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ONE HUNDRED TENTH CONGRESS

**U.S. House of Representatives**  
**Committee on Energy and Commerce**  
**Washington, DC 20515-6115**

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March 6, 2008

Mr. Matthew R. Weinberg  
Chief Executive Officer  
The Weinberg Group  
1220 Nineteenth St., N.W., Suite 300  
Washington, D.C. 20036

Dear Mr. Weinberg:

Under Rules X and XI of the Rules of the U.S. House of Representatives, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are investigating the use of the chemical Bisphenol A (BPA), which has led us to inquire about the work of your consulting firm.

Since our last letter to you dated February 5, 2008, we have discovered several case studies from your Web site in which the Weinberg Group appears to tout its successes in certain scientific and regulatory matters. We are curious as to the details of these case studies, which are attached to this letter.

We ask that you provide the following information:

1. The case study entitled "Support to Drug Manufacturers" states that the Weinberg Group worked to delay the cancellation of a new drug, allowing for "10 additional years of sales prior to the ultimate cancellation of the drug." Please name the drug, the two manufacturers of the drug who retained the Weinberg Group, and the experts identified for use in the administrative hearing;
2. The case study entitled "FDA Hearing Regarding Adverse Events" states that the Weinberg Group combined "epidemiological [sic] expertise with across-the-board strategic thinking" to lead a pharmaceutical company's effort in their dispute with the

Food and Drug Administration (FDA) over “life-threatening adverse events that were occurring with one of the company’s drugs.” Please name the pharmaceutical company, the drug in question, and provide a copy of the “convincing presentation” indicated in this case study;

3. The case study entitled “Adverse Event Linked to OTC Product” states that the Weinberg Group was retained by a pharmaceutical company to “audit the results of a FDA-requested, industry-sponsored case-control study that linked their over-the-counter (OTC) product and several others with a serious, life-threatening adverse event” and that the “unique ability” of the Weinberg Group “enabled them to lead the pharmaceutical company’s effort in their dispute with the FDA.” Please name the pharmaceutical company, the serious, life-threatening adverse event, and all products indicated in this case study;
4. The case study entitled “Hair Color and Health Risks” states that the Weinberg Group “developed a defensible message debunking this concern” related to allegations of cancer risk from a chemical in hair coloring. Please name the chemical and the manufacturer of the hair coloring relating to this case study;
5. The case study entitled “Developing a Media-Ready Panel of Experts” states that the Weinberg Group “prepared a spokesperson strategy and identified a national team of expert scientists” for a major chemical company to be called upon by journalists and for use in community and product-user outreach efforts. These experts also prepared reviews for publication. Please name the chemical company and the members of the “national team of expert scientists.” Also, please provide copies of all expert-prepared reviews indicated in this case study.
6. The case study entitled “Hormonally Active Agents” states that the Weinberg Group “has been at the forefront” of addressing chemical modulation of the endocrine system since the early 1990s. Based on the information indicated in this case study, please provide copies of:
  - a. the studies designed “to evaluate chemical leaching from food containers”;
  - b. “risk assessments of health effects from exposure to alleged endocrine disruptors in food and food wraps”;
  - c. evaluations of the “safety of chemicals in children’s toys”;
  - d. “toxicological assessments of alleged endocrine disrupting chemicals”; and
  - e. evaluations of “ecological risks from wildlife exposures.”

7. The case study entitled "Technical Literature and Analysis Strengthened Case" states that the Weinberg Group prepared a series of white papers that "set the record straight on the environmental profile" of pentachlorophenol. Please name the manufacturers that retained the Weinberg Group and provide copies of the white papers mentioned in this case study;
8. The case study entitled "Analyzed Existing Studies to Find Any Design Flaws to Support Legal Defense" states that the Weinberg Group assisted "a company with a superfund site issue" and that a biostatistician reanalyzed data to "demonstrate the study's numerous design and analysis flaws," leading to successful defense of a case. Please name the company, the Government-sponsored study in question, and the biostatistician from the Weinberg Group indicated in this case study;
9. The case study entitled "Probabilistic Risk Assessments" states that the Weinberg Group's "probabilistic risk assessments (PRA) using Monte Carlo and other uncertainty analyses" are a "powerful tool to challenge USEPA decisions to deny product registration." Please indicate for us all products for which the Weinberg Group has conducted a PRA, and provide copies of each PRA;
10. The case study entitled "Global Climate Change Modeling" states that the Weinberg Group used mathematical models to demonstrate "no environmental benefit" to the phase out of chlorofluorocarbons. Please name the manufacturer and their "particular product" described in this case study. In addition, please provide a copy of the analysis that demonstrated no benefit.

Also, this case study indicates that the Weinberg Group has "critically evaluated the human epidemiology that studied the association between ozone layer reduction and skin cancer." Please provide all records relating to this evaluation; and

11. The case study entitled "Injury Study Design and Critical Review" states that the Weinberg Group provided "critical review of natural resource injury assessments conducted or proposed by natural resource trustees, including work associated with the Exxon Valdez spill." Please provide all records relating to the Exxon Valdez spill.

