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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SEMLER RESEARCH CENTER PRIVATE LIMITED, an Indian Corporation

Plaintiff,

vs.

UNITED STATES FOOD AND DRUG ADMINISTRATION; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; THE UNITED STATES OF AMERICA; ERIC D. HARGAN, In His Official Capacity As The Acting Secretary of the United States Department of Health and Human Services; SCOTT GOTTLIEB, M.D., In His Official Capacity As The Commissioner of the United States Food and Drug Administration; ARINDAM DASGUPTA, PH.D., In His Official Capacity; CHARLES BONAPACE, PHARM.D., In His Official Capacity; DIPESH K. SHAH, In His Official Capacity; DANIEL J. ROBERTS, In His

Case No.: 2:18-CV-00534

PLAINTIFF SEMLER RESEARCH CENTER PRIVATE LIMITED'S COMPLAINT FOR DAMAGES

JURY TRIAL DEMANDED

Official Capacity; SEAN KASSIM, In His Official Capacity; DAVID BURROW, PHARM.D., J.D., In His Official Capacity; CHRISSY J. COCHRAN, PH.D., In Her Official Capacity; DOUGLAS PHAM, PHARM.D., J.D., In His Official Capacity; and DOES 1 through 20, Inclusive,

Defendants.

Plaintiff, Semler Research Center Private Limited (hereinafter also referred to as "Plaintiff" or "SRC"), for its Complaint against Defendants, United States Food and Drug Administration ("FDA"), United States Department of Health and Human Services ("HHS"), The United States of America ("USA"), Eric D. Hargan, in his official capacity as the Acting Secretary of HHS ("Hargan"), Scott Gottlieb, M.D., in his official capacity as the Acting Commissioner of FDA ("Gottlieb"), Arindam Dasgupta, Ph.D., in his official capacity ("Dasgupta"), Charles Bonapace, Pharm.D., in his official capacity ("Bonapace"); Dipesh K. Shah, in his official capacity ("Shah"), Daniel J. Roberts, in his official capacity ("Roberts"), Sean Kassim, in his official capacity ("Kassim"), David Burrow, Pharm.D., J.D., in his official capacity ("Burrow"), Chrissy J. Cochran, Ph.D., in her official capacity ("Cochran"), Douglas Pham, Pharm.D., J.D., in his official capacity ("Pham"), and DOES 1 through 20, alleges as follows:

Nature of the Action

1. This is an action for violation of the Due Process Clause of the Fifth Amendment of the United States Constitution, intentional infliction of financial distress under the Federal Tort Claims Act, intentional interference with economic advantage under the Federal Tort Claims Act, and negligence under the Federal Tort Claims Act.

2. The violations of the Fifth Amendment are based on the arbitrary treatment of SRC by FDA (an agency under the auspices of the HHS), HHS, Federal

Employee Defendants (as defined hereinbelow), and USA (as a result of the actions of Federal Employee Defendants (as defined hereinbelow) denying SRC life, liberty, or property outside the sanction of law. SRC is suing in its capacity as an entity, which entity is considered a person under Federal Law entitled to the protections of due process. SRC has been arbitrarily denied life, liberty, or property without meaningful opportunity to be heard, have matters pertaining to it heard and determined by an impartial trier of fact and trier of law, and the right to give testimony and present relevant evidence to (and have said testimony and evidence considered by) an impartial trier of fact and trier of law.

3. The violations of the FTCA are based on the intentional actions of Federal Employee Defendants, and by association, FDA and HHS, including those actions taken to interfere with SRC's economic advantage (of which all or some of Federal Employee Defendants (as defined herein below)), and thus FDA and HHS, had knowledge) and those intentional actions taken to inflict financial distress on SRC by knowingly and intentionally denying SRC procedural due process, arbitrarily and willfully ignoring and disregarding relevant and exculpatory information and evidence, and arbitrarily refusing to accept results of studies for which there is not, was not, and has never been any evidence of unreliability. The violations of the FTCA are also based on USA's negligent hiring, retention, training, and supervision of its employees and, by association its administrative agencies, namely FDA and HHS.

The Parties

4. Semler Research Center Private Limited, an Indian Corporation, is a corporation organized and existing under the laws of India, with the principal place of business in India having been at PA Arcade, #21, 22, 23, Kodigehalli Main Road, Sahakarnagar, Bangalore, 560092 ("Clinical facility"), and its United States based corporate offices being located at 28001 Dorothy Drive, Agoura Hills, California 91301, in Los Angeles County, California. Semler Research Center Private Limited

was, at all time relevant hereto, engaged in the business of acting as a Contract Research Organization (or "CRO") formulating and testing pharmaceutical products for pharmaceutical companies and developers in the United States and throughout the world.

5. United States Food and Drug Administration, or FDA, is a federal agency within HHS. FDA's mission is to implement the federal Food Drug and Cosmetic Act ("FFDCA") and has been delegated the authority to administer the FFDCA.

6. United States Department of Health and Human Services, or HHS, is a United States Government Agency, whose responsibilities include, without limitation, oversight of the actions of FDA.

7. The United States of America, or USA, is the government of the United States of America. Under the Federal Tort Claims Act, USA is liable in the same manner and to the same extent as a private individual under like circumstances. 21 U.S.C. § 2674. USA is properly named a defendant for claims for money damages for injury or loss of property or personal injury or death caused by the negligent or wrongful act or omission of any employee of any governmental agency while acting within the scope of his or her office or employment. 21 U.S.C. § 2672. The Federal Employee Defendants, as named and defined hereinafter, were acting within the scope of their office or employment under circumstances where the United States, if a private person, would be liable to Plaintiff in accordance with the laws of the State of California and is sued accordingly.

8. Eric D. Hargan, or Hargan, is a U.S. citizen who works for HHS as the Acting Secretary of HHS and is being sued in his official capacity, and stands in the shoes of his predecessors-in-interest whom held the capacity as Secretary or Acting Secretary of HHS prior to his acceding to that position. Mr. Hargan is responsible for supervising the activities of HHS and, in that capacity, has oversight of the actions of FDA. Mr. Hargan has been delegated the authority by Congress to

administer the FFDCA, including the provisions for the approval of New Drug Applications ("NDAs") and Abbreviated New Drug Applications ("ANDAs").

9. Scott Gottlieb, M.D., or Gottlieb, is a U.S. Citizen who works for FDA as the Commissioner and is being sued in his official capacity as Commissioner of FDA, and stands in the shoes of his predecessors-in-interest whom held the capacity as Commissioner or Acting Commissioner of FDA prior to his acceding to that position. Mr. Gottlieb is responsible for supervising the activities of FDA. Mr. Gottlieb has been delegated the authority by Mr. Hargan to administer the FDA's regulations, policies, and procedures for approval of NDAs and ANDAs.

