S. 852

At the request of Mr. LOTT, the names of the Senator from West Virginia [Mr. ROCKEFELLER] and the Senator from Kansas [Mr. ROBERTS] were added as cosponsors of S. 852, a bill to establish nationally uniform requirements regarding the titling and registration of salvage, nonrepairable, and rebuilt vehicles.

S. 1113

At the request of Mr. GRASSLEY, the name of the Senator from Hawaii [Mr. INOUYE] was added as a cosponsor of S. 1113, a bill to extend certain temporary judgeships in the Federal judiciary.

SENATE CONCURRENT RESOLUTION 51

At the request of Mr. HELMS, the name of the Senator from California [Mrs. FEINSTEIN] was added as a cosponsor of Senate Concurrent Resolution 51, a concurrent resolution expressing the sense of Congress regarding elections for the legislature of the Hong Kong Special Administrative Region.

AMENDMENTS SUBMITTED

THE DEPARTMENT OF THE INTERIOR AND RELATED AGENCIES APPROPRIATIONS ACT, 1998

DEWINE AMENDMENT NO. 1134

(Ordered to lie on the table.)

Mr. DEWINE submitted an amendment intended to be proposed by him to the bill (H.R. 2107) making appropriations for the Department of the Interior and related agencies for the fiscal year ending September 30, 1998, and for other purposes; as follows:

At the end of title III, insert the following:

SEC. . (a) In providing services or awarding financial assistance under the National Foundation on the Arts and the Humanities Act of 1965 from funds appropriated under this Act, the Chairperson of the National Endowment for the Arts and the Chairperson of the National Endowment for the Humanities shall ensure that priority is given to providing services or awarding financial assistance for projects, productions, workshops assistance for projects, productions, workshops, or programs that serve underserved populations.

(b) In this section:

(1) The term ''underserved population'' means a population of individuals who have historically been outside the purview of arts and humanities programs due to a high incidence of income below the poverty line or to geographic isolation.

(2) The term ''poverty line'' means the poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2))) applicable to a family of the size involved.

DEWINE AMENDMENT NO. 1135

(Ordered to lie on the table.)

Mr. DEWINE submitted an amendment intended to be proposed by him to an amendment intended to be proposed by Mr. JEFFORDS to the bill, H.R. 2107, supra; as follows:

On page 9, strike lines 21 through 24, and insert the following:

''(9) UNDERSERVED POPULATION.—The term 'underserved population' means a population of individuals who have historically been outside the purview of arts and humanities programs due to a high incidence of income below the poverty line or to geographic isolation. For purposes of the preceding sentence, the term 'poverty line' means the poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2)) applicable to a family of the size involved.

On page 20, lines 9 and 10, strike ''UNDERSERVED COMMUNITIES GRANTS.—'' and insert ''UNDERSERVED POPULATIONS GRANTS.—''.

On page 21, line 12, strike ''UNDERSERVED COMMUNITIES GRANTS.—'' and insert ''UNDERSERVED POPULATIONS GRANTS.—''.

On page 25, lines 21 and 22, strike ''in rural and urban underserved communities'' and insert ''for rural and urban underserved populations''.

On page 30, lines 7 and 8, strike ''underserved communities'' and insert ''underserved populations''.

On page 31, lines 3 and 4, strike ''in rural and urban underserved communities'' and insert ''for rural and urban underserved populations''.

On page 33, lines 17 and 18, strike ''underserved communities'' and insert ''underserved populations''.

On page 38, line 10, strike ''underserved communities'' and insert ''underserved populations''.

On page 41, line 14, strike ''underserved communities'' and insert ''underserved populations''.

On page 43, lines 10 and 11, strike ''UNDERSERVED COMMUNITIES GRANTS.—'' and insert ''UNDERSERVED POPULATIONS GRANTS.—''.

On page 43, lines 15 and 16, strike ''in underserved communities'' and insert ''for underserved populations''.

On page 45, lines 2 and 3, strike ''in underserved communities'' and insert ''for underserved populations''.

On page 45, lines 5 and 6, strike ''in underserved communities'' and insert ''serving underserved populations''.

On page 45, lines 9 and 10, strike ''in underserved communities'' and insert ''serving underserved populations''.

On page 47, line 18, strike ''underserved communities'' and insert ''underserved populations''.

On page 54, line 12, strike ''underserved communities'' and insert ''areas serving underserved populations''.

On page 58, line 7, strike ''underserved community'' and insert ''underserved population''.

THE FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997; PRESCRIPTION DRUG USERS FEE REAUTHORIZATION ACT OF 1997

DEWINE AMENDMENT NO. 1136

(Ordered to lie on the table.)

