underlying FDA's decision to treat noncorrective lenses as cosmetics. For that reason, the bill includes a rule of construction stating that the bill should not be construed as having any effect on any product regulated by the FDA other than the specific contact lenses at issue here. I thank the gentleman from Ohio and the distinguished chairman of the Subcommittee on Health, and I join with every Member who has spoken on this bill in urging support for it.

Mr. BILIRAKIS. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

Mr. BROWN of Ohio. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

The SPEAKER pro tempore (Mr. OSE). The question is on the motion offered by the gentleman from Florida (Mr. BILIRAKIS) that the House suspend the rules and pass the bill, H.R. 2218, as amended.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the bill, as amended, was passed.

The title of the bill was amended so as to read: ''A bill to amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of all contact lenses as medical devices, and for other purposes.''.

A motion to reconsider was laid on the table.

FURTHER MESSAGE FROM THE SENATE

A further message from the Senate by Mr. Monahan, one of its clerks, announced that the Senate has passed with an amendment in which the concurrence of the House is requested, a bill of the House of the following title:

H.R. 2297. An act to amend title 38, United States Code, to improve benefits under laws administered by the Secretary of Veterans Affairs, and for other purposes.

The message also announced that the Senate has passed a bill of the following title in which the concurrence of the House is requested:

S. 1156. An act to amend title 38, United States Code, to improve and enhance provision of health care for veterans, to authorize major construction projects and other facilities matters for the Department of Veterans Affairs, to enhance and improve authorities relating to the administration of personnel of the Department of Veterans Affairs, and for other purposes.

PEDIATRIC RESEARCH EQUITY ACT OF 2003

Mr. BILIRAKIS. Mr. Speaker, I move to suspend the rules and pass the Senate 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.

The Clerk read as follows:

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 formulation necessary for that age group have failed.

''(C) PEDIATRIC FORMULATION NOT POSSIBLE.—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation.

''(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

''(b) MARKETED DRUGS AND BIOLOGICAL PRODUCTS.—

''(1) IN GENERAL.—After providing notice in the form of a letter and an opportunity for written response and a meeting, which may include an advisory committee meeting, the Secretary may (by order in the form of a letter) require the holder of an approved application for a drug under section 505 or the holder of a license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262) to submit by a specified date the assessments described in subsection (a)(2) if the Secretary finds that—

''(A)(i) the drug or biological product is used for a substantial number of pediatric patients for the labeled indications; and

''(ii) the absence of adequate labeling could pose significant risks to pediatric patients; or

''(B)(i) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for 1 or more of the claimed indications; and

''(ii) the absence of adequate labeling could pose significant risks to pediatric patients.

''(2) WAIVERS.—

''(A) FULL WAIVER.—At the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to

submit assessments 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 in that age group is so small or patients in that age group are geographically dispersed); or

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

''(B) PARTIAL WAIVER.—At the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments 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)(I) the drug or biological product—

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

''(bb) is not likely to be used in a substantial number of pediatric patients in that age group; and

''(II) the absence of adequate labeling could not pose significant risks to pediatric patients; or

''(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

''(C) PEDIATRIC FORMULATION NOT POSSIBLE.—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation.

''(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

''(3) RELATIONSHIP TO OTHER PEDIATRIC PROVISIONS.—

''(A) NO ASSESSMENT WITHOUT WRITTEN REQUEST.—No assessment may be required under paragraph (1) for a drug subject to an approved application under section 505 unless—

''(i) the Secretary has issued a written request for a related pediatric study under section 505A(c) of this Act or section 409I of the Public Health Service Act (42 U.S.C. 284m);

''(ii)(I) if the request was made under section 505A(c)—

''(aa) the recipient of the written request does not agree to the request; or

''(bb) the Secretary does not receive a response as specified under section 505A(d)(4)(A); or

''(II) if the request was made under section 409I of the Public Health Service Act (42 U.S.C. 284m)—

''(aa) the recipient of the written request does not agree to the request; or

''(bb) the Secretary does not receive a response as specified under section 409I(c)(2) of that Act; and

''(iii)(I) the Secretary certifies under subparagraph (B) that there are insufficient funds under sections 409I and 499 of the Public Health Service Act (42 U.S.C. 284m, 290b) to conduct the study; or

''(II) the Secretary publishes in the Federal Register a certification that certifies that—

''(aa) no contract or grant has been awarded under section 409I or 499 of the Public Health Service Act (42 U.S.C. 284m, 290b); and

''(bb) not less than 270 days have passed since the date of a certification under subparagraph (B) that there are sufficient funds to conduct the study.

''(B) NO AGREEMENT TO REQUEST.—Not later than 60 days after determining that no holder will agree to the written request (including a determination that the Secretary has not received a response specified under section 505A(d) of this Act or section 409I of the Public Health Service Act (42 U.S.C. 284m), the Secretary shall certify whether the Secretary has sufficient funds to conduct the study under section 409I or 499 of the Public Health Service Act (42 U.S.C. 284m, 290b), taking into account the prioritization under section 409I.