10. Arindam Dasgupta, Ph.D., or Dasgupta, is a U.S. Citizen who works for FDA and is being sued in his official capacity.

11. Charles Bonapace, Pharm.D., or Bonapace, is a U.S. Citizen who works for FDA and is being sued in his official capacity.

12. Dipesh K. Shah, or Shah, is a U.S. Citizen who works for FDA and is being sued in his official capacity.

13. Daniel J. Roberts, or Roberts, is a U.S. Citizen who works for FDA and is being sued in his official capacity.

14. Sean Kassim, or Kassim, is a U.S. Citizen who works for FDA as the Director of Office of Study Integrity and Surveillance and is being sued in his official capacity.

15. David Burrow, Pharm.D., J.D., or Burrow, is a U.S. Citizen who works for FDA as Acting Director of Office of Scientific Investigations within Office of Compliance and is being sued in his official capacity.

16. Chrissy J. Cochran, Ph.D., or Cochran, is a U.S. Citizen who works for FDA as Director of Division of Enforcement and Postmarketing Safety and is sued in her official capacity.

17. Douglas Pham, Pharm.D., J.D., or Pham, is a U.S. Citizen who works for FDA as Acting Branch Chief of Compliance Enforcement Branch of Division

of Enforcement and Postmarketing Safety and is sued in his official capacity.

18. Dasgupta, Bonapace, Shah, Roberts, Kassim, Burrow, Cochran, Pham, Gottlieb, Hargan, and DOES 1 through 10, are referred to collectively hereinafter as "Federal Employee Defendants".

19. The true names and capacities of Defendant DOES 1 through 20, inclusive, whether individual, corporate, associate, or otherwise, are unknown to Plaintiff at this time, who therefore sues said DOE Defendants by such fictitious names; and when the true names and capacities of such DOE Defendants are ascertained, Plaintiff will seek leave of this Court to amend this Complaint to insert same. Plaintiff is informed and believes, and thereon alleges, that each Defendant named as a DOE is responsible for each and every act and obligation hereinafter set forth. Plaintiff is informed and believes, and based thereon alleges that each of those DOE Defendants was in some manner intentionally as well as negligently and proximately responsible for the events and happenings alleged in this Complaint and for SRC's injuries and damages. DOES 1 through 20 are referred to herein collectively with all other named defendants, as "Defendants."

20. Plaintiff is informed and believes and thereon alleges that each of the Defendants caused, and is liable for the unconstitutional and unlawful conduct and resulting injuries by, among other things, personally participating in said conduct or acting jointly with others who did so; by authorizing, acquiescing or setting in motion policies, plans or actions that led to the unlawful conduct; by failing or refusing with deliberate indifference to maintain adequate supervision; and/or by ratifying the unlawful conduct taken by employees under their direction and control. Defendants' actions were taken pursuant to policies, customs or usages of FDA, HHS, or both.

Jurisdiction and Venue

21. This is an action for violation of the Due Process Clause of the Fifth Amendment of the United States Constitution, intentional interference with

economic advantage under the Federal Tort Claims Act, intentional infliction of financial distress under the Federal Tort Claims Act, and negligence under the Federal Tort Claims Act.

22. This Court has subject matter jurisdiction over all claims pursuant to 28 U.S.C. § 1331 and personal jurisdiction over Defendants pursuant to the Fifth Amendment of the United States Constitution and 28 U.S.C. §§ 1331 and 1346(b)(1).

23. This Court is the appropriate venue for bringing this action pursuant to 28 U.S.C. § 1391(e) and 28 U.S.C. § 1402(b).

General Facts

24. SRC is an independent company that offered cutting-edge pharmaceutical and clinical solutions for the bio-pharmaceutical industry. SRC's primary focus was the testing of generics and NCEs (New Chemical Entities). SRC offered its customers service in three different areas, namely: Formulation development, Bioavailability and Bio-equivalence ("BA/BE") studies on healthy population, and Clinical trials on patient population. SRC provided its services to many customers in India and abroad, including to United States based companies. SRC had a dedicated business development team wherein potential customers were approached both in India and abroad. SRC's customer base was approximately sixty percent (60%) domestic and forty percent (40%) was international. SRC had world-class state of the art infrastructure, availability of competent and trained talent pool and extensive experience in the domain area. SRC also won many accolades in India and abroad for its significant contribution in the pharmaceutical industry and other related services in the life-science sector.

25. SRC always performed its services in accordance with law and established standard procedures, to the best of its knowledge. It always obtained the necessary approvals before commencing operations from BBMP for trade license, Pollution Control Board approval, and BA/BE facility approval from Drug

Controller, Government of India ("DCGI"). SRC also followed all the necessary guidelines, provided by the FDA, World Health Organization ("WHO"), and European Medical Agency ("EMA") for conducting studies for these Institutions. SRC's nature of work constituted only research for the particular investigational product that was provided by its customers, who majorly consisted of Pharmaceutical/Drug Companies where the end result of the research, being negative or positive, did not affect SRC in any way. To ensure SRC's services were provided in accordance with law and to the best of its ability, SRC chose its employees after careful consideration and scrutiny in an effort to ensure the employees had expertise in their field of area and contributed towards the objectives of SRC.

26. SRC was made up of three major departments: Clinical, Analytical ("BA/BE"), and Formulation. In the BA/BE department there were two main sub-divisions, which formed the pillars of SRC in providing BA/BE services - the Bio Analytical team and the Clinical team - both of which were supported by a Quality Control (QC) and Quality Assurance (QA) team. The Clinical Team did the work of screening the subject, dosing the investigation product, and withdrawing blood samples from the volunteers/subjects. Once the blood samples were taken, the investigational product was tested in the blood samples through Bio-Analytical equipment by the Bio Analytical team. The results obtained by the Bio Analytical team were then analyzed through use of a statistical program utilized by a blinded statistician, and the report thus generated was thereafter submitted to the pharmaceutical companies (i.e. the customers of SRC), whom in turn would submit the same to the regulatory agencies (e.g. FDA, WHO, EMA) from whom the customers sought approval of the generic pharmaceutical tested by SRC, for marketing the products in the respective geographical location overseen by the specific regulator agency.

27. Each of SRC's departments were headed by a business

leader/department head who was responsible for the functioning of that vertical with respect to its people management, customer management, operations and profitability. This Department head reported directly to the President and CEO of SRC. However, it was the Department head that undertook the entire responsibility of performing the respective tasks assigned to the Department and ensuring that their respective activities were in accordance with law and the standard operating procedures developed for a particular study. In order to fulfill this responsibility, the Department head was given the right to interact with SRC's employees and also to engage with SRC's customers, for whom the study/research was being conducted, in case of obtaining further details or information for performing the research.

