blessed are those who are persecuted because of righteousness, for theirs is the kingdom of Heaven. Let us now work to bring that kingdom of Heaven closer to Earth.

RECESS

The SPEAKER pro tempore. Pursuant to clause 12(a) of rule I, the Chair declares the House in recess until 2 p.m. today.

Accordingly (at 12 o'clock and 6 minutes p.m.), the House stood in recess.

□ 1400

AFTER RECESS

The recess having expired, the House was called to order by the Speaker pro tempore (Mr. DENHAM) at 2 p.m.

PRAYER

The Chaplain, the Reverend Patrick J. Conroy, offered the following prayer:

Gracious God, we give You thanks for giving us another day. In this Chamber where the people's House gathers, we pause to offer You gratitude for the gift of this good land on which we live and for this great Nation which You have inspired in developing over so many years. Continue to inspire the American people that, through the difficulties of these days, we might keep liberty and justice alive in our Nation and in the world.

A week after many Members of this assembly traveled to Selma to remember historic and heroic actions 50 years ago, may the House be energized to guarantee the very rights so many suffered to obtain back then and which still elude so many of their American descendants today.

May all that is done this day be for Your greater honor and glory.

Amen.

THE JOURNAL

The SPEAKER pro tempore. The Chair has examined the Journal of the last day's proceedings and announces to the House his approval thereof.

Pursuant to clause 1, rule I, the Journal stands approved.

PLEDGE OF ALLEGIANCE

The SPEAKER pro tempore. Will the gentleman from Michigan (Mr. KILDEE) come forward and lead the House in the Pledge of Allegiance.

Mr. KILDEE led the Pledge of Allegiance as follows:

I pledge allegiance to the Flag of the United States of America, and to the Republic for which it stands, one nation under God, indivisible, with liberty and justice for all.

ANOTHER OBAMACARE DEBACLE

(Ms. FOXX asked and was given permission to address the House for 1 minute.)

Ms. FOXX. Mr. Speaker, last month, the Obama administration admitted that it sent inaccurate tax forms to 820,000 Americans who receive health insurance through ObamaCare. Individuals who received subsidies must fill out the 1095–A form to document what they have received for the past year.

The government is advising people not to file their tax returns until they have the correct forms, but just last week Kevin Counihan, the man responsible and accountable for leading healthcare.gov, declined to say when ObamaCare participants will get the correct tax forms and if all of the new forms have been created.

Since its implementation, the President's health care law has proved to be a hindrance, not a help, to the health care market. This debacle is yet another example of why we must continue to work towards repealing this ill-conceived law and replacing it with policies that empower patients and promote access to affordable health care options.

JOBS

(Mr. KILDEE asked and was given permission to address the House for 1 minute.)

Mr. KILDEE. Well, Mr. Speaker, I just got back from spending a week at home in Michigan talking with the people that I work for and meeting with small business owners. I heard a lot of frustration—frustration about the priorities of the Republican leadership in the House and of Congress in general.

Instead of legislation to create jobs here in America to make it easier for hardworking families to buy their own home, to afford to send their kids to school, and to save for retirement, this Congress has bounced from one manufactured political crisis to the next and has not taken on the big challenges that the people sent us here to take on.

Let's put away this dysfunction and this paralysis. Let's get back to the work of the American people.

As we now are set to consider our Nation's budget, let's make sure that the priorities of the American people—good paying jobs, affordable college, homeownership, and the ability to save for a decent retirement—that those priorities are the priorities that we include in this important budget document. This is what the American people expect of us, and this is what we should take on.

COMMUNICATION FROM THE CLERK OF THE HOUSE

The SPEAKER pro tempore laid before the House the following communication from the Clerk of the House of Representatives:

OFFICE OF THE CLERK,
HOUSE OF REPRESENTATIVES,
Washington, DC, March 16, 2015.

Hon. JOHN A. BOEHNER,
The Speaker, House of Representatives, Washington, DC.

DEAR MR. SPEAKER: Pursuant to the permission granted in Clause 2(h) of Rule II of the Rules of the U.S. House of Representatives, the Clerk received the following message from the Secretary of the Senate on March 16, 2015 at 10:38 a.m.:

That the Senate agreed to S. Con. Res. 7.

With best wishes, I am

Sincerely,

ROBERT F. REEVES,
Deputy Clerk.

