

COMMITTEE ON THE JUDICIARY

Mr. COCHRAN. Mr. President, I ask unanimous consent that the Committee on the Judiciary be authorized to meet to conduct a hearing on "Oversight Hearing: Law Enforcement and Terrorism" on Wednesday, July 23, 2003, at 10:00 a.m. in the Hart Senate Office Building Room 216.

Agenda

The Honorable Robert S. Mueller, Director, Federal Bureau of Investigation, Department of Justice, Washington, DC; The Honorable Asa Hutchinson, Under Secretary for Border & Transportation Security, Department of Homeland Security, Washington, DC.

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

COMMITTEE ON THE JUDICIARY

Mr. COCHRAN. Mr. President, I ask unanimous consent that the Committee on the Judiciary be authorized to meet to conduct an Executive Nominations hearing on Wednesday, July 23, 2003, at 2:00 p.m. in the Dirksen Senate Office Building Room 226.

Agenda

Panel I: Senators.

Panel II: Rene Alexander Acosta to be Assistant Attorney General, Civil Rights Division, United States Department of Justice and Daniel J. Bryant to be Assistant Attorney General, Office of Legal Policy, United States Department of Justice.

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

SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

Mr. COCHRAN. Mr. President, I ask unanimous consent that the Senate Committee on the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights be authorized to meet to conduct a hearing on "Agriculture, Consolidation and the Smithfield/Farmland Deal" on Wednesday, July 23, 2003, at 4:00 p.m. in Room 138 of the Dirksen Senate Office Building.

Agenda

Panel I: Senator Tim Johnson.

Panel II: Mr. Joseph Sebring, CEO, John Morrell, Inc., Cincinnati, OH; Mr. William Hughes, Administrator, Division of Agricultural Development, Wisconsin Department of Agriculture, Trade and Consumer Protection, Madison, WI; Dr. Luther Tweeten, Agriculture Consultant, Columbus, OH; Mr. Russ Kremer, President, Missouri Farmers' Union, Jefferson City, MO; Mr. Patrick Bell, Farmer, Kenansville, NC; and Mr. Michael Stumo, General Counsel, Organization for Competitive Markets, Winstead, CT.

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

SUBCOMMITTEE ON HOUSING AND TRANSPORTATION

Mr. COCHRAN. Mr. President, I ask unanimous consent that the Subcommittee on Housing and Transportation of the Committee on Banking, Housing, and Urban Affairs be authorized to meet during the session of the

Senate on July 23, 2003, at 2:30 p.m. to conduct a hearing on "Enhancing the Role of the Private Sector in Public Transportation."

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

PRIVILEGE OF THE FLOOR

Mr. BAUCUS. Mr. President, I ask unanimous consent that Jeff Klein and Matt Linstroth of my staff be granted the privilege of the floor for the day.

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

PEDIATRIC RESEARCH EQUITY ACT OF 2003

Mr. DEWINE. Mr. President, I ask unanimous consent the Senate proceed to the immediate consideration of calendar 183, S. 650.

The PRESIDING OFFICER. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (S. 650) to amend the Federal Food, Drug, and Cosmetic Act to authorize the Food and Drug Administration to require certain research into drugs used in pediatric patients.

There being no objection, the Senate proceeded to consider the bill which had been reported from the Committee on Health, Education, Labor, and Pensions, with amendments, as follows:

[Strike the part shown in black brackets and insert the part shown in italic.]

S. 650

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Pediatric Research Equity Act of 2003".

SEC. 2. RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.

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

"SEC. 505B. RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.

"(a) NEW DRUGS AND BIOLOGICAL PRODUCTS.—

"(1) IN GENERAL.—A person that submits an application (or supplement to an application)—

"(A) under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration; or

"(B) under section 351 of the Public Health Service Act (42 U.S.C. 262) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration;

shall submit with the application the assessments described in paragraph (2).

"(2) ASSESSMENTS.—

"(A) IN GENERAL.—The assessments referred to in paragraph (1) shall contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate—

"(i) to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations; and

"(ii) to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective.

"(B) SIMILAR COURSE OF DISEASE OR SIMILAR EFFECT OF DRUG OR BIOLOGICAL PRODUCT.—

"(i) IN GENERAL.—If the course of the disease and the effects of the drug are sufficiently similar in adults and pediatric patients, the Secretary may conclude that pediatric effectiveness can be extrapolated from adequate and well-controlled studies in adults, usually supplemented with other information obtained in pediatric patients, such as pharmacokinetic studies.

"(ii) EXTRAPOLATION BETWEEN AGE GROUPS.—A study may not be needed in each pediatric age group if data from 1 age group can be extrapolated to another age group.

"(3) DEFERRAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1) until a specified date after approval of the drug or issuance of the license for a biological product if—

"(A) the Secretary finds that—

"(i) the drug or biological product is ready for approval for use in adults before pediatric studies are complete;

"(ii) pediatric studies should be delayed until additional safety or effectiveness data have been collected; or

"(iii) there is another appropriate reason for deferral; and

"(B) the applicant submits to the Secretary—

"(i) certification of the grounds for deferring the assessments;

"(ii) a description of the planned or ongoing studies; and

"(iii) evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time.

"(4) WAIVERS.—

"(A) FULL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection if the applicant certifies and the Secretary finds that—

"(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients is so small or the patients are geographically dispersed);

"(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups; or

"(iii) the drug or biological product—

"(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

"(II) is not likely to be used in a substantial number of pediatric patients.

"(B) PARTIAL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—

"(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);

"(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

"(iii) the drug or biological product—

"(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

"(II) is not likely to be used by a substantial number of pediatric patients in that age group; or

"(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric