EXHIBIT E







Mount Sinai School of Medicine Research Integrity Investigation Case No. DIO 3801

FINAL INVESTIGATION COMMITTEE REPORT REGARDING DR. HENGJUN CHAO

CONFIDENTIAL

I. Introduction

On March 18, 2008, Dr. Dennis Charney, Dean, Mount Sinai School of Medicine ("MSSM") and "Deciding Official" ("D.O."), informed the NIH Office of Research Integrity ("ORI") of Mount Sinai's intention to conduct a formal two-part investigation into allegations of research misconduct alleged by Ellen Cohn, Ph.D. (formerly Ellen Block) (Complainant) against Hengjun Chao, M.D., Assistant Professor, Department of Medicine, Division of Hematology and Medical Oncology (Respondent) (Part 1) and Dr. Hengjun Chao (Complainant) against Dr. Ellen Cohn (Respondent), former postdoctoral fellow to Dr. Chao (Part 2). Due to the overlapping nature of the allegations in this case and at the recommendation of the Division of Investigative Oversight at ORI, the Investigation Committee ("Committee") appointed by Dr. Charney conducted one investigation to review both sets of allegations. As stated in both Inquiry Reports in this matter, the Inquiries and subsequent Investigation have proceeded in accordance with Chapter VI of the MSSM Faculty Handbook and the federal regulations governing inquiries and investigations into research misconduct, 42 CFR Part 93, Subpart A.

The Investigation Committee consisted of five members:

- Marek Mlodzik, Ph.D. (Chairman), Professor & Chair, Developmental and Regenerative Biology
- Hans Snoeck, M.D., Ph.D., Associate Professor, Gene and Cell Medicine and Associate Professor, Infectious Diseases
- · Terry Krulwich, Ph.D., Professor, Pharmacology and Systems Therapeutics
- Helen Vlassara, M.D., Professor, Geriatrics and Adult Development, Experimental Diabetes and Aging; Professor, Gene and Cell Medicine; Professor, Medicine
- James Godbold, Ph.D., Research Professor, Community and Preventive Medicine

Reginald Miller, DVM is the MSSM Research Integrity Officer ("RIO") and Sally Strauss, Senior Associate General Counsel, served as Counsel to the Committee. Karen Jones, Assistant to the Research Integrity Officer, served as staff to the Committee.



II. Procedural History & Background

A. Summary of Allegations

On September 26, 2007, Dr. Miller commenced an informal preliminary review into allegations of possible research misconduct after Dr. Hengjun Chao contacted him regarding a complaint against his former postdoctoral fellow, Dr. Ellen Cohn. Dr. Chao alleged that Dr. Cohn fabricated research data while in his lab. During this informal review it was determined that the specific allegation, fabricated research data, could not be supported. Therefore, Dr. Chao withdrew his formal complaint against Dr. Cohn.

On October 3, 2007, Dr. Cohn submitted a written statement alleging that Dr. Chao had directed her to switch antibody data results from two distinct mice groups and omit data that did not support Dr. Chao's hypothesis. Dr. Cohn also alleged that Dr. Chao relied on very small sample sizes to support his hypothesis and did not use statistical analysis to analyze his data. Additionally, Dr. Cohn alleged that Dr. Chao submitted a manuscript where she was listed as coauthor without giving her adequate opportunity to review and comment on the manuscript. Finally, Dr. Cohn alleged that Dr. Chao lodged an unsubstantiated complaint of misconduct (fabrication of research data) against her in retaliation for her bringing these issues to her Division Chief, Dr. George Atweh, for resolution. (Dr. Cohn's October 3, 2007 Complaint is attached as Exhibit 1.) On October 5, 2007, the RIO reviewed the allegations with the MSSM Research Integrity Committee ("RIC"). The RIC, after determining that the allegations against Dr. Chao were credible and specific, convened an Inquiry Panel to investigate the above-referenced allegations.

On November 20, 2007, Dr. Chao submitted a written statement alleging that Dr. Cohn had engaged in "multiple counts of research data fabrication, research data manipulation, and intentional or reckless disregard of research data/recordings." (Dr. Chao's November 20, 2007 Complaint is attached as Exhibit 2.) On December 21, 2007, the RIO met with the RIC to review the allegations against Dr. Cohn. The RIC concluded that the allegations were sufficiently credible and specific to require review by an institutional Inquiry Panel. The RIC further determined that since Dr. Chao's allegations were integrally intertwined with Dr. Cohn's allegations, the existing Inquiry Panel should review Dr. Chao's allegations, albeit as a separate review.

B. Panel of Inquiry

The Inquiry Panel reviewing the allegations against Dr. Chao completed its Inquiry on December 6, 2007 and, pursuant to Chapter VI of the MSSM Faculty Handbook and the governing federal regulations, distributed its report to Dr. Chao for comment before delivering it to Dean Charney, MSSM D.O. In its report, the Inquiry Panel concluded that Dr. Cohn's allegations against Dr. Chao were sufficiently substantiated to require the matter to proceed to an Investigation pursuant to Chapter VI of the MSSM Faculty Handbook and the applicable federal regulations.

After discussing with ORI the interlacing issues involved in this case, with its two sets of allegations, a decision was made to complete the second Inquiry before beginning an Investigation into the first set of allegations (i.e., those made by Dr. Cohn). This decision was

2

made in order to ensure that both sets of allegations were reviewed in the most comprehensive and efficient way possible and to ensure "due process" to both parties.

On February 25, 2008, the Inquiry Panel completed its review of the allegations against Dr. Cohn. The Panel concluded that certain of the allegations against Dr. Cohn were also sufficiently substantiated to require the matter to proceed to an Investigation. Pursuant to Chapter VI of the MSSM Faculty Handbook and the governing federal regulations, the Panel distributed its report to Dr. Cohn for comment before forwarding it to Dr. Charney, D.O.

On March 18, 2008, after the conclusion of the second Inquiry, Dr. Charney informed ORI that MSSM would be commencing a formal investigation into both sets of allegations and that the matter would go forward as one investigation.

C. Sequestration of Research Records and Evidence

In response to the initial allegation of possible research misconduct filed by Dr. Chao on September 26, 2007 (but later retracted), Dr. Miller, the RIO, sequestered lab notebooks (Ellen Block/Cohn) and computer hard drives from Dr. Chao's lab. As a result of the allegations against Dr. Cohn, Dr. Miller also sequestered Meagan Kelly's lab notebooks and six three-ring binders containing raw ELISA data. The sequestered materials are stored in a locked file cabinet and are under supervision of the RIO.

D. Federal Funding Support

The research and papers in question list the following sources of federal support:

- (1) Nature Medicine Manuscript (2007): "High level of antigen induces antigen-specific tolerance mediated by CD4+CD25+FoxP3+ regulatory T cells" (NIH RO1 HL076699), referred to herein as the "Nature Medicine Manuscript" and attached as Exhibit 3 (submitted but not published).
- (2) Blood Manuscript (2007): "AAV-dose/FIX-level-dependent FIX tolerance" (NIH RO1 HL076699), referred to herein as the "Blood Manuscript" and attached as Exhibit 4 (submitted but not published).
- (3) Progress Report submitted to the NIH for RO1 HL076699, dated January 22, 2007, and attached as Exhibit 5.

