

FDA Amendments Act (FDAAA), Section 801: Adverse Events Provision

[Source: Pub L. 110-85, Sec. 801, adding new 42 U.S.C. 282(j)(3)(I)(i)-(iii), *as amended by Pub L. 110-316, Sec. 302(2)*]

“(I) ADVERSE EVENTS.—

“(i) REGULATIONS.—Not later than 18 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall by regulation determine the best method for including in the registry and results data bank appropriate results information on serious adverse and frequent adverse events for *applicable clinical trials* described in subparagraph (C) in a manner and form that is useful and not misleading to patients, physicians, and scientists.

“(ii) DEFAULT.—If the Secretary fails to issue the regulation required by clause (i) by the date that is 24 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, clause (iii) shall take effect.

“(iii) ADDITIONAL ELEMENTS.—Upon the application of clause (ii), the Secretary shall include in the registry and results data bank for *applicable clinical trials* described in subparagraph (C), in addition to the clinical trial information described in subparagraph (C), the following elements:

“(I) SERIOUS ADVERSE EVENTS.—A table of anticipated and unanticipated serious adverse events grouped by organ system, with number and frequency of such event in each arm of the clinical trial.

“(II) FREQUENT ADVERSE EVENTS.—A table of anticipated and unanticipated adverse events that are not included in the table described in subclause (I) that exceed a frequency of 5 percent within any arm of the clinical trial, grouped by organ system, with number and frequency of such event in each arm of the clinical trial.