



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 27 2005

THE ADMINISTRATOR

The Honorable Scott J. Bloch
Special Counsel
U.S. Office of Special Counsel
1730 M Street, N.W., Suite 300
Washington, D.C. 20036-4505

Re: OSC File No. DI-05-0430

Dear Mr. Bloch:

Please accept this letter and enclosure as the report of my findings pursuant to 5 U.S.C. § 1213(d), in lieu of the letter and enclosure sent to you on June 20, 2005, by Ann R. Klee, my General Counsel.

By letter dated April 19, 2005, you referred to me for investigation a whistleblower disclosure by Dr. Ted Martonen, an employee of the Environmental Protection Agency (EPA or Agency). Dr. Martonen alleges violations of law, rule, or regulation, an abuse of authority, and a substantial and specific danger to public health arising out of actions taken by an EPA researcher and supervisory personnel at the EPA National Health and Environmental Effects Research Laboratory, Research Triangle Park, North Carolina. Additionally, Dr. Martonen alleges that EPA officials actively concealed the wrongdoing of the EPA researcher in the matter. Pursuant to the requirements of 5 U.S.C. § 1213(d), this letter is the report of my findings of the investigation of the disclosure allegations.

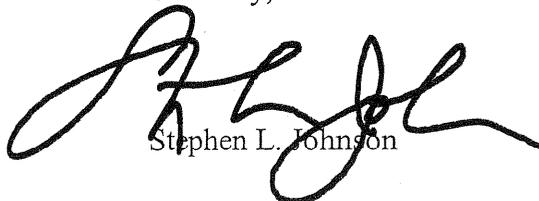
By memorandum of April 26, 2005, I requested that the EPA Office of the Inspector General investigate all matters raised in the disclosure by Dr. Martonen and in your letter and report. By memorandum dated June 6, 2005, the Inspector General provided me with her report of investigation regarding the matter. The Inspector General's investigation addressed the potential violations of conspiracy and protection of human testing subjects. The findings of the investigation were based in large part on the independent scientific review conducted by an outside expert consultant, who reported his findings in September 2001 and March 2002, and the statements provided by members of the Institutional Review Board and the Human Subject Review Panel, and EPA scientists. The investigation did not include an additional review of the research log books to validate the conclusions of the independent review.

In summary, the investigation 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 was not discovered by Dr. Martonen; that sebacate is not a hazardous substance and did not pose a health risk to the subjects; and that there was no evidence that the over-exposure was the result of intentional or willful misconduct by Dr. Kim. Additionally, the investigation concluded that EPA had timely addressed the issues raised by the over-exposure and there was no evidence that EPA officials covered up the over-exposure. I have fully reviewed the Report of Investigation, and I concur in its findings.

Because the issue of the over-exposure has been a matter which EPA has taken very seriously, I have taken the additional step of enclosing with this report a copy of the narrative prepared by the Special Investigations Unit of the Office of the Inspector General. This narrative summarizes each element of the allegations and details the actions taken by EPA in investigating the over-exposure and in correcting its procedures and protocols. It also identifies the disciplinary actions taken by EPA.

Should you have any questions concerning this report, please feel free to contact me at (202) 564-4700, or to have your staff contact Ray Spears, my Deputy Chief of Staff, at (202) 564-4715.

Sincerely,



Stephen L. Johnson

Enclosure

OFFICE OF INSPECTOR GENERAL
OFFICE OF INVESTIGATIONS

OI FILE NO.: 05-0002

DATE: JUN 6 2005

REPORT OF: David L. Cotner

OFFICE: Special Investigations Unit

SECTION A - NARRATIVE

Predication

By memorandum dated April 26, 2005, Stephen L. Johnson, Administrator, transmitted a referral for investigation from Scott J. Bloch, Special Counsel, U.S. Office of Special Counsel (OSC), dated April 19, 2005, OSC File No. DI-05-0430 (Exhibit 1). Administrator Johnson requested an investigation into the whistleblower disclosure to OSC by Dr. Ted Martonen, Senior Research Scientist, National Health and Environmental Effects Research Laboratory (NHEERL), Office of Research and Development (ORD), EPA, Research Triangle Park, North Carolina. Dr. Martonen alleges violations of law, rule, or regulation, an abuse of authority, and a substantial and specific danger to public health arising out of actions taken by an EPA researcher and supervisory personnel at NHEERL. The allegations pertain to a study proposed in 1991 by Dr. Chong Kim, principle investigator, Clinical Research Branch (CRB), Human Studies Division (HSD), NHEERL, ORD, EPA, at the University of North Carolina (UNC), Department of Medicine, which was sponsored by EPA and UNC. The title of the study was "Determination of Deposition Dose of Inhaled Particles in Human Lungs." Specifically, in his disclosure to OSC, Dr. Martonen contends that he discovered:

1. From 1997 through 2002, Dr. Kim led a research team that intentionally and systematically exposed human subjects to doses of di-2-ethylhexyl sebacate (sebacate), itself a potentially hazardous compound, at least one hundred times greater than the doses to which the subjects consented. As a result of the over-exposure, Dr. Kim's experiments created a substantial and specific danger to health and violated federal regulations that embody the minimum requirements of ethical scientific research.
2. Sebacate, itself a potentially hazardous compound, was used as a control in Dr. Kim's experiments and, consequently, the human subjects involved must have been exposed to other potentially more dangerous substances in similar doses, creating a substantial and specific danger to health.
3. EPA officials actively concealed the wrongdoing of Dr. Kim in this matter by repeatedly mischaracterizing the wrongdoing as minor, unintentional violations of EPA protocol.

4. According to a witness of the proceeding of the independent review panel, Dr. Linda Birnbaum, then Acting Director, HSD, NHEERL, ORD, EPA, misdirected the panel's deliberations in order to avoid any serious consideration of the concerns raised during Dr. Kim's experiments.
5. Any notice provided to the subjects of Dr. Kim's experiments was necessarily inadequate and misleading because EPA management mischaracterized the wrongdoing as minor, unintentional violations of EPA protocol.

Potential violations include: 18 U.S.C. 371 (Conspiracy to commit offense or to defraud United States) and 40 CFR 26.116-117 (Protection of Human Subjects).

Summarization

In summary, the investigation found that, although test subjects were exposed to sebacate in amounts greater than that to which they consented, sebacate is not a hazardous substance, the over-exposure was not discovered by Dr. Martonen, the over-exposure was not intentional, was not at the levels alleged by Dr. Martonen, did not pose a health risk to the subjects, and was addressed by EPA. No evidence was found that the over-exposure was the result of intentional or willful misconduct by Dr. Kim. Additionally, no evidence was found that EPA officials covered up the over-exposure or otherwise misdirected the Human Subject Review Panel's (HSRP) deliberations concerning this matter. The investigation consisted of numerous record reviews and interviews of individuals who had knowledge of the facts pertaining to the alleged events. These witnesses included numerous EPA officials; officials from the Institutional Review Board (IRB), which is a scientific review board at UNC; participants of the HSRP, which is an independent, external panel comprised of scientific experts convened to review EPA's protocol and procedures; independent experts; EPA's human ethics officials; EPA's Quality Assurance Officer; and supervisors, co-workers, and colleagues of both Dr. Martonen and Dr. Kim. Drs. Martonen and Kim were also interviewed. During the investigation, scientific reports, official findings, correspondence, and memoranda concerning these events were obtained and administrative and law enforcement records checks were conducted. Certain aspects of this report were reviewed for technical sufficiency by Rick A. Linthurst, Ph.D., EPA OIG's Senior Science Advisor, who concurred with these findings. This report addresses each of Dr. Martonen's allegations, in order.

