

Risk Communication Advisory Committee

Risk Communication Issues in the Food and Drug Administration Amendments Act of 2007

February 28, 2008



Food and Drug Administration Amendments Act of 2007 (FDAAA)

- Public Law 110-85, enacted September 27, 2007
- Includes reauthorization of the Prescription Drug User Fees (PDUFA), Medical Device User Fees (MDUFA), Best Pharmaceuticals for Children Act (BPCA), Pediatric Research Equity Act (PREA) as well as new and/or expanded provisions on pediatric medical devices, new foundation for FDA research, clinical trials databases, conflicts of interest and advisory committees, postmarket safety of drugs, and food safety



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FDAAA

- Title I – Prescription Drug User Fee Amendments
- Title II – Medical Device User Fee Amendments
- Title III – Pediatric Medical Device Safety and Improvement Act
- Title IV – Pediatric Research Equity Act
- Title V – Best Pharmaceuticals for Children Act
- Title VI – Reagan-Udall Foundation
- Title VII – Conflicts of Interest
- Title VIII – Clinical Trial Databases
- Title IX – Enhanced Authorities Regarding Postmarket Safety of Drugs
- Title X – Food Safety
- Title XI – Other Provisions



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Relevant (or Potential) Risk Communication Provisions in FDAAA

- FDAAA includes requirements for consultation of the Risk Communication Advisory Committee (RCAC) or work that must involve members of the committee
- Other provisions do not necessarily mandate involvement but the expertise of the RCAC members may be essential or, at the least, useful in the implementation of the particular provision



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Risk Communication Provisions in FDAAA – Mandates

Title IX – Enhanced Authorities Regarding Postmarket Safety of Drugs

- **Section 901(d)(5)**, 121 Stat. 942 - REPORT ON DIRECT-TO-CONSUMER ADVERTISING. Not later than 24 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall report to the Congress on direct-to-consumer advertising and its ability to communicate to subsets of the general population, including elderly populations, children, and racial and ethnic minority communities. *The Secretary shall utilize the Advisory Committee on Risk Communication established under this Act to advise the Secretary with respect to such report. The Advisory Committee shall study direct-to-consumer advertising as it relates to increased access to health information and decreased health disparities for these populations. The report required by this paragraph shall recommend effective ways to present and disseminate information to these populations.*



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Risk Communication Provisions in FDAAA – Mandates

- **Section 901(d)(5)** (con't) Such report shall also make recommendations regarding impediments to the participation of elderly populations, children, racially and ethnically diverse communities, and medically underserved populations in clinical drug trials and shall recommend best practice approaches for increasing the inclusion of such subsets of the general population. The Secretary of Health and Human Services shall submit the report under this paragraph to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.



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Risk Communication Provisions in FDAAA – Mandates

- **Section 906(b)**, 121 Stat. 950 – STUDY (1) IN GENERAL. In the case of direct-to-consumer television advertisements, the Secretary of Health and Human Services, *in consultation with the Advisory Committee on Risk Communication* ... shall, not later than 6 months after the date of the enactment of this Act, conduct a study to determine if the statement in section 502(n) of such Act ... required with respect to published direct-to-consumer advertisements is appropriate for inclusion in such television advertisements. [“You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.”]



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Risk Communication Provisions in FDAAA – Mandates

- **Section 915**, 121 Stat. 958 POSTMARKET DRUG SAFETY INFORMATION FOR PATIENTS AND PROVIDERS - (Section 502(r)(6), FD&C Act) REVIEW. The Advisory Committee on Risk Communication ... shall, on a regular basis, perform a comprehensive review and evaluation of the types of risk communication information provided on the Internet Web site established under paragraph (1) [requires certain information on Internet Web site] and, through other means, shall identify, clarify, and define the purposes and types of information available to facilitate the efficient flow of information to patients and providers, and shall recommend ways for the Food and Drug Administration to work with outside entities to help facilitate the dispensing of risk communication information to patients and providers



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Risk Communication Provisions in FDAAA – Mandates

- **Section 917**, 121 Stat. 960 RISK COMMUNICATION – adds Section 567 of the FD&C Act **ADVISORY COMMITTEE ON RISK COMMUNICATION**. (1) IN GENERAL. The Secretary shall establish an advisory committee to be known as the ‘Advisory Committee on Risk Communication’ ... (2) DUTIES OF COMMITTEE. The Committee shall advise the Commissioner on methods to effectively communicate risks associated with the products regulated by the Food and Drug Administration. (3) MEMBERS. The Secretary shall ensure that the Committee is composed of experts on risk communication, experts on the risks described in subsection (b), and representatives of patient, consumer, and health professional organizations. (4) PERMANENCE OF COMMITTEE. Section 14 of the Federal Advisory Committee Act shall not apply to the Committee established under this subsection.



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Risk Communication Provisions in FDAAA Possible Involvement/Consultation

Title IV – Pediatric Research Equity Act

- **Section 402(a)**, 121 Stat. 869, 870 – provisions relating to determination of whether the absence of adequate pediatric labeling could pose a risk (or significant risk) to pediatric patients

Title VIII – Clinical Trial Databases

- **Section 801(a)**, 121 Stat. 909, Section 402(j)(3)(B)(iv) (Public Health Service (PHS) Act) - INCLUSION OF RESULTS - The Secretary, acting through the Director of NIH, shall . . . (iv) *in consultation with experts on risk communication*, provide information with the information included under subparagraph (C) in the registry and results data bank to help ensure that such information does not mislead the patients or the public



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Risk Communication Provisions in FDAAA Possible Involvement/Consultation

- **Section 801(a)**, 121 Stat. 911, Section 402(j)(3)(D)(iii) (PHS Act) REQUIRED ELEMENTS
- **Section 801(a)**, 121 Stat. 912, Section 402(j)(3)(D)(v) (PHS Act) ADDITIONAL Provisions
- **Section 801(a)**, 121 Stat. 915, Section 402(j)(3)(I) ADVERSE EVENTS – (i) REGULATIONS - Not later than 18 months after the date of the enactment ...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 drugs described in subparagraph (C) in a manner and form that is useful and not misleading to patients, physicians and scientists . . . (ii) ... If the Secretary fails to issue the . . . regulation . . . 24 months after the date of the enactment . . . clause (iii) shall take effect.