28. SRC began operation February 5, 2006 and in the ten (10) years in which it was in operation, it received many accolades and became one of the most sought-after research companies. SRC always did its best to provide quality services so that it could maintain its reputation in India and abroad, and also progress further in hopes of helping to provide safe, effective, and affordable pharmaceuticals to all persons of the world.

29. SRC undertook various studies for companies seeking to introduce their pharmaceuticals into the United States thereby requiring FDA approval. FDA came for regular inspections of SRC's facilities and records for these studies. On several occasions, FDA praised SRC for the quality of services provided. On a few occasions, FDA raised queries about certain aspects of research conducted by SRC, which is common to FDA's practice in the evaluation and review of nearly all similar type studies; only once was a Form 483 issued prior to October 2015. SRC promptly replied to that Form 483 and addressed the queries raised by FDA; FDA accepted the reply and approved the pharmaceutical for entry into the marketplace. Any inquiries directed to SRC's customers were also always duly responded to by SRC, which FDA inquiries were only a few in the ten (10) years SRC operated.

The 2015-2016 Inspection and Actions by FDA

30. On September 29, 2015, FDA, by and through its employees Dasgupta, Bonapace, Shah, and Roberts (hereinafter, Dasgupta, Bonapace, Shah, and Roberts are collectively referred to as "FDA Inspectors"), conducted a surprise/unannounced inspection of SRC's BA/BE facility and corporate offices, which were then located at located at #75A, 15th Cross, 1st Phase, J.P. Nagar, Bangalore 560078 ("BA/BE facility").

31. FDA Inspectors arrived at approximately 7:30 a.m. local time to the JP Nagar facility, which was prior to normal operating hours. Upon arriving, FDA Inspectors interacted with security personnel and informed him they wanted to visit the BA/BE laboratory. FDA Inspectors insisted upon accessing the BA/BE laboratory without waiting for the responsible staff members of SRC to arrive. Within one (1) hour of arrival, SRC senior team members reached JP Nagar facility and began escorting FDA Inspectors throughout the facility during the inspection.

32. FDA Inspectors informed SRC that this was not a project specific inspection, but rather was an inspection to verify the computer validation and related aspects of BA/BE testing. FDA Inspectors specifically told SRC's staff not to retrieve any documents until they made a request for the same.

33. Previously, FDA had conducted approximately six (6) inspections of SRC's facilities, all of which were project specific.

34. As of the time of the September 29, 2015 inspection, FDA had approved at least eight (8) generic drugs for which SRC had conducted the BA/BE study, Clinical study, or both. Of these, for only six (6) of those studies did FDA do an inspection of SRC's BA/BE facility or Clinical facility, including one (1) inspection of a clinical facility in Salem, India ("Salem Facility"), which SRC had previously, and which facility was closed in June 2014 upon opening the Bangalore Clinical facility.

35. FDA Inspectors inspected all different areas of the BA/BE facility

including, without limitation, the instrumentation area, weighing area, the blood sample storage room ("ULTF room"), and the computer server room. FDA Inspectors also inspected the computer systems attached to the LCMS instruments (the machines used for processing and testing blood samples for BA/BE studies), the access control to those systems, and the data files contained on the hard drives attached to those instruments ("Instrument Computer(s)").

36. FDA Inspectors interacted with the SRC staff responsible for the area being inspected, respectively, at the BA/BE facility, inquiring as to the processes followed, responsibilities of the SRC employees, and also verifying the documents associated with each area being inspected.

37. FDA Inspectors requested access to one of the Instrument Computers and were provided the same. To access the files on the hard drives of the Instrument Computer, a BA/BE analyst (who until the arrival of FDA Inspectors had been working with the instrumentation to process blood samples for a then ongoing study being conduct by SRC for one of its then customers) entered his username and password to access the system.

38. As the system was set up, BA/BE analysts' access was restricted to certain folders or subfolders on SRC's server based on the username and password entered. The restriction on access was also the same for other Departments, such as QC and QA. Therefore, the analysts' access may differ from other departments' access, including what folders appeared available based on the permissions provided by the username and password used for access.

39. Specifically, at this time, Dasgupta was one of the inspectors in the instrumentation lab and was looking at the screen attached to the Instrument Computer to which FDA Inspectors had been provided access. Dasgupta looked at the screen for some time and was opening certain folders and documents.

40. FDA Inspectors requested connectivity to SRC's servers and upon said request SRC provided FDA Inspectors with an SRC laptop with server connectivity,

which FDA Inspectors set up in one of SRC's conference rooms on a separate floor from the instrumentation area.

41. Multiple times FDA Inspectors went to the BA/BE instrument room and checked the Instrument Computer system connected to the instrument and compared that with the access given in the conference room. The SRC laptop did not have access to what the Instrument Computer had access to, as the SRC laptop did not have a BA/BE analysts' username and password used to login to the laptop.

42. Eventually, FDA Inspectors retrieved an FDA tablet and used that to take photographs of the folders listed on the Instrument Computer and attempted to match them with those available in conference room.

43. Additionally, one SRC employee saw Dasgupta looking at a picture on the FDA tablet and saw the picture he was viewing was a of a photo of a computer screen showing a File Explorer window open to a server identified by the letter "Y" and showing a document path to a particular folder. However, FDA Inspectors had not been given access to a server identified by the letter "Y" on SRC's system and leading to the folder titled "DUMP".

44. After viewing that photo, FDA Inspector then went back to the instrument area and again searched the same Instrument Computer, using the search function to search a specific document name, accessed a file on the SRC server system, took a picture of the contents of one part of that file, and requested a printout of that portion of which he took a picture.

45. The file accessed by FDA Inspectors was a Microsoft Excel spreadsheet file titled "March 2010 version 1xls.xls" ("the File"), specifically the portion named "Book 3" (hereinafter, "the Suspect Spreadsheet").

46. FDA Inspectors, having seemingly found what they were looking for from the start, thereafter immediately asked the head of SRC's QA department if she knew what the Suspect Spreadsheet was, to which she responded that she did not, had never seen it before, and would have to look into it.

