. Farooqui has entered into a Voluntary Exclusion Agreement with ORI in which he has voluntarily agreed, for the 3-year period beginning April 3, 1996, that he will (1) certify in every PHS research application or report that all contributors to the application or report are properly cited or otherwise acknowledged, that an institutional official must endorse the certification, and that the institution must send a copy of the certification to ORI and (2) exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

No scientific publications were required to be corrected as part of this agreement.

Andrew Friedman, M.D., Harvard Medical School (HMS). Based on a report from HMS and Dr. Friedman's admission, ORI found that Dr. Friedman former HMS Associate Professor of Obstetrics, Gynecology, and Reproductive Biology at the Brigham and Women's Hospital (BWH), committed scientific misconduct by falsifying and fabricating data in research supported in part by a PHS grant to the BWH General Clinical Research Center.

Between 1992 and 1995, Dr. Friedman altered and fabricated information in permanent patient medical records and notes by changing dates, changing and adding text, and fabricating notes for clinical visits that did not occur. Dr. Friedman admitted that he had falsified and fabricated approximately 80 percent of the data in research reports published in Friedman, A.J. and Thomas, P.P. "Gonadotrophin-releasing hormone agonist plus estrogen-progestin 'add-back' therapy for endometriosis-related pelvic pain." *Fertility and Sterility* 30:236-41, 1993, in Friedman, A.J. and Thomas, P.P. "Does low-dose combination oral contraceptive use affect uterine size or menstrual flow in premenopausal women with leiomyomas?" *Obstetrics and Gynecology*, pp. 631-635, 1995, and in an unpublished manuscript.

Dr. Friedman has entered into a Voluntary Exclusion Agreement with ORI in which he has voluntarily agreed (1) to exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in Federal grants and cooperative agreements for a period of 3 years beginning April 19, 1996; (2) that for a period of 2 years immediately following the 3 year voluntary exclusion above, any institution that submits an application for PHS support for a research project on which Dr. Friedman's participation is proposed or that uses him in any capacity on PHS supported research must concurrently submit a plan for supervision of his duties; the supervisory plan must be designed to ensure the scientific integrity of Dr. Friedman's research contribution, and the institution must submit a copy of the plan to ORI; and (3) to exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of 3 years beginning April 19, 1996.

The voluntary exclusion in (1) above shall not apply to Dr. Friedman's future training or practice of clinical medicine whether as a medical student, resident, fellow, or licensed practitioner, as the case may be, unless that practice involves research or research training.

A statement retracting the article entitled "Gonadotrophin-releasing hormone agonist plus estrogen-progestin 'add-back' therapy for endometriosis-related pelvic pain" has been published in *Fertility and Sterility* (65(1):211, January 1996) and a statement retracting the article entitled "Does low-dose combination oral contraceptive use affect uterine size or menstrual flow in premenopausal women with leiomyomas?" has been published in *Obstetrics and Gynecology* (85(5):728, November 1995).

Joan Gans, R.N., Denver Department of Health and Hospitals (DDHH). Based on an audit of records conducted by NIH and Ms. Gans' admission, ORI found that Ms. Gans, while employed at the Denver Community Program for Clinical Research on AIDS at the Department of Public Health, DDHH, committed scientific misconduct by falsifying and fabricating data related to patients entered on clinical trials. The research was supported by an NIH contract.

Ms. Gans has entered into a Voluntary Exclusion Agreement with ORI in which she has voluntarily agreed: (1) to exclude herself from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in grants and cooperative agreements for a period of 2 years beginning April 4, 1996; (2) that for a period of 1 year immediately following the 2-year voluntary exclusion above, any institution that submits an application for PHS support for a research project on which Ms. Gans' participation is proposed or that uses her in any capacity in PHS-supported research must concurrently submit a plan for supervision of her duties, the supervisory plan must be designed to ensure the scientific integrity of Ms. Gans' research contribution, and the institution must submit a copy of the plan to ORI; and (3) to exclude herself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of 3 years beginning April 4, 1996. The voluntary exclusion, however, shall not apply to Ms. Gans' future training or practice of clinical nursing whether as a nursing student, resident, fellow, or licensed nurse, as the case may be, unless that practice involves research or research training. No scientific publications were required to be corrected as part of this Agreement. The questioned data will be excluded before any findings of the affected clinical trials are reported.