''(c) MEANINGFUL THERAPEUTIC BENEFIT.—For the purposes of paragraph (4)(A)(iii)(I) and (4)(B)(iii)(I) of subsection (a) and paragraphs (1)(B)(i) and (2)(B)(iii)(I)(aa) of subsection (b), a drug or biological product shall be considered to represent a meaningful therapeutic benefit over existing therapies if the Secretary estimates that—

''(1) if approved, the drug or biological product would represent a significant improvement in the treatment, diagnosis, or prevention of a disease, compared with marketed products adequately labeled for that use in the relevant pediatric population; or

''(2) the drug or biological product is in a class of products or for an indication for which there is a need for additional options.

''(d) SUBMISSION OF ASSESSMENTS.—If a person fails to submit an assessment described in subsection (a)(2), or a request for approval of a pediatric formulation described in subsection (a) or (b), in accordance with applicable provisions of subsections (a) and (b)—

''(1) the drug or biological product that is the subject of the assessment or request may be considered misbranded solely because of that failure and subject to relevant enforcement action (except that the drug or biological product shall not be subject to action under section 303); but

''(2) the failure to submit the assessment or request shall not be the basis for a proceeding—

''(A) to withdraw approval for a drug under section 505(e); or

''(B) to revoke the license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262).

''(e) MEETINGS.—Before and during the investigational process for a new drug or biological product, the Secretary shall meet at appropriate times with the sponsor of the new drug or biological product to discuss—

''(1) information that the sponsor submits on plans and timelines for pediatric studies; or

''(2) any planned request by the sponsor for waiver or deferral of pediatric studies.

''(f) SCOPE OF AUTHORITY.—Nothing in this section provides to the Secretary any authority to require a pediatric assessment of any drug or biological product, or any assessment regarding other populations or uses of a drug or biological product, other than the pediatric assessments described in this section.

''(g) ORPHAN DRUGS.—Unless the Secretary requires otherwise by regulation, this section does not apply to any drug for an indication for which orphan designation has been granted under section 526.

''(h) INTEGRATION WITH OTHER PEDIATRIC STUDIES.—The authority under this section shall remain in effect so long as an application subject to this section may be accepted for filing by the Secretary on or before the date specified in section 505A(n).''.

(b) CONFORMING AMENDMENTS.—

(1) Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) is amended in the second sentence—

(A) by striking ''and (F)'' and inserting ''(F)''; and

(B) by striking the period at the end and inserting '', and (G) any assessments required under section 505B.''.

(2) Section 505A(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(h)) is amended—

(A) in the subsection heading, by striking ''REGULATIONS'' and inserting ''PEDIATRIC RESEARCH REQUIREMENTS''; and

(B) by striking ''pursuant to regulations promulgated by the Secretary'' and inserting ''by a provision of law (including a regulation) other than this section''.

(3) Section 351(a)(2) of the Public Health Service Act (42 U.S.C. 262(a)(2)) is amended—

(A) by redesignating subparagraph (B) as subparagraph (C); and

(B) by inserting after subparagraph (A) the following:

''(B) PEDIATRIC STUDIES.—A person that submits an application for a license under this paragraph shall submit to the Secretary as part of the application any assessments required under section 505B of the Federal Food, Drug, and Cosmetic Act.''.

SEC. 3. TECHNICAL AND CONFORMING AMENDMENTS.

(a) ABBREVIATED NEW DRUG APPLICATION.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended in subparagraphs (A) and (B) of subsection (b)(2) and subparagraphs (A) and (B) of subsection (c)(2) by striking ''505(j)(4)(B)'' and inserting ''505(j)(5)(B)''.

(b) PEDIATRIC ADVISORY COMMITTEE.—

(1) Section 505A(i)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(i)(2)) is amended by striking ''Advisory Subcommittee of the Anti-Infective Drugs'' each place it appears.

(2) Section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note; Public Law 107–109) is amended—

(A) in the section heading, by striking ''PHARMACOLOGY'';

(B) in subsection (a), by striking ''(42 U.S.C. 217a),'' and inserting (42 U.S.C. 217a) or other appropriate authority,'';

(C) in subsection (b)—

(i) in paragraph (1), by striking ''and in consultation with the Director of the National Institutes of Health''; and

(ii) in paragraph (2), by striking ''and 505A'' and inserting ''505A, and 505B''; and

(D) by striking ''pharmacology'' each place it appears and inserting ''therapeutics''.

(3) Section 15(a)(2)(A) of the Best Pharmaceuticals for Children Act (115 Stat. 1419) is amended by striking ''Pharmacology''.

(4) Section 16(1)(C) of the Best Pharmaceuticals for Children Act (21 U.S.C. 355a note; Public Law 107–109) is amended by striking ''Advisory Subcommittee of the Anti-Infective Drugs''.