III. The Investigation Process

The Committee met on April 14, 2008 to discuss the scope of the Investigation and the process to be followed. The Committee decided to address Dr. Cohn's allegations first since her written complaint was submitted before Dr. Chao's written complaint. Dr. Chao's allegations were addressed in the second part of the Investigation.

The Committee interviewed the following individuals during thirteen formal sessions and one less formal session¹:

- Dr. Ellen Cohn, interviewed on April 28, August 11, and September 23, 2008
- Dr. Hengjun Chao, interviewed on June 4, August 12, and September 18, 2008
- Meagan Kelly, interviewed on June 19 and October 16, 2008
- Dr. Gwendalyn Randolph, interviewed on April 30 and September 18, 2008
- Dr. Liliana Ossowski, interviewed on May 12
- Dr. Christopher Walsh, interviewed on June 19, 2008
- Dr. Carl Nathan, interviewed by phone on July 7, 2008
- Dr. George Atweh, interviewed on March 13, 2009

All of the witnesses were cooperative with the Committee's requests for information and interviews.

IV. Allegations & Committee Determinations

A. Overall Assessment of Credibility

In assessing the veracity of the allegations brought forth by Dr. Cohn and Dr. Chao, the Committee, in many instances, had to rely on the respective witnesses' forthrightness and demeanor as well as the consistency of their testimony. The reason for this is that for the majority of the allegations and cross-allegations, there was no "smoking gun" direct evidence for the Committee to rely upon. Rather, in many cases, the allegations by Dr. Cohn and Dr. Chao represent the classic "he said-she said" dispute where Dr. Cohn alleges that Dr. Chao directed her to manipulate data; he denies doing so and alleges that she independently took these actions². There is only one allegation, Allegation #1 by Dr. Cohn, whereby she alleges that Dr. Chao directed her to switch data, which is supported by written evidence and corroborating testimony of a third party. This evidence will be detailed in the following section.

Overall, the Committee found Dr. Chao to be defensive, remarkably ignorant about the details of his protocol and the specifics of his raw data, and cavalier with his selective memory. Furthermore, he made several overbroad and speculative allegations of misconduct against Dr.

¹ The transcripts of each interview (with the exception of the Panel's less formal discussion with Dr. Gwen Randolph on September 18, as well as Dr. Atweh's March 13, 2009 interview) are attached with their corresponding errata as Exhibit 6. Dr. Atweh's transcript and corresponding errata are attached as Exhibit 1 to the Committee's Addendum in response to Dr. Chao's February 11, 2009 submission.

² Dr. Cohn does admit to taking certain actions on her own, without Dr. Chao's knowledge. However, she claims that she did so in response to Dr. Chao's unyielding pressure to generate data consistent with his hypothesis.

Cohn without any substantiation. In several of these instances, the evidence to assess the accuracy of the allegation was readily available. Yet, Dr. Chao never made the effort to review this evidence before making his allegations against Dr. Cohn, nor identify the evidence for the Committee. When the Committee, itself found the raw data, it showed that certain of Dr. Chao's allegations were specious. Dr. Chao's repeated unsubstantiated allegations and refusal to retract them despite the contrary evidence further undermined his credibility before the Committee. In fact, whenever, Dr. Chao was confronted with documents or information that contradicted some of his statements or conflicted with his allegations (such as emails he received or contrary data) he would inevitably retreat to the position that he had no memory of reviewing the documents or discussing these issues with the relevant parties. See Chao 6/4/08 Tr. at 118-119; Chao 8/11/08 Tr. at 7-8, 13-14, 42, 54, 69-71, 90-91, 154-156; Chao 9/18/08 Tr. at 60-61, 63-65, 70-72, 75-77. The Committee found his failure to re-acquaint himself with the facts and verify the facts surprising given the fact that he was both under investigation for scientific misconduct and making serious allegations that his post doc committed scientific misconduct.

Moreover, Dr. Chao reported to the Committee that he felt a tremendous pressure to publish (Chao 9/18/08 Tr. at 139). The Committee came to a unanimous impression that he was willing to use sloppy data, selective data and manipulated data in order to support his thesis and generate papers for publication⁴. These actions will be discussed in more detail in connection with the discussion of each of the remaining allegations.



³ For example, Dr. Chao alleged that Dr. Cohn lied about conducting an experiment on 5/8/07 and never actually injected the mice as reported in her later lab book notations of 7/24/07. He made this allegation in his written submission to the RIO and reiterated it during his interviews with the Committee several months later. Yet, Dr. Chao never reviewed the mice logs or the raw ELISA results which would have revealed whether the experiment was actually done prior to lodging his complaint. The raw data, in fact, confirmed that Dr. Cohn had injected the mice and her contemporaneous mice logs also confirmed that the experiment was conducted. When presented with the mice logs, which showed that the mice were injected on 5/8/07, Dr. Chao simply concluded that these too were probably just fabricated. He had no explanation for the ELISA results, but even in the face of this cogent evidence, he never retracted his allegation that she may have "falsely marked" the mice and that she "cheated in virtually every stage of her project and every file/figure." (Chao's 10/2/08 errata submission)

⁴ Dr. Chao's testimony regarding his use of data in Figure 2 highlights his lack of rigor in his approach to data to be included in publications. Figure 2 involved flow cytometry tests that were ultimately completed by Dr. Cohn's successor Dr. Bharadwaj. In this case, Dr. Chao relied on the expertise of Dr. Frank Tacke a former post doc in Dr. Randolph's laboratory for interpretation of the results. Dr. Tacke advised Dr. Chao that the flow data was "not the best" but "acceptable." (Chao 8/11/08 Tr. at 86-87, 91) Similarly, Dr. Bharadwaj, also advised Dr. Chao that the results were mediocre at best. (Chao 8/11/08 Tr. at 90) When the Committee asked Dr. Chao whether he had presented this marginal data to Dr. Randolph who was an expert in this area for her feedback, he stated that he had done so but couldn't remember her comments. (Chao 8/11/08 Tr. at 90)

Not only did Dr. Chao readily use this mediocre data, but he didn't scrutinize the data sufficiently to ensure its accuracy. During the interview, several Committee members identified clear contradictions and differences in the figures and questioned Dr. Chao about these errors. Dr. Chao, in turn, advised the Committee that he didn't realize such mistakes existed until the Committee pointed them out. (Chao 8/11/08 Tr. at 85-86). The Committee found Dr. Chao's belated discovery of the mistakes in his manuscript very troubling in light of the fact that he had submitted the paper one year earlier and he was aware that it was the subject of this investigation.

B. Allegations against Dr. Hengjun Chao

1. Allegation #1 - Directive to Switch Data

Dr. Cohn alleged that Dr. Chao directed her to switch select blood data of two mice that he believed were inadvertently switched by Dr. Cohn and Meagan Kelly in an experiment that was conducted in May 2007. According to Dr. Cohn, these particular results were not consistent with Dr. Chao's expectations, but if the results were reversed they would have fit more neatly into his hypothesis. Therefore, he assumed that she and Meagan Kelly had mixed up the blood data of these two mice. Following are the details of this experiment.