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Risk Communication Provisions in FDAAA Possible Involvement/Consultation

- **Section 801(a)**, 121 Stat. 915, Section 402(j)(3)(I) ADVERSE EVENTS (con't) (iii) . . . (I) . . . 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) . . . A table of anticipated and unanticipated serious 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, groups by organ system, with number and frequency of such event in each arm of the clinical trial (iv) ... In carrying out clause (iii), the Secretary shall, *in consultation with experts in risk communication*, post with the tables information to enhance patient understanding and to ensure such tables do not mislead patients or the lay public



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Risk Communication Provisions in FDAAA Possible Involvement/Consultation

Title IX – Enhanced Authorities Regarding Postmarket Safety of Drugs

- **Section 901(b)**, 121 Stat. 926, Section 505-1(FD&C Act) – RISK EVALUATION AND MITIGATION STRATEGIES
 - Section 505-1(e)(3), 121 Stat. 929 COMMUNICATION PLAN.
 - Section 505-1(h)(6), 121 Stat. 936 REVIEW OF PROPOSED STRATEGIES; REVIEW OF ASSESSMENTS OF APPROVED STRATEGIES – USE OF ADVISORY COMMITTEES (provisions allow for convening a meeting of 1 or more advisory committee to review certain safety issues and certain risk evaluation and mitigation strategies of drugs.
 - Section 505-1(i)(2), 121 Stat. 938 ACTION BY SECRETARY
- **Section 901(d)(2)**, 121 Stat. 939, Section 503B (FD&C Act) – PREREVIEW OF TELEVISION ADVERTISEMENTS

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Risk Communication Provisions in FDAAA Possible Involvement/Consultation

- **Section 901(d)(3)**, 121 Stat. 940(3) DIRECT-TO-CONSUMER ADVERTISEMENTS.— (A) IN GENERAL.—Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) is amended by adding at the end the following: “In the case of an advertisement for a drug subject to section 503(b)(1) presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner.”. (B) REGULATIONS TO DETERMINE CLEAR, CONSPICUOUS, AND NEUTRAL MANNER.—Not later than 30 months after the date of the enactment . . . , the Secretary of Health and Human Services shall by regulation establish standards for determining whether a major statement relating to side effects and contraindications of a drug, described in section 502(n) . . . is presented in the manner required under such section.

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Risk Communication Provisions in FDAAA Possible Involvement/Consultation

- **Section 904**, 121 Stat. 944 - BENEFIT-RISK ASSESSMENTS – Not later than 1 year after the date of the enactment of this Act, the Commissioner of Food and Drugs shall submit to the Congress a report on *how best to communicate to the public the risks and benefits of new drugs* and the role of the risk evaluation and mitigation strategy in assessing such risks and benefits. As part of such study, the Commissioner may consider the possibility of including in the labeling and any direct-to-consumer advertisements of a newly approved drug or indication a unique symbol indicating the newly approved status of the drug or indication for a period after approval

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Risk Communication Provisions in FDAAA Possible Involvement/Consultation

- **Section 905**, 121 Stat. 944, Section 505(k)(3) (FD&C Act) ACTIVE POSTMARKET RISK IDENTIFICATION AND ANALYSIS - DEVELOPMENT OF POSTMARKET RISK IDENTIFICATION AND ANALYSIS METHODS, The Secretary shall, not later than 2 years after the date of the enactment . . . in collaboration with public, academic, and private entities . . . (iii) convene a committee of experts, including individuals who are recognized in the field of protecting data privacy and security, to make recommendations to the Secretary on the development of tools and methods for the ethical and scientific uses for, and communication of, postmarketing data specified under subparagraph (C), including recommendations on the development of effective research methods for the study of drug safety questions.

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Risk Communication Provisions in FDAAA Possible Involvement/Consultation

- **Section 917**, 121 Stat. 960 RISK COMMUNICATION - (b) PARTNERSHIPS FOR RISK COMMUNICATION.— (1) . . . The Secretary shall partner with professional medical societies, medical schools, academic medical centers, and other stakeholders to develop robust and multi-faceted systems for communication to health care providers about emerging postmarket drug risks (2) PARTNERSHIPS. The systems developed . . . shall (A) account for the diversity among physicians in terms of practice, willingness to adopt technology, and medical specialty (B) includes the use of existing communication channels, including electronic communication, in place at the Food and Drug Administration

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Risk Communication Provisions in FDAAA Possible Involvement/Consultation

Title X – FOOD SAFETY

- **Section 1003**, 121 Stat. 963 –ENSURING EFFICIENT AND EFFECTIVE COMMUNICATIONS DURING A RECALL - The Secretary shall, during an ongoing recall of human or pet food regulated by the Secretary— (1) work with companies, relevant professional associations, and other organizations to collect and aggregate information pertaining to the recall; (2) use existing networks of communication, including electronic forms of information dissemination, to enhance the quality and speed of communication with the public; and (3) post information regarding recalled human and pet foods on the Internet Web site of the Food and Drug Administration in a single location, which shall include a searchable database of recalled human foods and a searchable database of recalled pet foods, that is easily accessed and understood by the public.

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