Mr. DEWINE submitted an amendment intended to be proposed by him to the bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes; as follows:

Strike section 618 and insert the following:

SEC. 618. PEDIATRIC STUDIES MARKETING EXCLUSIVITY.

(a) GENERAL AUTHORITY.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505 the following:

''SEC. 505A. PEDIATRIC STUDIES OF DRUGS.

''(a) MARKET EXCLUSIVITY FOR NEW DRUGS.—If, prior to approval of an application that is submitted under subsection (b)(1) or (j) of section 505, the Secretary determines that information relating to the use of a drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which may include a timeframe for completing such studies), and such studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (d)(2) or completed within any such timeframe and the reports thereof are accepted in accordance with subsection (d)(3)—

''(1)(A) the period during which an application may not be submitted under subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 to four years, to forty-eight months, and to seven and one-half years shall be deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

''(B) the period of market exclusivity under subsections (c)(3)(D) (iii) and (iv) and (j)(4)(D) (iii) and (iv) of section 505 shall be three years and six months rather than three years; and

''(2)(A) if the drug is the subject of—

''(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

''(ii) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under subsection (c)(3) or (j)(4)(B) of section 505 shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

''(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under subsection (c)(3) or (j)(4)(B) of section 505 shall be extended by a period of six months after the date the patent expires (including any patent extensions).

''(b) SECRETARY TO DEVELOP LIST OF DRUGS FOR WHICH ADDITIONAL PEDIATRIC INFORMATION MAY BE BENEFICIAL.—Not later than 180 days after the date of enactment of this section, the Secretary, after consultation with experts in pediatric research (such as the American Academy of Pediatrics, the Pediatric Pharmacology Research Unit Network, and the United States Pharmacopoeia) shall develop, prioritize, and publish an initial list of approved drugs for which additional pediatric information may produce health benefits in the pediatric population. The Secretary shall annually update the list.

''(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—If the Secretary makes a written request for pediatric studies (which

may include a timeframe for completing such studies) concerning a drug identified in the list described in subsection (b) to the holder of an approved application under subsection (b)(1) or (j) of section 505 for the drug, the holder agrees to the request, and the studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (d)(2) or completed within any such timeframe and the reports thereof accepted in accordance with subsection (d)(3)—

''(1)(A) the period during which an application may not be submitted under subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 to four years, to forty-eight months, and to seven and one-half years shall be deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

''(B) the period of market exclusivity under subsections (c)(3)(D) (iii) and (iv) and (j)(4)(D) (iii) and (iv) of section 505 shall be three years and six months rather than three years; and

''(2)(A) if the drug is the subject of—

''(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

''(ii) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under subsection (c)(3) or (j)(4)(B) of section 505 shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

''(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under subsection (c)(3) or (j)(4)(B) of section 505 shall be extended by a period of six months after the date the patent expires (including any patent extensions).

''(d) CONDUCT OF PEDIATRIC STUDIES.—

''(1) AGREEMENT FOR STUDIES.—The Secretary may, pursuant to a written request for studies, after consultation with—

''(A) the sponsor of an application for an investigational new drug under section 505(i);

''(B) the sponsor of an application for a drug under subsection (b)(1) or (j) of section 505; or

''(C) the holder of an approved application for a drug under subsection (b)(1) or (j) of section 505,

agree with the sponsor or holder for the conduct of pediatric studies for such drug.

''(2) WRITTEN PROTOCOLS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary agree upon written protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied upon the completion of the studies and submission of the reports thereof in accordance with the original written request and the written agreement referred to in paragraph (1). Not later than 60 days after the submission of the report of the studies, the Secretary shall determine if such studies were or were not conducted in accordance with the original written request and the written agreement and reported in accordance with the requirements of the Secretary for filing and so notify the sponsor or holder.

''(3) OTHER METHODS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary have not agreed in writing on the protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied when such studies have been completed and the reports accepted by the Secretary. Not later than 90 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within the 90 days, whether the studies fairly respond to the written request, whether such studies have been conducted in accordance with commonly accepted scientific principles and protocols, and whether such studies have been reported in accordance with the requirements of the Secretary for filing.

''(e) DELAY OF EFFECTIVE DATE FOR CERTAIN APPLICATIONS; PERIOD OF MARKET EXCLUSIVITY.—If the Secretary determines that the acceptance or approval of an application under subsection (b)(2) or (j) of section 505 for a drug may occur after submission of reports of pediatric studies under this section, which were submitted prior to the expiration of the patent (including any patent extension) or market exclusivity protection, but before the Secretary has determined whether the requirements of subsection (d) have been satisfied, the Secretary shall delay the acceptance or approval under subsection (b)(2) or (j), respectively, of section 505 until the determination under subsection (d) is made, but such delay shall not exceed 90 days. In the event that requirements of this section are satisfied, the applicable period of market exclusivity referred to in subsection (a) or (c) shall be deemed to have been running during the period of delay.