Dr. Chao aimed to prove that AAV2 injected mice would show a low level of FIX and a high level of antibody (indicative of an immune response) whereas AAV1 injected mice would show a high level of FIX and a low level of antibody (indicative of tolerance). In addition, antigen-specific T cell proliferation and splenic cellularity were used as measures of immunity or tolerance. To prove this hypothesis he used three groups of mice; he injected the first group with AAV1, the second with AAV2; the third group was a control group. The first time the experiment was conducted, there was no correlation within the group on measures such as FIX antigen, anti-FIX antibody, and T cell proliferation. The second time they ran the experiment, at least two mice in the AAV1 group matched on these parameters (i.e., high level of FIX, low level of antibody, small spleen, low proliferation), but the results of the third mouse were inconsistent with Dr. Chao's expectations. In the AAV2 group, the results were also mixed. Dr. Cohn claims that Dr. Chao responded to these unexpected results by insisting that she must have confused the blood data from the mice (Exhibit 1 & 4/28/08 Cohn Tr. at 6-8, 15-15). She further alleges that Dr. Chao asked her to switch the data so that the results conformed to his hypothesis.

a. Determination of Misconduct and Rationale for Conclusions

The Committee concludes that Dr. Chao did request Dr. Cohn to switch the mice data and that his request to manipulate the data constituted research misconduct in the form of intentional falsification.

The most probative evidence in support of this finding is an email from Dr. Chao to Dr. Cohn dated 7/13/07 (Exhibit 9) where he explicitly and unequivocally confirmed that he had directed her to switch the data. In that email, he justified his request by invoking his authority as the PI and stated:

Do you think these are reasonable results? These cannot simply be explained as statistical outliers, either. I believe it is well scientifically justified and proper for me to ask you to switch these two mice when summarizing these results, and also to repeat the adoptive T cell transfer meanwhile.

⁵ It is relevant to note that both Dr. Cohn and Meagan Kelly firmly believed that they had not confused the blood vials. They each testified that they had taken great care to ensure the integrity of the separate groups of mice precisely to prevent an inadvertent mixup. (See Dr. Cohn's 5/3/07 lab notebook entry, which is attached as Exhibit 7 and Meagan Kelly's 5/8/07 lab notebook entry, which is attached as Exhibit 8. See also Cohn 4/28/08 Tr. at 13-14, 114-118, 120; Cohn 8/12/08 Tr. at 51; Chao 9/23/08 Tr. at 76; Kelly 6/19/08 Tr. at 24-28).

The Committee's finding is further supported by the testimony of Dr. Liliana Ossowski. Dr. Ossowski testified that during a meeting with Dr. Chao, he explicitly advised her that he had asked Dr. Cohn to "switch mice from one group to another." He apparently believed his directive was justified due to his greater experience and emotional commitment to his hypothesis. He explained to Dr. Ossowski that [Dr. Cohn] is a young scientist [and] doesn't know how the experiments should come out, and I in my heart know how it should be." (Ossowski Tr. at 14)

When asked to respond to Dr. Cohn's allegations and explain the incriminating email, Dr. Chao simply denied that he had ever asked anyone to manipulate research data and maintained that he never meant what he wrote with regard to the switching of data. (Chao 6/4/08 Tr. at 64-66) He contended that he was entrapped and unwittingly used the word "switch" in his email to Dr. Cohn because he was angry and upset that as a post doc, she questioned his judgment. (Chao 6/4/08 Tr. at 106-108, 113-114) When the Committee asked him whether he ever discussed the incident with Dr. Ossowski, he reiterated three times that he "could not remember exactly/ could not remember." (Chao 6/4/08 Tr. at 118). In his submission to the Committee's draft report, Dr. Chao discredits Dr. Ossowki's credibility, claiming that she was prejudiced against him because he criticized her handling of hiring Dr. Cohn. Accordingly, he suggests that the Committee must ignore her testimony. The Committee disagrees with Dr. Chao's description of Dr. Ossowski's lack of integrity in this matter. It found Dr. Ossowski to be a forthright and credible witness who offered relevant evidence for the Committee's consideration. The Committee further notes that the former Division Chief, Dr. George Atweh, also testified to Dr. Ossowski's impeccable honesty6 and rejected Dr. Chao's suggestion that she would provide false testimony to retaliate against Dr. Chao. This is particularly noteworthy since Dr. Chao had asked the Committee to interview Dr. Atweh because he would offer supporting testimony on behalf of Dr. Chao.

The Committee found the plain words of Dr. Chao's email and Dr. Ossowski's corroborating testimony compelling evidence that he made this request to Dr. Cohn. In contrast, the Committee found Dr. Chao's post-hoc explanation that "she forced me to say this" and that he didn't really mean what he wrote to Dr. Cohn lacking in credibility. The Committee also found his testimony that he could not remember whether he ever discussed the incident with Dr. Ossowski lacking in credibility. Surely if the incident caused him to be as angry and upset as he claimed, then he would have recalled discussing the incident with his colleague. In this regard, the Committee notes that Dr. Chao often claimed a lapse in memory when his testimony would have otherwise undermined his position.

2. Allegation #2 - Omission of Data

In her October 3, 2007 complaint (Exhibit 1), Dr. Cohn alleged that Dr. Chao omitted data in Figures 4A and 4B of the manuscript submitted to Nature Medicine on September 26, 2007 (Exhibit 3). During the course of the investigation, Dr. Cohn made additional allegations regarding omission of data on the part of Dr. Chao. Dr. Cohn alleged that Dr. Chao directed her to alter and omit data in Figures 1A-1, 1A-2, 1B-1 and 1B-2 of the Nature Medicine Manuscript.

⁶ Dr. Atweh testified that Dr. Ossowski is "one of the most honest and straightforward and outstanding scientists that I have interacted with." (Atweh Tr. at 2)

a. Figures 1A-1 & 1A-2

Dr. Cohn alleges that Dr. Chao instructed her to report that all mice receiving 1×10^{10} AAV1 had died at Week 16 when in fact they were alive. Additionally, Dr. Cohn alleges that Dr. Chao directed her to switch the following two data values in Figures 1A-1 and 1A-2: 1×10^{11} AAV1 and 5×10^{10} AAV1. Finally, Dr. Cohn claims that Dr. Chao asked her to omit 24 and 28-week data in these two figures. Dr. Cohn maintains that in each of these cases, Dr. Chao directed her to make the changes because the data as modified supported his hypothesis whereas the actual data conflicted with his hypothesis.

i. Determination of Misconduct and Rationale for Conclusions

(a) Omission of the 24 & 28 week data

The Committee concludes that at a minimum there is evidence to support the allegation that Dr. Chao saw or should have seen the data that was omitted and that he acted with reckless disregard when he selectively excluded this data in the papers he submitted for publication. While the Committee could not make a conclusive determination as to whether Dr. Chao explicitly directed Dr. Cohn to manipulate and/or omit this specific set of data in these figures, it was the Committee's view that as the Principal Investigator, Dr. Chao had a responsibility to review the raw data that supported these figures and confirm that the figures accurately represented the raw data. This basic responsibility of a Principal Investigator was even greater in this case, because Dr. Chao had been given and/or explicitly reviewed earlier versions of these figures that contained the accurate and complete set of data. Therefore, he had a heightened duty to verify the changes in the new versions of the graphs and his failure to take such steps constituted reckless disregard.

There was no question that Dr. Chao had received the 24 and 28 week data in earlier iterations of these figures. Dr. Cohn emailed her presentation, including these figures with this data to Dr. Chao for his review prior to presenting the data to their colleague Dr. Gwen Randolph and her laboratory staff for discussion and feedback at a group lab meeting. (See Exhibit 10, which is a 12/21/06 e-mail labeled "CH-041a". See also Exhibit 11 at page 4. Exhibit 11, labeled EC-3 and "Support File #1", was originally submitted by Dr. Chao to the Inquiry Panel). Furthermore, Dr. Cohn had an email record that Dr. Chao had responded to her e-mail, further confirming that he had received the data (Exhibit 12). In addition, this data was included in a progress report submitted to the NIH in connection with the grant that funded the Nature Medicine Manuscript (i.e., RO1 HL076699) (Exhibit 5, Figure 8). Presumably, Dr. Chao reviewed and approved of the data included in his submission to the NIH. Finally, Dr. Cohn had prepared this figure in three different instances, with end points of 20 weeks, 24 weeks and 28 weeks respectively. Since Dr. Cohn was no longer working in Dr. Chao's laboratory when he finalized the paper for Nature Medicine, she could not be held responsible for choosing which of the three versions of this figure to use in the manuscript. Dr. Chao chose to insert the figure that omitted the 24 and 28 week data. It was at these later points that the data began to converge, thereby contradicting his hypothesis.

When initially asked about whether he had ever seen the version that was part of the presentation to Dr. Randolph, Dr. Chao claimed he had no memory of ever receiving it or reviewing it at a laboratory meeting with his colleague Dr. Randolph (Chao 9/18/08 Tr. at 63-65). In fact, he initially testified that he never realized that this data existed until the Committee

pointed it out to him (Chao 8/11/08 Tr. at 14)⁷. Upon follow-up questioning, he modified his response and suggested that while he may have received the figures and data, "[U]sually I do not look at the data, I just look at the figures, the graph... and paste it to the PowerPoint." (Chao 8/11/08 Tr. at 24) When he was then presented with the email traffic demonstrating that he had received the 24 and 28 week data in an earlier version of the chart, Dr. Chao questioned whether he had ever received this email.

The Committee found Dr. Chao's various explanations inconsistent, and lacking in credibility, particularly in light of the fact that this data was used by Dr. Chao several years earlier in his RO1 submission. The Committee concludes however, that these emails and documents confirm that Dr. Chao had previously reviewed this data. It is the Committee's view that as the principal investigator and laboratory leader he had a duty to review each version of the data and its incorporation into a presentation and therefore, he should have known that there were prior versions of this figure with later data points that did not fit as neatly with his hypothesis. While there may be legitimate scientific reasons to exclude these later data points, Dr. Chao never presented any such reasons to the Committee. Rather, his decision to exclude them fits into his overall pattern of excluding data that did not conform to his hypothesis. Therefore, in the context of this case, the Committee believes that Dr. Chao's action constitutes reckless falsification of the data.

(b) Switching of graph lines

Dr. Chao testified that he closely monitored the raw data during the initial 8 to 10 week phase of this experiment (Chao 8/11/08 Tr. at 53-54) and observed that the trend lines for the two strains of AAV1 were moving in a direction that was inconsistent with his hypothesis. Despite his review of the initial raw data, Dr. Chao admitted that he neglected to review the raw data in the latter stages of these experiments when the graphed out trends "corrected" themselves to conform to Dr. Chao's hypothesis. When cross-examined on this point, Dr. Chao admitted that he neither reviewed the raw data in the latter phases, nor could he remember why he wouldn't have questioned the discrepancy arising from the switched graph lines (Chao 8/11/08 Tr. at 53-54). Again, it is the Committee's view that as the principal investigator and laboratory leader he had a duty to review the raw data at all phases of the study. This was particularly the case here where the later trend lines diverged from the earlier results. Therefore, even if he did not explicitly direct Dr. Cohn to switch the data values, his failure to review the raw data constitutes a significant departure from the accepted practices of the research community and represents a reckless action of misconduct in the form of falsification of data.

(c) Dead Mice at 16 Weeks

In this experiment involving 5 mice, 3 mice died, but the remaining 2 mice survived beyond the 16 week period through 28 weeks. Moreover, according to Dr. Cohn since the data relating to these mice did not fit Dr. Chao's hypothesis, he directed her to specify that all 5 of the mice died at week 16. Whereas, the Committee could not conclusively determine whether Dr.

⁷ The Committee found both this initial lapse of memory and failure to review the data prior to his interview with the Committee surprising. The investigation had been ongoing for more than 6 months and Dr. Chao had already testified before the Inquiry Panel regarding these allegations. Given the seriousness of this matter, the Committee would have expected Dr. Chao to immerse himself in the data and to refresh his recollection about all the related events so that he could testify accurately and comprehensively. Instead, the Committee perceived that Dr. Chao used his memory lapses as a shield to avoid accepting responsibility for lapses in his oversight.

Chao issued this directive, the Committee concluded that Dr. Chao had access to the raw data regarding the life span of these mice and as the Principal Investigator it was incumbent upon him to review the data in connection with his publication. His failure to do so represents a reckless disregard for the accuracy of his publication and as such constitutes research misconduct in the form of falsification of data.

b. Figures 1B-1 & 1B-2

Dr. Cohn alleges that Dr. Chao asked her to omit data for the 12 and 20-week points in Figures 1B-1 & 1B-2 because the data did not conform to his hypothesis.

i. Determination of Misconduct and Rationale for Conclusions

Dr. Chao denied issuing such a directive. Yet, he conceded that the protocol called for blood tests at four week intervals. Initially, he testified that he "should have asked her" why these results were missing (Chao 8/11/08 Tr. at 69). When further pressed on this point, he modified his answer and advised the Committee that he did in fact ask her why this data was missing, but he "could not remember exactly her answer" (Chao 8/11/08 Tr. at 71). Yet, despite this glaring gap in results, at no time did Dr. Chao go back to the original ELISA results which were stored in binders in his laboratory to assess whether the data existed and if so what it showed. The ELISA data showing the 12 and 20-week points are labeled CO-007-F and CO-007-G and are attached as Exhibits 13 and 14, respectively. See Cohn 9/23/08 Tr. at 5-52 for explanation of this data.

Although the Committee found Dr. Chao's responses, and memory lapses lacking in credibility, it could not make a conclusive determination as to whether he explicitly directed Dr. Cohn to omit these data points because he knew that the data was inconsistent with his results. However, the Committee concludes at a minimum, that Dr. Chao had an obligation to review the original data that was readily accessible to him and by failing to do so he acted with reckless disregard in the form of falsification of data in presenting these incomplete figures. Dr. Chao notes in his February 11, 2009 submission that the omission of these data points did not contradict his hypothesis and that "there was no sound scientific reason to include these specific time points as my hypothesis was testing the long term changes or variations" (p. 30). The Committee disagrees with this claim.

