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**Analysis of Disclosures, Agency Investigation and Reports,  
and Comments of the Special Counsel**

**OSC File No. DI-05-0430**

**Summary**

The disclosures in this matter were made by Dr. Ted Martonen, a Senior Research Scientist at the Environmental Protection Agency (EPA), National Health and Environmental Effects Research Laboratory (NHEERL), Research Triangle Park, North Carolina.

Dr. Martonen alleged that other research scientists at NHEERL experimented on human subjects without their informed consent and that EPA officials covered up this wrongdoing once it was brought to their attention. In particular, Dr. Martonen alleged that Chong Kim, a research scientist in the Human Studies Division (HSD) of NHEERL, led a research team that exposed human subjects to doses of di-2-ethylhexyl sebacate (sebacate) and other potentially dangerous compounds as much as one hundred times greater than the doses to which the subjects consented. Dr. Martonen further alleged that EPA officials repeatedly mischaracterized the wrongdoing he identified as merely technical violations of EPA protocol. Given these mischaracterizations, Dr. Martonen contended, any notice provided to the affected subjects regarding their overexposure must necessarily have been misleading.

The EPA Office of the Inspector General (OIG) investigated Dr. Martonen's allegations and found that although test subjects were exposed to sebacate in amounts greater than that to which they consented, the over-exposure was not proved to be intentional and was not at the levels alleged by Dr. Martonen. The investigation also found that the over-exposure posed no health risk to the subjects, as sebacate is not a hazardous substance; there was no evidence of intentional or willful misconduct on the part of Dr. Kim, and that EPA timely addressed the issues raised by the over-exposure.

OSC finds that the agency's report contains all of the information required by statute and that its findings appear to be reasonable.

**The Whistleblowers' Disclosures**

Dr. Martonen contended that he first discovered the wrongdoing that forms the basis of his disclosure when he was asked by Linda Birnbaum, his supervisor in the Experimental Toxicology Division at NHEERL, to mathematically model data collected in experiments conducted by Dr. Kim. According to Dr. Martonen, he later confirmed his understanding of the

data he had previously reviewed when a graduate student he supervised had an opportunity to study Dr. Kim's research in connection with her own dissertation research.

In particular, Dr. Martonen alleged that Dr. Kim conducted experiments on human subjects in which he and his research team systematically exposed subjects to doses of sebacate at least one hundred times greater than those to which they consented. Dr. Martonen believed that Dr. Kim's experiments were conducted from 1997 through 2002. For at least part of that time, Dr. Birnbaum oversaw Dr. Kim's work as director of HSD.

Dr. Martonen alleged that Dr. Kim's overexposure of his subjects constituted a violation of 40 C.F.R. § 26.116, which prohibits all human subject experimentation without "legally effective informed consent," and 40 C.F.R. § 26.117, which requires written documentation of that consent. In addition, Dr. Martonen alleged that Dr. Kim's experiments created a substantial and specific danger to public health. According to Dr. Martonen, the scientific literature suggests that sebacate may be hazardous to health. Even if it is not, however, Dr. Martonen maintained that he was able to determine from the log books he reviewed that sebacate was being used as a control in Dr. Kim's experiments. Dr. Martonen alleged, therefore, that the human subjects of Dr. Kim's experimentation must have been exposed to other compounds more dangerous than sebacate in doses greater than those to which they consented.

Dr. Martonen further stated that he repeatedly brought his concerns regarding Dr. Kim's experiments to the attention of EPA management, but management personnel, including Paul Gilman, a former Assistant Administrator, have insisted on characterizing the overexposure that occurred as a minor, unintentional violation of approved protocol. Dr. Martonen alleged, to the contrary, that Dr. Kim's experiments violated federal regulations that embody the minimum requirements of ethical scientific research. Based on the log books he reviewed, Dr. Martonen further alleged that Dr. Kim's data could only have been generated by the intentional overexposure of his subjects. That is, Dr. Martonen contended that Dr. Kim deliberately and systematically overexposed his subjects in violation of federal regulations and the basic principles of ethical scientific research.

According to Dr. Martonen, Dr. Gilman and Harold Zenick, Director of the Office of Health, informed him that an EPA investigation found no indication of intent on the part of Dr. Kim and that an independent review panel concluded that the overexposure occurring in the course of Dr. Kim's experiments posed no health risk to the human subjects involved. Dr. Martonen alleged, however, that he spoke with a witness to the proceedings of the independent review panel in question and determined that Dr. Birnbaum misdirected the panel's deliberations in order to avoid any serious consideration of the concerns he raised regarding Dr. Kim's experiments.

Finally, Dr. Martonen alleged that any notice provided to the subjects of Dr. Kim's experiments was necessarily inadequate. Dr. Martonen acknowledged Dr. Gilman's assertion in a July 27, 2004, letter that the EPA "mailed notification letters to the subjects of the experiment informing them of the error" in the dosage of sebacate to which they were exposed. Even so, he contended that to the extent that EPA management insisted on characterizing the overexposure in

question as a minor, unintentional violation of protocol, these notices must be misleading. Thus, Dr. Martonen maintained that the EPA has yet to adequately address the wrongdoing that occurred in the course of Dr. Kim's research.

### EPA Report

The OIG conducted the investigation of Dr. Martonen's allegations at the request of The Honorable Stephen L. Johnson, Secretary, EPA. The findings of the investigation were based largely on the results of an independent scientific review conducted by an outside expert consultant, and also on statements from members of the Institutional Review Board (IRB) and the Human Subject Review Panel (HSRP), as well as EPA scientists.