(5) Section 17(b)(1) of the Best Pharmaceuticals for Children Act (21 U.S.C. 355b(b)(1)) is amended in the second sentence by striking ''Advisory Subcommittee of the Anti-Infective Drugs''.

(6) Paragraphs (8), (9), and (11) of section 409I(c) of the Public Health Service Act (42 U.S.C. 284m(c)) are amended by striking ''Advisory Subcommittee of the Anti-Infective Drugs'' each place it appears.

SEC. 4. EFFECTIVE DATE.

(a) IN GENERAL.—Subject to subsection (b), this Act and the amendments made by this Act take effect on the date of enactment of this Act.

(b) APPLICABILITY TO NEW DRUGS AND BIOLOGICAL PRODUCTS.—

(1) IN GENERAL.—Subsection (a) of section 505B of the Federal Food, Drug, and Cosmetic Act (as added by section 2) shall apply to an application described in paragraph (1) of that subsection submitted to the Secretary of Health and Human Services on or after April 1, 1999.

(2) WAIVERS AND DEFERRALS.—

(A) WAIVER OR DEFERRAL GRANTED.—If, with respect to an application submitted to the Secretary of Health and Human Services between April 1, 1999, and the date of enactment of this Act, a waiver or deferral of pediatric assessments was granted under regulations of the Secretary then in effect, the waiver or deferral shall be a waiver or deferral under subsection (a) of section 505B of the Federal Food, Drug, and Cosmetic Act, except that any date specified in such a deferral shall be extended by the number of days that is equal to the number of days between October 17, 2002, and the date of enactment of this Act.

(B) WAIVER AND DEFERRAL NOT GRANTED.—If, with respect to an application submitted to the Secretary of Health and Human Services between April 1, 1999, and the date of enactment of this Act, neither a waiver nor deferral of pediatric assessments was granted under regulations of the Secretary then in effect, the person that submitted the application shall be required to submit assessments under subsection (a)(2) of section 505B of the Federal Food, Drug, and Cosmetic Act on the date that is the later of—

(i) the date that is 1 year after the date of enactment of this Act; or

(ii) such date as the Secretary may specify under subsection (a)(3) of that section;

unless the Secretary grants a waiver under subsection (a)(4) of that section.

(c) NO LIMITATION OF AUTHORITY.—Neither the lack of guidance or regulations to implement this Act or the amendments made by this Act nor the pendency of the process for issuing guidance or regulations shall limit the authority of the Secretary of Health and Human Services under, or defer any requirement under, this Act or those amendments.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Florida (Mr. BILIRAKIS) and the gentleman from Ohio (Mr. BROWN) each will control 20 minutes.

The Chair recognizes the gentleman from Florida (Mr. BILIRAKIS).

GENERAL LEAVE

Mr. BILIRAKIS. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and to insert extraneous material on the bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Florida?

There was no objection.

□ 1530

Mr. BILIRAKIS. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise today in support of S. 650, the Pediatric Research Equity Act. This bill gives the Food and Drug Administration new statutory authority to require certain pediatric tests, to require certain research into drugs used for pediatric patients, and it provides for appropriate enforcement of the requirement to submit timely pediatric assessments.

As chairman of the Energy and Commerce Subcommittee on Health, I have been a long-time supporter of pediatric research efforts. To that end, it is important that the FDA has the authority that it needs to require pediatric studies and also information for drugs and biological products in cases where the needed information is not generated by using existing incentive and funding mechanisms. S. 650 will provide that authority.

I think it is appropriate to express appreciation to Senator DEWINE for this piece of legislation and to the gentleman from Ohio (Mr. BROWN), the gentleman from California (Mr. WAXMAN), the gentlewoman from California (Ms. ESHOO) and so many others who have shown concern in this regard and, of course, join us here today.

I urge my colleagues to support the bill that the Senate has passed.

Mr. Speaker, I reserve the balance of my time.

Mr. BROWN of Ohio. Mr. Speaker, I yield myself such time as I may consume.

I would like to thank the gentleman from California (Mr. WAXMAN), the gentlewoman from California (Ms. ESHOO), the gentleman from Pennsylvania (Mr. GREENWOOD) and the gentleman from Michigan (Mr. STUPAK) for their leadership on the important issue of prescription drug research for children. The legislation we consider today is in large part the product of their hard work and their good work.

The FDA requires drug manufacturers to verify the safety and effectiveness of a new medicine before it can be sold in our country. But because most research has been done on adults, new medicines that are safe and effective in grownups may not be safe and effective when used in children. That is why we enacted legislation rewarding safety and efficacy testing that focuses on children. Drug companies that voluntarily conduct this testing are granted what amounts to a patent extension on the pediatric use of their medicines. Though progress has been made, an article published last year in the New England Journal of Medicine confirmed that fully 60 percent of drugs coming to the market remain unstudied and unlabeled for use in children. FDA's Pediatric Rule addressed that concern, but a Federal judge struck it down last year because, according to those judges, the agency lacked sufficient statutory authority.