''(f) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—The Secretary shall publish a notice of any determination that the requirements of subsection (d) have been met and that submissions and approvals under subsection (b)(2) or (j) of section 505 for a drug will be subject to the provisions of this section.

''(g) LIMITATION.—The holder of an approved application for a new drug that has already received six months of market exclusivity under subsection (a) or (c) may, if otherwise eligible, obtain six months of market exclusivity under subsection (c)(1)(B) for a supplemental application, except that the holder is not eligible for exclusivity under subsection (c)(2).

''(h) STUDY AND REPORT.—The Secretary shall conduct a study and report to Congress not later than January 1, 2003 based on the experience under the program. The study and report shall examine all relevant issues, including—

''(1) the effectiveness of the program in improving information about important pediatric uses for approved drugs;

''(2) the adequacy of the incentive provided under this section;

''(3) the economic impact of the program; and

''(4) any suggestions for modification that the Secretary deems appropriate.

''(i) TERMINATION OF MARKET EXCLUSIVITY EXTENSION AUTHORITY FOR NEW DRUGS.—Except as provided in section 618(b) of the Food and Drug Administration Modernization and Accountability Act of 1997, no period of market exclusivity shall be extended under subsection (a) for a drug if—

''(1) the extension would be based on studies commenced after January 1, 2002; or

''(2) the application for the drug under subsection (b)(1) or (j) of section 505 was not submitted by January 1, 2002.

''(j) DEFINITIONS.—In this section, the term 'pediatric studies' or 'studies' means at least 1 clinical investigation (that, at the Secretary's discretion, may include pharmacokinetic studies) in pediatric age-groups in which a drug is anticipated to be used.''.

(b) MARKET EXCLUSIVITY UNDER OTHER AUTHORITY.—

(1) THROUGH CALENDAR YEAR 2003.—

(A) DETERMINATION.—If the Secretary requests or requires pediatric studies, prior to January 1, 2002, under Federal law other than section 505A of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)), from the sponsor of an application, or the holder of an approved application, for a drug under subsection (b) or (j) of section 505 of such Act (21 U.S.C. 355), the Secretary shall determine whether the studies meet the completeness, timeliness, and other submission requirements of the Federal law involved.

(B) MARKET EXCLUSIVITY.—If the Secretary determines that the studies meet the requirements involved, the Secretary shall ensure that the period of market exclusivity for the drug involved is extended for 6 months in accordance with the requirements of subsection (a), (c), (e), and (g) (as appropriate) of section 505A of such Act (as in effect on the date of enactment of this Act.).

(2) CALENDAR YEAR 2002 AND SUBSEQUENT YEARS.—

(A) NEW DRUGS.—Effective January 1, 2002, if the Secretary requests or requires pediatric studies, under Federal law other than section 505A of the Federal Food, Drug, and Cosmetic Act, from the sponsor of an application for a drug under subsection (b) or (j) of section 505 of such Act, nothing in such law shall be construed to permit or require the Secretary to ensure that the period of market exclusivity for the drug is extended.

(B) ALREADY MARKETED DRUGS.—

(i) DETERMINATION.—Effective January 1, 2002, if the Secretary requests or requires pediatric studies, under Federal law other than section 505A of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)), from the holder of an approved application for a drug under subsection (b) or (j) of section 505 of such Act (21 U.S.C. 355), the Secretary shall determine whether the studies meet the completeness, timeliness, and other submission requirements of the Federal law involved.

(ii) MARKET EXCLUSIVITY.—If the Secretary determines that the studies meet the requirements involved, the Secretary shall ensure that the period of market exclusivity for the drug involved is extended for 6 months in accordance with the requirements of subsection (a), (c), (e), and (g) (as appropriate) of section 505A of such Act (as in effect on the date of enactment of this Act.).

(3) DEFINITIONS.—In this subsection:

(A) DRUG.—The term ''drug'' has the meaning given the term in section 201 of such Act.

(B) PEDIATRIC STUDIES.—The term ''pediatric studies'' has the meaning given the term in section 505A of such Act.

(C) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

NOTICE OF HEARING

COMMITTEE ON INDIAN AFFAIRS

Mr. CAMPBELL. Mr. President, I would like to announce that the Senate Committee on Indian Affairs will meet with the Senate Committee on the Judiciary on Wednesday, September 17, 1997, at 9 a.m. in room 226 of the Dirksen Senate Office Building to conduct a