Restoring eligibility would allow the University to continue its historic focus on research to close the gap between the burden of illness and premature mortality experienced more commonly by communities of color, as well as other medically underserved populations, as compared to the nation as a whole. It would also help to grow and enhance the University's capacity and infrastructure for health disparities research within the Urban Health Institute.

Respectfully Submitted,

DAVID M. CARLISLE, MD, PhD,

President and CEO, Charles R. Drew University of Medicine and Science.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. PALLONE) that the House suspend the rules and pass the bill, H.R. 4499, 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.

MAKING OBJECTIVE DRUG EVIDENCE REVISIONS FOR NEW LABELING ACT OF 2020

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5668) to amend the Federal Food, Drug, and Cosmetic Act to modernize the labeling of certain generic drugs, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 5668

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 ''Making Objective Drug Evidence Revisions for New Labeling Act of 2020'' or the ''MODERN Labeling Act of 2020''.

SEC. 2. MODERNIZING THE LABELING OF CERTAIN GENERIC DRUGS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 503C the following:

''SEC. 503D. PROCESS TO UPDATE LABELING FOR CERTAIN DRUGS.

''(a) DEFINITIONS.—For purposes of this section:

''(1) The term 'covered drug' means a drug approved under section 505(c)—

''(A) for which there are no unexpired patents included in the list under section 505(j)(7) and no unexpired period of exclusivity;

''(B) for which the approval of the application has been withdrawn for reasons other than safety or effectiveness; and

''(C) for which—

''(i)(I) there is new scientific evidence available pertaining to the existing conditions of use that is not reflected in the labeling;

''(II) the approved labeling does not reflect current legal and regulatory requirements for content or format; or

''(III) there is a relevant accepted use in clinical practice that is not reflected in the approved labeling; and

''(ii) updating the labeling would benefit the public health.

''(2) The term 'period of exclusivity', with respect to a drug approved under section 505(c), means any period of exclusivity under clause (ii), (iii), or (iv) of section 505(c)(3)(E), clause (ii), (iii), or (iv) of section 505(j)(5)(F), or section 505A, 505E, or 527.

''(3) The term 'generic version' means a drug approved under section 505(j) whose reference listed drug is a covered drug.

''(4) The term 'relevant accepted use' means a use for a drug in clinical practice that is supported by scientific evidence that appears to the Secretary to meet the standards for approval under section 505.

''(5) The term 'selected drug' means a covered drug for which the Secretary has determined through the process under subsection (c) that the labeling should be changed.

''(b) IDENTIFICATION OF COVERED DRUGS.—The Secretary may identify covered drugs for which labeling updates would provide a public health benefit. To assist in identifying covered drugs, the Secretary may do one or both of the following:

''(1) Enter into cooperative agreements or contracts with public or private entities to review the available scientific evidence concerning such drugs.

''(2) Seek public input concerning such drugs, including input on whether there is a relevant accepted use in clinical practice that is not reflected in the approved labeling of such drugs or whether new scientific evidence is available regarding the conditions of use for such drug, by—

''(A) holding one or more public meetings;

''(B) opening a public docket for the submission of public comments; or

''(C) other means, as the Secretary determines appropriate.

''(c) SELECTION OF DRUGS FOR UPDATING.—If the Secretary determines, with respect to a covered drug, that the available scientific evidence meets the standards under section 505 for adding or modifying information to the labeling or providing supplemental information to the labeling regarding the use of the covered drug, the Secretary may initiate the process under subsection (d).

''(d) INITIATION OF THE PROCESS OF UPDATING.—If the Secretary determines that labeling changes are appropriate for a selected drug pursuant to subsection (c), the Secretary shall provide notice to the holders of approved applications for a generic version of such drug that—

''(1) summarizes the findings supporting the determination of the Secretary that the available scientific evidence meets the standards under section 505 for adding or modifying information or providing supplemental information to the labeling of the covered drug pursuant to subsection (c);

''(2) provides a clear statement regarding the additional, modified, or supplemental information for such labeling, according to the determination by the Secretary (including, as applicable, modifications to add the relevant accepted use to the labeling of the drug as an additional indication for the drug); and

''(3) states whether the statement under paragraph (2) applies to the selected drug as a class of covered drugs or only to a specific drug product.