The legislation today before us corrects that deficiency and codifies the Pediatric Rule. S. 650 requires pediatric testing as a condition of new drug approval every time. It authorizes responsible exceptions, though, deferrals and waivers when these actions would be determined to serve the interests of patients. This approach will ensure that most medicines are testified for safety and effectiveness in children before they hit the market. It gives the FDA the flexibility to move drugs to market when testing is unwarranted or impossible or would hold up a drug important for adult patients.

I have, Mr. Speaker, one important concern with this otherwise laudable legislation. It relates to a controversial provision added by the other body which terminates the testing requirement when the pediatric marketing exclusivity provision expires. There is no policy justification for this change. If it is responsible to require pediatric testing today, it will be no less responsible to do so after the government subsidy for pediatric testing has expired. America's children, pure and simple, are not served by this language. The only ones who benefit again are drugmakers. It has been a really good week for drugmakers in this country. As good as this bill is, they get a benefit they do not deserve. They also get a benefit later in the week if this House passes the Medicare bill to the tune of about $140 billion more in profits on a bill that, frankly, they and the Republican majority and President Bush sat down and wrote to help the drug industry and the insurance industry.

This provision in our bill is objectionable on procedural grounds, also. The other body acted months ago, but the Committee on Energy and Commerce did not schedule a markup that would have permitted us to debate and vote on the sunset provision and consider related issues important especially to the gentleman from Michigan (Mr. STUPAK) and to other Members. I hope this process will not become the model for health legislation in this House.

Having said that, the bill is an important step forward in children's health. America's leading children's health advocates also strongly support the Pediatric Rule. The American Academy of Pediatrics called it an essential tool. The Elizabeth Glaser Pediatric AIDS Foundation said it will safeguard children by taking the guesswork out of children's medicine.

I hope Members will join me in voting to send the Pediatric Research Equity Act to the White House.

Mr. Speaker, I reserve the balance of my time.

Mr. BILIRAKIS. Mr. Speaker, I continue to reserve the balance of my time.

Mr. BROWN of Ohio. Mr. Speaker, I yield 5 minutes to the gentlewoman from California (Ms. ESHOO), one of the authors of this legislation.

Ms. ESHOO. I thank the distinguished ranking member for yielding me this time.

Mr. Speaker, I rise today in support of S. 650, the Pediatric Research Equity Act. As the Democratic sponsor of the House version of this legislation, along with the gentleman from Pennsylvania (Mr. GREENWOOD), I am very excited that this important bipartisan legislation is being considered before Congress departs and closes shop before the end of this year.

In the last session, the Congress took an important step toward increasing drug safety for children by reauthorizing the Best Pharmaceuticals for

Children Act, a bill that I also cosponsored with the gentleman from Pennsylvania (Mr. GREENWOOD). The law provided 6 months of marketing exclusivity for prescription drug manufacturers who undertake the costly, but very necessary, task of testing drugs for safety and efficacy in children. Prior to its enactment, there was little if any information on how drugs affected children. That surprised a lot of people. Most people assumed that the process was really very different. Doctors were cutting adult pills in half, hoping they would work in children, often with life-threatening results. In the years since its passage, the Best Pharmaceuticals for Children Act has yielded significant and lifesaving dosing and efficacy information for prescription drugs for children, and this law continues to work today and work very well. Anyone that is a parent can appreciate the success this bill has had in protecting children.

Despite this success, there are times when the Food and Drug Administration needs additional pediatric clinical data on a drug. Since the passage of the Best Pharmaceuticals for Children Act, a court struck down an important regulation crafted by the FDA that provided a framework for requiring drug manufacturers to perform clinical trials in pediatric populations when the Agency believed they were absolutely necessary. The court argued that the Congress had not given the FDA this authority, effectively tying the Agency's hands with respect to providing safer drugs for children.

In response to this court decision, the gentleman from Pennsylvania (Mr. GREENWOOD) and I introduced the Pediatric Research Equity Act, which specifically gives the FDA the authority that the court struck down, the authority to require prescription drug manufacturers to perform necessary tests for our children. The FDA's gold standard has protected American consumers and America's children for decades. The Congress has to take this step to equip the FDA with the resources and the authority it needs to continue this exceptional performance.

This bill has very important support. Amongst that honor roll of support is the American Academy of Pediatrics which has worked so well and so closely with us, and we want to thank them for that; the Elizabeth Glaser Pediatric AIDS Foundation; the pharmaceutical industry and other groups that are dedicated to providing safe and effective treatments to children. In years past, some have been critical of our work to increase drug safety for children, charging that it is really more about providing incentives to drug companies than it is about children. This effort, as with our work on the Best Pharmaceuticals for Children Act, has always been about making drug treatments safer and more effective for children. And while I understand that the process for moving this bill forward has not been perfect, as so many things around here are not, the underlying bill and the goals it contains are ones that every single Member of the House can and should support.

