HR 2900

Food and Drug Administration Amendments Act of 2007

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Chamber: House
Policy Area: Health
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Sponsor

Name: Rep. Dingell, John D. [D-MI-15]
Party: Democratic • **State:** MI • **Chamber:** House

Cosponsors (34 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Allen, Thomas H. [D-ME-1]	D · ME		Jun 28, 2007
Rep. Baldwin, Tammy [D-WI-2]	D · WI		Jun 28, 2007
Rep. Barrow, John [D-GA-12]	D · GA		Jun 28, 2007
Rep. Barton, Joe [R-TX-6]	R · TX		Jun 28, 2007
Rep. Bono, Mary [R-CA-45]	R · CA		Jun 28, 2007
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Rep. Upton, Fred [R-MI-6]	R · MI		Jun 28, 2007
Rep. Waxman, Henry A. [D-CA-30]	D · CA		Jun 28, 2007
Rep. Hill, Baron P. [D-IN-9]	D · IN		Jul 10, 2007
Rep. Wynn, Albert Russell [D-MD-4]	D · MD		Jul 10, 2007

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Reported By	Jul 11, 2007

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
110 HR 3580	Related bill	**Sep 27, 2007:** Became Public Law No: 110-85.
110 S 1082	Related bill	**May 10, 2007:** Held at the desk.

Summary (as of Jul 11, 2007)

Food and Drug Administration Amendments Act of 2007 - **Title I: Prescription Drug User Fee Amendments of 2007** - (Sec. 101) Prescription Drug User Fee Amendments of 2007 - (Sec. 102) Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to include postmarket safety activities within the process for the review of human drug applications or supplements, including: (1) developing and using improved adverse event data collection systems and improved analytical tools to assess potential safety problems; (2) implementing and enforcing provisions relating to postapproval studies, clinical trials, labeling changes, and risk evaluation and mitigation strategies; (3) preparing and making publicly available a summary analysis of the adverse drug reaction reports received for recently approved drugs; (4) conducting screenings of the Adverse Event Reporting System database and reporting on new safety concerns; and (5) developing postmarket safety performance measures. Repeals provisions limiting postmarket safety activities to the three years after approval of a new drug.

(Sec. 103) Reauthorizes prescription drug user fees beginning in FY2008.

Requires the Secretary of Health and Human Services to provide a partial refund of an applicant's user fees if the application is withdrawn without a waiver before filing.

Sets forth special rules for positron emission tomography drugs, including subjecting an applicant in an approved human drug application for a positron emission tomography drug to one-sixth of the annual prescription drug establishment fee.

Establishes the amount of revenue that fees are to generate for FY2008-FY2012. Requires that such fees be derived equally from fees related to human drug applications and supplements, prescription drug establishments, and prescription drug products. Sets forth provisions regarding adjustments to such fees.

Authorizes appropriations for FY2008-FY2012.

Exempts approved prescription drugs or licensed biological products designated for a rare disease or condition (orphan drugs) from product and facility fees if certain requirements are met, including having U.S. drug sales that fall below a certain amount.

(Sec. 104) Requires the Secretary to assess and collect fees for advisory review of proposed direct-to-consumer television advertisements of prescription drug products. Sets forth procedures for such review.

Subjects each person that is assessed an advisory review fee to an operating reserve fee. Establishes the amount of revenue that may be generated from such fees. Requires the Secretary to annually set the advisory review fee. Sets forth fee limits.

Terminates the advisory review program if revenue falls below a certain threshold.

Authorizes appropriations for FY2008-FY2012.

(Sec. 105) Requires the Secretary to report on the progress of the Food and Drug Administration (FDA) toward achieving goals related to expediting the drug development process and the process for the review of human drug applications.

(Sec. 106) Terminates provisions related to prescription drug users fees and advisory review fees on October 1, 2012.

Title II: Medical Device User Fee Amendments of 2007 - (Sec. 201) Medical Device User Fee Amendments of 2007 **-**

Subtitle A: Fees Related to Medical Devices - (Sec. 211) Defines terms relating to fees for medical devices, including defining "30-day notice" as a supplement to an approved premarket application or premarket report that is limited to a request to make modifications to manufacturing procedures or methods affecting the safety and effectiveness of the device.