''(e) RESPONSE TO NOTIFICATION.—Within 30 days of receipt of notification provided by the Secretary pursuant to subsection (d), the holder of an approved application for a generic version of the selected drug shall—

''(1) agree to change the approved labeling to reflect the additional, modified, or supplemental information the Secretary has determined to be appropriate; or

''(2) notify the Secretary that the holder of the approved application does not believe that the requested labeling changes are warranted and submit a statement detailing the reasons why such changes are not warranted.

''(f) REVIEW OF APPLICATION HOLDER'S RESPONSE.—

''(1) IN GENERAL.—Upon receipt of the application holder's response, the Secretary shall promptly review each statement received under subsection (e)(2) and determine which labeling changes pursuant to the Secretary's notice under subsection (d) are appropriate, if any. If the Secretary disagrees with the reasons why such labeling changes are not warranted, the Secretary shall provide opportunity for discussions with the application holders to reach agreement on whether the labeling for the covered drug should be updated to reflect available scientific evidence, and if so, the content of such labeling changes.

''(2) CHANGES TO LABELING.—After considering all responses from the holder of an approved application under paragraph (1) or (2) of subsection (e), and any discussion under paragraph (1), the Secretary may order such holder to make the labeling changes the Secretary determines are appropriate. Such holder of an approved application shall—

''(A) update its paper labeling for the drug at the next printing of that labeling;

''(B) update any electronic labeling for the drug within 30 days of such order; and

''(C) submit the revised labeling through the form, 'Supplement—Changes Being Effected'.

''(g) VIOLATION.—If the holder of an approved application for the generic version of the selected drug does not comply with the requirements of subsection (f)(2), such generic version of the selected drug shall be deemed to be misbranded under section 502.

''(h) LIMITATIONS; GENERIC DRUGS.—

''(1) IN GENERAL.—With respect to any labeling change required under this section, the generic version shall be deemed to have the same conditions of use and the same labeling as its reference listed drug for purposes of clauses (i) and (v) of section 505(j)(2)(A). Any labeling change so required shall not have any legal effect for the applicant that is different than the legal effect that would have resulted if a supplemental application had been submitted and approved to conform the labeling of the generic version to a change in the labeling of the reference drug.

''(2) SUPPLEMENTAL APPLICATIONS.—Changes to labeling made in accordance with this section shall not be eligible for an exclusivity period under this Act.

''(3) SELECTION OF DRUGS.—Nothing in this section shall be construed to give the Secretary the authority to identify a drug as a covered drug or select a drug label for updating solely based on the availability of new safety information. Upon identification of a drug as a covered drug, the Secretary may then consider the availability of new, additional, or different safety information in determining whether the drug is a selected drug and in determining what labeling changes are appropriate.

''(4) MAINTENANCE OF LABELING.—Nothing in this section shall be construed to affect the responsibility of the holder of an approved application under section 505(j) to maintain its labeling in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 314.97 of title 21, Code of Federal Regulations (or any successor regulations).

''(i) RULES OF CONSTRUCTION.—

''(1) APPROVAL STANDARDS.—This section shall not be construed as altering the applicability of the standards for approval of an application under section 505. No order shall be issued under this subsection unless the scientific evidence supporting the changed labeling meets the standards for approval applicable to any change to labeling under section 505.

''(2) SECRETARY AUTHORITY.—Nothing in this section shall be construed to limit the authority of the Secretary to require labeling changes under section 505(o).

''(j) REPORTS.—Not later than 4 years after the date of the enactment of the Making Objective Drug Evidence Revisions for New Labeling Act of 2020, and every 4 years thereafter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, a report that—

''(1) describes the actions of the Secretary under this section, including—

''(A) the number of covered drugs and description of the types of drugs the Secretary has selected for labeling changes and the rationale for such recommended changes; and

''(B) the number of times the Secretary entered into discussions concerning a disagreement with an application holder or holders and a summary of the decision regarding a labeling change, if any; and

''(2) includes any recommendations of the Secretary for modifying the program under this section.''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New Jersey (Mr. PALLONE) and the gentleman from Oregon (Mr. WALDEN) each will control 20 minutes.