47. SRC immediately began looking into the Suspect Spreadsheet and how it arrived on SRC's server. The results of SRC's investigation into the Suspect Spreadsheet are set forth herein in detail in heading "The Suspect Spreadsheet" at paragraphs 51-62, hereinbelow. The results of the investigation were presented to FDA Inspectors both immediately upon their discovery while FDA Inspectors were at the BA/BE facility, in the closing presentation provided by SRC to FDA Inspectors at the end of the ten (10) day inspection, and again later in SRC's written responses to FDA's observations and follow-up communications, which are discussed in greater detail herein under the heading "FDA Actions Subsequent to Inspection". In summary, the fabricated data set forth in the Suspect Spreadsheet was believed to have been created and placed on within the Suspect Spreadsheet by a rogue employee whom was acting in concert with a group of former employees of SRC that were working for a competing CRO in Bangalore, India after the BA/BE head (and the person who started the new CRO) had parted ways with SRC.[1]

48. At the end of the day on September 29, 2015, FDA Inspectors provided a list of more than thirty (30) studies for which they desired SRC to retrieve the method validation data and study data and announced they would be returning the following day(s) to review the requested documents.

49. FDA Inspectors also checked the statistician's computer and log books and asked the statistics department to create graphs of the data set forth in the Suspect Spreadsheet.

50. FDA Inspectors spent the next nine (9) days, until October 9, 2015, at the BA/BE facility and also inspected and retrieved blood samples from SRC's

[1] SRC has filed a criminal complaint in India against the group of former employees whom are believed to have taken the actions related to the Suspect Spreadsheet, including the implantation of the same on the SRC server and the contacting of FDA thereafter to lead FDA Inspectors to the fabricated information and raise suspicion regarding SRC's procedures and the reliability of its studies.

Clinical facility.

51. The remainder of the time FDA Inspectors were conducting their inspection, they were focused on the five (5) studies referenced in the Suspect Spreadsheet. The entirety of the information requested by FDA Inspectors to be discussed during the closing presentation provided by SRC at the conclusion of the inspection was with regard to the data set forth on the Suspect Spreadsheet.

52. FDA Inspectors were provided with all information requested, including the information for the more than thirty (30) studies requested at the conclusion of their initial inspection of September 29, 2015. This information included all data and documents regarding the five (5) studies referenced in the Suspect Spreadsheet including, without limitation, all raw data, all quality control data, and the final report provided to SRC's customer for each study. These final reports, and the other data and documents provided, evidenced the subjects whose results were considered and not considered and submitted and not submitted as part of each study and the reason why a given subject was not considered or submitted, if such was the case. FDA Inspectors were also provided with copies of the entire server backup of SRC's servers for December 2014, February 2015, and all that were done after February 2015 subsequent to the commencement of the September 29, 2015 through October 09, 2015 inspection, including the backup created June 27, 2015. FDA Inspectors were provided and in possession of all information needed to verify whether the contents of the Suspect Spreadsheet were accurate and authentic and determine whether it was indeed what it purported to be, namely a compilation of information evidencing the manipulation of study data by SRC regarding those five (5) studies.

THE SUSPECT SPREADSHEET

53. The Suspect Spreadsheet contained information purporting to evidence manipulation of study data for 5 different studies conducted by SRC between 2011 and 2014.

54. The information within the Suspect Spreadsheet was laid out horizontally and followed no particular timeline, with the information for the first study chronologically appearing last, the fourth and fifth studies chronologically (these were conducted at nearly the same time and were for the same proposed generic pharmaceutical) appearing second and being combined and identified as one or the other, the third study chronologically appearing first, and the second study appearing third between the newest and oldest studies.

55. The Suspect Spreadsheet was the third of three workbooks of one Microsoft Excel spreadsheet file on SRC's server, namely the File.

56. The File was created on February 3, 2010 on SRC's server by a then SRC employee working in the Salem Facility. Prior to June 17, 2015, the File was updated only one time, that time being March 1, 2010. As of March 1, 2010, and continuing until June 17, 2015, the File contained data in only two (2) of the three (3) workbooks therein, namely Book 1 – which had the title "Mar" and described itself as "SRC Salem Planner -MARCH 2010 VERSION 1" and contained column headings and several items of data for each column – and Book 2 – which had only headings for columns (the same as Book 1 titled "Mar") but the columns contained no data under the headings. Book 3, the Suspect Spreadsheet, was completely blank; the Suspect Spreadsheet contained no data until June 17, 2015.

57. On June 17, 2015, someone accessing the SRC Server system using a BA/BE login and password entered fabricated data into the Suspect Spreadsheet. This was done at 1:26 p.m. local time for the BA/BE facility, a time when the majority of SRC employees were at lunch.

58. The Suspect Spreadsheet is attached hereto as **Exhibit A** and incorporated herein by this reference.

59. The information contained on the Suspect Spreadsheet is verifiably inaccurate and non-representative of the study data for each of the referenced studies:

a. For example, regarding study S-11-299 (the first study listed going left to right), the Suspect Spreadsheet indicates that SRC substituted Subject No. 50's data with Subject No. 26's data when producing and providing the study results to SRC's customer undertaking the study.

   i. However, as can be determined from a review of the final study report and the data and documents regarding study S-11-299, all of which was provided to FDA Inspectors, Subject No. 50 was withdrawn from study S-11-299 and that subject's results were not used or submitted as part of the final results for study S-11-299. Therefore, SRC cannot possibly have replaced Subject 50's data with Subject No. 26's data and thereafter submitted the same as part of the final study results, since no data was considered or submitted as part of those results for Subject No. 50 in study S-11-299.

b. As another example, there are two (2) studies lumped together and labeled as "S-12-547 or S-12-548" indicating that the information goes to one study or the other; however, just that fact alone, that the information is not definitive as to one study or the other as to the alleged substitution of information, manipulation of sample volume, or substitution of period results, is evidence of the inherent fallibility of the Suspect Spreadsheet and supports that the information was fabricated for the purpose of potentially causing SRC harm should a reasonable and impartial review of the Suspect Spreadsheet not be undertaken.

c. Further with regard to the information for the studies labeled as "S-12-547 or S-12-548" again there are inherent inconsistencies. This table reflects: the alleged switching of period 1 for period 2 data for Subjects 50 and 59, Subject 57 as having had his or her sample volume increased and decreased by certain percentages, and Subject 62 as having had his

or her data substituted with that of Subject 5.

i. First, for study S-12-547, as can be determined from a review of the final study report and the data and documents regarding study S-12-547, all of which was provided to FDA Inspectors:

1. Subject Nos. 50, 57, and 59 were withdrawn from study S-12-547 and those subjects' results were not used or submitted as part of the final results for study S-12-547. Therefore, SRC cannot possibly have swapped their results based on which time period they were taken or increased or decreased their sample volumes.

ii. Next, for study S-12-548, as can be determined from a review of the final study report and the data and documents regarding study S-12-547, all of which was provided to FDA Inspectors:

1. Subject No. 62 was withdrawn from study S-12-548 and that subject's results were not used or submitted as part of the final results for study S-12-548. Therefore, SRC cannot possibly have replaced Subject No. 62's data with Subject No. 05's data and thereafter submitted the same as part of the final study results for study S-12-548.