Finally, Mr. Speaker, I want to offer my unending gratitude to our committee staff for their work on moving this bill forward. In particular, I would like to thank Patrick Ronan with the majority for his help and John Ford on the minority side for his assistance and his advice. As always, it has been invaluable. I also wish to recognize the leadership of the gentleman from Florida (Mr. BILIRAKIS) and always to my partner, the gentleman from Pennsylvania (Mr. GREENWOOD). I think we have been able to get some really important things done. I wish to recognize the inspiration of Dr. Phil Pizzo, dean of the Stanford Medical School, a pediatrician himself. And last but never least, Anne Wilson, my legislative director. This legislation becomes her swan song. She goes off to the private sector to do some really great work, but this is one of the signature pieces that she has really worked so hard on. I salute her for it.

I urge my colleagues to vote ''yes'' on S. 650, the Pediatric Research Equity Act, and my thanks to everyone that have been partners in this what I think has been a noble and important undertaking.

Mr. BILIRAKIS. Mr. Speaker, I yield such time as he may consume to the gentleman from Pennsylvania (Mr. GREENWOOD).

Mr. GREENWOOD. I thank the gentleman for yielding me this time.

Mr. Speaker, I rise in strong support of S. 650, the Pediatric Research Equity Act. This legislation was passed by the Senate by unanimous consent on July 23. Earlier this year, along with the gentlewoman from California (Ms. ESHOO) and the gentlewoman from Ohio (Ms. PRYCE), I introduced this legislation in the House. Both of these Members have been leaders on trying to get this legislation enacted into law.

Children, their physicians, and their parents need to know that the drugs they use are safe and effective. Just over a year ago, a Federal court struck down the 1998 Pediatric Rule on the grounds that Congress had not explicitly given the authority to require that these much-needed pediatric studies be done. The Pediatric Research Equity Act creates a critical safety net for children by restoring this authority. Before it was struck down, the Pediatric Rule led to invaluable pediatric safety and dosing information. The rule places children on equal therapeutic footing with adults by ensuring that medicines coming into the marketplace will be labeled for pediatric use and be available in formulations such as liquids or chewable tablets that children can take.

This legislation will also ensure that there will be no delay in the approval of drugs for adult use by allowing pediatric testing to be deferred until after approval if these studies would delay the availability of the product for adults.

Mr. Speaker, this legislation complements the Best Pharmaceuticals for Children Act which Congress passed 2 years ago. That law recognizes the importance of pediatric drug testing by offering an incentive to companies who conduct tests of drugs on children. However, certain medicines are not captured by the Best Pharmaceuticals for Children Act and, therefore, will be left unstudied for pediatric use without the rule. Both the BPCA and the rule are needed as a strong, two-prong approach to ensure that drugs are appropriately studied and labeled for infants, children and adolescents.

Mr. Speaker, this legislation was discharged from the Committee on Energy and Commerce. Many of us on both sides of the aisle had hoped that the committee would consider this through normal order as there were issues that both sides wanted to make about the legislation. But due to the Medicare and the energy conferences and the limitations those bills have created in the committees, it was necessary for this legislation to be discharged. While this was not the perfect process, I urge my colleagues to join our colleagues in the Senate and the 25 children's health groups, including the American Academy of Pediatrics and the Elizabeth Glaser Pediatric AIDS Foundation, who support this legislation. In their own words, quote, we cannot overstate the extraordinary contribution this legislation will make to children's health.

I would also like to thank my staff member Alan Eisenberg who has worked very hard for a long period on this issue. I urge passage of the legislation.

Mr. BROWN of Ohio. Mr. Speaker, I yield 5 minutes to the gentleman from Michigan (Mr. STUPAK) who has been an absolute leader with a great understanding on these very complicated drug issues.

Mr. STUPAK. I thank the gentleman for yielding me this time.

Mr. Speaker, the pediatric research equity bill is not a bad bill. I agree with the premise of the bill. As the ranking member of the Subcommittee on Health said, it is unfortunate that we have not had a hearing on this bill, we have not had a chance to mark it up, we have not had a chance to amend it. Because I would wish that Congress would stop for a minute and look at this bill before we make another fatal mistake when we deal with pharmaceuticals dealing with young people. As the other speakers said, it is necessary to test and do proper labeling on drugs before we give them to children. We need to know, I think is what the chairman said, all the ramifications before we give young people drugs. This bill goes halfway. This bill only goes halfway. This Congress should not allow the continuation of the practice of pharmaceutical companies being able to develop drugs but not put on proper labeling.

□ 1545

Or when it is time to change the label, to expeditiously change the label, as the other speakers have said, we have been cutting pills in half thinking for young people half a pill is better than a full pill. When they do this testing, when it comes time to label, doctors, families, patients need to know how should the drug be used in dispense. What is the proper dosage for young people? What duration of time should the pill be taken and how often? What are the side effects of the use of this drug? These are the questions that are required for proper use and labeling, but yet it is not required in this legislation nor was it required in the pharmaceutical act of 2002.