The Committee noted that Dr. Cohn provided written evidence of a separate instance where Dr. Chao explicitly approved of the omission of data that was inconsistent with his hypothesis. In an email from Dr. Cohn to Dr. Chao dated 2/27/07, she provided certain data and highlighted the fact that she had explicitly removed data for two mice because the data did not conform to Dr. Chao's hypothesis. (See Exhibit 15.) Although this e-mail is not related to the data in the Nature Medicine manuscript, it demonstrates Dr. Chao's general willingness to use selective data and omit inconsistent data. Moreover, his reaction when he was presented with this email only served to undermine his credibility further. When the Committee showed this email to Dr. Chao, he denied ever receiving it and speculated that the email was "doctored" (Chao 9/18/08 Tr. at 71-76, Chao 10/2/08 errata at Appendix 1). The Committee believes that it is highly unlikely that Dr. Cohn would have gone to the lengths of "doctoring" an email on the Mount Sinai network system while in the midst of a scientific misconduct investigation. Indeed, such an allegation underscores the extreme lengths that Dr. Chao has undertaken to discredit his former post doc. Furthermore, the evidence of this practice directly contradicts his testimony and statements to the Committee that he "never" participated in or condoned such practices.

c. Figure 3

According to Dr. Cohn, Figure 3 only includes data for 2 mice in two out of three of the experimental groups, even though there were 3 mice in each of the experimental groups.

i. Determination of Misconduct and Rationale for Conclusions

The Committee was not able to obtain clarity from Dr. Chao on how many mice were initially used in this experiment. Indeed, when questioned regarding this figure, Dr. Chao retreated into his general position that he had no knowledge of the specifics of the experiments and had no idea how many mice were initially in the group. (Chao 8/11//08 Tr. at 105) He was only able to confirm that he had results for two mice and he used those results in the figure.

While the Committee found that this use of such a small cohort did not constitute scientific misconduct, it finds the use of such a small sample size of N=2 in this experiment as well as in the experiments relating to Figures 2 and 4 did not meet acceptable standards of good laboratory practices. In addition, the Committee found Dr. Chao's lack of knowledge of the details of his experiments reflective of a sub-optimal rigor in tracking his projects and his willingness to rush to scientific conclusions without a full command of the underlying data.

d. Figure 4A & 4B

Dr. Cohn alleges that Dr. Chao omitted the data of two mice in Figure 4A of the Nature Medicine Manuscript. According to Dr. Cohn, the raw data for this figure shows that there were 7 mice in the naïve group and 10 in the AAV1 group, but only 5 mice were included in Figure 4A. According to Dr. Cohn, Figure 4B only includes the data from one experiment, even though two experiments were performed.

i. Determination of Misconduct and Rationale for Conclusions

The Committee did not have sufficient data to reach a conclusion regarding these allegations, but it was concerned about the process Dr. Chao used to select the final data for these figures. Dr. Chao never provided clarification on his selection process.

3. Allegation #3 – Use of Small Sample Sizes & Failure to Perform Statistical Analysis

Dr. Cohn alleges that Dr. Chao relied on small sample sizes in experiments related to Figures 3, 4A and 4B in the Nature Medicine Manuscript and did not perform statistical analyses on these samples.

a. Determination of Misconduct and Rationale for Conclusions

The Committee concludes that, while Dr. Chao did not perform proper statistical analysis on the data that are represented in Figures 3, 4A and 4B in the Nature Medicine Manuscript and relied on small sample sizes, these acts do not constitute research misconduct as defined by ORI.

These practices are of concern, however, and do not satisfy the institutional expectations of good laboratory practices.⁹

Dr. Chao defended his failure to use statistical analysis claiming that he was never trained to use statistics as a post doc, nor exposed to its importance as a junior faculty member (Chao 6/4/08 Tr. at 20-22; Chao 8/11/08 Tr. at 62). He claimed that he only started implementing statistical analysis recently after a colleague at a separate institution, who wants to remain anonymous, told him to do so (Chao 6/4/08 Tr. at 23-24). The Committee finds Dr. Chao's testimony lacking in credibility and directly contradicted by his mentor, Dr. Walsh, who trained Dr. Chao as a post doc, and his occasional advisor, Dr. Randolph.

Dr. Walsh testified that he had always made it clear to his trainees that statistical analysis was essential; he always used statistical analysis in his lab and he specifically testified to using statistical analysis in the work he did while Dr. Chao was his post doc. (Walsh Tr. at 10) He further testified that it was common practice in his scientific specialty to use statistical analysis and that one couldn't get a paper accepted without "minimal statistical analysis." (Walsh Tr. at 11) The Committee found Dr. Walsh to be a credible witness; he is an experienced researcher in the field with no motive to lie to the committee regarding his training of Dr. Chao.

Similarly, Dr. Chao's claim that he was never exposed to the use of statistical analysis while a junior faculty member was directly contradicted by Dr. Walsh and Dr. Randolph. Indeed, Dr. Chao had the opportunity to confer with researchers such as Dr. Randolph and Dr. Walsh who both used statistical sampling as an integral part of their research protocols. The Committee was at a loss to understand Dr. Chao's testimony about his background in and exposure to statistics and his apparent choice to work within a silo and to ignore the opportunities for expert advice during his initial faculty position.

4. <u>Allegation #4 – Failure to Provide Nature Medicine Manuscript in a Timely Manner</u>

Dr. Cohn alleges that Dr. Chao failed to provide her with the Nature Medicine Manuscript for review, despite the fact that she was listed as a second author. Dr. Cohn reported that Dr. Chao sent her a copy of the manuscript on September 24 the day before he submitted it. Moreover, he sent her a copy only after she explicitly requested it. As a result, Dr. Cohn did not have a meaningful chance to review the data represented in the manuscript, nor did she have a chance to discuss the manuscript with Dr. Chao, despite her request to meet with him before submission.

a. Determination of Misconduct and Rationale for Conclusions

Dr. Chao conceded that he failed to provide the manuscript to Dr. Cohn in a timely manner. Although this action does not constitute scientific misconduct as defined by ORI (i.e., it is not fabrication, falsification, or plagiarism), it does not comport with the standards for scientific publication. It is accepted practice within the scientific community that the principal

⁹ Dr. Chao states in his February 11, 2009 submission that statistical analysis was performed on the data in the multiple graphs of Figure 2 of the Nature Medicine Manuscript. However, statistical analysis would provide quantitative grounds (i.e., p-value, confidence interval) for an inference about the difference between the treatment groups. No such analysis is present.

investigator shares the final manuscript with all co-authors and secures their respective approval of the final version prior to submission. Dr. Chao violated this standard when he only gave Dr. Cohn one day to review the paper and failed to obtain her authorization. Moreover, it appears highly likely that Dr. Chao would have never shared the manuscript with Dr. Cohn absent her request. 11

Dr. Chao's testimony that he always intended to provide her a copy was belied by his contrary actions and serves as yet another example of his false testimony. There is no question that he had completed a draft of the manuscript at least one week earlier and could have shared the draft with his lab members at that time. Instead, on September 19, 2007, he emailed copies to the co-authors, Dr. Randolph and Dr. Tacke (Exhibit 16). Dr. Randolph returned the paper to Dr. Chao on the same day instructing him to remove her name as co-author because she wasn't convinced by the data, and was concerned about his decision to remove Dr. Cohn as first author. (Randolph Tr. at 52) Given Dr. Randolph's negative review, one would assume that Dr. Chao would have taken extra care to ensure that the remaining authors approved of the final manuscript before submission. But, he never did. During the seven days between when he gave Dr. Randolph and Dr. Tacke a copy of his submission he never took the initiative to provide Dr. Cohn a copy. When he finally responded to her request for a copy, he submitted the manuscript twelve hours later to Nature Medicine, thereby precluding her from providing any feedback and rendering his actions superfluous.