Cathy Q. Lee, Ph.D., Massachusetts General Hospital (MGH). ORI found that Dr. Lee, Postdoctoral Fellow, Molecular Endocrinology Laboratory at the MGH, committed scientific misconduct by engaging in falsification and fabrication of research data incorporated in a manuscript prepared for submission (but not submitted) to the *EMBO Journal* (Lee, C.Q., Yun, Y., and Habener, J.F. "Transactivation of functions of cAMP-responsive transcription factor CREB-327 mediated by amphiphatic helical domains flanking the requisite serine-119 phosphorylated by protein kinase-A.") and by engaging in improper data selection and falsification of data published in the *EMBO Journal* (Lee, C.Q., Yun, Y., Hoeffler, J.P., and Habener, J.F. "Cyclic-AMP

responsive transcriptional activation of CREB-327 involves interdependent phosphorylated subdomains." *EMBO Journal* 9:4455-4465, 1990.). This research was supported by a PHS grant.

Dr. Lee has entered into a Voluntary Exclusion Agreement with ORI in settlement of ORI's finding of scientific misconduct and has agreed: (1) to exclude herself voluntarily from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, Federal grants and cooperative agreements for a period of 2 years beginning on February 28, 1996. The voluntary exclusion, however, shall not apply to Dr. Lee's future clinical laboratory training or practice, unless that training or practice involves research or research training; (2) that for a period of 1 year beginning immediately after the 2-year voluntary exclusion above, any institution that submits an application for PHS support for a research project on which Dr. Lee's participation is proposed or which uses Dr. Lee in any capacity on PHS supported research, must concurrently submit a plan for supervision of her duties. The supervisory plan must be designed to ensure the scientific integrity of Dr. Lee's research contribution, and the institution must submit a copy of the supervisory plan to ORI; and (3) to exclude herself voluntarily from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of 3 years beginning on February 28, 1996.

A letter retracting the article entitled "Cyclic-AMP responsive transcriptional activation of CREB-327 involves interdependent phosphorylated subdomains" has been published in the *EMBO Journal* 13:2736, 1994.

Danya J. Vardi, Harvard Medical School (HMS). Based on an investigation conducted by the institution as well as information obtained by ORI during its oversight review, ORI found that Ms. Vardi, former HMS Research Associate in Psychology in the Department of Psychiatry at the Massachusetts Mental Health Center and former part-time Research Assistant at the Cambridge Hospital, committed scientific misconduct. ORI found that Ms. Vardi fabricated subject responses regarding recall and recognition of words having an emotional valence in research supported by a PHS grant entitled "Psychophysiologic study of child abuse imagery in adults" at the Manchester New Hampshire VA Research Center.

Ms. Vardi has entered into a Voluntary Exclusion Agreement with

ORI in which she has agreed to exclude herself voluntarily, for the 3-year period beginning March 28, 1996, from: (1) contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, grants and cooperative agreements of the United States Government, and (2) serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

The above voluntary exclusion, however, shall not apply to Ms. Vardi's future clinical training or practice whether as a student, resident, fellow, or licensed practitioner, as the case may be, unless that practice involves research or research training. No scientific publications were required to be corrected as part of this agreement.

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AAAS ANNOUNCES NEW VIDEO SERIES ON RESEARCH INTEGRITY

The American Association for the Advancement of Science (AAAS) has produced a series of five ten-minute videos for use in educational programs and discussions to help scientists assess their responsibilities for maintaining the quality and integrity of their research. The videos dramatize hypothetical situations in research that raise ethical issues, but leave them unresolved in order to stimulate discussion.

Issues such as the role and responsibilities of mentors and lab chiefs, determination of authorship, allocation of credit, data selection, whistleblowing, handling privileged information, as well as practices relating to the retention, sharing and reporting of data, are among the topics addressed. A discussion and resource guide accompanies the series. It includes discussion questions and a bibliography of related subject matter.

The video series was a collaborative project of the AAAS, Amram Nowak Associates, and the Health Sciences Communication Center of the Medical College of Georgia. It was funded by grants from ORI, NIH, and the Agricultural Research Service.

For additional information, contact the Directorate for Science and Policy Programs, AAAS, 1200 New York Ave., N.W., Washington, D.C. 20005; Fax: (202) 289-4950; or E-mail: science-policy@aaas.org.