(Sec. 212) Makes changes to medical device fees, including establishing a fee for: (1) a 30-day notice; (2) a request for classification information; and (3) periodic reporting for a class III device.

Subjects each medical device establishment to a fee for each initial or annual registration beginning with its registration for FY2008, except for establishments operated by a state or federal governmental entity or an Indian tribe.

Establishes the amount of revenue that may be generated from medical device fees.

Makes changes to provisions related to qualifications for fee waivers for small businesses.

Authorizes appropriations for FY2008-FY2012.

(Sec. 213) Sets forth reporting requirements, including requiring the Secretary to report to the relevant congressional committees on the FDA's progress in achieving medical device review goals.

(Sec. 214) Requires the Secretary to consult with the relevant organizations, individuals, and industry in developing recommendations for meeting goals for the process for the review of medical devices applications for fiscal years after FY2012 and for the reauthorization of provisions relating to device fees.

(Sec. 215) Authorizes additional appropriations for FY2008-FY2012 to collect, develop, review, and evaluate postmarket safety information on medical devices.

(Sec. 216) Makes amendments made by this title effective on the date of enactment of this title, except that fees shall be assessed for all premarket applications, premarket reports, supplements, and premarket notifications submissions received on or after October 1, 2007, regardless of such enactment date.

(Sec. 217) Terminates amendments made by this title on October 1, 2012.

Subtitle B: Amendments Regarding Regulation of Medical Devices - (Sec. 221) Extends the authority of accredited persons to review premarket reports for devices and make recommendations to the Secretary regarding the initial classification of devices.

(Sec. 222) Requires any establishment within a foreign country engaged in the manufacturing, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States to annually register with the Secretary.

(Sec. 223) Requires registered device producers to annually report to the Secretary with a list of new devices introduced by the registrant for commercial distribution, devices discontinued, a notice of resumption of processing of a device, and any material change in information previously submitted.

(Sec. 224) Requires registrations and listings to be submitted to the Secretary electronically unless the Secretary grants a waiver of such requirement.

(Sec. 225) Directs the Comptroller General to study the appropriate use of the process requiring registrants to report to

the Secretary before introduction of a device into interstate commerce on the classification of the device.

(Sec. 226) Requires the Secretary to promulgate regulations establishing a unique identification system for medical devices.

(Sec. 227) Makes changes to reporting requirements for devices that have malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(Sec. 228) Requires a person accredited to conduct inspections of device establishments to notify the Secretary within 30 days of any withdrawal, suspension, restriction, or expiration of certificate of conformance with the quality systems for any inspected establishment. Sets forth conditions that a device establishment must meet to be eligible for inspections by accredited persons.

(Sec. 229) Directs the Comptroller General to study and report on nosocomial infections attributed to new and reused medical devices and the causes of such infections.

Title III: Pediatric Medical Device Safety and Improvement Act of 2007- (Sec. 301) Pediatric Medical Device Safety and Improvement Act of 2007 - (Sec. 302) Requires applications for a humanitarian device exemption, an application for premarket approval of a medical device, or a product development protocol for a medical device to include, if readily available: (1) a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and (2) the number of affected pediatric patients.

Requires the Secretary to submit to the relevant congressional committees an annual report that includes: (1) the number of devices approved in the preceding year for which there is a pediatric subpopulation that suffers from the disease; (2) the number of approved devices labeled for use in pediatric patients; (3) the number of fee-exempt devices approved; and (4) the review time for each approved device.

Authorizes the Secretary to conclude that adult data on medical devices may be used to support a determination of a reasonable assurance of effectiveness in pediatric populations if the course of the disease or condition and the effects of the device are sufficiently similar in adults and pediatric patients.

(Sec. 303) Excludes a person granted a humanitarian device exemption from the prohibition against selling such a medical device for an amount that exceeds its research and development, fabrication, and distribution costs if: (1) the device is intended to treat or diagnose a disease or condition that occurs in pediatric patients; (2) the device was not approved for pediatric patients prior to enactment of this Act; (3) the number of devices distributed does not exceed an annual distribution number specified by the Secretary; and (4) the request for exemption is submitted on or before October 1, 2013.