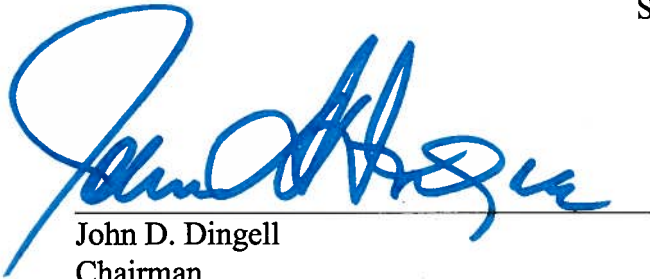
We ask that you do not destroy, dispose of, or tamper with any records relating to this request, or that may subsequently be found to be related to this request, until the conclusion of this inquiry and that you notify all contractors involved with your company of this preservation request.

Mr. Matthew R. Weinberg  
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Please deliver copies of the requested records to the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, Room 316, Ford House Office Building, no later than two weeks from the date of this letter. Please note that for the purpose of responding to this request, the terms "record" and "relating" should be interpreted in accordance with the attachment to this letter. After review of the records, we may require additional records and/or staff interviews with company staff.

Thank you for your prompt attention to this matter. If you have any questions related to this request, please contact John F. Sopko or Paul Jung with the Committee on Energy and Commerce staff at (202) 226-2424.

Sincerely,



John D. Dingell  
Chairman



Bart Stupak  
Chairman  
Subcommittee on Oversight and Investigations

cc: The Honorable Joe Barton, Ranking Member  
Committee on Energy and Commerce

The Honorable John Shimkus, Ranking Member  
Subcommittee on Oversight and Investigations

## ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.
2. The terms "relating," or "relate" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.



## Case Studies

### SUPPORT TO DRUG MANUFACTURERS

The Food and Drug Administration proposed cancellation of a registered new drug. Cancellation requires an administrative hearing. THE WEINBERG GROUP was retained by two manufacturers of the drug under attack, to define strategy for the administrative hearing, identify the experts to be used in the continued support of the drug; assist in the preparation of the experts for written testimony, analysis of the testimony of experts for the Food and Drug Administration, and preparation for oral cross-examinations and preparation of the summary brief. This led to an extensive process with a written appeal from the first decision to the Commissioner and leading to 10 additional years of sales prior to the ultimate cancellation of the drug.

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## Case Studies

### FDA HEARING REGARDING ADVERSE EVENTS

A pharmaceutical company turned to THE WEINBERG GROUP to assist them in preparing for a FDA hearing to discuss the implications of life-threatening adverse events that were occurring with one of the company's drugs. Although the product label had already undergone a "blackbox" addition to warn about instances of this life-threatening adverse event, there was regulatory pressure to remove the product from the market. THE WEINBERG GROUP worked with the company's safety surveillance, clinical, and regulatory departments to develop a comprehensive and convincing presentation that included an epidemiological assessment of the adverse events over time, and effectively placed the issue into clinical and historical perspective. The unique ability of the staff at THE WEINBERG GROUP to combine epidemiological expertise with across-the-board strategic thinking, led the pharmaceutical company's effort in their dispute with the FDA.

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## Case Studies

### ADVERSE EVENT LINKED TO OTC PRODUCT

A pharmaceutical company retained THE WEINBERG GROUP to audit the results of a FDA-requested, industry-sponsored case-control study that linked their over-the-counter (OTC) product and several others with a serious, life-threatening adverse event. There was a substantial concern from the FDA based on reports of adverse events that use of these OTC products would present a public health problem. The study was commissioned to answer the question of risk with a controlled investigation. According to the study investigators, the results of the study showed a strong association between these products and a severe, life-threatening adverse event. Epidemiologists at THE WEINBERG GROUP led experts and consultants to some of the other affected OTC companies, in an effort that included a reanalysis of the raw data from the case-control study, and an assessment of the study's methodological flaws. The unique ability of the experts at THE WEINBERG GROUP to combine their expertise in epidemiology and biostatistics with strategic thinking enabled them to lead the pharmaceutical company's effort in their dispute with the FDA.

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## Case Studies

### HAIR COLOR AND HEALTH RISKS

A leading manufacturer of hair coloring and their trade association were faced with allegations that a chemical in the product increases the risk of cancer. They were faced with biased media scrutiny, customer perception and public relations problems and potential class action litigation. THE WEINBERG GROUP reviewed the scientific information and developed a defensible message debunking this concern, and provided the means to deliver this message in three forums: regulatory, public and scientific. The problem was effectively resolved by communicating to all stakeholders and accurate presentation of the health consequences of hair coloring use.

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## Case Studies

### DEVELOPING A MEDIA-READY PANEL OF EXPERTS

For a major chemical company, THE WEINBERG GROUP prepared a spokesperson strategy and identified a national team of expert scientists including toxicologists, epidemiologists, risk assessors, physicians and experts in the psychology of risk perception. These experts were media-trained and kept apprised of the latest relevant, pro and con, scientific and political findings. Journalists, as well as regulatory and editorial boards called upon the experts for information and recommendations. Experts were also used in community and product-user outreach efforts and to prepare reviews for publication.

