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

joint oversight hearing on the problem of youth gang activity in Indian country.

Those wishing additional information should contact the Committee on Indian Affairs at 224–2251.

AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON GOVERNMENTAL AFFAIRS

Mr. WARNER. Mr. President, I ask unanimous consent on behalf of the Governmental Affairs Committee to meet on Friday, September 12, at 9 a.m. for a hearing on regulatory reform.

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON IMMIGRATION

Mr. WARNER. Mr. President, I ask unanimous consent that the Subcommittee on Immigration, of the Senate Committee on the Judiciary, be authorized to meet during the session of the Senate on Friday, September 12, 1997, at 10 a.m. to hold a hearing in room 226, Senate Dirksen Building, on: ''Religious Workers.''

The PRESIDING OFFICER. Without objection, it is so ordered.

ADDITIONAL STATEMENTS

REPEAL OF THE TOBACCO TAX CREDIT

• Mr. McCAIN. Mr. President, I supported the amendment offered this week by my colleagues, Senators DURBIN and COLLINS, to eliminate the tax credit for tobacco companies contained in the Balanced Budget Act of 1997.

I am amazed at the inventiveness of the process that resulted in this little known provision becoming law. The tax credit was not included in either the balanced budget or taxpayer relief bills that were first considered in the House and Senate. It was not included in the final, conference version of the 1,056-page Balanced Budget Act that the Senate approved on July 31. Instead, it was added to the Balanced Budget Act by means of an amendment quietly slipped into the final, conference version of the 809-page Taxpayer Relief Act, that the Senate passed just hours later on the same day.

This $50 billion giveaway was never discussed or reviewed in an open, public forum, but was added at the eleventh hour, in a conference meeting behind closed doors. This is not the way the Congress should conduct the people's business.

Not only did this unnecessary and undeserved multi-billion-dollar tax credit bypass the normal and appropriate procedures of both Houses of Congress, it also ignored the good intentions of both the Senate and House to provide health care to our Nation's children. This tax break would give the tobacco industry a share of the $50 billion raised from increased tobacco excise taxes, instead of protecting those funds to fund new children's health care initiatives. This tax break would benefit the tobacco industry by short-changing an important and widely supported public health initiative.

The overwhelming vote to repeal this unwarranted tax credit demonstrates clearly that the majority in the Senate did not intend to give a $50 billion tax break to tobacco companies, instead of providing funds to meet the health care needs of approximately 10 million uninsured children in our country. Congress intended to, and did, gradually raise the tax on tobacco products by 15 cents, to provide much-needed funds for health insurance for uninsured children.

I am very concerned that the tobacco tax credit provision that was inserted into the Balanced Budget Act was an attempt by some to begin drafting tobacco liability settlement legislation before Congress has had an opportunity to carefully review the proposed settlement. The provision the Senate voted to repeal would have credited a portion of the increased tobacco excise taxes toward liability payments the tobacco companies could be required to make under legislation implementing the settlement. Clearly, this is inappropriate since Congress is still conducting a thorough examination of the settlement and has not reached a consensus on this matter.

While Congress continues to examine the multibillion-dollar litigation settlement between the tobacco industry and several States, we need to remain mindful that the most important aspect of these discussion is public health, particularly the welfare of our children. By approving the Dubin-Collins amendment and repealing the tax break to tobacco companies, Congress sent a clear message to the American public that their health and well-being is the priority in the complex tobacco settlement discussions. Supporting the Durbin amendment returns $50 billion to the general Treasury while protecting the $24 billion necessary for funding the children's health care initiative.

We need to carefully examine utilizing the funds returned to the treasury as financial support for various public health initiatives. Particularly, we need to discuss using these funds for developing initiatives which would provide our children with the appropriate guidance and information regarding the potential health dangers associated with tobacco products. It is imperative that we create educational campaigns which utilize a variety of tools including advertisement, special events, and public service campaigns. By disseminating the appropriate information to the public, specifically children, we could significantly raise awareness on the perils associated with smoking.

History demonstrates that antismoking campaigns, particularly on television and the radio can serve as strong disincentives for smoking. During the late 1960's, the Federal Communications Commission mandated televised antismoking messages to counter the tobacco advertising which was filling the television airwaves. Anti-smoking advertisements and public service announcements caused a decline in the number of smokers in the country. However, in 1971, the FCC implemented a ban on radio and television advertisement. Since implementation of that ban, antismoking campaigns have also declined.

As chairman of the Commerce Committee, which has jurisdiction over many aspects of the tobacco settlement, I have already held one hearing on the settlement and fully intend on holding more hearings in the near future. Specifically, I intend to hold a hearing regarding the impact of television and radio messages in the antismoking campaign. I believe it is important to hold a hearing which examines the role of various media in the campaign to raise public awareness regarding the dangers associated with tobacco products, especially for the Nation's children.

Mr. President, it is important that we continue to give all aspects of the proposed tobacco settlement careful and coordinated consideration. At the same time, we need to remain mindful that a very important goal of any settlement ought to be the protection of the health and welfare of our children and the general public.•

RECOGNITION OF SEAN P. ALLERTON, BOY SCOUTS OF AMERICA, TROOP 189

• Mr. BREAUX. Mr. President, I would like to take this opportunity to recognize Sean P. Allerton, a member of the Boy Scouts of America's Troop 189 in New Orleans, LA. In 1992, the 102d Congress amended the Constitution of the United States of America by ratifying the 27th amendment. In doing so, thousands of Government textbooks and educational tools throughout the country became outdated. American government students around the world were retrieving information in libraries, in classrooms and in textbooks that reported the Constitution as only having 26 amendments.

Sean Allerton recognized this lack of current information, and as his Eagle Scout project, decided to rectify the problem. He called upon numerous organizations and individuals in the New Orleans area to sponsor his goal of getting 6,600 copies of the new Constitution distributed to every American government and civics student in New Orleans. On August 21 of this year, he received a letter and a check from State District Court Judge Lloyd J. Medley, Jr., who believed in the importance of Sean's project and donated the financial backing to carry it forth.

On September 17, mayor of New Orleans Marc Morial will hold a press conference to congratulate and thank