



U.S. SENATE COMMITTEE ON

Finance

SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN

<http://finance.senate.gov>

MEMORANDUM

To: Reporters and Editors
Re: SFBC and Human Subject Protection
Da: Monday, Feb. 13, 2006

Sen. Chuck Grassley, chairman of the Committee on Finance, has been reviewing allegations of unethical practices in human subject research. He is leading a wide-ranging review of the clinical trial system to determine if systemic weaknesses exist and to assess the limitations of current oversight in ensuring protections for human subjects of clinical research. Committee investigators have focused on troubling allegations involving SFBC International, Inc., which recently saw the resignation of key managers. Grassley has asked the company to provide details of its standard operating procedures and personnel qualifications. He made the following comment on his latest inquiry.

“I have my committee investigators looking at serious allegations involving one of the largest, most profitable clinical research organizations in the country. This company has shooed out some of the top birds, but we don't know yet how much of a mess is left in the coop. When you're looking at the integrity of clinical research, it's important to know whether corners were cut. Were patients protected and rights respected? Were study investigators appropriately credentialed? We're seeking answers to these questions.”

A copy of Grassley's latest letter follows below.

February 8, 2006

Via Electronic Transmission

Jeffrey P. McMullen
Chief Executive Officer
SFBC International
504 Carnegie Center
Princeton, NJ 08540

Dear Mr. McMullen:

The Committee on Finance (“Committee”) has jurisdiction over the Medicare and Medicaid programs, among other matters. Accordingly, the Committee is responsible to the more than 80 million Americans who receive health care coverage under those programs, including payment for drugs and medical devices. The Committee is reviewing allegations of unethical practices in human

subjects research that not only leave individuals participating in the studies uninformed and at risk, but also potentially compromise the study results that inform the Food and Drug Administration's ("FDA") review of drugs and devices covered by Medicare and Medicaid.

The purpose of this letter is to follow up on the meeting of January 11, 2006 with former SFBC International ("SFBC") employees Mr. Gerald Seifer and Dr. Lisa Krinsky and Committee staff. During the course of the interviews with Mr. Seifer and Dr. Krinsky, my staff requested additional information pertaining to the Committee's inquiry. For the purposes of this request, SFBC refers only to its Miami facility. The Committee appreciates your cooperation in providing the following information and/or documents:

1. A detailed description of the history behind SFBC's standard operating procedures (SOPs), including but not limited to when SFBC initiated a formal set of written SOPs, how the SOPs were developed, who was associated with drafting the SOPs, when actual implementation of the SOPs started, and the revision history of the SOPs.

2. A detailed description of Mr. Seifer's employment history at SFBC. In complying with this request, provide a copy of all documents relating to Mr. Seifer's employment at SFBC, including but not limited to his administrative file, and all official title(s), job description(s), and salaries and/or compensation package(s) while employed by SFBC. In addition, advise the Committee of any known/identified departure(s) from or violation(s) of SFBC's SOPs related to Mr. Seifer during his employment by SFBC. Finally, provide a detailed description of the due diligence done by SFBC or its counsel in complying with this request.

3. A list of all senior management officials and directors while Dr. Krinsky was an executive officer and/or board member of SFBC. In complying with this request, provide a table of employees (sorted alphabetically by last name), which identifies for each employee: full name, title, degree of education, dates of employment, salaries and/or compensation package(s); whether or not SFBC has a curriculum vitae and all applicable certification(s) on file; whether or not the employee was ever identified on an FDA form 1572 filed by SFBC; and whether the employee was identified as a principal investigator or sub-investigator;

4. A detailed description of SFBC's selection process for institutional review boards (IRBs). During the course of the interview, Dr. Krinsky indicated that IRBs, on occasion, were selected by SFBC and by the drug sponsor at other times. Please address what assurances are in place at SFBC to ensure that conflicts of interest do not exist in the selection of IRBs. In complying with this request, reference all applicable SOPs related to IRBs and advise the Committee of any known/identified departures or violations of SFBC's SOPs. Finally, provide a detailed description of the due diligence done by SFBC or its counsel in complying with this request.

5. A list of all IRBs identified by SFBC on an FDA form 1572 while Dr. Krinsky was an executive officer and/or board member of SFBC. In complying with this request, provide a table of IRBs (sorted alphabetically by name), which identifies for each IRB: the full name; the nature of the business relationship between SFBC and the IRB; whether or not potential conflict(s) of interest, including but not limited to financial conflict(s) of interest, existed between SFBC and the IRB; and, if so, a detailed description of the potential conflict(s) of interest. In addition, provide a copy of all SFBC agreements and/or contracts with all IRBs. Furthermore, reference all applicable SOPs related to conflict(s) of interest and IRBs and advise the Committee of any known/identified departures or violations of SFBC's SOPs. Finally, provide a detailed description of the due diligence done by

SFBC or its counsel in complying with this request.

6. A detailed description of how the human resources responsibilities developed while Dr. Krinsky was an executive officer and/or board member of SFBC, including but not limited to: identifying when a “human resources” department or office was first established; identifying all management level employees who ever worked in human resources; and the chain of managerial command within human resources (i.e. who reported to whom). In complying with this request, provide a table of “human resources” employees (sorted alphabetically by last name), which identifies for each employee: full name, title, dates of employment, and a brief description of job duties, responsibilities, and to whom the employee reported. Furthermore, reference all applicable human resources SOPs and advise the Committee of any known/identified departure(s) from or violation(s) of SFBC's human resource SOPs. Finally, provide a detailed description of the due diligence done by SFBC or its counsel in complying with this request.

7. Curricula vitae for REDACTED

8. A copy of all affidavits for Marlon Matos and Roberto Alvarez, including but not limited to all drafts, edited versions, and electronic file copies created subsequent to the release of the *Bloomberg Markets* December 2005 article entitled, “Big Pharma’s Shameful Secret”;

9. During the course of his interview, Mr. Seifer stated that a number of private investors were involved in Dr. Krinsky’s purchase of SFBC. Provide a list of the investors cited by Mr. Seifer, including but not limited to: their names and contact information (home address and telephone number and/or business address and telephone number); a detailed description of the nature of Mr. Seifer’s relationship with each investor; the type and amount of investment made by each investor; how each investor was compensated by SFBC and/or Mr. Seifer for all investment(s), including but not limited to the date(s) and amount(s) of all compensation. In addition, provide a copy of all documents related to obtaining and compensating private investors, including but not limited to all agreement(s), contract(s), and check(s). Finally, provide a detailed description of the due diligence done by SFBC or its counsel in complying with this request; and

10. A copy of SFBC’s response(s) to the Securities and Exchange Commission’s (SEC) December 20, 2005 request for information/documents. In complying with this request, provide a copy of all documents provided to the SEC, including but not limited to all letters of transmittal. Finally, provide an SEC document production log identifying the date(s) of production and the applicable document bates range(s).

In addition, I would also like to reaffirm my request for Committee staff to interview Mr. Arnold Hantman, former Chief Executive Officer and Chairman of the Board, at a mutually agreed upon time at the Committee’s office. Please contact my Committee staff promptly to coordinate this meeting.

Thank you for your continued cooperation with the Committee’s inquiry. Please deliver the aforementioned requests no later than February 27, 2006.

Sincerely,

Charles E. Grassley

Chairman