

**NATIONAL INSTITUTES OF HEALTH**  
**Deputy Ethics Counselors/Ethics Coordinators**  
Minutes – July 13, 2004 – 1:00 pm – Bldg 50, Room 1227

**1. Update on OMA Investigation**

Holli Beckerman Jaffe

The purpose of the OMA investigation is to ensure consistency across the ICs. Congress identified a discrepancy between the names on the spreadsheets which NIH submitted and the lists of names received from the pharmaceutical companies. Names on the discrepancy list were sent to the ICs without any further information. Discrepancies may be caused by the pharmaceutical listing funds which actually went to an IC gift fund or were paid to the Government through the sponsored travel mechanism. Apparently, OMA opted to give only the names without further information to the ICs so the IC research and analysis to resolve the discrepancy would be 'less biased,' i.e., ICs would look more closely at all activities rather than just a single activity on the list. The contact at each IC for this exercise is the Executive Officer rather than the Deputy Ethics Counselor.

Attendees expressed a desire to resolve discrepancies themselves and then share information with OMA, both to better understand what they are looking for and to reduce the workload of copying everything for the employees on the list. In addition, they expressed a desire for clarification of the names on the list, where they came from, and whether the employee had been notified. It was noted that employees were not provided the names of the companies who divulged their name to prohibit the employee from contacting the company and to avoid any issues between Congress and the companies. Concern was expressed that employees are self-reporting all activities with drug companies, including CRADAs, which may be a source of some of the discrepancies.

**ACTION:** Ms. Jaffe will discuss the issues and process again with Dr. Kington and with the Office of Management Assessment staff, and inform the ethics community of the outcomes. Until then, OMA instructions are to be followed.

**2. Proposed Changes in the NIH Ethics Program**

Holli Beckerman Jaffe

Until further notice, all current rules and policies remain in effect. The NIH is considering several changes in policies and procedures regarding the ethics program at NIH (see Dr. Zerhouni's testimony before Congress on June 22, 2004 at [http://www.nih.gov/about/ethics\\_COI.htm](http://www.nih.gov/about/ethics_COI.htm)). NIH staff are working with the Department to draft regulations where needed. In addition, NIH is drafting working definitions, policies, and procedures, which will be distributed as it becomes available. In the interim, ethics staff need to carefully review the science for a proposed outside activity, confirm that the scientific content is not related to current official work, and that the employee has no official interaction or relationship with the outside organization for the outside activity.

Follow up: See the memo from Dr. Kington to IC Directors entitled "Update on NIH Policies for Managing Conflicts of Interest and the attached COI Discussion Points, dated 7/16/04.

**3. Expert Witness Outside Activity**

Holli Beckerman Jaffe

Attendees were reminded that employees must obtain separate approval to serve as an expert witness, unless it was included in the original request. For example, an NIH physician providing patient care in a local facility as an outside activity cannot be an expert witness based on that outside position. If the physician is asked to provide expert witness services as a result of that position, s/he must still obtain advance approval to serve as an expert witness. Emphasize to your employees the

need to be thorough in describing the extent of consultation and expected activities with law firms to avoid unapproved expert witness service.

An employee who happens to be an attorney may receive approval to conduct private legal practice without identifying each client. The blanket approval would permit the attorney to practice in a state court, as long as no other statutes or regulations are violated (e.g., representational or partnership income resulting from federal case).

Reminder: Only the HHS DAEO can approve service as an expert witness in relation to a case pending or to be filed in Federal court. That request must receive approval by the supervisor and DEC prior to review/decision by the DAEO. See the sample memo distributed at the 2003 HHS DEC Workshop for requesting DAEO approval.

**4. Office of Inspector General Investigation** Holli Beckerman Jaffe

The OIG staff emphasized that they are conducting an evaluation of how policies and procedures are followed, not an investigation into any specific allegation or issue.

**5. NEAC Issues** Holli Beckerman Jaffe

It was noted that the process continues to be very time-consuming and decisions are not always readily available. Ms. Jaffe emphasized that anyone can call and request that a particular activity be moved up the queue for review. She also emphasized again that employees must adequately distinguish between current official duties and the proposed outside activity (i.e., the responses on the unnumbered supplemental information form).

**ACTION:** Ethics staff will inform Ms. Jaffe if a particular request is withdrawn so it does not go to NEAC for review.

**6. Training** Holli Beckerman Jaffe

Attendees discussed how to strengthen the annual ethics training, possibly by providing in-person training to every employee this year. Some ICs already require all employees to complete annual training, using the web-based training system via the NIH Ethics Program web site. Those ICs which require new employees to complete the New Employee Ethics Orientation may require fewer modules for the annual ethics training.

**ACTION:** Elton Croy will lead a group to develop ideas for training for presentation to Dr. Kington.

**7. Working Groups** Sheila Pohl

Sheila Pohl, Jeanellen Kallevang, Anne Stroh, Genia Bohrer, Elaine Ayres, and Eileen Dominick-Holschuh met to draft ideas for setting up working groups to assist the NIH Ethics Program (all ICs). The draft proposal was distributed electronically to the DEC/EC community. The purpose of each group would be to look at a specific area and develop recommendations for review and approval by the DEC/EC group, the Director of the NIH Ethics Office, and the NIH Deputy Ethics Counselor. Suggested groups include: EMIS, Training, Financial Disclosure. Groups could be convened for a short term to review a specific issue, or could be standing committees of the NIH ethics community. The consensus was to establish such groups; there were no objections. Suggestions were made for group topics, including training and defining official duty activities (already being worked on by NIH Ethics Office staff).

**ACTION:** Elton Croy is already working on training issues so will form and lead the training working group. Let him know if you are interested in joining. The first meeting will occur immediately after today's DEC/EC meeting.

**ACTION:** Let Sheila Pohl know if you wish to join a group, or if you have suggestions for needed groups.

**Follow Up:** On 7/21, Ms. Pohl distributed via email a request to vote on needed groups and/or volunteer to serve. Due date is Monday, July 26<sup>th</sup>.

## 8. Financial Disclosure and Criminal Violations

Gretchen Weaver

Ms. Weaver recently drafted language to inform staff about the consequences of incorrect reporting on financial disclosure reports and obtaining advance approval for outside activities. The issue was whether there are penalties for not reporting outside activities on a financial disclosure report, or reported but the employee did not obtain advance approval. Draft language is summarized as follows:

Under the Ethics in Government Act, an individual who knowingly and willfully falsified or fails to disclose reportable information on a public financial disclosure report (SF 278) can be subject to civil penalties in an action brought by the Department of Justice (DoJ). If an agency has reasonable cause to believe that an individual has willfully failed to file a report, or failed to report required information, the agency must refer the matter to DoJ for further action. In addition, in all cases (e.g., both public and confidential OGE 450 filers), where an employee fails to file or report required information, and regardless of whether such failure is knowingly and willfully, agencies may take appropriate administrative action. Failure to seek prior approval for an outside activity does not, itself, constitute a criminal act.

At issue is whether it is perjury to report the activity in one place but not in another, e.g., give a speech without approval and then report it, or if they get approval and then do not report it on the financial disclosure report. These actions could result in administrative penalties.

**RECOMMENDATION:** Ethics staff should subscribe to the OGE LISTSERV to receive updated information and DAEOgrams, to keep abreast of the latest information. For example, the recent "Prosecution Summary" provides helpful examples to understand the effect of infractions.

**Next Regularly Scheduled DEC/EC Meeting:** Tuesday, August 10, 2004; 1:00 pm  
Bldg 50, Room 1227