The Chair recognizes the gentleman from New Jersey.

GENERAL LEAVE

Mr. PALLONE. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material on H.R. 5668.

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

There was no objection.

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

Mr. Speaker, I rise today in support of H.R. 5668, the MODERN Labeling Act.

Prescription drug labels contain the most authoritative drug-related information available to prescribers. These labels let prescribers know about approved uses for a drug and important patient safety information.

However, over time, labels can become outdated as more information becomes known about a drug, but a manufacturer may not update the label with the Food and Drug Administration to identify new uses for drugs. This is especially likely to happen with some older generic drugs where there may be commonly accepted off-label uses but no FDA-sanctioned method of communicating those safe uses.

In some cases, a generic drug may have an outdated label due to a loophole in the law. Under this loophole, if a listed brand drug leaves the market while a generic competitor remains, there is no way for the generic drug to update its label with approved new uses. This is because generic drugs must maintain the same drug information on their labels as their branded counterparts, even when their branded counterpart has left the market.

This bipartisan legislation, Mr. Speaker, would fix this problem. H.R. 5668 would allow FDA to identify drugs that have out-of-date labels and pursue revised labeling, allowing new uses and new indications to be listed. This will allow FDA and generic drug manufacturers to ensure that drug labels, the most trusted source of drug use information, include the best information available.

Mr. Speaker, it is important to note that both brand and generic manufacturers have the responsibility to work with FDA to update drug safety information that becomes known and that does not change under this bill.

Amendments adopted through our committee process ensure that, when a manufacturer needs to update a label solely with new safety information, manufacturers and FDA must pursue such changes through the current process. Drug safety is paramount, and we want patients to have certainty that they will have up-to-date safety information.

As Dr. Jeff Allen from the Friends of Cancer Research said at our hearing on this bill: ''Preserving the accuracy and reliability of labeling may be viewed as tantamount to preserving trust in and the relevance of the drug approval system.''

And I cannot agree more, Mr. Speaker. Maintaining our trust in the FDA approval process is critical, and this bill will help strengthen the system.

Mr. Speaker, I urge all Members to support this bill, and I reserve the balance of my time.

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

Mr. Speaker, I rise today in support of H.R. 5668. This is the MODERN Labeling Act, and I want to thank our colleagues, Representatives GUTHRIE and MATSUI, for their leadership on this important legislation which will allow the FDA to require modifications be made to outdated labeling for generic drugs.

Now, while drug manufacturers are required to update a label when it becomes inaccurate, false, or misleading, there is no such requirement when new scientific information indicates there may be a new use for the product.

Generic drugs are generally required to have the same labeling as the brand drug they reference; however, once the brand drug is no longer on the market, the generic manufacturer is actually prohibited from updating their label to reflect the most accurate, up-to-date information, information that is often discovered through postmarket use. So the inability to update labeling can result in information gaps for providers and patients when discussing treatments.

For example, it has been estimated that more than half, Mr. Speaker—half—of all uses of cancer drugs are off-label, meaning the drug is used for a disease or medical condition that it is not approved to treat. Many of these uses are widely accepted in the medical community and based on the most up-to-date scientific evidence; however, they are not reflected in FDA-approved labeling.

So H.R. 5668 would help. It would close this existing information gap. It would give doctors and patients the information they need when making decisions about their treatment options.

Mr. Speaker, I urge support of this bill, and I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I believe we have a speaker on the other side, so I continue to reserve the balance of my time.

Mr. WALDEN. Mr. Speaker, I yield 3 minutes to the gentleman from Kentucky (Mr. GUTHRIE), one of our terrific leaders on the Energy and Commerce Committee on the Republican side and someone who put a lot of time and effort into this bipartisan legislation.

Mr. GUTHRIE. Mr. Speaker, I thank the ranking member for yielding.

I appreciate working with the chairman and with everyone involved in this piece of legislation.