Requires the Secretary to: (1) refer any adverse event report related to a device to the Office of Pediatric Therapeutics for review; and (2) provide for an annual review by the Pediatric Advisory Committee of all devices subject to the humanitarian device exemption to ensure that such exemption remains appropriate for the pediatric population for which it is granted.

Directs the Comptroller General to report on the impact of allowing persons granted a humanitarian device exemption to profit from such a device.

(Sec. 304) Requires the Director of National Institutes of Health (NIH) to designate a contact point to help innovators and physicians access funding for pediatric medical device development.

Requires the Commissioner of Food and Drugs to report to the relevant congressional committees a plan for expanding pediatric medical device research and development.

(Sec. 305) Requires the Secretary to award grants or contracts for demonstration projects to promote pediatric device development.

Authorizes appropriations for FY2008-FY2012.

(Sec. 306) Includes as a duty of the Office of Pediatric Therapeutics increasing pediatric access to medical devices.

Expands the duties of the advisory committee on pediatric therapeutics to include providing advice and recommendations on matters relating to medical devices.

(Sec. 307) Allows the Secretary to require: (1) postmarket surveillance as a condition to approval or clearance of certain medical devices; (2) postmarket surveillance on class II or class III medical devices that are indicated for, or have significant use in, pediatric populations; and (3) a prospective surveillance period of more than 36 months for a device that is expected to have significant use in pediatric populations.

Title IV: Pediatric Research Equity Act of 2007 - (Sec. 401) Pediatric Research Equity Act of 2007 - (Sec. 402) Requires an applicant seeking to defer submission of some or all pediatric assessments of the safety and effectiveness of a new drug or biological product to submit to the Secretary a timeline for the completion of pediatric studies. Sets forth annual reporting requirements for an applicant following the approval of such a deferral.

Requires an applicant seeking a full or partial waiver of pediatric assessment submission requirements to submit to the Secretary documentation detailing why a pediatric formulation cannot be developed.

Authorizes the Secretary to require submission of a pediatric assessment if the Secretary finds that: (1) adequate pediatric labeling could confer a benefit on pediatric patients; or (2) the absence of adequate pediatric labeling could pose a risk (currently, significant risk) to pediatric patients.

Directs the Secretary to utilize an internal committee to consult with reviewing divisions on: (1) all pediatric plans and assessments prior to approval of an application or supplement for which a pediatric assessment is required; and (2) all deferral and waiver requests granted.

Requires the Secretary to track and make publicly available information related to pediatric assessments, including: (1) the number of assessments conducted; (2) the specific drugs and biological products and uses assessed; (3) the number of deferrals requested and granted; and (4) the labeling changes made as a result of such assessments.

Considers a supplement to any new drug or biological license application proposing a labeling change as a result of any pediatric assessments to be a priority application or supplement. Sets forth dispute resolution procedures if the Commissioner and the sponsor are unable to reach agreement on appropriate labeling changes for such drug.

Requires the Secretary to: (1) order the label of a product to include information about the results of the assessment and a statement that a pediatric assessment does or does not demonstrate that the drug is safe and effective in pediatric populations; (2) make publicly available the pharmacology reviews of pediatric assessments; (3) require the sponsors of the assessments that result in labeling changes to distribute such information to physicians and other heath care providers; and (4) ensure that all adverse event reports that have been received for a drug are referred to the Office of Pediatric Therapeutic for review.

Requires the Secretary to contract with the Institute of Medicine to study and report to Congress regarding the pediatric studies and the labeling changes made as a result of such studies.

(Sec. 403) Requires the Comptroller General to submit a report to Congress that addresses the effectiveness of FFDCA pediatric research provisions in ensuring that medicines used by children are tested and properly labeled.