The Committee was also troubled by Dr. Chao's removal of Dr. Cohn as first author and his replacement with his technician Meagan Kelly. It is highly unusual to place a technician as first author when a post doc was involved in the research. Moreover, his explanation that both worked equally on the underlying experiments does not justify such a radical decision (Chao 6/4/08 Tr. at 142). Finally, his admission that he might not have replaced Dr. Cohn if she had not objected to his practices and left his lab confirms that he took this action out of anger and in retaliation for her "disloyalty" to him (Chao 8/11/08 Tr. at 147-148).

5. Allegation #5 - Retaliation

Dr. Cohn alleged that Dr. Chao brought a retaliatory complaint against her (i.e., the verbal complaint brought on September 26, 2007) in order to prevent her from pursuing her allegations against him. She also alleged that his actions to remove her as first author were in retaliation for her decision to question his authority and leave his lab.

a. Determination of Misconduct and Rationale for Conclusions

As discussed above the Committee concludes that Dr. Chao's decision to remove Dr. Cohn as first author was retaliatory in nature. The Committee further concludes that several of Dr. Chao's unsubstantiated and extreme allegations were lodged against Dr. Cohn out of anger and in retaliation for her complaint against him. As discussed herein, Dr. Chao made several spurious and wholesale attacks against Dr. Cohn without conducting any preliminary review of

¹⁰ Dr. Chao also failed to provide the manuscript to Meagan Kelly in a timely manner. Although he gave her the position of first author, he only gave her one day to review the paper.

¹¹ Dr. Cohn was made aware of the manuscript by Dr. Tacke. When he received his copy, he contacted Dr. Cohn to find out what she thought of it and to express his concerns about the order of authorship (Cohn 8/12/08 Tr. at 45-46).

the available data. Such review would have demonstrated that several of his allegations had no merit. As this investigation progressed, he accelerated his allegations and began to claim that absolutely every piece of data and experiment she touched was manipulated and false and even alleged that the emails she submitted as evidence of his orchestration and involvement were fabricated. (See Chao's 10/2/08 errata sheet and its attachments.) The Committee found certain of these broad scaled attacks lacking in foundation and retaliatory in nature.

C. Recommendations

In summary, the Committee found that Dr. Chao promoted research misconduct by directing Dr. Cohn to switch data or omit data without any scientific or statistical basis for doing so. He promoted a laboratory culture of misconduct and authoritarianism by rewarding results consistent with his theories and berating his staff if the results were inconsistent with his expectations. The Committee finds Dr. Chao's actions unacceptable and makes the following recommendations:

- 1. Disciplinary Action. The Committee recommends that the Dean institute disciplinary action against Dr. Chao based on the findings of research misconduct, and his failure to be torthright during the investigation.
- 2. Monitoring of Educational Program for Dr. Chao. In the event that Dr. Chao remains on the Faculty, he should be required to complete a Responsible Conduct of Research program on good research practices and ethics in research. He should also be assigned a senior mentor to monitor his activities for the duration of his Term appointment and the mentor should provide bi-annual reports to Dr. Chao's Chairman and the Dean's office. The Committee also notes that Dr. Chao was permitted to work within an isolated silo without regular oversight and guidance. The Division Chief, Dr. Atweh, apparently tried to encourage Dr. Chao to balance his attention to the research work with his grant-writing efforts as his lab grew quickly. It is not clear whether greater insistence and specific inquiry into lab practices would have been effective.
- 3. Retraction of any Manuscripts and Abstracts. The Committee recommends that Dr. Chao issue a retraction of each of the abstracts listed in Appendix A which were reviewed by the Committee and found to include data involved in the findings of research misconduct. The Committee further recommends that Dr. Chao be directed to review the remainder of his manuscripts and abstracts and identify any others that used tainted data to the Dean's office and issue retractions for these documents as well.
- 4. Retraction to the NIH: The Committee notes that Dr. Chao included several of the graphs containing false data in his 2007 Progress Report to the NIH on RO1 HL076699. The Committee recommends that the NIH Program officer be advised of this false data so that the NIH can determine whether this subset of data was material to its final year of funding, and if so, whether a refund is warranted.
- 5. Training of and Seminars for Lab Personnel in Small, Insular Labs The Committee recommends that the Institution develop and require a research conduct

training program for all members of research laboratories that includes explicit information about where to turn for assistance with problems. It also recommends that the Institution require all departments and divisions to ensure that junior research faculty have one or more senior faculty member's integration into joint lab meetings and seminars that will expose the faculty member and his lab group to ongoing feedback. The mentor should also be alert to issues such as large lab turnover that may be an early sign of problems.

6. Improved Guidance Program for Post Docs and Improved Training and Oversight for Young Investigators. The Committee recommends that the School expand its guidance program for young investigators so that they have a clearly identified forum and specific individuals to turn to for advice and questions when they feel they cannot go to their mentors. The Committee also notes that when Dr. Cohn ultimately brought her concerns forward to more senior faculty members they failed to follow institutional policy and report her allegations of misconduct to the Dean's Office or Department Chair. The Committee recommends that these faculty are provided education about their institutional obligations and that the faculty in general are reminded about their reporting obligations with regards to research misconduct.

Marek Modzik, Ph.D./

Hans Shoeck, M.D., Ph.D.

Terry Krulwich, Ph.D.

Helen Vlassara, M.D.

Hans Shoeck, M.D., Ph.D.

Mann Mann Modell

Hans Shoeck, M.D., Ph.D.

Respectfully submitted,

James Godbold, Ph.D.

Appendix A

Abstracts to be Retracted

- 1. Any abstracts submitted at the 2006 American Society of Hematology conference, which contain falsified or fabricated data
- 2. Any abstracts submitted at the 2007 American Society of Gene Therapy conference, which contain falsified or fabricated data
- 3. Any abstracts submitted at the 2007 Congress of the International Society of Thrombosis and Haemostasis, which contain falsified or fabricated data
- 4. Any abstracts submitted at the 2007 Annual Meeting of the National Haemophilia Foundation, which contain falsified or fabricated data



MOUNT SINAL SCHOOL OF MEDICINE



Mount Sinai School of Medicine Research Integrity Investigation Case No. DIO 3801

ADDENDUM TO THE INVESTIGATION COMMITTEE'S FINAL REPORT (IN RESPONSE TO DR. HENGJUN CHAO'S 2/11/09 COMMENTS ON THE COMMITTEE'S DRAFT REPORT)

CONFIDENTIAL

The Committee has carefully reviewed Dr. Chao's submission ("Chao Response") dated February 11, 2009 regarding the Investigation Committee's Report ("Report") and is attaching this addendum. Since many of these issues are repetitious of the points Dr. Chao has previously made to the Committee, which have been reviewed and addressed, we will not reassess them here. This addendum will concentrate on the new allegations raised by Dr. Chao and his attorney that have not been addressed in the body of the report.