1. Dr. Martonen alleged that he discovered that, from 1997 through 2002, Dr. Kim led a research team that intentionally and systematically exposed human subjects to doses of di-2-ethylhexyl sebacate, itself a potentially hazardous compound, at least one hundred times greater than the doses to which the subjects consented. As a result of the over-exposure, Dr. Kim's experiments created a substantial and specific danger to health and violated federal regulations that embody the minimum requirements of ethical scientific research. The investigation addressed the four subsets to this allegation as follows:

a) Sebacate as a dangerous substance:

The investigation found that sebacate is not considered a dangerous compound as alleged by Dr. Martonen. A September 11, 2001, report prepared by Dr. Frederick J. Miller, an independent dosimetry modeler who calculated the potential risks of over-exposure to sebacate, reported that based on numerous studies, "... one may infer that [sebacate] is of minimal toxicity to healthy subjects even at high exposure levels" (Exhibit 2, attachment 1). Additionally, Dr. Robert Devlin, Chief, CRB, HSD, NHEERL, ORD, EPA, reported in an April 4, 2002, memorandum 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 (Exhibit 2, attachments 4 and 5). Additionally, Dr. Philip Bromberg, Scientific Director, Center for Environmental Medicine, Asthma and Lung Biology, UNC, and Faculty Professor of Medicine at UNC, was interviewed and he stated that there was no danger to the subjects as the result of the over-exposure (Exhibit 3). Dr. Devlin was interviewed and stated that sebacate was an inert, innocuous substance (Exhibit 4). Dr. Martonen was interviewed and was equivocal as to whether sebacate is a dangerous substance (Exhibit 16). Additionally, eight other scientists and officials were interviewed and said sebacate was not a dangerous compound and there were no health risks posed through either the exposure or over-exposure to sebacate. Sebacate was described as a harmless, innocuous, non-reactive, and inert substance. (See Exhibits 5, 6, 7, 8, 9, 10, 11, and 12.)

b) Dr. Martonen alleged he discovered the over-exposure incident:

The investigation found that the over-exposure of the subjects was not discovered by Dr. Martonen, as he alleged. Dr. Martonen stated that he told Dr. Linda Birnbaum, now Division Director, Experimental Toxicology Division, NHEERL, ORD, EPA, of the over-exposure around 1997 or 1998, after he reviewed Dr. Kim's log books (Exhibit 16). In a later interview, Dr. Martonen said he was instructed by Dr. Birnbaum to obtain the log books from Dr. Kim as part of a collaboration between the two (Exhibit 17). However, witnesses refuted this statement. Dr. Birnbaum was interviewed a second time and stated that she never told Dr. Martonen to obtain Dr. Kim's log books nor told Dr. Kim to provide his log books to Dr. Martonen (Exhibit 18). Dr. Kim said that no one, including Dr. Martonen, had seen his log books. Dr. Kim stated that, although he and Dr. Martonen collaborated on some articles, there was no way Dr. Martonen had seen the log books. Moreover, Dr. Kim stated that Dr. Martonen did not have access to the data necessary to calculate the dosage of sebacate given to subjects (Exhibit 12). Additionally, Dr. Lawrence Reiter, Director, NHEERL, ORD, EPA, was interviewed and said there was no proper way that Dr. Martonen should have had authorized access to the log books from Dr. Kim's study (Exhibit 19). According to an "Incident Time Line: PM Protocol," which was one of many documents provided by EPA to the HSRP, the incident was reported to EPA management on August 16, 2001, and EPA took a series of steps over the following thirteen months to address the matter. Specifically, on page 20, paragraph 3, it is reported that the individual who discovered this problem was a "Post Doc in the principal investigator's laboratory" (Exhibit 13, attachment 1, enclosure a). Dr. James Brown, Health Scientist, National Center for Environmental Assessment, EPA,

was a co-investigator in the study with Dr. Kim. He was interviewed and stated that he was the post-doctoral fellow who, on August 14, 2001, discovered the over-exposure while working with Dr. Kim. Dr. Brown reported this matter to Dr. Bromberg on August 16, 2001 (Exhibit 14). Dr. Bromberg stated that Dr. Brown reported the matter to him, and his first notification was then to Dr. Devlin (Exhibit 3). Dr. Birnbaum was interviewed and said Dr. Brown was the person who reported the over-exposure (Exhibit 15). Dr. Kim was interviewed and stated that it was Dr. Brown who identified "the question of the accuracy of the dosage of sebacate" in the study (Exhibit 12). No evidence was found that Dr. Martonen reported this matter to EPA prior to Dr. Brown's discovery of the over-exposure in August of 2001. The investigation found that the earliest documented complaint made by Dr. Martonen concerning the over-exposure of sebacate was in a letter to the EPA Administrator, dated January, 31, 2002, nearly five months after the over-exposure had been identified and corrective action had been initiated by EPA (Exhibit 20, attachment 1, and Exhibit 16).

c) Amount of over-exposure:

While EPA officials acknowledged, and documents support, that over-exposure occurred, no evidence or scientific findings indicate that test subjects were exposed to sebacate in doses at least one hundred times greater than that to which they consented. Dr. Birnbaum was interviewed and said Dr. Martonen "exaggerates" on this point (Exhibit 15). Dr. Reiter was interviewed and said the allegation that subjects were exposed to sebacate at levels one hundred times more than they consented to was "not based on data" (Exhibit 19). Dr. Miller stated that, even in the worst case scenario, subjects were exposed to only 50-60 times the amount of sebacate than they consented to receive (Exhibit 7). Further, Dr. Miller co-authored a March 15, 2002, report for EPA that documented the worst case scenario as 50-60 times more than the subjects consented to receive (Exhibit 2, attachment 2). Dr. Kim was interviewed and said the amount was only 40-50 times the amount of sebacate they consented to receive (Exhibit 12). However, when Dr. Martonen was interviewed he said that he could not recall the actual amount of the over-exposure he saw in Dr. Kim's log books, and said it could have been "67.1 or 113.4" (Exhibit 21). Additionally, five other scientists and officials were interviewed and said the over exposure ranged from 30-60 times the amount of sebacate than the test subjects consented to receive. (See Exhibits 4, 8, 9, 14, and 22).

d) Dr. Martonen alleged the over-exposure was intentional:

No witnesses nor documentary evidence was identified that supports the assertion that the over-exposure was intentional or otherwise willful on the part of Dr. Kim. Dr. Dan Nelson, Director, IRB, UNC, was interviewed and stated that he had no basis to conclude that the error was intentional by Dr. Kim (Exhibit 9). Dr. Peter Preuss, Director, National Center for Environmental Research and Quality Assurance, ORD, and Human Subject Research and Review Official, was interviewed and stated that there was no intention by Dr. Kim to cause the over-exposure and that it was a "straight forward mistake on his part" (Exhibit 23). Dr. Brown was interviewed and stated that he did not believe there was any intent by Kim (Exhibit 14). Michael Ray, Quality Assurance Officer, NHEERL, ORD, EPA, reviewed the research documentation and found no evidence to

believe Dr. Kim intentionally over-exposed test subjects (Exhibit 5). Dr. James Samet, former Acting Chief, CRB, HSD, NHEERL, ORD, EPA, was interviewed and opined that the errors by Dr. Kim occurred because of sloppiness and inattention to detail on Dr. Kim's part (Exhibit 6). Several other witnesses opined that the over-exposure was the result of "sloppy work" or used similar descriptive terms to describe Dr. Kim's error in the over-exposure of sebacate. 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. It was this resulting increase in particle mass, not particle quantity that resulted in the over-exposure. (See Exhibits 4, 7, 15, and 22.) Dr. Bromberg was interviewed and characterized this type of error as "protocol creep" (Exhibit 3). Dr. Kim stated that he did not intentionally over-expose subjects to sebacate and, furthermore, even included his own son as part of the study (Exhibit 12).

2. Dr. Martonen alleged that because sebacate, itself a potentially hazardous compound, was used as a control in Dr. Kim's experiments, consequently the human subjects involved must have been exposed to other potentially more dangerous substances in similar doses, creating a substantial and specific danger to health.