RECESS

The SPEAKER pro tempore. Pursuant to clause 12(a) of rule I, the Chair declares the House in recess subject to the call of the Chair.

Accordingly (at 2 o'clock and 5 minutes p.m.), the House stood in recess.

□ 1530

AFTER RECESS

The recess having expired, the House was called to order by the Speaker pro tempore (Mr. DUNCAN of Tennessee) at 3 o'clock and 30 minutes p.m.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, the Chair will postpone further proceedings today on motions to suspend the rules on which a recorded vote or the yeas and nays are ordered, or on which the vote incurs objection under clause 6 of rule XX.

Record votes on postponed questions will be taken later.

IMPROVING REGULATORY TRANSPARENCY FOR NEW MEDICAL THERAPIES ACT

Mr. PITTS. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 639) to amend the Controlled Substances Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 639

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 ''Improving Regulatory Transparency for New Medical Therapies Act''.

SEC. 2. SCHEDULING OF SUBSTANCES INCLUDED IN NEW FDA-APPROVED DRUGS.

(a) EFFECTIVE DATE OF APPROVAL.—

(1) EFFECTIVE DATE OF DRUG APPROVAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

''(x) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

''(1) IN GENERAL.—In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

''(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), the term 'date of approval' shall mean the later of—

''(A) the date an application under subsection (b) is approved under subsection (c); or

''(B) the date of issuance of the interim final rule controlling the drug.''.

(2) EFFECTIVE DATE OF APPROVAL OF BIOLOGICAL PRODUCTS.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

''(n) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

''(1) IN GENERAL.—In the case of an application under subsection (a) with respect to a biological product for which the Secretary provides notice to the sponsor that the Secretary intends to recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the biological product is issued in accordance with section 201(j) of the Controlled Substances Act.

''(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), references to the date of approval of such application, or licensure of the product subject to such application, shall mean the later of—

''(A) the date an application is approved under subsection (a); or

''(B) the date of issuance of the interim final rule controlling the biological product.''.

(3) EFFECTIVE DATE OF APPROVAL OF ANIMAL DRUGS.—

(A) IN GENERAL.—Section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) is amended by adding at the end the following:

''(q) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

''(1) IN GENERAL.—In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

''(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), the term 'date of approval' shall mean the later of—

''(A) the date an application under subsection (b) is approved under subsection (c); or

''(B) the date of issuance of the interim final rule controlling the drug.''.

(B) CONDITIONAL APPROVAL.—Section 571(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc(d)) is amended by adding at the end the following:

''(4)(A) In the case of an application under subsection (a) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to recommend controls under the Controlled Substances Act, conditional approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

''(B) For purposes of this section, with respect to an application described in subparagraph (A), the term 'date of approval' shall mean the later of—

''(i) the date an application under subsection (a) is conditionally approved under subsection (b); or

''(ii) the date of issuance of the interim final rule controlling the drug.''.

(C) INDEXING OF LEGALLY MARKETED UNAPPROVED NEW ANIMAL DRUGS.—Section 572 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc–1) is amended by adding at the end the following:

''(k) In the case of a request under subsection (d) to add a drug to the index under subsection (a) with respect to a drug for which the Secretary provides notice to the person filing the request that the Secretary intends to recommend controls under the Controlled Substances Act, a determination to grant the request to add such drug to the index shall not take effect, and the Secretary shall not list the drug on such index, until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.''.

(4) DATE OF APPROVAL FOR DESIGNATED NEW ANIMAL DRUGS.—Section 573(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc–2(c)) is amended by adding at the end the following:

''(3) For purposes of determining the 7-year period of exclusivity under paragraph (1) for a drug for which the Secretary intends to recommend controls under the Controlled Substances Act, the drug shall not be considered approved or conditionally approved until the date that the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.''.

(b) SCHEDULING OF NEWLY APPROVED DRUGS.—Section 201 of the Controlled Substances Act (21 U.S.C. 811) is amended by inserting after subsection (i) the following:

''(j)(1) With respect to a drug referred to in subsection (f), if the Secretary of Health and Human Services recommends that the Attorney General add the drug to schedule II, III, IV, or V pursuant to subsections (a) and (b), the Attorney General shall, not later than 90 days after the date described in paragraph (2), issue an interim final rule controlling the drug in accordance with such subsections and section 202(b) using the procedures described in paragraph (3).