So before a drug is marketed, it should be properly labeled with all the necessary information to be used in pediatric patients. Doctors and patients and families have no idea on how to administer drugs or what the effect will be on young people without proper labeling. All I am saying is we should have had an opportunity to amend this legislation to make sure before a patent is extended, before a drug is given for pediatric patients, that the proper labeling is done and made available to doctors, patients, and their families. It is marketed and given to children before we know what the effects are on young people.

As we said earlier, the Best Pharmaceutical Act of 2002 did require a strengthening of labeling requirements, but it did not mandate proper labeling before marketing of these drugs. While the FDA can misbrand a drug for improper labeling, it has never used the enforcement power it has. It has never used the enforcement power granted to it by Congress. As a result, case after case, the pharmaceutical companies have been granted patent extensions and then not gone through with the labeling of the drugs for years. And these drugs were not labeled misbranded by the FDA. Between 1997 and 2002, the year of the Best Pharmaceutical Act for children, the average time for labeling was 9 months after the extension of that patent. Now based upon the Best Pharmaceutical Act of 2002, it is still 5 months after the drug has been used in the marketplace. How on God's green Earth can we stand here and say we will label the proper use of drugs after it is marketed? Five months, that is what it is right now. Some of them are a year. The average is 5 months.

If we would have had a chance to have this before our committee, we could at least have offered some amendments. To uphold the true intention of this legislation and the true intent of the Best Pharmaceutical Act is to make sure we have labeling before drugs are put on the marketplace and not after, requiring, and not suggesting, that the Secretary of HHS label drugs as misbranded if companies fail to test and label these drugs for use in children.

I would like to see this legislation defeated. That will not happen here today. But once again, the Congress of the United States has punted an opportunity to protect our children. We once again said we will allow drugs to be used; we will worry about the side effects on young people after. There is no reason why we could not mandate proper labeling before. And if my colleagues read the language of the bill, it says may, the Secretary may.

We have asked and we have talked to the sponsor in the Senate and we have talked to others. We said why can they not just make it mandatory, label before they market and use in young people? Once again, Congress is avoiding its responsibility to protect the health, safety, and welfare of our young people. The ideas behind this legislation are great. The intent is great, but we have to follow it through. And we have all sat in committees and heard the stories of young people receiving drugs that were improperly used or administered that were not to be used for young people. We find out after the fact, after the drug has been used in the mainstream of commerce and being used by physicians.

Mr. BILIRAKIS. Mr. Speaker, I yield such time as she may consume to the gentlewoman from Ohio (Ms. PRYCE).

Ms. PRYCE of Ohio. Mr. Speaker, I thank the gentleman for yielding me this time and for his strong leadership on this measure.

Mr. Speaker, today is a great day for America's children. Today we will stand with the President of the United States on an extraordinary piece of legislation, legislation that will have the effect of dramatically improving the health and well-being of our Nation's children.

About this time last year, my good friend and former Member, Connie Morella, and I introduced this legislation to put into law the Pediatric Rule, a rule that required drug companies to conduct safety tests of adult medicines that were likely to be given to children. We introduced that bill even before a U.S. district court struck down that rule finding that the FDA did not have the authority to enforce it. We felt then, as we do now, that this rule must be strengthened and codified to ensure advancements and effectiveness in medicines that we give to our children.

In light of the district court's ruling, Members of this body renewed our efforts this year to see that the rule would be put into law for good. With the hard work of the gentleman from Pennsylvania (Mr. GREENWOOD) and the gentlewoman from California (Ms. ESHOO) and the blessings of the gentleman from Louisiana (Chairman TAUZIN) and the gentleman from Florida (Chairman BILIRAKIS) and the gentleman from Ohio (Mr. BROWN), ranking member, we have found ourselves today ready to move forward.

The rule is so important for a few very simple reasons. Many people wrongly assume that children's bodies are just smaller versions of adult bodies. That is just not the case. Simply reducing the dosage of medicine for the treatment of a child is not always effective and is definitely not always safe. By protecting this rule, the Pediatric Rule, and continuing to provide incentives for testing medicines for kids, we will give doctors the information they need to provide our children with the best quality health care.

Mr. Speaker, when I told my constituents at Children's Hospital in Columbus, Ohio, that this legislation would be up for consideration today, I was greeted with elation. Those who care for and treat our children want the very best for them. They know what they need to deliver the very best. They need the Pediatric Rule and believe it is critical to preserving the long-term health and safety of our kids. That is exactly what this bill does. I am proud to be a part of making these safeguards permanent and this bill a reality.

Mr. Speaker, I urge my colleagues to join me in strengthening the health of our children by adopting this legislation. Every pediatrician will rest easier. I am certain that every parent will.