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## Case Studies

### HORMONALLY ACTIVE AGENTS

Chemical modulation of the endocrine system has been a topic of scientific investigation for decades, but the publication of *Our Stolen Future* during the Spring of 1996 elevated the issue from the ranks of academic interest to one of national and international concern. THE WEINBERG GROUP has been at the forefront of addressing this issue on behalf of our clients since the early 1990s. Our work in this area has spanned a broad range of topics in the areas of exposure, toxicity, risk assessment, and risk communication. For example, we have: (1) designed studies to evaluate chemical leaching from food containers, (2) conducted risk assessments of health effects from exposure to alleged endocrine disruptors in food and food wraps, (3) evaluated the safety of chemicals in children's toys, (4) conducted toxicological assessments of alleged endocrine disrupting chemicals, and (5) evaluated ecological risks from wildlife exposures. We also have served as a spokesperson on behalf of industry, assisted our clients in developing business strategies to address this issue, and worked to champion the use sound science and risk assessment instead of "precautionary principles" to evaluate the alleged threats of these compounds.

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## Case Studies

### TECHNICAL LITERATURE AND ANALYSIS STRENGTHENED CASE

The manufacturers of a highly effective utility pole preservative, pentachlorophenol, retained THE WEINBERG GROUP as a member of its team to develop and implement a global strategy to keep the product on the market despite growing pressure to ban its use. A combination of past improper use practices, old misinformation regarding persistence and bioaccumulation, and very low but measurable levels of non-2,3,7,8 TCDD dioxins have resulted in continuous pressure in Europe, Canada and now the U.S. because a re-registration is in progress. As part of the overall strategy THE WEINBERG GROUP prepared a series of white papers that set the record straight on the environmental profile of penta and thereby provided for sound science based risk management decisions. By getting right at the heart of the issue, using the best available science literature presented in an understandable manner, we established technical high ground that has strengthened the case in several venues.

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## Case Studies

**ANALYZED EXISTING STUDIES TO FIND ANY DESIGN FLAWS TO SUPPORT LEGAL DEFENSE**

**THE WEINBERG GROUP** was retained by legal counsel, which represented a company with a superfund site issue. A government-sponsored study of the residents near this superfund site showed a significant increase in insulin levels in this sample of residents. By reanalyzing the raw data from this study, a biostatistician from **THE WEINBERG GROUP** helped to demonstrate the study's numerous design and analysis flaws. In addition, epidemiologists from **THE WEINBERG GROUP** prepared a report for counsel outlining the numerous alternative causes of elevated insulin levels. Through these efforts, counsel was armed with both strategic and scientific evidence to successfully defend their case.

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## Case Studies

### PROBABILISTIC RISK ASSESSMENTS

THE WEINBERG GROUP conducts probabilistic risk assessments (PRA) using Monte Carlo and other uncertainty analyses to support our client's registration and re-registration efforts. For example, we conducted a probabilistic avian risk assessment to support registration of a newly developed pesticide. We have found that PRA is a powerful tool to challenge USEPA decisions to deny product registration, when that decision is based on conservative deterministic risk assessments typically relied upon by the Agency to make their decisions. Our PRA analyses help our clients take advantage of the considerable amount of data they have collected to support their product development. By providing clients information on the magnitude as well as the likelihood of risk, our PRA/s offer the type of insight and perspective necessary to make sound environmental decisions for pesticides.

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## Case Studies

### GLOBAL CLIMATE CHANGE MODELING

THE WEINBERG GROUP assists our clients in addressing global climate change issues raised by regulatory agencies and environmental groups. For example, we were asked to determine if phase-out of a minor source of CFCs would have a beneficial environmental effect. This use of CFCs, although minor in amount, was highly significant to the manufacturer of a particular product. We examined the potential impact on the ozone layer and on CFCs as greenhouse gases and, using mathematical models, demonstrated that there was no environmental benefit to this phase out. The outcome of this analysis was integrated with economic information to develop a comprehensive strategy. In related work, we have critically evaluated the human epidemiology that studied the association between ozone layer reduction and skin cancer.

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## Case Studies

### INJURY STUDY DESIGN AND CRITICAL REVIEW

THE WEINBERG GROUP has assisted in the design of a study to assess population-level injury in migratory birds utilizing a Superfund site. The study focused on analysis of reproductive success of the seasonally resident bird population. The study also included documentation of bird movement on and off the site through use of radio-telemetry, analysis of the dietary and chemical contaminant composition of the seasonally resident birds, and an analysis of migratory return rate. We also have provided critical review of natural resource injury assessments conducted or proposed by natural resource trustees, including work associated with the Exxon Valdez spill. Our critical reviews have been used in a number of ways, including to improve the design of Trustees' studies, and to provide insight to legal teams of the technical strength of any potential Trustee claims.

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