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SOME APPLICANTS FALSIFY CREDENTIALS FOR RESIDENCY PROGRAM

Emergency medicine residency applications may contain

misrepresented citations, according to a recent study published in the March 1996 issue of *Annals of Emergency Medicine* ["Misrepresentation of research publications among emergency medicine residency applicants" by S.V. Gurudevan and W.R. Mowe, 1996; 27: 327-330]. The study also found that the number of misrepresentations increased significantly as the number of citations increased.

Publications were cited on 113 applications (32.3%) of the 350 applications submitted to UCLA Emergency Medicine Residency Program for the 1995 and 1996 entering classes. All cited publications were examined to determine whether the citations were genuine or misrepresented. Twenty-three applicants were found to have misrepresented citations, representing 20.4% of those who cited publications and 6.6% of all applicants. Misrepresentations were found in 8 of 56 applications listing single citations (14.3%), 8 of 46 applications (17.4%) claiming 2-4 citations, and 7 of 11 (63.6%) applications claiming 5 or more citations.

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MACFARLANE NAMED ACTING DRI DIVISION DIRECTOR

Dorothy K. Macfarlane, M.D., has been appointed Acting Director of the Division of Research Investigations (DRI) within ORI. She replaces Chris B. Pascal, J.D., who was appointed Acting Director, ORI, after Dr. Bivens' retirement in March. Dr. Macfarlane served as Deputy Director, DRI, before assuming her new position.

Previously, Dr. Macfarlane served as Acting Director, DRI, for 19 months before becoming Deputy Director, DRI, in February 1995. She joined the former Office of Scientific Integrity (OSI) in February 1992 as Senior Medical Officer and continued in that position when it became ORI. Dr. Macfarlane worked for the National Cancer Institute for 15 years before joining OSI.

PUBLICATIONS*

"Scientific Misconduct and the Plagiarism Cases" by Debra Parrish. *Journal of College and University Law* 21(3): 517-554. (Winter, 1995). Examines how plagiarism has been defined and applied to scientific misconduct.

Moral Reasoning in Scientific Research: Cases for Teaching and Assessment is a 100-page booklet of materials for teaching the responsible conduct of science in college and university courses. For more information, contact Kenneth Pimple, Poynter Center, 410 North Park Ave., Indiana University, Bloomington, IN 47405, (812)

855-0261; Fax (812) 855-3315; or pimple@indiana.edu.

"The False Claims Act: Litigating Scientific Misconduct" by Susan E. Sherman. *Public Health Reports*, Vol. 110: 784-789 (November/December, 1995). Compares litigation with administrative resolution of scientific misconduct allegations and discusses implications for recipients of PHS research funds. For copies, contact the author at Room 2B-50, Building 31, NIH, 31 Center Drive, MSC 2111, Bethesda, MD 20892-2111; tel. (301) 496-6043; fax (301) 402-1034.

The False Claims Act and Qui Tam Quarterly Review is published by Taxpayers Against Fraud, The False Claims Act Center. It provides an overview of major False Claims Act and qui tam developments, including case decisions, Department of Justice interventions, and settlements. For more information, contact the Center at 1220 19th St. N.W., Suite 51, Washington, D.C. 20036; (202) 296-4826; Fax (202) 296-4838; or Internet: http://www.taf.org/taf or taf-info@taf.org.

Scientific Deception is a 120-page book written by Leslie Grayson. London: British Library, 1996. A review by Stephen Lock, former editor, appeared in the March 16 issue of the *British Medical Journal*.

MEETINGS*

July 21-25, 1996. A four-day conference will be held on "Ethics in the Professions and Practice." Participants will take part in a focused seminar on a topic of special relevance to their teaching, research, or practical or professional interests and will have an opportunity to present their own work. Plenary lectures on practical and professional ethics topics cutting across the disciplines are part of each day. Contact the Association for Practical and Professional Ethics, 410 North Park Ave., Bloomington, IN 47405; (812) 855-6450; Fax (812) 855-3315; appe@indiana.edu; http://ezinfo.ucs.indiana.edu/ appe/home.html.

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U.S.Department of Health and Human Services
Office of the Secretary
Office of Research Integrity
5515 Security Lane, Suite 700
Rockville, Maryland 20852

Office of the Director.....(301) 443-3400
FAX.....(301) 443-5351
Division of Policy and Education...(301) 443-5300

FAX.....(301) 443-5351
Assurances Program.....(301) 443-5300
FAX.....(301) 443-0042
Div. of Research Investigations....(301) 443-5330
FAX.....(301) 443-0039
Research Integrity Branch/OGC.....(301) 443-3466
FAX.....(301) 443-0041

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