Title V: Best Pharmaceuticals for Children Act of 2007 - (Sec. 501) Best Pharmaceuticals for Children Act of 2007 - (Sec. 502) Amends the Federal Food, Drug, and Cosmetic Act to revise provisions regarding market exclusivity for pediatric drug studies on new or already approved drugs, including to: (1) change the definition of "pediatric studies" to authorize the Secretary to include preclinical studies; (2) require that the studies are completed using appropriate formulations for each age group for which such a study is requested; (3) require that appropriate labeling changes are made within a time frame requested by the Secretary; and (4) prohibit the Secretary from extending the period of market exclusivity later than one year prior to the expiration of the period.

Requires an applicant or holder that does not agree to the request for a pediatric study to submit to the Secretary the reasons such pediatric formulations cannot be developed. Requires an applicant or holder that agrees to such a request to provide the Secretary with all postmarket adverse event reports regarding the drug.

Extends to 180 days (currently, 90 days) the period the Secretary has to accept or reject reports on pediatric studies and notify the sponsor or holder.

Directs the Secretary to: (1) publish a notice identifying any drug for which a pediatric formulation was developed, studied, and found to be safe and effective in the pediatric population if the pediatric formulation is not introduced onto the market within one year after the determination regarding market exclusivity; (2) establish an internal committee to review all written requests for pediatric studies issued; (3) track and make publicly available information on the pediatric studies conducted; (4) order the labeling of a product to include information about the results of the study and a statement that a pediatric study does or does not demonstrate that the drug is safe and effective in pediatric populations; and (5) ensure that all adverse event reports that have been received for a drug are referred to the Office of Pediatric Therapeutics.

Sets forth actions for the Secretary to take if pediatric studies have not been completed and there is a continuing need for information relating to the use of the drug in the pediatric population.

Requires the Secretary to contract with the Institute of Medicine to study and report to Congress regarding written requests for pediatric studies made and the studies conducted.

Requires the Secretary, acting through the Director of NIH, to: (1) develop and publish a priority list of needs in pediatric therapeutics, including drugs or indications that need study; and (2) study and report to Congress on the feasibility of establishing a compilation of information on pediatric drug use.

Authorizes appropriations.

Includes activities relating to the support of studies of drugs on pediatric populations within the process for the review of human drug applications.

Authorizes the Foundation for the National Institutes of Health to solicit and accept gifts, grants, and other donations, establish accounts, and invest and expend funds in support of activities relating to studies on the Secretary's priority list of needs in pediatric therapeutics.

Amends the Best Pharmaceuticals for Children Act to require the advisory committee on pediatric therapeutics to continue to operate for five years after enactment of this Act. Requires the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee to: (1) provide recommendations to the internal committee that reviews pediatric research requests with respect to the treatment of pediatric cancer; and (2) continue to operate for five years after enactment of this Act. Sets forth reporting requirements.

Directs that the proposed rule issued by the Commissioner entitled "Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products" take effect on January 1, 2008, unless the final rule is issued before such date.

Title VI: Reagan-Udall Foundation - (Sec. 601) Establishes the Reagan-Udall Foundation for the Food and Drug Administration as a nonprofit corporation to advance the mission of the FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety. Requires the Foundation to: (1) identify unmet needs in the development, manufacture, and evaluation of the safety and effectiveness of such products; (2) establish goals and priorities; (3) identify federal research and development programs and minimize duplication; (4) award grants to scientists and entities to efficiently and effectively advance such goals and priorities; and (5) provide objective clinical and scientific information to the FDA and other federal agencies.

(Sec. 602) Requires the Secretary to establish an Office of the Chief Scientist to: (1) oversee, coordinate, and ensure quality and regulatory focus of FDA intramural research programs; (2) track and coordinate intramural research awards made by each FDA center or science-based office; (3) develop and advocate for a budget to support intramural research; (4) develop a peer review process by which intramural research can be evaluated; and (5) identify and solicit intramural research proposals from across the FDA.

(Sec. 603) Requires the Secretary, acting through the Commissioner, to enter into Critical Path Public-Private Partnerships with eligible entities to implement the Critical Path Initiative of FDA by developing research, education, and outreach projects to foster medical product innovation, accelerate medical product development, and enhance medical product safety.

Authorizes appropriations for FY2008-FY2012.