The investigation found the protocols used from 1991-2002 by Dr. Kim show no other dangerous substances were used in the study (Exhibit 13, attachment 1, enclosure b). Additionally, the Standard Operating Procedures for Dr. Kim's study also do not reflect the use of other dangerous substances (Exhibit 13, attachment 1, enclosure i). Several scientists further reported that the only chemical substance used in the study was sebacate itself. (See Exhibits 7, 12, 24, and 25.) Finally, during an interview with Dr. Martonen, he admitted there were no other substances tested by Dr. Kim; therefore, he contradicted his original allegation reported through OSC (Exhibit 21).

3. Dr. Martonen alleged that EPA officials actively concealed the wrongdoing of Dr. Kim in this matter by repeatedly mischaracterizing the wrongdoing as minor, unintentional violations of EPA protocol.

The investigation found no evidence that EPA officials concealed, in any way, any wrongdoing by Dr. Kim. All witnesses interviewed reported that the over-exposure was the result of unintentional violations of EPA protocol. None of the witnesses interviewed believed that EPA management attempted to down-play or minimize Dr. Kim's violations of EPA protocol. To the contrary, several experts and HSRP members said EPA provided full disclosure and was forthcoming in the review process. The investigation found EPA took several actions in response to this incident, as identified on the "Incident Time Line: PM Protocol" used by the HSRP during its review (Exhibit 13, attachment 1, enclosure a). Dr. Elston Seal, former Medical Ethics Official, HSD, NHREEL, ORD, EPA, was interviewed and said he prepared the timeline in which it was reported that the IRB was notified on August 16, 2001, and Dr. Kim's study was suspended by August 17, 2001 (Exhibit 8). Additionally, on September 6, 2001, Dr. Seal informed Dr. Steven Bernard, Chair, IRB, of the protocol violations and actions taken by EPA to shut down the study (Exhibit 13, attachment 1, enclosure g). According to the timeline, Dr. Miller was contacted on August 23, 2001, and asked to conduct the risk estimate concerning the

over-exposure. He ultimately produced two reports on the matter, dated September 11, 2001, and March 15, 2002. (See Exhibit 2, attachments 1 and 2; Exhibit 7; and Exhibit 13, attachment 1, enclosure a). On September 24, 2001, Dr. Kim was indefinitely banned from human subject testing by EPA and, subsequently, on November 6, 2001, he received a seven-day suspension from EPA effective January 2 through 8, 2002 (Exhibit 2, attachment 7).

According to Dr. Harold Zenick, Associate Director for Health, NHEERL, ORD, EPA, there was a several month delay in notifying the subjects of the dosage error due to various factors, including disciplinary action against Dr. Kim, as well as to attempts to calculate the amount of over-exposure (Exhibit 25). The notification to the test subjects was delayed until June 6, 2002, during which time EPA officials attempted to determine the actual amount of over-exposure per subject, obtained the results of the Dr. Miller reports, and notified EPA Headquarters. (See Exhibit 13, attachment 1, enclosure a; and Exhibit 31, attachment 1). Dr. Preuss stated it was his decision, with the approval of Paul Gilman, former Assistant Administrator, ORD, EPA, to utilize the HSRP as an external panel to look at the over-exposure in Dr. Kim's study, as well as procedures, to ensure EPA Human Subject Studies were in order. He said his goal in using HSRP was to ensure they were independent of the laboratory and EPA (Exhibit 23). The HSRP was formed by EPA after it was discovered that two research projects involving human subjects within the HSD, NHEERL, ORD, EPA, had dosing errors. The two projects were a "Bromdichloromethane Study," and Dr. Kim's study. The HSRP convened from August 19-21, 2002, and produced their "Site Visit Report" dated August 21, 2002. In summary, the HSRP did find there were delays in notification to EPA ORD Headquarters concerning the incident (though not to the IRB or NHEERL management) and an excessive amount of time to notify the test subjects due to various factors. However, their findings reported that officials took timely actions to suspend all human subject testing and reported that EPA performed "timely, serious, and expeditious investigations following their notification about the incidents." The HSRP recommended a number of actions concerning changes or improvements to protocol, and reported EPA's implementation of "revised General Policy Guidelines for Conduct of Human Research at the NHEERL appears to be an excellent beginning and reflects the serious priority of human subject protection." (See Exhibit 31, attachment 1). On August 28, 2002, Dr. Reiter submitted a "Human Studies Evaluation and Corrective Action Plan" to Dr. Preuss outlining HSRP's recommendation and corrective actions to be taken by EPA (Exhibit 31, attachment 2). According to many witnesses, EPA has incorporated, and continues to incorporate, these recommendations. (See Exhibits 7, 8, 10, 14, 15, 19, 25, and 30.) On September 23, 2002, Dr. Preuss lifted an EPA-wide ban on further human subject testing (Exhibit 25, attachment 4). Dr. Seal said the HSRP recommended approximately 20 items for EPA to address in procedures with human testing and EPA adopted virtually all of the recommendations (Exhibit 8).

Additionally, Dr. Zenick was interviewed and said there was no intent by EPA or Dr. Kim to cover up the error of over-exposure (Exhibit 25). Dr. Birnbaum was interviewed and said there was not a cover-up; NHEERL management went public within a day of the problem; and both EPA and UNC personnel were involved in numerous discussions about the matter (Exhibit 15). Dr. Nelson was interviewed and said there was

no cover-up, and EPA handled the matter very openly (Exhibit 9). Dr. Henry Gong, Jr., a panel member of the HSRP, was interviewed and said he did not see any attempt by EPA to cover up anything regarding Dr. Kim's study. He further said the fact that EPA brought in an outside group of experts showed that EPA was open with the facts and review process (Exhibit 26). Dr. Kerm Henriksen, Human Factors Advisor for Patient Safety, and a panel member of the HSRP, was interviewed and said he did not see any cover-up, and such a cover-up would have been difficult with so many parties involved (Exhibit 27). Dr. Michael L. Gargas, a panel member of the HSRP, was interviewed and asked if there was an EPA cover-up concerning the over exposure of sebacate, to which he responded "Nah, baloney." He said the fact that EPA asked for an outside review was not indicative of a cover-up (Exhibit 28). Additionally, Dr. Ernest Prentice, Associate Vice Chancellor for Academic Affairs, University of Nebraska Medical Center, and chairman of the HSRP, was interviewed and said that there was no cover-up with EPA and that he would have recalled any interference with the HSRP review because he had reviewed other programs (not EPA) that had "stone walled" their reviewers and had attorneys present for every person talked to by the review panel. He emphasized that was not the case with EPA (Exhibit 29). In addition, eleven other scientists and officials were interviewed, all of whom stated there was no concealment or cover-up by EPA in this matter. (See Exhibits 3, 4, 5, 6, 7, 8, 10, 19, 22, 24, and 30.)

4. Dr. Martonen alleged that, according to a witness of the proceeding of the independent review panel, Dr. Birnbaum misdirected the panel's deliberations in order to avoid any serious consideration of the concerns raised during Dr. Kim's experiments.

The investigation found no evidence that Dr. Birnbaum, or anyone else, misdirected or interfered with the HSRP panel. Dr. Birnbaum stated that, regarding the HSRP, she was "totally uninvolved," had no role in selecting panel members, did not know who was on the panel, and was not asked to speak to the panel (Exhibit 18). Dr. Reiter was interviewed and stated that Dr. Birnbaum reacted as conscientiously and meticulously as could be expected and aggressively managed the over-exposure incident, including documentation and communications with the IRB and stated that there was no way Dr. Birnbaum could have influenced the external review panel (Exhibit 19). Mr. Gilman was interviewed and said that Dr. Birnbaum did not downplay the significance of the sebacate exposure; in fact, she took steps to contact the U.S. Department of Health and Human Services to benchmark what to do; and she had little or no role with respect to the outside review committee set up to study this situation (Exhibit 11). Drs. Bernard and Bromberg also were interviewed and did not believe Dr. Birnbaum downplayed or misdirected this matter (Exhibits 3 and 22). The witness Dr. Martonen identified in his allegation above was found to be Dr. Rex Pegram, who was interviewed and refuted the allegation (Exhibit 32). All HSRP panel members were interviewed and also refuted Dr. Martonen's allegations. (See Exhibits 26, 27, 28, and 29.)