Dr. Chao raises two categories of objections to the Committee's report. The first are "procedural" objections where he complains about various stages of the investigatory process suggesting that it was biased against him. In the second category, he objects to the Committee's substantive findings.

Dr. Chao's critique of the process is predicated on a fundamental misunderstanding of the nature of these proceedings. The process for research misconduct investigations is governed by a highly prescriptive and detailed set of federal regulations 42 C.F.R. 93 et al. Both the Committee and the Research Integrity Officer ("RIO") closely adhered to their respective responsibilities as set forth in the regulations and as specifically directed by the Office of Research Integrity.

As the regulations make clear, there are two distinct stages of a research misconduct proceeding: the institutional investigative process and the administrative adjudicatory process. The institutional process is an investigatory one; the administrative hearing within the Department of Health and Human Services ("HHS") is more akin to a trial and provides all the attendant due process rights associated with a hearing. Dr. Chao seems to have confused the rights he would have before an Administrative Law Judge ("ALJ") during such a hearing with the investigative stage of the process that is undertaken within the institution. As the regulations make clear, Dr. Chao only has a right to attend every session, cross-examine every witness and call his own witnesses during the administrative hearing before the ALJ (See 42 C.F.R. 93.505). On the other hand, the institutional review is a peer review investigatory process whereby the Committee is directed to interview the respondent, complainant and those witnesses with "information regarding [the] relevant aspects of the investigation." 93.310 (g). The Committee is charged

¹ Dr. Chao alleges that the Committee selectively called witnesses who would support Dr. Cohn and her credibility and attack Dr. Chao. To the contrary, the Committee determined its list of potential interviews based solely on

with the responsibility for deciding who to interview and it conducts the interviews, not the respondent.

Moreover, the record makes clear that the Committee conducted its interviews in an impartial and objective manner. The Committee gave Dr. Chao multiple opportunities to present evidence and explain his data. It interviewed Dr. Chao on three occasions for several hours each. During each interview, the Committee asked and/or offered Dr. Chao with the opportunity to clarify the relevant issues, explain his process, and identify responsive materials to specific questions. Yet, he never presented the detailed data, despite the Committee's specific requests.

Moreover, the Committee did not "rush to judgment" as suggested by Dr. Chao. Rather, each member acted in good faith to investigate this rather complicated set of cross-allegations in an impartial and objective manner. It carefully reviewed all the evidence and made its findings based on an objective analysis of the evidence. Since much of this case involved cross-allegations between Dr. Cohn and Dr. Chao, it was necessary for the Committee to make credibility assessments of both respondents. But it only made these determinations after it had completed all the interviews and reviewed the available evidence and based its findings on this evidence.

Dr. Chao's misunderstanding of the process extends to his demand that the Committee set forth its definition of "recklessness." The Committee followed the definitions and standards set forth in the pertinent regulations and never considered deviating from these standards. The regulations provide that for each allegation of research misconduct, the Institution must "identify whether the research misconduct was falsification, fabrication or plagiarism, and if it was intentional, knowing or in reckless disregard." 42 C.F.R. 93.313. These terms are well accepted terms for describing differing levels of intent. Indeed, the term "reckless disregard" had been recently defined by the United States Supreme Court in <u>Safeco Insurance Co. v. Burr</u>, 127 S. Ct. 2201 (2007) and doesn't require further elaboration by this Committee.

Dr. Chao also suggests that the process was to blame for his failure to retain an attorney at an earlier stage. He suggests that he interpreted the directives to keep this matter confidential to mean that he could not consult with an advisor or an attorney. Yet, the policy on confidentiality is mandated by the regulations and is designed to protect Dr. Chao and his reputation until the Institution and the ORI have made their respective findings. These rules were never designed to preclude Dr. Chao from hiring an attorney or consulting with an advisor. Dr. Chao was always afforded that right. At the earliest stages of this process, Dr. Chao was provided with the policy and applicable rules and reminded repeatedly to read these materials. Both the regulations and Mount Sinai's policies make patently clear that Dr. Chao had a right to an attorney and/or

whether the individuals might have relevant information to the cross-allegations of misconduct. As it turned out, most of these witnesses were collaborators with Dr. Chao, not Dr. Cohn, including, Dr. Walsh, Meagan Kelly and Dr. Randolph. Dr. Randolph's testimony was particularly compelling in her descriptions of Dr. Chao's lab and research work. As earlier stated, the Committee found her to be a highly credible witness and found it noteworthy that Dr. Chao did not rebut her testimony. If the Committee were inclined to interview additional technicians and post does in Dr. Chao's lab, it would solicit information from all his prior members, including those who left after only a short tenure or were terminated. The Committee has determined it is not necessary to interview all these additional witnesses but it has conducted a follow-up interview with Dr. George Atweh. Dr. Atweh's transcript and accompanying errata are attached as Exhibit 1, and his testimony is discussed in the body of this addendum.

advisor at all stages of the process. Moreover, if he had any questions with regard to the scope of this right, he could have asked the Committee. He never did. Dr. Chao's effort to blame the very policy intended to protect him is yet another example of his own failure to take responsibility for his actions throughout this process.

Dr. Chao also incorrectly states that he was never notified of Dr. Cohn's allegations against him. To the contrary, Dr. Chao was notified in writing of the general allegations that he falsified data at the outset of both the inquiry and the investigation. He was clearly aware of the specific allegations as the investigation unfolded. The Committee specifically asked Dr. Chao about the data in each of the figures and whether he pressured Dr. Cohn to conform the data to his hypothesis (e.g. Chao. 6/4/08 Tr. at 136; Chao 9/18/08 Tr. at 126, 131). Moreover, in his errata submission dated 9/18/08, he explicitly acknowledged that he was aware of Dr. Cohn's admissions. Thus, the record makes clear that Dr. Chao was fully aware of the allegations lodged against him.

Dr. Chao attributes his failure to respond to the Committee's request for details to his busy academic schedule and to the fact that he never understood the seriousness of this investigation. His explanation at this late date is unacceptable. Dr. Chao describes himself as an intelligent, careful and honest scientist. Someone of this caliber would have surely recognized the seriousness of this process particularly after receiving the Inquiry Report which implicated his improper conduct. Moreover, all the committee members maintain both busy academic schedules and shoulder significant administrative responsibilities. Yet, each member has taken extensive time to conduct this investigation as part of one's faculty responsibility. The Committee expects no less from Dr. Chao, and believes that Dr. Chao must take responsibility for his decisions on how he devoted his time.

Dr. Chao's substantive comments are similarly littered with contorted interpretations and misstatements. For example, in his response, Dr. Chao mistakenly states that the Committee "concluded that there was no evidence of scientific misconduct in Figure 4." (Chao Response, p. 15) In fact, the Committee made no such conclusion. To the contrary, the Committee unequivocally stated in its report that it could not make any judgment regarding Figure 4 because it was never provided the raw data necessary to reach a conclusion. It repeatedly asked Dr. Chao for this data in each of the three interviews. Dr. Chao never responded to the Committee on this point, never provided the data and still has not done so. His continued failure to provide the raw data to the Committee to verify the summary points in Figure 4 gives the Committee grave concerns about the accuracy of this figure. Indeed, his failure to produce the data despite multiple requests, is grounds for a finding of research misconduct under 42 C.F.R. 93.106 (b). While the Committee is not prepared to make such a finding at this juncture, it is certainly not clearing Dr. Chao on this point unless he provides the relevant data.