The agency report contained a summary of the information resulting from the investigation, which addressed five specific issues involved in the allegations. These included whether 1) Dr. Kim intentionally exposed human subjects to doses of sebacate at least one hundred times greater than the doses to which the subjects consented; 2) the human subjects involved were exposed to other potentially more dangerous substances; 3) EPA officials concealed or downplayed the wrongdoing; 4) Dr. Birnbaum misdirected the HSRP in order to avoid serious consideration of the concerns about Dr. Kim's experiments; and 5) notice to the human subjects was inadequate and misleading.

According to the agency report, the investigation substantiated Dr. Martonen's allegations that human test subjects were exposed to sebacate in amounts greater than that to which they consented. The agency report did not substantiate Dr. Martonen's allegations that the over-exposure was intentional, or at the levels alleged by Dr. Martonen or which would be dangerous. The report found that sebacate is not a hazardous substance and did not pose a health risk to the subjects. Further, the agency report did not substantiate Dr. Martonen's allegations that the over-exposure was intentional or willful, or that the agency attempted to cover-up or minimize the over-exposure.

First, the agency examined the question whether or not sebacate is considered a dangerous compound as Dr. Martonen alleged. The OIG investigators relied on the opinions of twelve scientists, including those at EPA and independent experts. All concluded that based on scientific studies, it appeared that sebacate is of "minimal toxicity to healthy subjects even at high exposure levels. The agency concluded, based on these scientific opinions, that the concentration of particles used in Dr. Kim's study were below concentrations used in published studies in which there were no reported adverse health effects. When Dr. Martonen was interviewed, he was "equivocal as to whether sebacate is a dangerous substance."

Although sebacate is not considered a dangerous substance, according to the agency report, the OIG found that the amounts to which the test subjects were exposed was no more than 60 times greater than that to which they consented. Estimates by EPA and outside experts who reviewed the data, including Dr. Kim, put the range of over-exposure between 30 and 60 times the amount to which the test subjects consented to receive.

The agency report also found that neither testimony nor documentary evidence supported the allegation that the over-exposure was intentional or otherwise willful on the part of Dr. Kim. The OIG concluded, based on the evidence, that Dr. Kim's miscalculation was a straight-forward mistake, caused by inattention to detail. Dr. Kim's study was intended to measure the dispersal of sebacate in the lungs. As Dr. Kim changed the protocol of his study to use larger particles of sebacate, he failed to account for the exponential increase of particle mass. Therefore, the particle mass, not the particle quantity, was the source of the over-exposure.

The report did not substantiate Dr. Martonen's allegation that the human subjects in Dr. Kim's study were exposed to other potentially more dangerous substances in similar doses. Dr. Martonen believed that sebacate was used as a control in Dr. Kim's experiments. In fact, sebacate was the only chemical substance used in the study. Dr. Martonen admitted this fact in his OIG interviews.

Dr. Martonen's allegations that agency officials concealed Dr. Kim's wrongdoing were not supported by the evidence, and the agency report did not substantiate them. The investigation found that EPA took several actions in response to the incident, as supported by the Incident Time Line (time line) prepared for use by the HSRP during its review. The time line indicated that IRB was notified on August 16, 2001, and Dr. Kim's study was suspended by August 17, 2001. On September 24, 2001, Dr. Kim was indefinitely banned from human subject testing by EPA, and on November 6, 2001, he received a seven-day suspension from EPA. Dr. Martonen's belief that the study continued into 2002 was not substantiated by the investigation.

The report also found no evidence that Dr. Birnbaum, or anyone else, misdirected or interfered with the HSRP panel. Dr. Birnbaum stated that she did not select panel members, did not know who was on the panel, and was not asked to speak to the panel. Other opinions were that Dr. Birnbaum aggressively managed the over-exposure incident, bringing in outside experts and other federal agencies to review the incident. All HSRP panel members were interviewed and refuted the allegations that Dr. Birnbaum influenced the panel deliberations.

The report did note that there was a several month delay in notifying subjects of the dosage error. This delay occurred in part due to the disciplinary action against Dr. Kim, attempts to calculate the amount of over-exposure, pending receipt of an independent report, and notification to EPA Headquarters. According to the report, EPA took timely actions to suspend all human subject testing and performed timely investigations following notification about the incidents.

In response to the various outside and internal recommendations, EPA adopted the recommendations of the HSRP and implemented corrective action to address human testing procedures. On September 23, 2002, Dr. Peter Preuss, Director, National Center for Environmental Research and Quality Assurance, Office of Research and Development, and Human Subject Research and Review Official, lifted an EPA-wide ban on further human subject testing, based on these improvements.

Finally, the investigation found that the notice provided to the subjects of Dr. Kim's study was adequate and provided full disclosure. The subjects were notified of the over-exposure in June 2002. Dr. Martonen stated in his interview that he did not know letters had been sent to the subjects informing them of the over-exposure.

In summary, according to the agency report, the investigation found that although there was a violation of 40 CFR 26.116-117 (Protection of Human Subjects), the violation was not intentional and there was no substantial and specific danger to public health as a result. The report confirmed deviations from EPA policy and procedures by Dr. Kim, particularly as to changes in study protocols.

As a result of the investigation and the identification of deviations from EPA policy, EPA has taken and is continuing to implement actions to assure better compliance with human subject experiments. Dr. Kim was disciplined and indefinitely banned from human subject testing. Subjects were notified of the over-exposure, and there was no evidence that any subjects suffered any adverse health consequences as a result of the over-exposure. Agency-wide, human subject testing was not resumed until additional controls were put in place according to the recommendations of the HSRP.

#### **The Whistleblower's Comments**

The Whistleblower did not comment on the agency's report.

#### **Conclusion**

Based on my review of the original disclosures and the EPA report, I have determined that the agency's report contains all of the information required by statute and that its findings appear to be reasonable.