Mr. BROWN of Ohio. Mr. Speaker, I yield 5 minutes to the gentleman from California (Mr. WAXMAN).

Mr. WAXMAN. Mr. Speaker, I rise in support of the Pediatric Research Equity Act, and I urge other Members to support it as well. This legislation has been a long time in coming. Physicians have known for decades that failing to test drugs in children could have deadly consequences.

It was not until the late 1990s that Congress and the FDA finally acted to ensure testing of drugs in children. In 1997 Congress enacted a bill giving pharmaceutical companies generous financial incentives for voluntarily conducting pediatric studies. A year later, FDA finalized a regulation known as the Pediatric Rule, requiring companies to conduct studies in children for important or widely used drugs, and that regulation was regarded by both the FDA and by physician and patient groups as essential because the financial incentives still left many important drugs and many age groups unstudied. Unfortunately, the Pediatric Rule was struck down by a district court last year. I believe the case was wrongly decided and that FDA had adequate authority; but we need to codify the rule now, as this bill would do, in order to provide children with the strongest protection of their right to receive medicines that are as safe and as effective as the medicines given to adults.

While I strongly support this bill, there is one provision I do not support. The bill contains a sunset provision which will repeal in 5 years the protections for children that this bill is designed to provide. I regret this bill did

not go through the committee allowing us the opportunity to strike this provision. Sunsetting the bill is simply bad policy. There is no serious medical or public health argument that it would enhance the health of American children to repeal this law in 5 years. Certainly no one makes the argument that the rules regarding testing of drugs in adults need to be reassessed every 5 years.

Since the sunset provision is not based on improving the public health, why is it in the bill? I have been told that the law giving companies financial incentives for conducting pediatric studies sunsets every 5 years, so this bill should too. But the financial incentives bill raises very different concerns. Those incentives extend drug company monopolies on popular drugs, which in turn raises the price of those drugs for all Americans.

The Congress has an obligation to reassess the size of the incentives periodically to make sure that the cost in higher drug prices is worth the benefit being gained.

There is no similar reason to reassess the Pediatric Rule, and I am very concerned that by sunsetting the two bills together, the Congress will be put in a position where reauthorization of the Pediatric Rule is held hostage to reauthorization of the incentives.

The fact that we have been denied the opportunity to strike the sunset is unfortunate. Similarly, I regret that the gentleman from Michigan (Mr. STUPAK) was denied the opportunity to offer his amendment which addresses an extremely serious issue. I strongly support his amendment and would have liked to have voted for it in committee.

Nevertheless, despite my concern with the process, I will vote for this bill. It is urgent that we pass this legislation as quickly as possible. Every day that we do not act to put the Pediatric Rule back into effect, we run an additional risk that the health of American children will be compromised.

For more than 40 years, the Food and Drug Act has offered a guarantee to adult Americans that their drugs will be safe and effective. It is time we assured our children of the same guarantee.

This bill will also assure that all contact lens care products will be regulated as device accessories.

Mr. DINGELL. Mr. Speaker, I support S. 650, the ''Pediatric Research Equity Act of 2003.'' This bill will make clear that the Food and Drug Administration (FDA) has the authority to require testing for drugs that are administered to children in appropriate cases. This legislation will effectively moot pending litigation. Last year, a Federal district court held that FDA lacked statutory authority to promulgate the pediatric rule. While appeals are pending, this bill will provide a speedy and certain resolution of that question.

Mr. Speaker, I do want to express my concerns with a provision in this bill which sunsets FDA's authority on October 1, 2007. Why on earth should a regulatory authority to protect the health of children be time limited? There are reasons, none of them good. This date just happens to coincide with the expiration of a provision of existing law which provides a financially powerful incentive to drug makers to test drugs for children. Whatever the perceived merits of the incentive, it costs consumers a lot of money because it delays generic drug entry into the market for six months beyond what would normally be the case. The rule is being tied to the incentive and that, in my view, is just plain wrong.

We should have had an opportunity to debate and offer amendments to improve S. 650, but this bill is being brought to the floor without being reported or otherwise considered by the Committee on Energy and Commerce. This is an unnecessary and unwise bypass of the committee of jurisdiction. The health of America's children is too important for us to avoid careful consideration of matters that affect them. For us to merely adopt the work product of the Senate is to shirk our duty for our children. We can do better, and the fact that we did not do better is unfortunate.

Mr. BROWN of Ohio. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

Mr. BILIRAKIS. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

The SPEAKER pro tempore (Mr. OSE). The question is on the motion offered by the gentleman from Florida (Mr. BILIRAKIS) that the House suspend the rules and pass the Senate bill, S. 650.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the Senate bill was passed.

A motion to reconsider was laid on the table.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, proceedings will resume on motions to suspend the rules previously postponed.

Votes will be taken in the following order:

H.R. 2420, by the yeas and nays;

House Resolution 427, by the yeas and nays;

House Concurrent Resolution 83, by the yeas and nays.