iii. Finally, regarding Subject No. 70, there were no results for Subject No. 04 for study S-12-548 as that subject was withdrawn from study S-12-548. Further, the "P2" column appears incomplete, further calling into question the accuracy and legitimacy of the Suspect Spreadsheet.

d. As a third example, regarding study S-12-518, the Suspect Spreadsheet indicates that SRC substituted Subject No. 64's data with Subject No. 07's data when producing and providing the study results to SRC's customer undertaking the study.

i. However, as can be determined from a review of the final study report and the data and documents regarding study S-12-518, all of which was provided to FDA Inspectors, Subject No. 64 was withdrawn from study S-12-518 and that subject's results were not used or submitted as part of the final results for study S-12-518. Therefore, SRC cannot possibly have replaced Subject 64's data with Subject No. 07's data and thereafter submitted the same as part of the final study results, since no data was considered or submitted as part of those results for Subject No. 64 in study S-12-518.

e. As a final example, regarding study S-11-273:

i. The Suspect Spreadsheet indicates that SRC substituted Subject Nos. 33, 34, and 35's data with Subject No. 47, 38, and 44's data, respectively, when producing and providing the study results to SRC's customer undertaking the study.

1. However, as can be determined from a review of the final study report and the data and documents regarding study S-11-273, all of which was provided to FDA Inspectors, Subject Nos. 33, 34, and 35 were withdrawn from study S-11-273 and those subject's results were not used or submitted as part of the final results for study S-11-273. Therefore, SRC cannot possibly have replaced Subject Nos. 33, 34, and 35's data with Subject No. 47, 38, and 44's data and thereafter submitted the same as part of the final study results, since no data was considered or submitted as part of those results for Subject No. 33, 34, and 35 in study S-11-273.

ii. For Subject Nos. 29 and 62, the Suspect Spreadsheet reflects that Subject No. 17's data was used in lieu of those two subjects and

for Subject Nos. 59 and 69, the Suspect Spreadsheet reflects that Subject No. 49's data was used in lieu of those two subjects.

1. However, as can be determined from a review of the final study report and the data and documents regarding study S-11-273, all of which was provided to FDA Inspectors, the data for Subject Nos. 17, 29, and 62 varied from one another regardless of time period used, as did the data for Subject Nos. 49, 59, and 69.

iii. For Subject No. 77, the Suspect Spreadsheet reflects that for "P3" Subject No. 77's data was substituted for Subject No. 46's data from "P6".

1. However, as can be determined from a review of the final study report and the data and documents regarding study S-11-273, all of which was provided to FDA Inspectors, there was no "P6" for study S-11-273.

iv. Study S-11-273 was a failed study for the customer, meaning there was no bio-equivalency found between the generic formulated by the customer and the name-brand already on the market. Thus, this study was never submitted by the customer to any oversight agency including, without limitation, FDA, and this drug was not brought to market (at least not as a result of SRC's study and not with the formulation tested by SRC, as SRC informed the customer the formulation did not have bio-equivalency and therefore did not qualify as an appropriate or acceptable generic alternative to the name-brand on the market.)

60. The SRC staff put together the information and graphs requested by FDA Inspectors regarding the data contained on the Suspect Spreadsheet and presented that data to FDA Inspectors at the closeout meeting. The graphs revealed

variations in the data and did not evidence substitution or replacement of one subject's data for another.

61. Pursuant to procedures of and regulations governing SRC, for all studies identified on the Suspect Spreadsheet, all subjects' blood samples had been disposed of a significant time prior to commencement of FDA Inspectors' inspection from September 29, 2015 through October 09, 2015. As a result, duplicating the studies using the same subjects' blood samples previously collected by SRC that were used to perform the initial studies for each respective proposed generic pharmaceutical.

62. Regarding study S-11-299, FDA had previously issued an inquiry to the customer regarding the results of the data shown by SRC's BA/BE study. SRC had previously prepared a response to FDA on behalf of the customer for the customer to submit to FDA; SRC was and is unaware whether the customer submitted the same to FDA. SRC provided a copy of that response to FDA Inspectors during their inspection from September 29, 2015 through October 9, 2015 with a complete folder of data supporting the information contained in that response, which explained the reasons there could be the trends and variations in the data inquired about by FDA.

63. Prior to FDA Inspectors' inspection from September 29, 2015 through October 9, 2015, SRC was informed by the customer for whom it had performed study S-11-299 that it was not going forward with its application for that generic drug for factors unrelated to SRC's work or the results of the study.

64. SRC also informed FDA Inspectors that through its own investigation it could not locate anything showing something was wrong with the results of study S-11-299 or any of the other studies on the Suspect Spreadsheet (though FDA Inspectors were focused mainly on study S-11-299), that any data had been manipulated in any of the studies identified on the Suspect Spreadsheet, or that any Standard Operating Procedures or study-specific protocols were not followed for

any of the studies identified on the Suspect Spreadsheet, other than typical minor deviations that would have been and were appropriately catalogued and disclosed in the final reports and underlying study data.

FDA's ACTIONS SUBSEQUENT TO INSPECTION

65. All of the information set forth in Paragraphs 51-62 was either provided to FDA at the closeout meeting or available to FDA pursuant to a reasonable and impartial review of the information and data provided to FDA Inspectors.

66. Subsequent to the September 29, 2015 through October 9, 2015 inspection, on the basis of the Suspect Spreadsheet, FDA concluded there were serious inconsistencies in the research conducted by SRC and asked SRC to explain the reasons for the Suspect Spreadsheet and to justify that the information of the Suspect Spreadsheet is false, concluding without any basis that it is not biologically possible to have data results shown in study S-11-299.

67. SRC gave a preliminary reply to FDA on October 29, 2015, and a second reply on January 14, 2016, stating that it was shocked to know these issues raised, as there were never such issues raised by FDA for any of SRC's prior studies that were submitted by its customer and since SRC had provided FDA all of the information responsive to FDA's observations and inquiries during the September 29, 2015 through October 09, 2015 inspection and closeout meeting.

68. In its October 29, 2015 preliminary reply, SRC informed FDA that it was having the studies audited by an independent third-party entity (as agreed to between FDA and SRC at the October 09, 2015 closeout meeting) and would provide the results upon completion of the audit. SRC also offered and requested FDA to have an independent audit of the studies identified by the Suspect Spreadsheet performed to compare to the results of SRC's independent audit.

69. In its January 14, 2016 follow-up reply, SRC provided the results of its independent audit, which audit revealed no evidence of data manipulation and

confirmed that all Standard Operating Procedures and study specific protocols were followed, and in the rare instance there was a deviation it was documented and explained and had no impact on the results of the study. Further, it was again presented to FDA that the Suspect Spreadsheet was not representative of data tracking or collection by SRC, was not authorized or reflective of the results of the identified studies, and was believed to have been planted on SRC's server.