''(2) The date described in this paragraph shall be the later of—

''(A) the date on which the Attorney General receives the scientific and medical evaluation and recommendations from the Secretary of Health and Human Services in accordance with subsection (b); or

''(B) the date on which the Attorney General receives notification from the Secretary of Health and Human Services that the Secretary has approved an application under section 505(c), 512, 571, or 572 of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act with respect to the drug described in paragraph (1).

''(3) A rule issued by the Attorney General under paragraph (1) shall be in accordance with the procedures provided in subsection (a), except that the rule shall become immediately effective as an interim final rule without requiring the Attorney General to demonstrate good cause therefor. After publication of the interim final rule, the Attorney General shall issue a final rule in accordance with the procedures provided in subsection (a).''.

(c) EXTENSION OF PATENT TERM.—Section 156 of title 35, United States Code, is amended—

(1) in subsection (d)(1), in the matter preceding subparagraph (A), by inserting '', or in the case of a drug product described in subsection (i) within the sixty-day period beginning on the covered date (as defined in subsection (i))'' after ''marketing or use''; and

(2) by adding at the end the following:

''(i)(1) For purposes of this section, if the Secretary of Health and Human Services provides notice to the sponsor of an application or request for approval, conditional approval, or indexing of a drug product for which the Secretary intends to recommend controls under the Controlled Substances Act, beginning on the covered date, the drug product shall be considered to—

''(A) have been approved under the relevant provision of the Public Health Service Act or Federal Food, Drug, and Cosmetic Act; and

''(B) have permission for commercial marketing or use.

''(2) In this subsection, the term 'covered date' means the later of—

''(A) the date an application is approved—

''(i) under section 351(a)(2)(C) of the Public Health Service Act; or

''(ii) under section 505(b) or 512(c) of the Federal Food, Drug, and Cosmetic Act;

''(B) the date an application is conditionally approved under section 571(b) of the Federal Food, Drug, and Cosmetic Act;

''(C) the date a request for indexing is granted under section 572(d) of the Federal Food, Drug, and Cosmetic Act; or

''(D) the date of issuance of the interim final rule controlling the drug under section 201(j) of the Controlled Substances Act.''.

SEC. 3. ENHANCING NEW DRUG DEVELOPMENT.

Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

''(i)(1) For purposes of registration to manufacture a controlled substance under subsection (d) for use only in a clinical trial, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c), not later than 180 days after the date on which the application is accepted for filing.

''(2) For purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing. Not later than 90 days after the date on which the period for comment pursuant to such notice ends, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c), unless the Attorney General has granted a hearing on the application under section 1008(i) of the Controlled Substances Import and Export Act.''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Pennsylvania (Mr. PITTS) and the gentleman from Texas (Mr. GENE GREEN) each will control 20 minutes.

The Chair recognizes the gentleman from Pennsylvania.

GENERAL LEAVE

Mr. PITTS. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and insert extraneous materials into the RECORD on the bill.

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

There was no objection.

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

I will include an exchange of letters between the Committee on Energy and Commerce and the Committee on the Judiciary.

Mr. Speaker, H.R. 639 seeks to improve the transparency and consistency of the Drug Enforcement Administration's first scheduling of new FDA-approved drugs under the Controlled Substances Act, the CSA, and, secondly, its registration process for the manufacture of controlled substances for use in clinical trials. Ultimately, this will allow new and innovative treatments to get to patients who desperately need them.

Due to the cost and uncertainty of the drug development process, there is broad agreement that a predictable timeline for approval decisions is a necessary component to successful drug development.

Industry, the FDA, and Congress have taken steps to provide more transparency and consistency in the drug approval process through the negotiation and authorization of the Prescription Drug User Fee program and a commitment to review goals embedded in the PDUFA agreements.

However, drugs that contain substances that have not been previously marketed in the U.S. and that have abuse potential must also be scheduled under the Controlled Substances Act, the CSA, by the DEA before they can reach patients.

Under the CSA, there is no deadline for the DEA to make a scheduling decision, and the delays in DEA decisions have increased significantly. Between 1997 and 1999 and 2009 and 2013, the average time between FDA approval and DEA's final scheduling increased from an average of 49.3 days to an average of 237.6 days. Recently, a company had to wait over 13 months after FDA approval to receive a final scheduling recommendation from the DEA.