Title VII: Conflicts of Interest - (Sec. 701) Directs the Secretary, through the Office of Women's Health, the Office of Orphan Product Development, the Office of Pediatric Therapeutics, and other relevant offices within FDA, to develop and implement strategies on effective outreach to potential members of advisory committees. Requires the Secretary to review the expertise and financial disclosure report of an individual when considering an appointment to an advisory committee.

Prohibits any member of an advisory committee from voting on any matter in which the member has a financial interest without a waiver by the Secretary.

Title VIII: Clinical Trials Databases - (Sec. 801) Amends the Public Health Service Act to require the Secretary, acting through the Director of NIH, to establish and administer a clinical trials registry database and a clinical trials results database. Requires the responsible party for an applicable clinical trial to submit the relevant information and periodic updates to the Director of NIH for inclusion in the databases. Sets forth penalties for failure to submit the required clinical trial information and for the submission of false or misleading information.

Authorizes appropriations.

Prohibits a state or political subdivision from establishing any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database.

(Sec. 802) Requires the Comptroller General to study whether information on the trials registry and database is considered promotional and to evaluate the implementation of the database.

Title IX: Enhanced Authorities Regarding Postmarket Safety of Drugs - (Sec. 901) Prohibits a responsible person from introducing into interstate commerce a new drug if the person is in violation of a requirement related to postapproval clinical trials or labeling changes.

Authorizes the Secretary to: (1) require a responsible person for a drug to conduct a postapproval study or clinical trial of the drug to assess a known serious risk or signals of serious risk or to identify such a risk; (2) require a postapproval study or trial for an already approved drug only if the Secretary becomes aware of new safety information; and (3) issue an order directing a responsible person to make a labeling change to address new safety information. Sets forth procedures for dispute resolution.

Prohibits a person from introducing into interstate commerce a new drug or biological product for which a risk evaluation and mitigation strategy is required if: (1) the person fails to maintain compliance with the requirements of such strategy; or (2) does not cooperate in developing such a strategy.

Prohibits the Secretary from approving the application for a new drug or a biological products license unless the person involved has submitted a statement as to whether a risk evaluation and mitigation strategy and a postmarket study or clinical trial should be required.

Requires a person to submit a risk evaluation and mitigation strategy as part of the application if determined necessary to ensure that the benefits of the drug involved outweigh the risks. Sets forth factors the Secretary must consider in making such a determination.

Requires a proposed risk evaluation and management strategy to include a timetable for assessment of the strategy. Allows the Secretary to require such a strategy to include additional elements, including: (1) distribution to each patient of a Medication Guide and a patient package insert; (2) a communication plan to health care providers; and (3) restrictions on distribution.

Requires the elements of a risk evaluation and mitigation strategy to be commensurate with a specific serious risk listed in the labeling of the drug.

Establishes the Drug Safety Oversight Board.

Authorizes the Secretary to: (1) require the submission of any television advertisement for a drug for review before dissemination; (2) recommend but not require changes in such advertisements; and (3) require inclusion in advertisements of certain disclosures about a serious risk listed in the labeling of the drug.

Requires the Secretary to establish a permanent advisory committee to advise the Secretary on a report to Congress on direct-to-consumer advertising and its ability to communicate to subsets of the general population.

(Sec. 902) Deems to be misbranded a drug: (1) subject to an approved risk evaluation and mitigation strategy if the responsible person fails to comply with the strategy's requirements; or (2) if the responsible person is in violation of a requirement relating to postmarket studies and clinical trials or labeling.

(Sec. 903) Authorizes the Secretary to withdraw or suspend the approval of a new drug application without first ordering the applicant to submit an assessment of the approved risk evaluation and mitigation strategy.

(Sec. 904) Directs the Commissioner to report to Congress 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.

(Sec. 905) Requires the Secretary to establish public-private partnerships to develop tools and methods to enable the Secretary and others to use available electronic databases to create a robust surveillance system that will support active surveillance on important drug safety questions.

Authorizes appropriations for FY2008-FY2012.