I rise today to voice my support for H.R. 5668, the MODERN Labeling Act of 2020. This important bill will ensure that certain drug labels are updated and accurate, which will result in better care for many Americans who are suffering. This bill grants FDA the authority to work with generic drug companies to update their product label when there are strong, scientific bases for another indication or use of the drug.

Innovation in America is constantly evolving, and we must ensure drug labels are updated and not frozen in time just because the brand-name drug is off the market and preventing the generic drug from updating its label.

I would like to thank Representative MATSUI, Chairman PALLONE, and the majority and minority Energy and Commerce Committee staff who worked with me to make this legislation possible.

I urge my colleagues to support this important bill.

Mr. PALLONE. Mr. Speaker, may I inquire if the gentleman has any additional speakers.

Mr. WALDEN. Mr. Speaker, no, I do not.

I yield back the balance of my time.

Mr. PALLONE. Mr. Speaker, I ask all of our Members to support this bill, and I yield back the balance of my time.

Ms. ESHOO. Mr. Speaker, I rise in support of H.R. 5668, the MODERN Labeling Act. I'm proud to have advanced this bipartisan bill through my Health Subcommittee and I'm proud to support it on the Floor today.

The MODERN Labeling Act was introduced by Representatives DORIS MATSUI and BRET GUTHRIE, and allows generic drug companies to update outdated labeling

Drug labeling can become outdated when new scientific evidence is discovered after a drug is on the market, yet drug manufacturers are not required by law to update their products' labeling with new uses.

Because of this system, the labeling of many cancer drugs, especially older generic products, are out of date. Outdated labeling can affect insurance and Medicare coverage of the drugs, creating potentially high out-of-pocket costs for consumers.

H.R. 5668 addresses this problem by giving the FDA the authority to require labels to reflect new information relevant to the drug and its use.

This is a commonsense bill that will help more cancer patients have access to the treatments they need and I urge all my colleagues to support this legislation.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. PALLONE) that the House suspend the rules and pass the bill, H.R. 5668, 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.

FAIRNESS IN ORPHAN DRUG EXCLUSIVITY ACT

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 4712) to amend the Federal Food, Drug, and Cosmetic Act with respect to limitations on exclusive approval or licensure of orphan drugs, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 4712

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 ''Fairness in Orphan Drug Exclusivity Act''.

SEC. 2. LIMITATIONS ON EXCLUSIVE APPROVAL OR LICENSURE OF ORPHAN DRUGS.

(a) IN GENERAL.—Section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended—

(1) in subsection (a), by striking ''Except as provided in subsection (b)'' and inserting ''Except as provided in subsection (b) or (f)''; and

(2) by adding at the end the following:

''(f) LIMITATIONS ON EXCLUSIVE APPROVAL, CERTIFICATION, OR LICENSE.—

''(1) IN GENERAL.—For a drug designated under section 526 for a rare disease or condition pursuant to the criteria set forth in subsection (a)(2)(B) of such section, the Secretary shall not grant, recognize, or apply exclusive approval or licensure under subsection (a), and, if such exclusive approval or licensure has been granted, recognized, or applied, shall revoke such exclusive approval or licensure, unless the sponsor of the application for such drug demonstrates—

''(A) with respect to an application approved or a license issued after the date of enactment of this subsection, upon such approval or issuance, that there is no reasonable expectation at the time of such approval or issuance that the cost of developing and making available in the United States such drug for such disease or condition will be recovered from sales in the United States of such drug, taking into account all sales made or reasonably expected to be made within 12 years of first marketing the drug; or

''(B) with respect to an application approved or a license issued on or prior to the date of enactment of this subsection, not later than 60 days after such date of enactment, that there was no reasonable expectation at the time of such approval or issuance that the cost of developing and making available in the United States such drug for such disease or condition would be recovered from sales in the United States of such drug, taking into account all sales made or reasonably expected to be made within 12 years of first marketing the drug.

''(2) CONSIDERATIONS.—For purposes of subparagraphs (A) and (B) of paragraph (1), the Secretary and the sponsor of the application for the drug designated for a rare disease or condition described in such paragraph shall consider sales from all drugs that—

''(A) are developed or marketed by the same sponsor or manufacturer of the drug (or a licensor, predecessor in interest, or other related entity to the sponsor or manufacturer); and

''(B) are covered by the same designation under section 526.