5. Dr. Martonen alleged that any notice provided to the subjects of Dr. Kim's experiments was necessarily inadequate and misleading because EPA management mischaracterized the wrongdoing as minor, unintentional violations of EPA protocol.

The investigation found no evidence that any notice provided to the subjects of Dr. Kim's study was inadequate or misleading. Witnesses who reviewed or recalled the notice to subjects, including members of the HSRP and the EPA Human Ethics Official, reported it was accurate and provided full disclosure. Dr. Henricksen reviewed a copy of the notification letter sent to the subjects and stated that it provided full disclosure, included "familiar language," and also provided a point of contact for questions and follow-up (Exhibit 27). Dr. Gargas stated that he did not recall anything unusual about the notification letter sent to the subjects. Furthermore, the HSRP had been provided the notice and if there were anything out of the ordinary in the notification, they would have noted it in their report (Exhibit 28). Dr. Martonen provided a sworn statement that the cover-up "will continue until the federal government properly notifies the subjects and their families of the facts surrounding their illegal experiments so that they can make informed decisions about how to proceed." Dr. Martonen stated that he believes that because EPA "did not immediately inform the human subjects that their consent forms were violated, the cover-up *per se* was in effect" (Exhibit 21, attachment 1, emphases in original). Additionally, in another interview, Dr. Martonen stated he did not know letters had been sent to the subjects informing them of the over-exposure (Exhibit 16). As found in the investigation, the subjects were notified of the over exposure in June 2002.

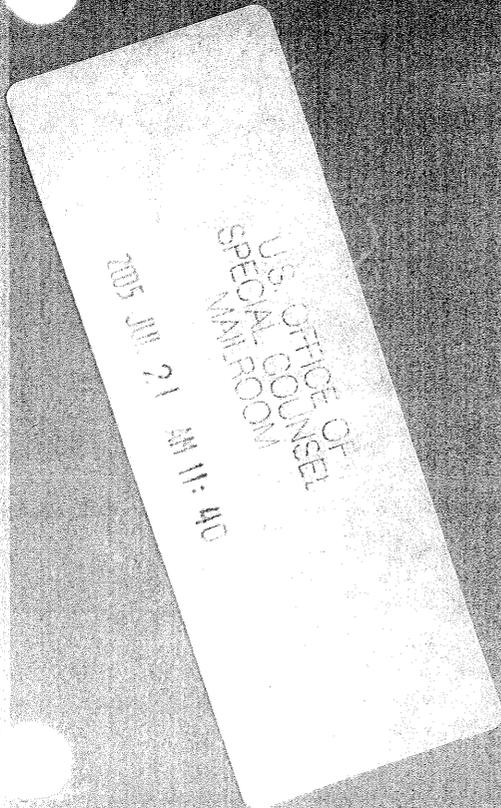
Status

No evidence was found to indicate any criminal violations by Dr. Kim, Dr. Birnbaum, or any other officials in conjunction with this matter, nor any administrative violations that were not previously known. The results of this investigation were not presented to the U.S. Attorney's office because no information was found to substantiate the allegations, nor was there evidence of any violations of Federal law which would warrant presentation to, or prosecution by, the Department of Justice.



Investigative Report

Assistant
Inspector General
for Investigations



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UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY



OFFICE OF THE INSPECTOR GENERAL
OFFICE OF INVESTIGATIONS

REPORT OF INVESTIGATION CONCERNING

CHONG S. KIM
Research Physical Scientist, GS-15
Human Studies Division
National Health and Environmental Effects Research Laboratory
Office of Research and Development
Research Triangle Park, North Carolina
Case Number 05-0002

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Distribution

Stephen L. Johnson
EPA Administrator

Approvals:

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Special Agent

A handwritten signature in black ink, appearing to be "A. V.", written over a horizontal line.

Director, Financial Fraud Directorate

OFFICE OF INSPECTOR GENERAL
OFFICE OF INVESTIGATIONS

OI FILE NO.: 05-0002

DATE: JUN _ 6 2005

REPORT OF: David L. Cotner

OFFICE: Special Investigations Unit

SECTION A - NARRATIVE

Predication

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Dr. Martonen alleges violations of law, rule, or regulation, an abuse of authority, and a substantial and specific danger to public health arising out of actions taken by an EPA researcher and supervisory personnel at NHEERL. The allegations pertain to a study proposed in 1991 by Dr. Chong Kim, principle investigator, Clinical Research Branch (CRB), Human Studies Division (HSD), NHEERL, ORD, EPA, at the University of North Carolina (UNC), Department of Medicine, which was sponsored by EPA and UNC. The title of the study was "Determination of Deposition Dose of Inhaled Particles in Human Lungs." Specifically, in his disclosure to OSC, Dr. Martonen contends that he discovered:

1. From 1997 through 2002, Dr. Kim led a research team that intentionally and systematically exposed human subjects to doses of di-2-ethylhexyl sebacate (sebacate), itself a potentially hazardous compound, at least one hundred times greater than the doses to which the subjects consented. As a result of the over-exposure, Dr. Kim's experiments created a substantial and specific danger to health and violated federal regulations that embody the minimum requirements of ethical scientific research.
2. Sebacate, itself a potentially hazardous compound, was used as a control in Dr. Kim's experiments and, consequently, the human subjects involved must have been exposed to other potentially more dangerous substances in similar doses, creating a substantial and specific danger to health.
3. EPA officials actively concealed the wrongdoing of Dr. Kim in this matter by repeatedly mischaracterizing the wrongdoing as minor, unintentional violations of EPA protocol.

4. According to a witness of the proceeding of the independent review panel, Dr. Linda Birnbaum, then Acting Director, HSD, NHEERL, ORD, EPA, misdirected the panel's deliberations in order to avoid any serious consideration of the concerns raised during Dr. Kim's experiments.
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Potential violations include: 18 U.S.C. 371 (Conspiracy to commit offense or to defraud United States) and 40 CFR 26.116-117 (Protection of Human Subjects).

Summarization

In summary, the investigation found that, although test subjects were exposed to sebacate in amounts greater than that to which they consented, sebacate is not a hazardous substance, the over-exposure was not discovered by Dr. Martonen, the over-exposure was not intentional, was not at the levels alleged by Dr. Martonen, did not pose a health risk to the subjects, and was addressed by EPA. No evidence was found that the over-exposure was the result of intentional or willful misconduct by Dr. Kim. Additionally, no evidence was found that EPA officials covered up the over-exposure or otherwise misdirected the Human Subject Review Panel's (HSRP) deliberations concerning this matter. The investigation consisted of numerous record reviews and interviews of individuals who had knowledge of the facts pertaining to the alleged events. These witnesses included numerous EPA officials; officials from the Institutional Review Board (IRB), which is a scientific review board at UNC; participants of the HSRP, which is an independent, external panel comprised of scientific experts convened to review EPA's protocol and procedures; independent experts; EPA's human ethics officials; EPA's Quality Assurance Officer; and supervisors, co-workers, and colleagues of both Dr. Martonen and Dr. Kim. Drs. Martonen and Kim were also interviewed. During the investigation, scientific reports, official findings, correspondence, and memoranda concerning these events were obtained and administrative and law enforcement records checks were conducted. Certain aspects of this report were reviewed for technical sufficiency by Rick A. Linthurst, Ph.D., EPA OIG's Senior Science Advisor, who concurred with these findings. This report addresses each of Dr. Martonen's allegations, in order.

