

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. INOUE] 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