Dr. Chao similarly exaggerated his claim that he reported his findings "as soon as [he] discovered data fabrication and falsification by Dr. Cohn." (Chao Response, p. 15) According to Dr. Chao, his concerns arose in July 2007. Yet, Dr. Atweh advised the Committee that Dr. Chao continued to praise Dr. Cohn as "the best post doc he[had] ever had" (Atweh 3/13/09 Tr. at 32) during this same period. In fact, Dr. Chao did not raise any concerns about Dr. Cohn until

after she brought her concerns to Dr. Atweh and then to the RIO. It is the Committee's view that this timing bespeaks of retaliation, not of his purported concern about scientific integrity.

In a later section of his response, Dr. Chao reiterates that as soon as he identified problems with the data while his paper was under peer review at Nature Magazine, he took "immediate" actions to redress these errors and prevent the possibility of incorrect information being "released into the body of scientific literature." (Chao Response, p. 24) He did no such thing. Rather, he ignored the suspicions that he claims to have had as early as July, 2007 and sent out his paper in September, 2007 with the incorrect graphs. Furthermore, once this investigation commenced, Dr. Chao still took no action with regard to the potential publication of his paper. In fact, the RIO had explicitly requested that Dr. Chao withdraw his paper from consideration during the pendency of the investigation specifically to prevent the possibility of publication of incorrect information. Rather than embracing this request, Dr. Chao specifically objected to it, claiming that such an action would be professionally devastating at a time when he was under significant pressure to publish. He stated that he would prefer to let the peer review process run its course. (See Exhibit 2, including RIO letter dated 10/8/07 and Dr. Chao's response dated 10/12/07.) This is hardly the action of someone who wants to ensure the integrity of the science.

In yet another statement, Dr. Chao contends that the technician, Ms. Kelly testified that she had "sufficient time to review the manuscript" and provide her input. Again, that is not consistent with her testimony. Rather, she specified that she was given the manuscript only one day before Dr. Chao actually submitted it. She had several suggestions and points regarding the paper and planned to meet with him to discuss her comments. Yet, he submitted the paper before she had an opportunity to schedule her meeting and she explicitly testified that she was not comfortable with his actions.²

Finally, Dr. Chao asked the Committee to hear testimony from his former Division Chief, Dr. George Atweh, claiming that Dr. Atweh "possesses pertinent, relevant and favorable evidence on my behalf." (Chao Response, p. 7). The Committee interviewed Dr. Atweh on March 13, 2009³. Dr Atweh's testimony was entirely consistent with the testimony of Dr. Randolph, Dr. Ossowski and Dr. Cohn. He advised the Committee that Dr. Chao was highly authoritarian, refused to accept criticism and denounced any challenge of data from his post docs. (Atweh Tr. at 32-34) Moreover, Dr. Atweh explained that he had specifically counseled Dr. Chao not to run his lab in such a controlling manner but also recognized that Dr. Chao never modified his behavior. As a result, Dr. Atweh noted that Dr. Chao had an unusually high turn-over rate in laboratory staff. Dr. Atweh also confirmed that Dr. Chao was a hands-off laboratory leader who failed to review the primary data generated from his post docs. (Atweh Tr. at 43-44) He criticized Dr. Chao's failure to work side by side at the bench with his laboratory staff and attributed Dr. Chao's loose supervision and lack of rigor to his ambitious desire to churn out

² The exact exchange was as follows: When the Committee asked Ms. Kelly whether she was "comfortable with the fact the paper was submitted, that he wouldn't wait for you," she answered: "No, but what could I do at that point?" It was already submitted, I didn't know what to do." (Kelly 10/16/08 Tr. at 70)

³ Since Dr. Atweh has left Mount Sinai and assumed the position as Chief of the Hematology/Oncology Program and Director of the Adult Cancer Center at University Hospital, University of Cincinnati, it took some time to schedule a mutually convenient date for the interview.

more grant applications in the hopes of getting promoted. (Atweh Tr. at 44-45) In short, Dr. Atweh's testimony was relevant, but not favorable to Dr. Chao.

Accordingly, for all the reasons set forth above, the Committee stands by all of its findings and recommendations as set forth in the Report.

Appendix B

List of Attachments 12

Exhibit No.	Description
Exhibit 1	Complaint by Dr. Cohn, dated 10/3/07 [CH-011, EC 2]
Exhibit 2	Complaint by Dr. Chao, dated 11/20/07
Exhibit 3	Nature Medicine Manuscript: "High level of antigen induces antigen-specific
	tolerance mediated by CD4+CD25+FoxP3+regulatory T cells" (Kelly, et al.)
	[CH-013.01, EC 1]
Exhibit 4	Blood Manuscript: "AAV-dose/FIX-level-dependent FIX tolerance" (Cohn,
	et al.) [CH-040]
Exhibit 5	2007 Progress Report re: RO1-HL076699
Exhibit 6	Transcripts of Witness Testimony:
	Ellen Cohn, Ph.D. – 4/28/08, 8/12/08 & 9/23/08, with corresponding errata
	Hengjun Chao, M.D6/4/08, 8/11/08 & 9/18/08, with corresponding errata
	Meagan Kelly – 6/19/08 & 10/16/08, with corresponding errata
	Gwendalyn Randolph, Ph.D. – 4/30/08, with corresponding errata
	Liliana Ossowski, Ph.D. – 5/12/08, with corresponding errata
	Christopher Walsh, M.D., Ph.D. – 6/19/08 (no errata submitted)
	Carl Nathan, M.D. – 7/7/08, with corresponding errata
Exhibit 7	Dr. Cohn's 5/3/07 lab notebook entry [CH-006.P020, EC 7]
Exhibit 8	Meagan Kelly's 5/8/07 lab notebook entry [CO-010.P018, MK 1]
Exhibit 9	E-mail exchange between H. Chao and E. Cohn re: "switching" of mice data,
	dated 7/13/07 [CH-010, EC 9]
Exhibit 10	E-mail from E. Cohn (Block) to H. Chao attaching presentation to be shown
	to G. Randolph, dated 12/21/06 [CH-041-a, HC 12]
Exhibit 11	"Support File #1" submitted by H. Chao to Inquiry Panel as part of his
	response to the Draft Inquiry Panel Report [CH-018.01-a, EC 3]
Exhibit 12	E-mail exchange between E. Cohn and H. Chao re: presentation to be shown
	to G. Randolph, dated 12/21/06 [CH-049]
Exhibit 13	ELISA data, dated 2/5/07 [CO-007-F, EC 27]
Exhibit 14	ELISA data, dated 2/7/07 [CO-007-G, EC 28]
Exhibit 15	E-mail from E. Cohn (Block) to H. Chao forwarding data and informing H.
	Chao that she "took out data for 2 mice", dated 2/27/07
Exhibit 16	E-mail from G. Randolph to H. Chao re: Nature Medicine manuscript, dated
	9/19/07 [CH-030, GR 9]

¹² Exhibits 17 and 19-20, which were included in the Draft Investigation Committee Report provided to Dr. Chao on January 22, 2009 are not included in the present report, as those exhibits relate solely to the allegations against Dr. Cohn.