70. On April 19, 2016, without having conducted its own independent audit, without interviewing the persons involved in the studies identified on the Suspect Spreadsheet (all of whom were known to and contactable by FDA), and without providing SRC the ability or a forum to present its evidence to an impartial tribunal or trier of fact, FDA summarily disregarded the results of the agreed-upon independent audit of the studies identified on the Suspect Spreadsheet that SRC had undertaken to have performed, similarly summarily disregarded the evidence and explanation of SRC regarding the origin of the Suspect Spreadsheet, and issued an untitled letter to SRC alleging SRC had failed to follow applicable FDA guidelines and law in providing its services to customers. The entire basis of FDA's position was the Suspect Spreadsheet and FDA's position that Plaintiff had failed to explain the existence of the Suspect Spreadsheet and prove the information on the Suspect Spreadsheet was untrue, specifically focusing on study S-11-299.

71. FDA gave SRC thirty (30) working days from receipt of the April 19, 2016 letter to give FDA notice in writing of the actions SRC has or would be taking to correct the observations identified and prevent similar situations in the future.

72. However, on April 20, 2016, only one (1) working day later, FDA posted a "Notification to Pharmaceutical Companies: Clinical and Bioanalytical Studies Conducted by Semler Research are Unacceptable" on its website stating that all studies by SRC, whether previously approved and whether Clinical or BA/BA, were unacceptable ("April 20, 2016 Notice").

73. On or around April 20, 2016, FDA began sending Information Request

Letters to SRC's customers whom had undertaken studies with SRC with the intention of obtaining FDA's approval of the generic drug to be studied by SRC ("Customer Letters"). This included customers whose generic pharmaceuticals had already previously been approved and were on the market.

74. FDA took the above described actions despite having no evidence of data manipulation other than the Suspect Spreadsheet and despite there never having been any negative reports related to any pharmaceutical FDA had previously approved and that was on the market.

75. FDA further took said actions without allowing SRC to respond to the April 19, 2016 letter, or to seek judicial intervention or an impartial tribunal to determine the matter.

76. As a further consequence of FDA's actions, WHO and EMA also withdrew their respective prior approvals of generic pharmaceuticals whose studies had been conducted by SRC; except, EMA left on the market generic drugs for which SRC had conducted the study and whose utility was needed by society, namely anti-HIV pharmaceuticals, anti-malarial pharmaceuticals, and anti-Hepatitis B pharmaceuticals.

77. In fact, EMA has stated that alternative studies were conducted by EMA for some of the studies conducted by SRC and these alternative studies proved that the studies conducted by SRC have the necessary Bio-equivalence and therefore the pharmaceuticals related thereto were allowed to remain on the market. This, in and of itself, is also evidence that the studies conducted by SRC were in fact properly conducted and provided reliable results. FDA has ignored this as well.

78. The EMA never conducted any inspection but only relied on FDA's claims and April 19, 2016 letter to conclude adversely to Plaintiff. On the basis of the conclusions of WHO, EMA, and the FDA, several other countries' governing bodies regarding pharmaceutical testing, such as the Ministry of Health of Malaysia and the customers of SRC are rejecting the studies conducted by SRC and

demanding compensation from SRC. These companies include, without limitation, Lupin Limited, Microlabs Limited, Dr. Reddy's Limited, and Inventia Healthcare Pvt Ltd. In fact, these other Countries and customers, such as in the case of the Ministry of Health of Malaysia, never conducted any independent inspection and the only reason for doubting the credibility of SRC's research is the FDA's April 20, 2016 Notice and its Customer Letters.

79. Further, while FDA's adverse observations were only in case of certain studies, other regulatory agencies have doubted the credibility of all the research that was conducted by Plaintiff, even though they were not a part of the studies with respect to which the FDA had doubts about credibility of the research, because FDA made a blanket determination that none of the research conducted by SRC was reliable.

80. This has resulted in huge damage to the Complainant, to their reputation and good will and also financially affected them, as a result of the failure to provide SRC due process and an impartial tribunal, and also as a result of Federal Employee Defendants' intent to inflict financial distress on SRC, to interfere with SRC's economic advantage, and Federal Employee Defendants' failure to act with reasonable care and diligence in performing their duties.

81. SRC is informed and believes, and based on said information and belief alleges, that FDA and HHS, by and through Federal Employee Defendants', and each of them, also acted with the intent to inflict financial distress on SRC and to interfere with SRC's economic advantage, by releasing the April 20, 2016 Notice prior to SRC's time to respond to the April 19, 2016 letter having run.

82. FDA's actions - which actions were taken without providing SRC any due process, with the intent to inflict financial distress, with the intent to intentionally interfere with SRC's economic advantage, and without reasonable care and diligence - have caused the loss of a potential sale of SRC which at the time had an approximate value of Thirty Million Dollars ($30,000,000.00) and has

further caused SRC to have claims made against it by its former customers exposing SRC to claims upwards of Twenty Million Dollars ($20,000,000.00), for total damages of approximately Fifty Million Dollars ($50,000,000.00).

COUNT ONE – VIOLATION OF FIFTH AMENDMENT

(Violation of Procedural Due Process – Against All Defendants)

83. SRC realleges and incorporates herein by reference paragraphs 1 through 80.

84. SRC's right to engage in a legitimate business, its interest in its reputation and not having a negative stigma regarding its actions while engaging in said business and its ability to continue to engage in said business, its need and ability to clear its name when false allegations and the resulting deprivation of its ability to conduct its business are implicated, and its right to the benefits of the substantive criteria of the Federal Regulations governing acceptance and rejection of ANDAs and appropriate actions and guidelines for BA/BE studies including without limitation those regulations found in Title 21 of the Code of Federal Regulations governing BA/BE studies and Clinical studies for Human Drugs and acceptance and rejection of ANDAs, are all property interests, liberty interests, or both, giving rise to procedural due process.

85. FDA's April 20, 2016 Notice and Customer Letters, and the decision noticed therein, namely to reject and deem unacceptable all Clinical and Bioanalytical studies of SRC while SRC's response time was still pending and without providing SRC the ability to have a name-clearing hearing or to present its evidence to an impartial tribunal deprived SRC of the fundamental property interests and liberty interests mentioned herein above, probably most importantly its ability to conduct its business and its interest in its reputation and not having the stigma that the actions of Defendants, and each of them, caused; which stigma led to the complete annihilation of SRC's business and its exposure to monetary claims from its customers based on the actions of Defendants' and each of them.