1. Dr. Martonen alleged that he discovered that, from 1997 through 2002, Dr. Kim led a research team that intentionally and systematically exposed human subjects to doses of di-2-ethylhexyl sebacate, itself a potentially hazardous compound, at least one hundred times greater than the doses to which the subjects consented. As a result of the over-exposure, Dr. Kim's experiments created a substantial and specific danger to health and violated federal regulations that embody the minimum requirements of ethical scientific research. The investigation addressed the four subsets to this allegation as follows:

a) Sebacate as a dangerous substance:

The investigation found that sebacate is not considered a dangerous compound as alleged by Dr. Martonen. A September 11, 2001, report prepared by Dr. Frederick J. Miller, an independent dosimetry modeler who calculated the potential risks of over-exposure to sebacate, reported that based on numerous studies, "... one may infer that [sebacate] is of minimal toxicity to healthy subjects even at high exposure levels" (Exhibit 2, attachment 1). Additionally, Dr. Robert Devlin, Chief, CRB, HSD, NHEERL, ORD, EPA, reported in an April 4, 2002, memorandum 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 (Exhibit 2, attachments 4 and 5). Additionally, Dr. Philip Bromberg, Scientific Director, Center for Environmental Medicine, Asthma and Lung Biology, UNC, and Faculty Professor of Medicine at UNC, was interviewed and he stated that there was no danger to the subjects as the result of the over-exposure (Exhibit 3). Dr. Devlin was interviewed and stated that sebacate was an inert, innocuous substance (Exhibit 4). Dr. Martonen was interviewed and was equivocal as to whether sebacate is a dangerous substance (Exhibit 16). Additionally, eight other scientists and officials were interviewed and said sebacate was not a dangerous compound and there were no health risks posed through either the exposure or over-exposure to sebacate. Sebacate was described as a harmless, innocuous, non-reactive, and inert substance. (See Exhibits 5, 6, 7, 8, 9, 10, 11, and 12.)

b) Dr. Martonen alleged he discovered the over-exposure incident:

The investigation found that the over-exposure of the subjects was not discovered by Dr. Martonen, as he alleged. Dr. Martonen stated that he told Dr. Linda Birnbaum, now Division Director, Experimental Toxicology Division, NHEERL, ORD, EPA, of the over-exposure around 1997 or 1998, after he reviewed Dr. Kim's log books (Exhibit 16). In a later interview, Dr. Martonen said he was instructed by Dr. Birnbaum to obtain the log books from Dr. Kim as part of a collaboration between the two (Exhibit 17). However, witnesses refuted this statement. Dr. Birnbaum was interviewed a second time and stated that she never told Dr. Martonen to obtain Dr. Kim's log books nor told Dr. Kim to provide his log books to Dr. Martonen (Exhibit 18). Dr. Kim said that no one, including Dr. Martonen, had seen his log books. Dr. Kim stated that, although he and Dr. Martonen collaborated on some articles, there was no way Dr. Martonen had seen the log books. Moreover, Dr. Kim stated that Dr. Martonen did not have access to the data necessary to calculate the dosage of sebacate given to subjects (Exhibit 12). Additionally, Dr. Lawrence Reiter, Director, NHEERL, ORD, EPA, was interviewed and said there was no proper way that Dr. Martonen should have had authorized access to the log books from Dr. Kim's study (Exhibit 19). According to an "Incident Time Line: PM Protocol," which was one of many documents provided by EPA to the HSRP, the incident was reported to EPA management on August 16, 2001, and EPA took a series of steps over the following thirteen months to address the matter. Specifically, on page 20, paragraph 3, it is reported that the individual who discovered this problem was a "Post Doc in the principal investigator's laboratory" (Exhibit 13, attachment 1, enclosure a). Dr. James Brown, Health Scientist, National Center for Environmental Assessment, EPA,

was a co-investigator in the study with Dr. Kim. He was interviewed and stated that he was the post-doctoral fellow who, on August 14, 2001, discovered the over-exposure while working with Dr. Kim. Dr. Brown reported this matter to Dr. Bromberg on August 16, 2001 (Exhibit 14). Dr. Bromberg stated that Dr. Brown reported the matter to him, and his first notification was then to Dr. Devlin (Exhibit 3). Dr. Birnbaum was interviewed and said Dr. Brown was the person who reported the over-exposure (Exhibit 15). Dr. Kim was interviewed and stated that it was Dr. Brown who identified "the question of the accuracy of the dosage of sebacate" in the study (Exhibit 12). No evidence was found that Dr. Martonen reported this matter to EPA prior to Dr. Brown's discovery of the over-exposure in August of 2001. The investigation found that the earliest documented complaint made by Dr. Martonen concerning the over-exposure of sebacate was in a letter to the EPA Administrator, dated January, 31, 2002, nearly five months after the over-exposure had been identified and corrective action had been initiated by EPA (Exhibit 20, attachment 1, and Exhibit 16).

c) Amount of over-exposure:

While EPA officials acknowledged, and documents support, that over-exposure occurred, no evidence or scientific findings indicate that test subjects were exposed to sebacate in doses at least one hundred times greater than that to which they consented. Dr. Birnbaum was interviewed and said Dr. Martonen "exaggerates" on this point (Exhibit 15). Dr. Reiter was interviewed and said the allegation that subjects were exposed to sebacate at levels one hundred times more than they consented to was "not based on data" (Exhibit 19). Dr. Miller stated that, even in the worst case scenario, subjects were exposed to only 50-60 times the amount of sebacate than they consented to receive (Exhibit 7). Further, Dr. Miller co-authored a March 15, 2002, report for EPA that documented the worst case scenario as 50-60 times more than the subjects consented to receive (Exhibit 2, attachment 2). Dr. Kim was interviewed and said the amount was only 40-50 times the amount of sebacate they consented to receive (Exhibit 12). However, when Dr. Martonen was interviewed he said that he could not recall the actual amount of the over-exposure he saw in Dr. Kim's log books, and said it could have been "67.1 or 113.4" (Exhibit 21). Additionally, five other scientists and officials were interviewed and said the over exposure ranged from 30-60 times the amount of sebacate than the test subjects consented to receive. (See Exhibits 4, 8, 9, 14, and 22).

d) Dr. Martonen alleged the over-exposure was intentional:

No witnesses nor documentary evidence was identified that supports the assertion that the over-exposure was intentional or otherwise willful on the part of Dr. Kim. Dr. Dan Nelson, Director, IRB, UNC, was interviewed and stated that he had no basis to conclude that the error was intentional by Dr. Kim (Exhibit 9). Dr. Peter Preuss, Director, National Center for Environmental Research and Quality Assurance, ORD, and Human Subject Research and Review Official, was interviewed and stated that there was no intention by Dr. Kim to cause the over-exposure and that it was a "straight forward mistake on his part" (Exhibit 23). Dr. Brown was interviewed and stated that he did not believe there was any intent by Kim (Exhibit 14). Michael Ray, Quality Assurance Officer, NHEERL, ORD, EPA, reviewed the research documentation and found no evidence to

believe Dr. Kim intentionally over-exposed test subjects (Exhibit 5). Dr. James Samet, former Acting Chief, CRB, HSD, NHEERL, ORD, EPA, was interviewed and opined that the errors by Dr. Kim occurred because of sloppiness and inattention to detail on Dr. Kim's part (Exhibit 6). Several other witnesses opined that the over-exposure was the result of "sloppy work" or used similar descriptive terms to describe Dr. Kim's error in the over-exposure of sebacate. 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. It was this resulting increase in particle mass, not particle quantity that resulted in the over-exposure. (See Exhibits 4, 7, 15, and 22.) Dr. Bromberg was interviewed and characterized this type of error as "protocol creep" (Exhibit 3). Dr. Kim stated that he did not intentionally over-expose subjects to sebacate and, furthermore, even included his own son as part of the study (Exhibit 12).

2. Dr. Martonen alleged that because sebacate, itself a potentially hazardous compound, was used as a control in Dr. Kim's experiments, consequently the human subjects involved must have been exposed to other potentially more dangerous substances in similar doses, creating a substantial and specific danger to health.