The lack of predictability in the timing of DEA scheduling decisions leads to unnecessary uncertainty in the drug development process and needless delays in patient access to new therapies.

Section 2 of H.R. 639, as amended by the full committee, would require DEA to issue an interim final rule, scheduling the new drug no later than 90 days after it is approved or when it receives the FDA's scheduling recommendation, whichever comes later. After receiving the FDA's recommendation, the DEA would continue to conduct its own analysis prior to scheduling the drug, but patients would now have peace of mind in knowing this will no longer be an open-ended process. Of note: since 1996, the DEA has not made any scheduling decision for a new drug that was contrary to the FDA recommendation.

Further, section 3 of this bill would bring much-needed certainty to another open-ended DEA process. Manufacturers of controlled substances are required to be registered with the DEA. The requirement to register extends to manufacturers of controlled substances intended to be used in clinical trials for products not yet approved by the FDA. There is no timetable for the DEA to grant approval of registration applications, and there is not a process for the applicant to determine the reasons for delay in the application. The lack of transparency, predictability, and timeliness in the registration process leaves companies unable to properly plan clinical trial schedules for prospective new therapies.

For registration applications related to schedule III, IV, and V drugs that will only be used in clinical trials, section 3, as amended by the full committee, would require the DEA to register the applicant or serve an order to show cause on why the applicant shall not be registered within 180 days of the filing of the application.

For drugs in schedule I and II that will only be used in a clinical trial, the DEA would be required to issue a notice of application not later than 90 days after an application is accepted for filing. Ninety days after the end of the comment period, pursuant to the notice, the DEA would be required to register the applicant or serve an order to show cause on why the registrant should not be registered.

Such a solution does not force the DEA to make a particular decision but will provide transparency to the process so companies can better plan when regulatory decisions will be made.

I would urge all Members to support this critical piece of legislation.

I reserve the balance of my time.

HOUSE OF REPRESENTATIVES,
COMMITTEE ON THE JUDICIARY,
March 16, 2015.

Hon. FRED UPTON,
Chairman, Committee on Energy and Commerce, Rayburn House Office Building, Washington, DC.

DEAR CHAIRMAN UPTON: I am writing with respect to H.R. 639, the ''Improving Regulatory Transparency for New Medical Therapies Act.'' As a result of your having consulted with us on provisions in H.R. 639 that fall within the Rule X jurisdiction of the Committee on the Judiciary, I agree to discharge our Committee from further consideration of this bill so that it may proceed expeditiously to the House floor for consideration.

The Judiciary Committee takes this action with our mutual understanding that by foregoing consideration of H.R. 639 at this time, we do not waive any jurisdiction over subject matter contained in this or similar legislation, and that our Committee will be appropriately consulted and involved as this bill or similar legislation moves forward so that we may address any remaining issues in our jurisdiction. Our Committee also reserves the right to seek appointment of an appropriate number of conferees to any House-Senate conference involving this or similar legislation, and asks that you support any such request.

I would appreciate a response to this letter confirming this understanding with respect to H.R. 639, and would ask that a copy of our exchange of letters on this matter be included in the Congressional Record during Floor consideration of H.R. 639.

Sincerely,

BOB GOODLATTE,
Chairman.

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC, March 16, 2015.

Hon. BOB GOODLATTE,
Chairman, Committee on the Judiciary, Rayburn House Office Building Washington, DC.

DEAR CHAIRMAN GOODTETTE: Thank you for your letter regarding H.R. 639, the ''Improving Regulatory Transparency for New Medical Therapies Act.'' As you noted, there are provisions of the bill that fall within the Committee on the Judiciary's Rule X jurisdiction.

I appreciate your willingness to forgo action on H.R. 639, and I agree that your decision is not a waiver of any of the Committee on the Judiciary's jurisdiction over the subject matter contained in this or similar legislation, and that the Committee will be consulted appropriately and involved as the bill or similar legislation moves forward. In addition, I understand the Committee reserves the right to seek the appointment of an appropriate number of conferees to any House-Senate conference involving this or similar legislation, for which you will have my support.

I will include a copy of your letter and this response in the Congressional Record during consideration of H.R. 639 on the House floor.

Sincerely,

FRED UPTON,
Chairman.