The first electronic vote in this series will be conducted as a 15-minute vote. The remaining votes in this series will be 5-minute votes.

MUTUAL FUNDS INTEGRITY AND FEE TRANSPARENCY ACT OF 2003

The SPEAKER pro tempore. The pending business is the question of suspending the rules and passing the bill, H.R. 2420, as amended.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Ohio (Mr. OXLEY) that the House suspend the rules and pass the bill, H.R. 2420, as amended, on which the yeas and nays are ordered.

The vote was taken by electronic device, and there were—yeas 418, nays 2, not voting 14, as follows:

[Roll No. 638]

YEAS—418

Abercrombie
Ackerman
Aderholt
Akin
Alexander
Allen
Baca
Bachus
Baird
Baker
Baldwin
Ballance
Ballenger
Barrett (SC)
Bartlett (MD)
Barton (TX)
Bass
Beauprez
Becerra
Bell
Bereuter
Berkley
Berman
Berry
Biggert
Bilirakis
Bishop (GA)
Bishop (UT)
Blackburn
Blumenauer
Blunt
Boehlert
Boehner
Bonilla
Bonner
Bono
Boozman
Boswell
Boucher
Boyd
Bradley (NH)
Brady (PA)
Brady (TX)
Brown (OH)
Brown (SC)
Brown, Corrine
Brown-Waite, Ginny
Burgess
Burns
Burr
Burton (IN)
Buyer
Calvert
Camp
Cannon
Cantor
Capito
Capps
Capuano
Cardin
Cardoza
Carson (IN)
Carson (OK)
Carter
Case
Castle
Chabot
Chocola
Clay
Clyburn
Coble
Cole
Cooper
Costello
Cox
Cramer
Crane
Crenshaw
Crowley
Culberson
Cummings
Cunningham
Davis (AL)
Davis (CA)
Davis (FL)
Davis (IL)
Davis (TN)
Davis, Jo Ann
Davis, Tom
Deal (GA)
DeFazio
DeGette
Delahunt
DeLauro
DeLay
Deutsch
Diaz-Balart, L.
Diaz-Balart, M.
Dicks
Dingell
Doggett
Dooley (CA)
Doolittle
Doyle
Dreier
Duncan
Dunn
Edwards
Ehlers
Emanuel
Emerson
Engel
English
Eshoo
Etheridge
Evans
Everett
Farr
Fattah
Feeney
Ferguson
Filner
Foley
Forbes
Ford
Fossella
Frank (MA)
Franks (AZ)
Frelinghuysen
Frost
Gallegly
Garrett (NJ)
Gerlach
Gibbons
Gilchrest
Gillmor
Gingrey
Gonzalez
Goode
Goodlatte
Gordon
Goss
Granger
Graves
Green (TX)
Green (WI)
Greenwood
Grijalva
Gutierrez
Gutknecht
Hall
Harman
Harris
Hart
Hastings (FL)
Hastings (WA)
Hayes
Hayworth
Hefley
Hensarling
Herger
Hill
Hinchey
Hinojosa
Hobson
Hoeffel
Hoekstra
Holden
Holt
Honda
Hooley (OR)
Hostettler
Houghton
Hoyer
Hulshof
Hunter
Hyde
Inslee
Israel
Issa
Jackson (IL)
Jackson-Lee (TX)
Janklow
Jefferson
Jenkins
John
Johnson (CT)
Johnson (IL)
Johnson, E. B.
Johnson, Sam
Jones (NC)
Jones (OH)
Kanjorski
Kaptur
Keller
Kelly
Kennedy (MN)
Kennedy (RI)
Kildee
Kilpatrick
Kind
King (IA)
King (NY)
Kingston
Kirk
Kleczka
Kline
Knollenberg
Kolbe
Kucinich
LaHood
Lampson
Langevin
Lantos
Larsen (WA)
Larson (CT)
Latham
LaTourette
Leach
Lee
Levin
Lewis (CA)
Lewis (GA)
Lewis (KY)
Linder
Lipinski
LoBiondo
Lofgren
Lowey
Lucas (KY)
Lucas (OK)
Lynch
Majette
Maloney
Manzullo
Markey
Marshall
Matheson
Matsui
McCarthy (MO)
McCarthy (NY)
McCollum
McCotter
McDermott
McGovern
McHugh
McInnis
McIntyre
McKeon
McNulty
Meehan
Meek (FL)
Meeks (NY)
Menendez
Mica
Michaud
Millender-McDonald
Miller (FL)
Miller (MI)
Miller (NC)
Miller, Gary
Miller, George
Mollohan
Moore
Moran (KS)
Moran (VA)
Murphy
Murtha
Musgrave
Myrick
Nadler
Napolitano
Neal (MA)
Nethercutt
Neugebauer
Ney
Northup
Norwood
Nunes
Nussle
Oberstar
Obey
Olver
Ortiz
Osborne