''(3) CRITERIA.—No drug designated under section 526 for a rare disease or condition pursuant to the criteria set forth in subsection (a)(2)(B) of such section shall be eligible for exclusive approval or licensure under this section unless it met such criteria under such subsection on the date on which the drug was approved or licensed.''.

(b) RULE OF CONSTRUCTION.—The amendments made in subsection (a) shall apply to any drug that has been or is hereafter designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) for a rare disease or condition pursuant to the criteria under subsection (a)(2)(B) of such section regardless of—

(1) the date on which such drug is designated or becomes the subject of a designation request under such section;

(2) the date on which such drug is approved under section 505 of such Act (21 U.S.C. 355) or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) or becomes the subject of an application for such approval or licensure; and

(3) the date on which such drug is granted exclusive approval or licensure under section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) or becomes the subject of a request for such exclusive approval or licensure.

SEC. 3. DETERMINATION OF BUDGETARY EFFECTS.

The budgetary effects of this Act, for the purpose of complying with the Statutory Pay-As-You-Go Act of 2010, shall be determined by reference to the latest statement titled ''Budgetary Effects of PAYGO Legislation'' for this Act, submitted for printing in the Congressional Record by the Chairman of the House Budget Committee, provided that such statement has been submitted prior to the vote on passage.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New Jersey (Mr. PALLONE) and the gentleman from Oregon (Mr. WALDEN) each will control 20 minutes.

The Chair recognizes the gentleman from New Jersey.

GENERAL LEAVE

Mr. PALLONE. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include any extraneous material on H.R. 4712.

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

There was no objection.

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

Mr. Speaker, today I rise in support of H.R. 4712, the Fairness in Orphan Drug Exclusivity Act, a bill that will close a loophole in the orphan drug program to ensure generic drugs are not unfairly being blocked from entering the market.

Since it was first passed in 1983, the Orphan Drug Act has been successful in driving research and discovery of new therapies to treat and even cure rare diseases. The law creates two pathways for manufacturers to be designated as an orphan drug and to gain certain incentives, including 7 years of market exclusivity.

The first and most commonly used pathway is for developing drugs approved to treat diseases with patient populations of 200,000 or fewer. There is also the rarely used cost-recovery pathway, where the drug research and development costs are not expected to be recouped by sales of the underlying drug.

Now, under certain circumstances, a manufacturer may also receive additional rounds of exclusivity for drugs in their portfolio if they treat the same conditions and have the same active ingredient, even if the second drug does not meet the orphan drug qualifications. This provision has allowed some manufacturers to circumvent the original intent of the Orphan Drug Act, which was to incentivize creation of novel drugs for small populations, all the while blocking generic competitors from coming to market.

An example of this recently occurred when a formulation of Buprenorphine, a drug to treat opioid use disorder, was approved in 2017. It was allowed to carry the orphan drug designation granted to its manufacturer's original Buprenorphine drug more than 20 years earlier, in 1994.

When the original 1994 orphan drug designation was granted, it was expected that Buprenorphine would not be prescribed frequently; however, as the opioid crisis worsened and our response to the crisis evolved, millions were eventually prescribed the drug, generating billions of dollars in sales.

Clearly, we knew in 2017 that Buprenorphine was not an orphan drug. Nevertheless, the drug was granted orphan drug status and exclusivity, delaying additional forms of generic competition. So while the Food and Drug Administration eventually recognized this issue with this particular drug and revoked its orphan drug designation, its exclusivity delayed generic competition that otherwise would have been on the market.

We need every tool available to us to combat the opioid epidemic, and loopholes like this one should not be allowed to limit access to treatment, Mr. Speaker.

H.R. 4712 will stop this from happening again in the future by requiring drug manufacturers to demonstrate in their application to the FDA that each drug application considered under the cost recovery pathway would fail to recoup development costs.

This bill is narrowly tailored. It is a fix for a small but very real loophole in the law, and I want to thank Representative DEAN for introducing the legislation.

Mr. Speaker, I urge all of my colleagues to support it, and I reserve the balance of my time.