HR 4730

To amend the Federal Food, Drug, and Cosmetic Act to require labeling containing information applicable to pediatric patients.

Congress: 107 (2001–2003, Ended)
Chamber: House
Policy Area: Health
Introduced: May 14, 2002
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Jun 3, 2002)
Official Text: https://www.congress.gov/bill/107th-congress/house-bill/4730

Sponsor

Name: Rep. Waxman, Henry A. [D-CA-29]
Party: Democratic • **State:** CA • **Chamber:** House

Cosponsors (33 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Brown, Sherrod [D-OH-13]	D · OH		May 14, 2002
Rep. DeLauro, Rosa L. [D-CT-3]	D · CT		May 14, 2002
Rep. Dingell, John D. [D-MI-16]	D · MI		May 14, 2002
Rep. Eshoo, Anna G. [D-CA-14]	D · CA		May 14, 2002
Rep. Jones, Stephanie Tubbs [D-OH-11]	D · OH		Jun 4, 2002
Rep. Kaptur, Marcy [D-OH-9]	D · OH		Jun 4, 2002
Rep. Mink, Patsy T. [D-HI-2]	D · HI		Jun 4, 2002
Rep. Pallone, Frank, Jr. [D-NJ-6]	D · NJ		Jun 4, 2002
Rep. Roybal-Allard, Lucille [D-CA-33]	D · CA		Jun 4, 2002
Rep. Sanders, Bernard [I-VT-At Large]	I · VT		Jun 4, 2002
Del. Norton, Eleanor Holmes [D-DC-At Large]	D · DC		Jun 18, 2002
Rep. Berman, Howard L. [D-CA-26]	D · CA		Jun 18, 2002
Rep. Davis, Danny K. [D-IL-7]	D · IL		Jun 18, 2002
Rep. Frank, Barney [D-MA-4]	D · MA		Jun 18, 2002
Rep. Frost, Martin [D-TX-24]	D · TX		Jun 18, 2002
Rep. Maloney, Carolyn B. [D-NY-14]	D · NY		Jun 18, 2002
Rep. Meek, Carrie P. [D-FL-17]	D · FL		Jun 18, 2002
Rep. Millender-McDonald, Juanita [D-CA-37]	D · CA		Jun 18, 2002
Rep. Rangel, Charles B. [D-NY-15]	D · NY		Jun 18, 2002
Rep. Rivers, Lynn N. [D-MI-13]	D · MI		Jun 18, 2002
Rep. Schiff, Adam B. [D-CA-27]	D · CA		Jun 18, 2002
Rep. Slaughter, Louise McIntosh [D-NY-28]	D · NY		Jun 18, 2002
Rep. Carson, Julia [D-IN-10]	D · IN		Jun 25, 2002
Rep. Hilliard, Earl F. [D-AL-7]	D · AL		Jun 27, 2002
Rep. Bonior, David E. [D-MI-10]	D · MI		Jul 9, 2002
Rep. Fattah, Chaka [D-PA-2]	D · PA		Jul 9, 2002
Rep. Snyder, Vic [D-AR-2]	D · AR		Jul 9, 2002
Rep. Stark, Fortney Pete [D-CA-13]	D · CA		Jul 9, 2002
Rep. Nadler, Jerrold [D-NY-8]	D · NY		Jul 17, 2002
Rep. Woolsey, Lynn C. [D-CA-6]	D · CA		Sep 4, 2002
Rep. Cummings, Elijah E. [D-MD-7]	D · MD		Sep 26, 2002
Rep. Miller, George [D-CA-7]	D · CA		Sep 26, 2002
Rep. Payne, Donald M. [D-NJ-10]	D · NJ		Sep 26, 2002

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jun 3, 2002

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
107 S 2394	Identical bill	**Oct 8, 2002:** By Senator Kennedy from Committee on Health, Education, Labor, and Pensions filed written report. Report No. 107-300. Additional views filed.

Summary (as of May 14, 2002)

Amends the Federal Food, Drug, and Cosmetic Act to require license applications for new drug and biological product to assess such drug's or product's safety and effectiveness for relevant pediatric subpopulations, including dosage. Permits extrapolation from adult studies where the course of the disease and the effects of the drug are sufficiently similar in all populations.

Permits deferral of such assessments if adult studies are completed earlier and the applicant submits a plan for or a description of planned or ongoing pediatric studies.

Authorizes the Secretary of Health and Human Services to specify a date for submission of pediatric assessments if a drug's or product's use or need in the pediatric populations so dictates. States that drugs or products with delayed assessments will be deemed misbranded and subject to seizure and injunctive proceedings, though not penalties.

Permits full waiver of such assessments if: (1) studies are highly impracticable or impossible and the evidence suggests that the drug or product would be ineffective or unsafe in all pediatric age groups; or (2) there is no meaningful therapeutic advantage or benefit in the pediatric population and little risk if used as labeled. Permits partial waivers at the request of an applicant for a specific pediatric subpopulation if any of the full waiver grounds apply to that subpopulation or reasonable attempts for a pediatric formulation for that subpopulation have failed. Requires labels of these drugs or products to reflect such waivers.

Actions Timeline

- **Jun 3, 2002:** Referred to the Subcommittee on Health.
- **May 14, 2002:** Introduced in House
- **May 14, 2002:** Introduced in House
- **May 14, 2002:** Referred to the House Committee on Energy and Commerce.