The investigation found the protocols used from 1991-2002 by Dr. Kim show no other dangerous substances were used in the study (Exhibit 13, attachment 1, enclosure b). Additionally, the Standard Operating Procedures for Dr. Kim's study also do not reflect the use of other dangerous substances (Exhibit 13, attachment 1, enclosure i). Several scientists further reported that the only chemical substance used in the study was sebacate itself. (See Exhibits 7, 12, 24, and 25.) Finally, during an interview with Dr. Martonen, he admitted there were no other substances tested by Dr. Kim; therefore, he contradicted his original allegation reported through OSC (Exhibit 21).

3. Dr. Martonen alleged that EPA officials actively concealed the wrongdoing of Dr. Kim in this matter by repeatedly mischaracterizing the wrongdoing as minor, unintentional violations of EPA protocol.

The investigation found no evidence that EPA officials concealed, in any way, any wrongdoing by Dr. Kim. All witnesses interviewed reported that the over-exposure was the result of unintentional violations of EPA protocol. None of the witnesses interviewed believed that EPA management attempted to down-play or minimize Dr. Kim's violations of EPA protocol. To the contrary, several experts and HSRP members said EPA provided full disclosure and was forthcoming in the review process. The investigation found EPA took several actions in response to this incident, as identified on the "Incident Time Line: PM Protocol" used by the HSRP during its review (Exhibit 13, attachment 1, enclosure a). Dr. Elston Seal, former Medical Ethics Official, HSD, NHREEL, ORD, EPA, was interviewed and said he prepared the timeline in which it was reported that the IRB was notified on August 16, 2001, and Dr. Kim's study was suspended by August 17, 2001 (Exhibit 8). Additionally, on September 6, 2001, Dr. Seal informed Dr. Steven Bernard, Chair, IRB, of the protocol violations and actions taken by EPA to shut down the study (Exhibit 13, attachment 1, enclosure g). According to the timeline, Dr. Miller was contacted on August 23, 2001, and asked to conduct the risk estimate concerning the

over-exposure. He ultimately produced two reports on the matter, dated September 11, 2001, and March 15, 2002. (See Exhibit 2, attachments 1 and 2; Exhibit 7; and Exhibit 13, attachment 1, enclosure a). On September 24, 2001, Dr. Kim was indefinitely banned from human subject testing by EPA and, subsequently, on November 6, 2001, he received a seven-day suspension from EPA effective January 2 through 8, 2002 (Exhibit 2, attachment 7).

According to Dr. Harold Zenick, Associate Director for Health, NHEERL, ORD, EPA, there was a several month delay in notifying the subjects of the dosage error due to various factors, including disciplinary action against Dr. Kim, as well as to attempts to calculate the amount of over-exposure (Exhibit 25). The notification to the test subjects was delayed until June 6, 2002, during which time EPA officials attempted to determine the actual amount of over-exposure per subject, obtained the results of the Dr. Miller reports, and notified EPA Headquarters. (See Exhibit 13, attachment 1, enclosure a; and Exhibit 31, attachment 1). Dr. Preuss stated it was his decision, with the approval of Paul Gilman, former Assistant Administrator, ORD, EPA, to utilize the HSRP as an external panel to look at the over-exposure in Dr. Kim's study, as well as procedures, to ensure EPA Human Subject Studies were in order. He said his goal in using HSRP was to ensure they were independent of the laboratory and EPA (Exhibit 23). The HSRP was formed by EPA after it was discovered that two research projects involving human subjects within the HSD, NHEERL, ORD, EPA, had dosing errors. The two projects were a "Bromdichloromethane Study," and Dr. Kim's study. The HSRP convened from August 19-21, 2002, and produced their "Site Visit Report" dated August 21, 2002. In summary, the HSRP did find there were delays in notification to EPA ORD Headquarters concerning the incident (though not to the IRB or NHEERL management) and an excessive amount of time to notify the test subjects due to various factors. However, their findings reported that officials took timely actions to suspend all human subject testing and reported that EPA performed "timely, serious, and expeditious investigations following their notification about the incidents." The HSRP recommended a number of actions concerning changes or improvements to protocol, and reported EPA's implementation of "revised General Policy Guidelines for Conduct of Human Research at the NHEERL appears to be an excellent beginning and reflects the serious priority of human subject protection." (See Exhibit 31, attachment 1). On August 28, 2002, Dr. Reiter submitted a "Human Studies Evaluation and Corrective Action Plan" to Dr. Preuss outlining HSRP's recommendation and corrective actions to be taken by EPA (Exhibit 31, attachment 2). According to many witnesses, EPA has incorporated, and continues to incorporate, these recommendations. (See Exhibits 7, 8, 10, 14, 15, 19, 25, and 30.) On September 23, 2002, Dr. Preuss lifted an EPA-wide ban on further human subject testing (Exhibit 25, attachment 4). Dr. Seal said the HSRP recommended approximately 20 items for EPA to address in procedures with human testing and EPA adopted virtually all of the recommendations (Exhibit 8).

Additionally, Dr. Zenick was interviewed and said there was no intent by EPA or Dr. Kim to cover up the error of over-exposure (Exhibit 25). Dr. Birnbaum was interviewed and said there was not a cover-up; NHEERL management went public within a day of the problem; and both EPA and UNC personnel were involved in numerous discussions about the matter (Exhibit 15). Dr. Nelson was interviewed and said there was

no cover-up, and EPA handled the matter very openly (Exhibit 9). Dr. Henry Gong, Jr., a panel member of the HSRP, was interviewed and said he did not see any attempt by EPA to cover up anything regarding Dr. Kim's study. He further said the fact that EPA brought in an outside group of experts showed that EPA was open with the facts and review process (Exhibit 26). Dr. Kerm Henriksen, Human Factors Advisor for Patient Safety, and a panel member of the HSRP, was interviewed and said he did not see any cover-up, and such a cover-up would have been difficult with so many parties involved (Exhibit 27). Dr. Michael L. Gargas, a panel member of the HSRP, was interviewed and asked if there was an EPA cover-up concerning the over exposure of sebacate, to which he responded "Nah, baloney." He said the fact that EPA asked for an outside review was not indicative of a cover-up (Exhibit 28). Additionally, Dr. Ernest Prentice, Associate Vice Chancellor for Academic Affairs, University of Nebraska Medical Center, and chairman of the HSRP, was interviewed and said that there was no cover-up with EPA and that he would have recalled any interference with the HSRP review because he had reviewed other programs (not EPA) that had "stone walled" their reviewers and had attorneys present for every person talked to by the review panel. He emphasized that was not the case with EPA (Exhibit 29). In addition, eleven other scientists and officials were interviewed, all of whom stated there was no concealment or cover-up by EPA in this matter. (See Exhibits 3, 4, 5, 6, 7, 8, 10, 19, 22, 24, and 30.)

4. Dr. Martonen alleged that, according to a witness of the proceeding of the independent review panel, Dr. Birnbaum misdirected the panel's deliberations in order to avoid any serious consideration of the concerns raised during Dr. Kim's experiments.

The investigation found no evidence that Dr. Birnbaum, or anyone else, misdirected or interfered with the HSRP panel. Dr. Birnbaum stated that, regarding the HSRP, she was "totally uninvolved," had no role in selecting panel members, did not know who was on the panel, and was not asked to speak to the panel (Exhibit 18). Dr. Reiter was interviewed and stated that Dr. Birnbaum reacted as conscientiously and meticulously as could be expected and aggressively managed the over-exposure incident, including documentation and communications with the IRB and stated that there was no way Dr. Birnbaum could have influenced the external review panel (Exhibit 19). Mr. Gilman was interviewed and said that Dr. Birnbaum did not downplay the significance of the sebacate exposure; in fact, she took steps to contact the U.S. Department of Health and Human Services to benchmark what to do; and she had little or no role with respect to the outside review committee set up to study this situation (Exhibit 11). Drs. Bernard and Bromberg also were interviewed and did not believe Dr. Birnbaum downplayed or misdirected this matter (Exhibits 3 and 22). The witness Dr. Martonen identified in his allegation above was found to be Dr. Rex Pegram, who was interviewed and refuted the allegation (Exhibit 32). All HSRP panel members were interviewed and also refuted Dr. Martonen's allegations. (See Exhibits 26, 27, 28, and 29.)