Mr. GENE GREEN of Texas. Mr. Speaker, I yield myself as much time as I may consume.

Mr. Speaker, I rise in support of H.R. 639, the Improving Regulatory Transparency for New Medical Therapies Act. This legislation was introduced by the chair of our Health Subcommittee, JOE PITTS of Pennsylvania; the ranking member of the full committee, FRANK PALLONE of New Jersey; and myself to provide a solution to delays experienced by patients in need.

Currently, new drugs and substances that previously have not been marketed in the United States and that have abuse potential must be scheduled by the Drug Enforcement Administration prior to being marketed.

The amount of time the DEA has taken before acting on FDA recommendations has significantly lengthened in recent years, which delays the availability of new therapies.

This legislation will improve patient access by bringing clarity and transparency to the process of scheduling a new FDA-approved therapy.

I was pleased to join the gentleman from Pennsylvania (Mr. PITTS) and the gentleman from New Jersey (Mr. PALLONE) in supporting this legislation to continue the great work they started last Congress. I thank them and their staff for working on this important access issue.

I want to acknowledge the leadership of Chairman UPTON and the work of the committee's minority and majority staff in advancing this bill through the Energy and Commerce Committee. I

support this bipartisan bill and urge my colleagues to do the same.

Mr. Speaker, I yield back the balance of my time.

Mr. PITTS. Mr. Speaker, I urge all Members to support this bipartisan legislation, and I yield back the balance of my time.

Mr. BURGESS. Mr. Speaker, I would like to submit the cost estimate prepared by the Congressional Budget Office for H.R. 639.

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, March 16, 2015.

Hon. FRED UPTON,
Chairman, Committee on Energy and Commerce, House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 639, the Improving Regulatory Transparency for New Medical Therapies Act.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Julia Christensen.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

AS ORDERED REPORTED BY THE HOUSE COMMITTEE ON ENERGY AND COMMERCE ON FEBRUARY 12, 2015

H.R. 639 would modify the administrative procedures followed by the Department of Justice in regulating new drugs that are already approved by the Food and Drug Administration (FDA) and in authorizing drugs to be used in clinical trials. The legislation would aim to streamline the current review and approval process. CBO estimates that implementing the bill would have no significant effect on spending subject to appropriation. Enacting the legislation would affect direct spending and revenues related to federal health care costs; therefore, pay-as-you-go procedures apply. CBO estimates that that those effects would also not be significant over the 2015–2025 period.

The legislation would change the effective date of FDA approval for certain new drugs that undergo review by the Drug Enforcement Agency (DEA) to determine if the drug should be marketed with restrictions as a controlled substance. Such a change could extend certain regulatory periods during which FDA will not accept marketing applications or permit another manufacturer to market a version of an affected drug and could also result in the extension of patent terms for certain products. Extending such periods of marketing exclusivity could delay the entry of lower-priced generic drugs on the market, and such a delay would increase the average cost for prescription drugs. Any increase in health care costs resulting from delaying the market entry of generic drugs would affect direct spending and revenues by increasing the cost of prescription drugs for federal health programs and private health insurance.

CBO expects that the bill's provisions would apply to a limited number of drugs subject to DEA classification after enactment. Because most drugs generally retain patent protections after FDA approval for more than 10 years, CBO anticipates that the likelihood that drugs affected by the bill will face generic competition before 2025 under current law would be small. As a result, we estimate that enacting the bill would not significantly affect direct spending or revenues over the 2015–2025 period. Beyond 2025, however, the potential for the legislation to delay the market entry of generic drugs would be greater, and the effect on direct spending and revenues would increase in later years.

H.R. 639 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments. The bill would impose a private-sector mandate, as defined under UMRA, on manufacturers of generic drugs by delaying the entry of those products in the market. The cost of the mandate would be the net loss of income, which could be significant depending on the drug. Based on information from industry sources, CBO estimates that the cost of the mandate would probably fall below the annual threshold established in UMRA for private-sector mandates ($154 million in 2015, adjusted annually for inflation).

The CBO staff contacts for this estimate are Julia Christensen and Mark Grabowicz (for federal costs) and Amy Petz (for private sector costs). The estimate was approved by Theresa Gullo, Deputy Assistant Director for Budget Analysis.

