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.

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

There was no objection.

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

Mr. Speaker, I am pleased that the House today will consider two bills relating to Federal support for trauma care. These bills have both passed the Energy and Commerce Committee at the subcommittee and full committee levels on voice votes.

Trauma is the leading cause of death under the age of 65. It is expensive, costing over $400 billion per year, third only to heart disease and cancer. It affects individuals of all ages—35 million Americans annually, or one person every 15 minutes.

Over many years, the gentleman from Texas (Mr. GENE GREEN) and I have worked closely on this issue to update the law and ensure the reauthorization of crucial trauma grant programs occurs. As a result of this coordination, today we will be voting on two bills that continue our long bipartisan record of support for efforts to shore up the Nation's trauma systems and centers.

The Access to Life-Saving Trauma Care for All Americans Act, H.R. 647, will authorize two grant programs, which will expire this year, that provide critically needed Federal funding to help cover uncompensated costs in trauma centers, support core mission trauma services, provide emergency funding to trauma centers, and address trauma center physician shortages in order to ensure the future availability of trauma care for all our citizens.

Trauma can happen at any time to anyone. It can happen to a family in a highway crash or a gunshot victim or a construction worker who is injured at the worksite. Trauma centers must be available for all victims of traumatic injury. Getting a trauma victim to a trauma center right away is the first step in saving that person's life.

These bills draw support from the American Association of Neurological Surgeons, the American Association of Orthopedic Surgeons, the American Burn Association, the American College of Emergency Physicians, the American College of Surgeons, the American Trauma Society, the Congress of Neurological Surgeons, the Association of Critical Care Transport, the American Heart Association, the American Stroke Association, Emergency Nurses Association, Society of Trauma Nurses, the American Association for the Surgery of Trauma, Eastern Association for the Surgery of Trauma, National Association of Emergency Medical Technicians, the Orthopedic Trauma Association, and the Trauma Center Association of America.

I strongly urge the House to support both of these bills.

I reserve the balance of my time.

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. 647, the Access to Life-Saving Trauma Care for All Americans Act. My colleague and fellow Texan, Dr. MIKE BURGESS, and I have introduced this legislation. I thank him for his leadership and partnership on this issue.

The bill would reauthorize vital programs to prevent more trauma center closures and improve access to trauma care.

The trauma center care grants were created to prevent trauma center closures by supporting their core missions, covering a portion of the losses from uncompensated care, and providing emergency awards to centers at risk of closing.

The trauma service availability grants are awarded through the States to address shortfalls in trauma services and improve access and availability of trauma care in underserved areas.

□ 1545

Despite our best prevention efforts, trauma injury will continue to occur. Unfortunately, access to trauma care is threatened by losses associated with the high cost of treating severely injured patients, including those unable to pay for their care, and a growing shortage of trauma-related physicians.

The public expects that appropriate trauma care will always be available to them wherever they reside or travel, yet this is not a reality. Profound challenges face our Nation's trauma centers, trauma systems, and the physicians who treat the most vulnerable patients. Thus, I urge swift passage of this important legislation.

Again, I want to thank Representative BURGESS for championing this effort with me, and his staff, J.P. Paluskiewicz, for their hard work. I also want to acknowledge the leadership of Chairman UPTON, Chairman PITTS, Ranking Member PALLONE and the work of the committee's staff in advancing this bill through the Energy and Commerce Committee.

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

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

Mr. BURGESS. Mr. Speaker, I would just point out the gentleman's name is J.P. Paluskiewicz, and we do, indeed, thank him for his efforts on the bill.

I have no more speakers, and I reserve the balance of my time to close.

Mr. GENE GREEN of Texas. Mr. Speaker, we have no more speakers.

I yield back the balance of my time.

Mr. BURGESS. Mr. Speaker, I just want to point out many people nowadays are familiar with what is called the golden hour, that first hour that occurs after a traumatic injury where the ability to save life and limb is vastly increased if a person can be delivered to a center within that golden hour's time. It is imperative to reauthorize these programs. They are critically needed for our citizens. Mr. Speaker, I urge an ''aye'' vote on the bill.

I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Texas (Mr. BURGESS) that the House suspend the rules and pass the bill, H.R. 647.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. GENE GREEN of Texas. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, further proceedings on this motion will be postponed.

TRAUMA SYSTEMS AND REGIONALIZATION OF EMERGENCY CARE REAUTHORIZATION ACT

Mr. BURGESS. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 648) 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. 648

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 ''Trauma Systems and Regionalization of Emergency Care Reauthorization Act''.

SEC. 2. REAUTHORIZATION OF CERTAIN TRAUMA CARE PROGRAMS.

Section 1232(a) of the Public Health Service Act (42 U.S.C. 300d–32(a)) is amended by striking ''2014'' and inserting ''2020''.

SEC. 3. IMPROVEMENTS AND CLARIFICATIONS TO CERTAIN TRAUMA CARE PROGRAMS.

(a) ALLOCATION OF FUNDS FOR COMPETITIVE GRANTS FOR REGIONALIZED SYSTEMS FOR EMERGENCY CARE RESPONSE.—Section 1232(c) of the Public Health Service Act (42 U.S.C. 300d–31(c)) is amended—

(1) in paragraph (1), by striking ''and'' at the end;

(2) in paragraph (2), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following new paragraph:

''(3) for a fiscal year after fiscal year 2015, not more than 50 percent of such amounts remaining for such fiscal year after application of paragraphs (1) and (2) shall be allocated for the purpose of carrying out section 1204.''.

(b) CLARIFICATIONS UNDER TRAUMA SYSTEMS FORMULA GRANTS REQUIREMENTS RELATING TO THE AMERICAN BURN ASSOCIATION.—Section 1213 of the Public Health Service Act (42 U.S.C. 300d–13) is amended—

(1) in subsection (a)(3), by inserting ''and (for a fiscal year after fiscal year 2015) contains national standards and requirements of the American Burn Association for the designation of verified burn centers,'' after ''such entity,'';

(2) in subsection (b)(3)(A), by striking ''and the American Academy of Pediatrics,'' and inserting ''the American Academy of Pediatrics, and (for a fiscal year after fiscal year 2015) the American Burn Association,''; and

(3) in subsection (c)(1)—

(A) in the matter preceding subparagraph (A), by inserting ''and not later than 1 year