5. Dr. Martonen alleged that any notice provided to the subjects of Dr. Kim's experiments was necessarily inadequate and misleading because EPA management mischaracterized the wrongdoing as minor, unintentional violations of EPA protocol.

The investigation found no evidence that any notice provided to the subjects of Dr. Kim's study was inadequate or misleading. Witnesses who reviewed or recalled the notice to subjects, including members of the HSRP and the EPA Human Ethics Official, reported it was accurate and provided full disclosure. Dr. Henricksen reviewed a copy of the notification letter sent to the subjects and stated that it provided full disclosure, included "familiar language," and also provided a point of contact for questions and follow-up (Exhibit 27). Dr. Gargas stated that he did not recall anything unusual about the notification letter sent to the subjects. Furthermore, the HSRP had been provided the notice and if there were anything out of the ordinary in the notification, they would have noted it in their report (Exhibit 28). Dr. Martonen provided a sworn statement that the cover-up "will continue until the federal government properly notifies the subjects and their families of the facts surrounding their illegal experiments so that they can make informed decisions about how to proceed." Dr. Martonen stated that he believes that because EPA "did not immediately inform the human subjects that their consent forms were violated, the cover-up *per se* was in effect" (Exhibit 21, attachment 1, emphases in original). Additionally, in another interview, Dr. Martonen stated he did not know letters had been sent to the subjects informing them of the over-exposure (Exhibit 16). As found in the investigation, the subjects were notified of the over exposure in June 2002.

Status

No evidence was found to indicate any criminal violations by Dr. Kim, Dr. Birnbaum, or any other officials in conjunction with this matter, nor any administrative violations that were not previously known. The results of this investigation were not presented to the U.S. Attorney's office because no information was found to substantiate the allegations, nor was there evidence of any violations of Federal law which would warrant presentation to, or prosecution by, the Department of Justice.

LIST OF EXHIBITS

<u>Description</u>	<u>Exhibit</u>
Request for Investigation on Referral from the Special Counsel Memorandum, dated April 26, 2005.....	1
EPA Form 2720-15, Receipt of Documents from Rebecca Calderone, dated May 12, 2005.....	2
EPA Form 2720-15, Interview of Philip Bromberg, dated May 10, 2005.....	3
EPA Form 2720-15, Interview of Robert Devlin, dated May 10, 2005.....	4
EPA Form 2720-15, Interview of B. Michael Ray, dated May 5, 2005.....	5
EPA Form 2720-15, Interview of James M. Samet, dated May 5, 2005.....	6
EPA Form 2720-15, Interview of Fred Miller, dated May 9, 2005.....	7
EPA Form 2720-15, Interview of Elston Seal, dated May 9, 2005.....	8
EPA Form 2720-15, Interview of Dan Nelson, dated May 10, 2005.....	9
EPA Form 2720-15, Interview of Jacky Rosati, dated May 11, 2005.....	10
EPA Form 2720-15, Interview of John P. Gilman, dated May 17, 2005.....	11
EPA Form 2720-15, Interview of Chong S. Kim, dated May 19, 2005.....	12
EPA Form 2720-15, Interview of Rebecca Calderone, dated May 11, 2005.....	13
EPA Form 2720-15, Interview of James Brown, dated May 11, 2005.....	14
EPA Form 2720-15, Interview of Linda Birnbaum, dated May 4, 2005.....	15
EPA Form 2720-15, Interview of Ted Martonen, dated May 11, 2005.....	16
EPA Form 2720-15, Interview of Ted Martonen, dated May 12, 2005.....	17
EPA Form 2720-15, Interview of Linda Birnbaum, dated May 18, 2005.....	18
EPA Form 2720-15, Interview of Lawrence Reiter, dated May 12, 2005.....	19
EPA Form 2720-15, Receipt of Documents from Karcn Palmer, dated June 3, 2005.....	20

LIST OF EXHIBITS

<u>Description</u>	<u>Exhibit</u>
EPA Form 2720-15, Interview of Ted Martonen, dated May 18, 2005.....	21
EPA Form 2720-15, Interview of Steven Bernard, dated May 10, 2005.....	22
EPA Form 2720-15, Interview of Peter Preuss, dated May 31, 2005.....	23
EPA Form 2720-15, Interview of Roger S. Cortesi, dated May 5, 2005.....	24
EPA Form 2720-15, Interview of Harold Zenick, dated May 4, 2005.....	25
EPA Form 2720-15, Interview of Henry Gong, dated May 17, 2005.....	26
EPA Form 2720-15, Interview of Kerm Henriksen, dated May 23, 2005.....	27
EPA Form 2720-15, Interview of Michael Gargas, dated May 17, 2005.....	28
EPA Form 2720-15, Interview of Ernest Prentice, dated May 16, 2005.....	29
EPA Form 2720-15, Interview of Richard P. Hermann, dated May 5, 2005.....	30
EPA Form 2720-15, Interview of Rick Linthurst, dated May 3, 2005.....	31
EPA Form 2720-15, Interview of Rex Pegram, dated May 19, 2005.....	32



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D C 20460

PR 26 2

OFFICE OF THE
ADMINISTRATOR

MEMORANDUM

SUBJECT: Request for Investigation on Referral from the Special Counsel

FROM: Stephen J. Johnson
Acting Administrator

TO: Nikki L. Tinsley
Inspector General

In a letter dated and received on April 19, 2005, Scott J Bloch, Special Counsel, U S Office of Special Counsel, referred to me for investigation a whistleblower disclosure by Dr Ted Martonen, an employee of the Environmental Protection Agency (EPA or Agency) Dr Martonen alleges violations of law, rule, or regulation, an abuse of authority, and a substantial and specific danger to public health arising out of actions taken by an EPA researcher and supervisory personnel at the EPA National Health and Environmental Effects Research Laboratory, Research Triangle Park, North Carolina Additionally, Dr Martonen alleges that EPA officials actively concealed the wrongdoing of the EPA researcher in the matter I have included as an attachment to this memorandum a copy of the Special Counsel's letter and report of disclosures referred for investigation

By this memorandum, I am delegating to you the authority and responsibility to investigate all matters raised in the disclosure by Dr Martonen and in the letter and report of the Special Counsel Further, I am delegating to you the authority and responsibility to prepare a written report as required by 5 U S C § 1213 I am specifically reserving to myself, as Acting Administrator, the authority to review and sign the written report to the Special Counsel as required by 5 U S C § 1213, including a determination of any action necessary under 5 U S C § 1213(d)(5)

I am required to submit the written report to the Special Counsel within 60 days of the Agency's receipt of the Special Counsel's letter, that is, by June 20, 2005 To meet that deadline, I request that you complete your investigation and submit your written report to me by June 1, 2005 If you determine that you are unable to complete your investigation and submit your written report to me by that date, I request that you advise me at your earliest convenience so I can request an extension of time from the Special Counsel

Should you have any questions regarding this delegation or this matter, please do not
hesitate to contact me

Attachment

cc Ann R Klee



U.S. OFFICE OF SPECIAL COUNSEL
1730 M Street, N.W., Suite 300
Washington, D.C. 20036 4505

April 19, 2005

The Special Counsel

Mr Stephen L Johnson
Acting Administrator
Environmental Protection Agency
1200 Pennsylvania Ave, N W, MC 1101A
Washington, DC 20460

Re OSC File No. DI-05-0430

Dear Mr Johnson

Pursuant to my responsibilities as Special Counsel, I am referring to you a whistleblower disclosure that establishes a substantial likelihood of human subject experimentation conducted by Environmental Protection Agency (EPA) researchers without the informed consent of the subjects. It has long been recognized within the scientific research community that "[r]espect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them," and that "[t]his opportunity is provided when adequate standards for informed consent are satisfied. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Belmont Report Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979). The EPA has incorporated this principle into its rules governing human subject experimentation. See 40 C.F.R. §§ 26.101, 26.116, and 26.117. Yet, Ted Martonen, who has consented to the release of his name, alleges that in violation of 40 C.F.R. §§ 26.116 and 26.117, EPA researchers exposed subjects to at least one potentially dangerous compound in doses as much as one hundred times greater than those to which they consented. Dr Martonen also alleges that EPA officials actively concealed the wrongdoing of the EPA researcher in this matter. Accordingly, I am referring this information to you for an investigation of these allegations and a report of your findings.