Mr. PALLONE. Mr. Speaker, I am pleased to lend my support to H.R. 639, the Improving Regulatory Transparency for New Medical Therapies Act. This important public health bill aims to bring better reliability and transparency to medical therapies, while continuing to ensure that they reach patients in need quickly, but most importantly safely and effectively.

When a new drug is approved by the FDA, a company can begin marketing the product upon its approval. However, for a subset of drugs, FDA recommends to the DEA they be included in the Controlled Substance Act—or "scheduled," if there is abuse potential. Until DEA makes a final decision, a drug cannot be released to the public.

Unfortunately, there is no deadline for the DEA to make a decision. As a result, the process has lengthened over time, in some instances lasting years before a decision is made. So even if a drug is considered safe and effective, patients and physicians are being forced to wait to access these therapies. This bill would continue to allow DEA to conduct its own analysis, but would remove much of the uncertainty from the process. It also would speed up the DEA registration process allowing the manufacture and distribution of controlled substances for use only in clinical trials.

I want to thank Chairman PITTS for working with me on this bill last Congress, and committing to move forward early this Congress. Thank you to Mr. GREEN as well for joining us on this important bill.

I am glad that we have been able to work with both DEA and FDA, our Senate counterparts and the bill sponsors, to ensure that the goals of this bill is met.

I urge members to support H.R 639 and I look forward to its swift passage.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Pennsylvania (Mr. PITTS) that the House suspend the rules and pass the bill, H.R. 639, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

ACCESS TO LIFE-SAVING TRAUMA CARE FOR ALL AMERICANS ACT

Mr. BURGESS. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 647) to amend title XII of the Public Health Service Act to reauthorize certain trauma care programs, and for other purposes.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 647

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 "Access to Life-Saving Trauma Care for All Americans Act".

SEC. 2. REAUTHORIZATION OF TRAUMA AND EMERGENCY CARE PROGRAMS.

(a) TRAUMA CENTER CARE GRANTS.—Section 1245 of the Public Health Service Act (42 U.S.C. 300d–45) is amended in the first sentence—

(1) by striking "2009, and such" and inserting "2009, such"; and

(2) by inserting before the period at the end the following: ", and $100,000,000 for each of fiscal years 2016 through 2020".

(b) TRAUMA SERVICE AVAILABILITY GRANTS.—Section 1282 of the Public Health Service Act (42 U.S.C. 300d–82) is amended by striking "2015" and inserting "2020".

SEC. 3. ALIGNMENT OF PROGRAMS UNDER ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE.

Section 2811(c)(2)(F) of the Public Health Service Act (42 U.S.C. 300hh–10(c)(2)(F)) is amended by striking "trauma care under parts A through C of title XII" and inserting "trauma care under parts A through D of title XII and part H of such title".

SEC. 4. TECHNICAL CORRECTIONS RELATING TO TRAUMA CENTER GRANTS.

(a) CLARIFICATION ON ELIGIBLE TRAUMA CENTERS.—Section 1241(a) of the Public Health Service Act (42 U.S.C. 300d–41(a)) is amended by striking "qualified public, nonprofit Indian Health Service, Indian tribal, and urban Indian trauma centers" and inserting "qualified public trauma centers, qualified nonprofit trauma centers, and qualified Indian Health Service, Indian tribal, and urban Indian trauma centers".

(b) TRAUMA CENTER GRANTS QUALIFICATIONS FOR SUBSTANTIAL UNCOMPENSATED CARE COSTS.—Section 1241(b)(3)(B) of the Public Health Service Act (42 U.S.C. 300d–41(b)(3)(B)) is amended—

(1) in clause (i), by striking "35" and inserting "30"; and

(2) in clause (ii), by striking "50" and inserting "40".

(c) CLARIFICATION RELATING TO TRAUMA CENTER GRANTS.—The heading for part D of title XII of the Public Health Service Act (42 U.S.C. 300d–41 et seq.) is amended to read as follows:

"PART D—TRAUMA CENTERS".

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Texas (Mr. BURGESS) and the gentleman from Texas (Mr. GENE GREEN) each will control 20 minutes.

The Chair recognizes the gentleman from Texas (Mr. BURGESS).

GENERAL LEAVE

Mr. BURGESS. Mr. Speaker, I ask unanimous consent that all Members have 5 legislative days in which to revise and extend their remarks and insert extraneous materials in the RECORD on the bill.