Requires the Comptroller General to evaluate data confidentiality and security issues relating to collection, transmission, and maintenance of data for the surveillance system under this Act and make recommendations to relevant congressional committees regarding the need for any additional legislative or regulatory actions to ensure confidentiality and security.

(Sec. 907) Deems a drug or device to be misbranded if a direct-to-consumer advertisement does not include a specified statement related to reporting adverse effects.

(Sec. 908) Requires the Secretary, acting through the Commissioner, to issue guidance for the conduct of clinical trials with respect to antibiotic drugs.

(Sec. 909) Prohibits the introduction into interstate commerce of any food to which has been added an approved drug, a licensed biological product, or certain other drugs or biological products unless: (1) such drug or biological product was marketed in food prior to approval, licensure, or clinical investigation; or (2) the Secretary has issued a regulation approving the addition of such drug or biological product to food.

(Sec. 910) Requires the Secretary to: (1) develop standards to secure the prescription drug distribution system against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs; (2) prioritize and develop standards for the identification, validation, authentication, and tracking of prescription drugs; and (3) expand the Office of Regulatory Affairs of the FDA to protect the prescription drug distribution system.

(Sec. 911) Directs the Commissioner to convene a public meeting regarding which serious and life threatening infectious diseases potentially qualify for available grants and contracts under the Orphan Drug Act or other incentives for development.

Amends the Orphan Drug Act to reauthorize appropriations for grants and contracts to defray the costs of: (1) qualified testing expenses incurred in connection with the development of drugs for rare diseases and conditions, (2) developing medical devices for rare diseases or conditions, and (3) developing medical foods for rare diseases or conditions.

Authorizes appropriations for FY2008-FY2012 for grants under the Orphan Drug Act.

(Sec. 912) Prohibits the Secretary from delaying approval of an application on the basis of a citizen petition unless the Secretary determines that a delay is necessary to protect the public health and provides the applicant with a written explanation of the reasons for the delay.

(Sec. 913) Authorizes additional appropriations for FY2008-FY2012 for carrying out this title.

(Sec. 914) Makes this title effective 180 days after enactment. Deems already approved drugs to have an approved risk evaluation and mitigation strategy if specified restrictions on distribution or use are in effect, but requires the holder of such an approved drug application to submit a proposed risk evaluation and mitigation strategy within 180 days.

Actions Timeline

- **Jul 16, 2007:** Received in the Senate. Read twice. Placed on Senate Legislative Calendar under General Orders. Calendar No. 270.
- **Jul 11, 2007:** Reported by the Committee on Energy and Commerce. H. Rept. 110-225.
- **Jul 11, 2007:** Placed on the Union Calendar, Calendar No. 140.
- **Jul 11, 2007:** Mr. Dingell moved to suspend the rules and pass the bill, as amended.
- **Jul 11, 2007:** Considered under suspension of the rules. (consideration: CR H7568-7606)
- **Jul 11, 2007:** DEBATE - The House proceeded with forty minutes of debate on H.R. 2900.
- **Jul 11, 2007:** At the conclusion of debate, the Yeas and Nays were demanded and ordered. Pursuant to the provisions of clause 8, rule XX, the Chair announced that further proceedings on the motion would be postponed.
- **Jul 11, 2007:** Considered as unfinished business. (consideration: CR H7629)
- **Jul 11, 2007:** Passed/agreed to in House: On motion to suspend the rules and pass the bill, as amended Agreed to by the Yeas and Nays: (2/3 required): 403 - 16 (Roll no. 617).(text: CR H7568-7600)
- **Jul 11, 2007:** On motion to suspend the rules and pass the bill, as amended Agreed to by the Yeas and Nays: (2/3 required): 403 - 16 (Roll no. 617). (text: CR H7568-7600)
- **Jul 11, 2007:** Motion to reconsider laid on the table Agreed to without objection.
- **Jun 28, 2007:** Introduced in House
- **Jun 28, 2007:** Referred to the House Committee on Energy and Commerce.
- **Jun 28, 2007:** Mr. Pallone asked unanimous consent that the Committee on Energy and Commerce have until midnight on July 9 to file a report on H.R. 2900. Agreed to without objection.