

## Statement of Charges

We believe that the following charges can be brought against specific federal agencies and individuals at these agencies in their capacity as employees under the following statutes:

- I. FDA: Criminal negligence in failure to regulate the safety and effectiveness of biological products under Title 42, Ch1, Chapter 6A, Subchapter II., Part F., Subpart 1, Subsection 262, (2), (C): The secretary shall approve a biologics license application—(i) on the basis of demonstration that---(I) the biological product that is the subject of the application is SAFE, PURE, and POTENT;
- II. HHS, CDC, and FDA: Criminal negligence in failure to regulate and promote vaccines as provided for under the National Vaccine Injury Compensation Program, Title 42, Chapter 6A, Subchapter XIX, Part 2, Subpart C, Section 300aa-27: Mandate for safer childhood vaccines (a) General rule: In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall—(1) **promote the development of childhood vaccines that result in less serious adverse reactions than those licensed as of December 22, 1987, and promote the refinement of such vaccines**, and (2) make or assure improvements in, and otherwise use the authority of the Secretary with respect to, the **licensing, manufacturing, product testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.**
- III. FDA: Criminal negligence in not instituting a Class I recall of all vaccines administered to infants containing thimerosal in July of 1999 and again in June of 2000 when the results of VSD study were discussed at Simpsonwood. A Class I recall under 21 CFR Section 7.4(a) may be imposed by FDA after taking into consideration the following factors: 1) whether any disease or injuries have already occurred from the use of the product; 2) whether an existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard; 3) assessment of the hazard to various segments of the population e.g. children...who are expected to be exposed to the particular product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk, 4) assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed; 5) assessment of the likelihood of occurrence of the hazard, and 6) assessment of the consequences (immediate or long range) of the occurrence of the hazard.
- IV. HHS, FDA, CDC and ACIP employees and contractors: Criminal conspiracy to defraud the government by deception or artifice and to obstruct the wholesome administration of the laws and affairs of the United States. Includes any conspiracy for the purpose of impairing, obstructing or defeating the lawful function of any department of government. See,

e.g., Haas v. Henkel, 216 U.S. 462 (1910) (and progeny). Statutory reference, 18 USC Section 371, Part I Crimes, Chapter 19, Conspiracy: If 2 or more persons conspire to either commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or purpose and anyone or more of such persons do any act to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than five years or both.

- V. HHS, FDA, CDC and ACIP employees and contractors: Criminal obstruction of justice: whoever corruptly, or by threats or force, or by any threatening letter or communication influences, obstructs, or impedes or endeavors to influence, obstruct, or impede the due and proper administration of law under which any pending proceeding is being had before any department or agency of the US, or the due and proper exercise of the inquiry is being had by either House or any committee of either House or joint committee of the Congress, shall be fined under this Title or imprisoned not more than five years or both. Statutory reference, Title 18, Part 1, Crimes, Chapter 73, Obstruction of justice, Section 1505.