The U.S. Office of Special Counsel (OSC) is authorized by law to receive disclosures of information from federal employees alleging violations of law, rule, or regulation, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety. 5 U.S.C. § 1213(a) and (b). As Special Counsel, if I find, on the basis of the information disclosed, that there is a substantial likelihood that one of these conditions exists, I am required to advise the appropriate agency head of my findings, and the agency head is required to conduct an investigation of the allegations and prepare a report. 5 U.S.C. § 1213(c) and (g). OSC has received a disclosure alleging violations of law, rule, or regulation, an abuse of authority, and a substantial and specific danger to public health arising out of actions taken by an EPA researcher and supervisory personnel at the Environmental Protection Agency, National Health and Environmental Effects Research Laboratory (NHEERL), Research Triangle Park, North Carolina.

More specifically, Dr Martonen, a Senior Research Scientist at NHEERL, has disclosed that over a period of approximately five years, Chong Kim, an NHEERL research scientist, led a

The Special Counsel

Mr Stephen L Johnson

Page 2

research team that exposed human subjects to doses of di-2-ethylhexyl sebacate (sebacate) as much as one hundred times greater than those to which the subjects consented. According to Dr Martonen, sebacate, itself a potentially hazardous compound, was used as a control in Dr Kim's experiments, and, consequently, the human subjects involved must have been exposed to other, potentially more dangerous substances in similar doses. Dr Martonen further alleges that EPA officials have repeatedly mischaracterized the wrongdoing he has identified as merely technical violations of EPA protocol. Given these mischaracterizations, Dr Martonen contends that any notice provided to the affected subjects regarding their overexposure must necessarily have been misleading.

I have concluded that there is a substantial likelihood that the information Dr Martonen provided to OSC discloses violations of law, rule, or regulation, an abuse of authority, and a substantial and specific danger to public health. As previously stated, I am referring this information to you for an investigation of Dr. Martonen's allegations and a report of your findings within 60 days of your receipt of this letter. By law, the report must be reviewed and signed by you personally. Should you delegate your authority to review and sign the report to the Inspector General, or any other official, the delegation must be specifically stated and must include the authority to take the actions necessary under 5 U.S.C. § 1213(d)(5). Without this information, I would hasten to add that the report may be found deficient. The requirements of the report are set forth at 5 U.S.C. § 1213(c) and (d). A summary of § 1213(d) is enclosed.

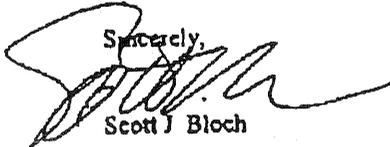
In the event it is not possible to report on the matter within the 60-day time limit under the statute, you may request in writing an extension of time not to exceed 60 days. Please be advised that an extension of time is normally not granted automatically, but only upon a showing of good cause. Accordingly, in the written request for an extension of time, please state specifically the reasons the additional time is needed. Any additional requests for an extension of time must be approved by the Special Counsel.

After making the determinations required by 5 U.S.C. § 1213(e)(2), copies of the report, along with any comments on the report from the person making the disclosure and any comments or recommendations by this office will be sent to the President and the appropriate oversight committees in the Senate and House of Representatives. 5 U.S.C. § 1213(e)(3).

Unless classified or prohibited from release by law, a copy of the report and any comments will be placed in a public file in accordance with 5 U.S.C. § 1219(a).

Please refer to our file number in any correspondence on this matter. If you need further information, please contact Catherine A. McMullen, Chief, Disclosure Unit, at (202) 254-3604. I am also available for any questions you may have.

Sincerely,



Scott J Bloch

Enclosures



U.S. OFFICE OF SPECIAL COUNSEL
1730 M Street, N.W. Suite 218
Washington, D.C. 20036-4595
202-354-3600

REPORT OF DISCLOSURES REFERRED FOR INVESTIGATION OSC FILE NO. DI-05-0430

I. SUMMARY

Ted Martonen, a Senior Research Scientist, alleges that other research scientists at the Environmental Protection Agency (EPA), National Health and Environmental Effects Research Laboratory (NHEERL), Research Triangle Park, North Carolina, 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 alleges 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 alleges that EPA officials have repeatedly mischaracterized the wrongdoing he has identified as merely technical violations of EPA protocol. Given these mischaracterizations, Dr. Martonen contends that any notice provided to the affected subjects regarding their overexposure must necessarily have been misleading.

II. THE INFORMATION DISCLOSED

Dr. Martonen, who has consented to the release of his name, is employed as a Senior Research Scientist with NHEERL and holds an adjunct professorship in the Department of Medicine at the University of North Carolina, Chapel Hill. Dr. Martonen contends that he first discovered the wrongdoing that forms the basis of his disclosure when he was asked by Linda Burnbaum, 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 alleges 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. According to Dr. Martonen, Dr. Kim's experiments were conducted from 1997 through 2002. For at least part of that time, Dr. Burnbaum oversaw Dr. Kim's work as director of HSD.

Dr. Martonen alleges that Dr. Kim's overexposure of his subjects constitutes 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 alleges that Dr. Kim's experiments created a substantial and specific danger to health. According to Dr. Martonen, the scientific literature suggests that sebacate may be hazardous to health. Even if it is not, however, Dr. Martonen maintains 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 alleges, 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 states that he has 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 alleges, 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 alleges that Dr Kim's data could only have been generated by the intentional overexposure of his subjects. That is, Dr Martonen contends 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 Zemck, 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 alleges, however, that he has spoken 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 alleges that any notice provided to the subjects of Dr Kim's experiments was necessarily inadequate. Dr Martonen acknowledges 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 contends that to the extent that EPA management insists on characterizing the overexposure in question as a minor, unintentional violation of protocol, these notices must be misleading. Thus, Dr Martonen maintains that the EPA has yet to adequately address the wrongdoing that occurred in the course of Dr Kim's research.

III THE SPECIAL COUNSEL'S FINDINGS

Given Dr Martonen's apparent expertise regarding the matters he has disclosed, the detail he has provided, and his first-hand knowledge of many of the incidents he has described, I have concluded that there is a substantial likelihood that the information Dr Martonen provided to the Office of Special Counsel discloses violations of law, rule, or regulation, an abuse of authority, and a substantial and specific danger to public health.

Enclosure

Requirements of 5 U S C § 1213(d)

Any report required under subsection (c) shall be reviewed and signed by the head of the agency¹ and shall include

- (1) a summary of the information with respect to which the investigation was initiated,
- (2) a description of the conduct of the investigation,
- (3) a summary of any evidence obtained from the investigation,
- (4) a listing of any violation or apparent violation of law, rule or regulation, and
- (5) a description of any action taken or planned as a result of the investigation, such as
 - (A) changes in agency rules, regulations or practices,
 - (B) the restoration of any aggrieved employee,
 - (C) disciplinary action against any employee, and
 - (D) referral to the Attorney General of any evidence of criminal violation

In addition, we are interested in learning of any dollar savings, or projected savings, and any management initiatives that may result from this review

¹ Should you decide to delegate authority to another official to review and sign the report, your delegation must be specifically stated