86. FDA's April 20, 2016 Notice and Customer Letters were the result of the actions of FDA Inspectors, Shah, Burrow, Cochran, and Pham, for which Gottlieb (as Commissioner) and FDA is responsible. HHS, as the governing body of FDA, and its employees, are similarly and equally responsible for the acts of FDA by way of its employees and therefore, Hargan (as Acting Secretary) and HHS are equally responsible for the damage caused by the violation of SRC's procedural due process rights. USA is additionally equally responsible for the damage caused by the violation of SRC's procedural due process rights by the actions of its employees and agencies, namely the Federal Employee Defendants, FDA, and HHS.

87. Defendants, and each of them, failed to provide SRC with notice and an opportunity to be heard by an impartial tribunal before depriving SRC of its property interests and liberty interests.

88. As a result, Defendants, and each of them, violated SRC's Fifth Amendment procedural due process rights and caused SRC damage of an amount to be proven at trial, but believed by SRC to be no less than Thirty Million Dollars ($30,000,000.00).

89. The actions of Defendants, and each of them, as described hereinabove, were wanton, intentional, malicious, oppressive, and taken in reckless disregard of SRC's rights, in that Defendants, and each of them, acted with ill will or spite and with the purpose of injuring SRC, acted with complete indifference to SRC's rights and in the face of a perceived risk that their actions would violate SRC's rights under federal law, specifically the Fifth Amendment procedural due process requirements, and, finally, acted with unnecessary harshness or severity by misusing their authority or power, entitling SRC to an award of punitive damages as allowed by law.

90. SRC does not believe that the damage can be undone by way of a name clearing hearing or withdrawal of the April 20, 2016 Notice and Customer Letters;

however, it is requesting, in addition to the monetary damages requested herein, a declaration from the Court ordering the April 20, 2016 Notice and Customer Letters be rescinded.

COUNT TWO – INTERFERENCE WITH ECONOMIC ADVANTAGE

(Pursuant to the FTCA – Against USA)

91. SRC realleges and incorporates therein by reference paragraphs 1 through 80.

92. Dasgupta, Bonapace, Shah, Roberts, Kassim, Burrow, Cochran, and Pham, employees of USA, by and through FDA, undertook an inspection and investigation of SRC with the intent to interfere with the economic advantage of SRC. Because Dasgupta, Bonapace, Shah, Roberts, Kassim, Burrow, Cochran, and Pham were acting within the scope of their respective employment and were an actual or apparent agent, servant, employee, or any combination thereof, of the United States at the time of the incident, SRC brings this action under the Federal Tort Claims Act, 28 U.S.C. Section 2671, et seq.

93. SRC has complied with the notice provision of the Federal Tort Claims Act, found at 28 U.S.C. §2675. Within two years of the incident, SRC notified the United States of its claim, provided the relevant information documenting its injuries and the actions of Dasgupta, Bonapace, Shah, Roberts, Kassim, Burrow, Cochran, and Pham, as alleged herein, and demanded Fifty Million Dollars ($50,000,000.00). More than six months have passed since SRC notified the government and made its claim.

94. Federal Employee Defendants, FDA, and HHS, and each of them, and by association USA, have tortiously interfered with SRC's existing and prospective advantageous business relationships in an intentional, improper, and malicious manner, resulting in significant financial damages to SRC.

95. Prior to the actions of Defendants, and each of them, SRC established business relationships with its customers that Defendants, and each of them, were

aware existed, to act as the CRO for its customers in conducting Clinical and BA/BE studies.

96. Defendants, and each of them, acted with the specific and malicious intent to redirect SRC's profits and business to other CRO's, or simply away from SRC, and to create claims for financial retribution by SRC's customers against SRC, by knowingly and intentionally interfering with SRC's existing and prospective business relationships through the improper release of the April 20, 2016 Notice and Customer Letters and intentionally, willfully, and wantonly disregarding exculpatory evidence, ignoring the availability of information from persons known and accessible to Defendants and failing to interview and obtain information from the same, and disregarding industry standards and procedures regarding Clinical and BA/BE studies.

97. On information and belief, the conduct of Defendants, and each of them, as described herein, caused SRC's customers to terminate their relationships with SRC for ongoing and planned-but-not-yet-commenced Clinical and BA/BE studies and forced SRC to dissolve its Clinical and BA/BE departments.

98. Due to the intentional, malicious, and improper interference with SRC's existing and prospective advantageous business relationships by Defendants, and each of them, SRC has suffered a loss of tens of millions of dollars in lost profits. These lost profits include, without limitation, the lost profits it would have recognized from the business already agreed upon to be conducted and that would have been realized by SRC in the future.

99. Defendants, and each of them, intentionally, maliciously, and improperly interfered with SRC's existing and prospective advantageous business relationships, without privilege or lawful justification. Defendants, and each of them, have acted with the improper intent of eliminating SRC from the marketplace to the benefit of other CROs, especially those (1) primarily based and conducting studies in the United States, (2) based in India and with whom FDA Inspectors had

a personal relationship with the owners or employees, (3) in which SRC's shareholders were not real parties in interest or owners, or any combination thereof.

100. The acts, omissions, or both, set forth above would constitute a claim under the laws of the State of California.

COUNT THREE – INTENTIONAL INFLICTION OF FINANCIAL DISTRESS

(Pursuant to the FTCA – Against USA)

101. SRC realleges and incorporates therein by reference paragraphs 1 through 80.

102. Dasgupta, Bonapace, Shah, Roberts, Kassim, Burrow, Cochran, and Pham, employees of USA, by and through FDA, undertook an inspection and investigation of SRC with the intent to inflict severe financial distress on SRC. Because Dasgupta, Bonapace, Shah, Roberts, Kassim, Burrow, Cochran, and Pham were acting within the scope of their respective employment and were an actual or apparent agent, servant, employee, or any combination thereof, of the United States at the time of the incident, SRC brings this action under the Federal Tort Claims Act, 28 U.S.C. Section 2671, et seq.

103. SRC has complied with the notice provision of the Federal Tort Claims Act, found at 28 U.S.C. §2675. Within two years of the incident, SRC notified the United States of its claim, provided the relevant information documenting its injuries and the actions of Dasgupta, Bonapace, Shah, Roberts, Kassim, Burrow, Cochran, and Pham, as alleged herein, and demanded Fifty Million Dollars ($50,000,000.00). More than six months have passed since SRC notified the government and made its claim.

104. The actions of Defendants, and each of them, as described and alleged herein, were extreme and outrageous and went beyond all possible bounds of decency in that it was vindictive and punitive in that Defendants, and each of them, undertook no independent investigation of the information appearing on the Suspect

Spreadsheet, refused to meet in person or allow a presentation by SRC of its position to an impartial tribunal, represented to SRC that it would have thirty (30) working days to respond to its April 19, 2016 letter and the immediately following day publicly issued a final decision deeming all prior SRC studies "unacceptable", and by doing so intended to and did cause SRC severe financial distress.

105. Defendants, and each of them, took the actions alleged herein with the intent of inflicting severe financial distress upon SRC or knew that such severe financial distress was substantially certain to result from the conduct of Defendants, and each of them.

106. The financial distress suffered by SRC was severe in that it was substantial and permanent as SRC was forced to dissolve its Clinical and BA/BE departments and sell-off its assets for a considerable loss and at a value significantly lower than that which they were valued prior to the intentional, outrageous, and vindictive actions of Defendants, and each of them, and no reasonable entity or person should be expected to bear such severe financial distress.

107. As an actual and proximate result of the intentional, outrageous, and vindictive conduct of Defendants, and each of them, SRC suffered the above-described sever financial distress, was forced to cease its operations, has suffered a loss of tens of millions of dollars in lost profits, and has been exposed to tens of millions of dollars of potential claims by its former customers.

108. The acts, omissions, or both, set forth herein would constitute a claim under the laws of the State of California.

COUNT FOUR – NEGLIGENCE

(Pursuant to the FTCA – Against USA)

109. SRC realleges and incorporates therein by reference paragraphs 1 through 80.

110. Federal Employee Defendants, employees of USA, by and through FDA and HHS, undertook an inspection and investigation of SRC negligently and

carelessly and undertook the oversight of said inspection and investigation negligently and carelessly as well. Because Federal Employee Defendants were acting within the scope of their respective employment and were an actual or apparent agent, servant, employee, or any combination thereof, of the United States at the time of the incident, SRC brings this action under the Federal Tort Claims Act, 28 U.S.C. Section 2671, et seq.

111. SRC has complied with the notice provision of the Federal Tort Claims Act, found at 28 U.S.C. §2675. Within two years of the incident, SRC notified the United States of its claim, by and through FDA, provided the relevant information documenting its injuries and the negligence of Federal Employee Defendants, FDA, and HHS, and demanded Fifty Million Dollars ($50,000,000.00). More than six months have passed since SRC notified the government and made its claim.

112. Federal Employee Defendants negligently failed to observe the rules and regulations governing their conduct in investigating CROs and Biomonitoring of studies conducted by CROs and in overseeing their respective employees and charges. Federal Employee Defendants further negligently failed to undertake a reasonable and careful investigation and failed to provide reasonable and careful oversight over said investigation, the natural and foreseeable consequence of which was to cause financial damage to SRC.

113. USA, by and through its agents, servants, employees, or any combination thereof, namely Federal Employee Defendants, FDA, and HHS, was negligent and careless in that it:

a. failed to conduct a proper and reasonable investigation under the circumstances to avoid making baseless and unsupported conclusions regarding SRC's Clinical and BA/BE studies, including failing to independently verify and review all relevant and available data and information regarding SRC's Clinical and BA/BE studies;

b. failed to conduct its investigation in a reasonable and prudent manner;

c. failed to supervise its employees and, by association its administrative agencies, namely FDA and HHS, in a reasonable and prudent manner;

d. failed to act reasonably and prudently when training FDA Inspectors;

e. failed to act reasonably and prudently when retaining FDA Inspectors and Defendants Kassim, Burrow, Cochran, and Pham as employees; and

f. failed to comply with the applicable standards of care under the circumstances presented and was otherwise negligent and careless.

114. As a direct and proximate result of the negligence of USA, by and through Federal Employee Defendants, FDA, and HHS, SRC was publicly ostracized, criticized, and identified as being a company who engaged in misconduct and violations of federal regulations, had data integrity concerns, and from whom FDA would not accept any Clinical or BA/BE studies, which result caused SRC to suffer severe and permanent injury including, without limitation, lost earnings, and other injuries and damages.

115. All of the injuries and damages suffered by SRC were directly and proximately caused by the acts or omissions of Federal Employee Defendants, and each of them, FDA, HHS, or any combination thereof, without any negligence on the part of Plaintiff contributing thereto.

116. As a direct and proximate result of the conduct of Federal Employee Defendants, and each of them, FDA, HHS, or any combination thereof, SRC has suffered and continues to suffer damages in an amount to be proven at trial.

117. The acts, omissions, or both, set forth above would constitute a claim under the laws of the State of California.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment in its favor as follows:

For Count One:

1. Awarding Plaintiff general damages against the United States, FDA, HHS, Federal Employee Defendants, and Does 11-20, jointly and severally, in an

amount to be proven at trial;

2. Awarding Plaintiff special damages against the United States, FDA, HHS, Federal Employee Defendants, and Does 11-20, jointly and severally, in an amount to be proven at trial;

3. Awarding Plaintiff punitive and exemplary damages against United States, FDA, HHS, Federal Employee Defendants, and Does 11-20, jointly and severally, as allowed by law, in an amount to be proven at trial;

4. Awarding Plaintiff its attorney fees and reasonable costs and expenses incurred in bringing this action against United States, FDA, HHS, Federal Employee Defendants, and Does 11-20, jointly and severally, as allowed by applicable law;

5. Awarding Plaintiff declaratory or injunctive relief in the form of an Order that the April 20, 2016 Notice and Customer Letters be rescinded and any other declaratory or injunctive relief the Court deems just and proper;

6. For such other relief as the Court deems just and proper.

For Count Two:

1. Awarding Plaintiff general damages against the United States in an amount to be proven at trial;

2. Awarding Plaintiff special damages against the United States in an amount to be proven at trial;

3. Awarding Plaintiff its attorney fees and reasonable costs and expenses incurred in bringing this action against United States, as allowed by the FTCA;

4. For such other relief as the Court deems just and proper.

For Count Three:

1. Awarding Plaintiff general damages against the United States in an amount to be proven at trial;

2. Awarding Plaintiff special damages against the United States in an amount to be proven at trial;

3. Awarding Plaintiff its attorney fees and reasonable costs and expenses incurred in bringing this action against United States, as allowed by the FTCA;

4. For such other relief as the Court deems just and proper.

For Count Four:

1. Awarding Plaintiff general damages against the United States in an amount to be proven at trial;

2. Awarding Plaintiff special damages against the United States in an amount to be proven at trial;

3. Awarding Plaintiff its attorney fees and reasonable costs and expenses incurred in bringing this action against United States, as allowed by the FTCA;

4. For such other relief as the Court deems just and proper.

Respectfully submitted,

Dated: January 22, 2018 By: /s/ Evan L. Bardo
EVAN L. BARDO
Attorney for Plaintiff
SEMLER RESEARCH CENTER PRIVATE LIMITED