MOTION TO RECOMMIT H.R. 6

M__. _____ moves to recommit the bill H.R. 6 to the Committee on Energy and Commerce and the Committee on Ways and Means with instructions to report the same back to the House forthwith with the following amendment:

Page 84, after line 14, insert the following:

SEC. 208. DISTRIBUTION OF ADDITIONAL RESIDENCY POSITIONS TO HELP COMBAT OPIOID CRISIS.

(a) IN GENERAL.—Section 1886(h) of the Social Security Act (42 U.S.C. 1395ww(h)) is amended—

(1) in paragraph (4)(F)(i), by striking ''paragraphs (7) and (8)'' and inserting ''paragraphs (7), (8), and (9)'';

(2) in paragraph (4)(H)(i), by striking ''paragraphs (7) and (8)'' and inserting ''paragraphs (7), (8), and (9)'';

(3) in paragraph (7)(E), by inserting ''paragraph (9),'' after ''paragraph (8),''; and

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

''(9) DISTRIBUTION OF ADDITIONAL RESIDENCY POSITIONS TO HELP COMBAT OPIOID CRISIS.—

''(A) ADDITIONAL RESIDENCY POSITIONS.—For each of fiscal years 2021 through 2025 (and succeeding fiscal years if the Secretary determines that there are additional residency positions available to distribute under subparagraph (D)), the Secretary shall increase the otherwise applicable resident limit for each qualifying hospital that submits a timely application under this subparagraph by such number as the Secretary may approve for portions of cost reporting periods occurring on or after July 1 of the fiscal year of the increase. Except as provided in subparagraph (B)(iv) or (D), the aggregate number of increases in the otherwise applicable resident limit under this subparagraph shall be equal to 500 over the period of fiscal years 2021 through 2025, distributed in accordance with the succeeding subparagraphs of this paragraph.

''(B) DISTRIBUTION FOR FISCAL YEAR 2021.—

''(i) IN GENERAL.—For fiscal year 2021, the positions available for distribu-

tion with respect to the fiscal year as described in subparagraph (A) shall be distributed to hospitals that have existing established approved programs in addiction medicine, addiction psychiatry, or pain medicine as determined by the Secretary. The Secretary shall establish standards and a process for ensuring additional residency positions under this subparagraph are used to increase the number of residents studying in the fields specified in the previous sentence.

''(ii) NUMBER OF POSITIONS HOSPITAL ELIGIBLE TO RECEIVE.—Subject to clauses (iii) and (iv), the aggregate number of positions a hospital may receive under this subparagraph with respect to fiscal year 2021 is equal to the sum of the following:

''(I) The number of full-time-equivalent residents that will be training in addiction medicine, addiction psychiatry, or pain medicine as determined by the Secretary with respect to the fiscal year.

''(II) The associated number, as defined by the Secretary, of residents training in a pre-requisite program, such as internal medicine, necessary for the number of full-time residents for the programs described in subclause (I).

''(iii) ADDITIONAL POSITIONS FOR EXPANSION OF EXISTING PROGRAM.—If a hospital demonstrates to the Secretary that the hospital is planning to increase the number of full-time-equivalent residents in existing programs described in clause (i), the Secretary may increase the number of positions a hospital is eligible to receive under clause (ii) in order to accommodate that expansion, as determined by the Secretary.

''(iv) CONSIDERATIONS IN DISTRIBUTION.—The Secretary shall distribute additional residency positions under this subparagraph based on—

''(I) in the case of positions made available under clause (ii), the demonstrated likelihood, as defined by the

Secretary, of the hospital filling such positions by July 1, 2021; and

''(II) in the case of positions made available under clause (iii), the demonstrated likelihood, as so defined, of the hospital filling such positions within the first three cost reporting periods beginning on or after July 1, 2021.

''(v) LIMITATION.—Notwithstanding clauses (ii) and (iv), an individual hospital may not receive more than 25 full-time-equivalent residency positions under this paragraph.

''(vi) POSITIONS NOT DISTRIBUTED DURING THE FISCAL YEAR.—If the number of resident full-time-equivalent positions distributed under this subparagraph is less than the aggregate number of positions available for distribution in the fiscal year (as described in subparagraph (A)), the difference between such number distributed and such number available for distribution shall be added to the aggregate

number of positions available for distribution under subparagraph (C).

''(C) DISTRIBUTION FOR FISCAL YEARS 2022 THROUGH 2025.—

''(i) IN GENERAL.—For the period of fiscal years 2022 through 2025, the positions available for distribution with respect to such period (as described in subparagraph (A), including after application of subparagraph (B)(vi)) shall be distributed to hospitals which demonstrate to the Secretary that the hospital—

''(I) will establish an approved program in addiction medicine, addiction psychiatry, or pain medicine; and

''(II) will use all of the additional positions made available under this subparagraph in such program or a prerequisite residency program for such program within the first four cost reporting periods after the increase would be effective.

''(ii) REQUIREMENTS.—Subject to clause (iii), a hospital that receives an increase in the otherwise applicable resident

limit under this subparagraph shall ensure, during the 10-year period beginning after the date of such increase, that the hospital uses the positions received under clauses (i)(I) and (i)(II) for the programs for which the positions were distributed, or similar programs (as determined by the Secretary). The Secretary may determine whether a hospital has met the requirements under this clause during such 10-year period in such manner and at such time as the Secretary determines appropriate, including at the end of such 10-year period.

''(iii) REDISTRIBUTION OF POSITIONS IF HOSPITAL NO LONGER MEETS CERTAIN REQUIREMENTS.—In the case where the Secretary determines that a hospital described in clause (ii) does not meet the requirements of such clause, the Secretary shall—

''(I) reduce the otherwise applicable resident limit of the hospital by the amount by which such limit was

increased under this subparagraph; and

''(II) provide for the distribution of positions attributable to such reduction in accordance with the requirements of this paragraph.

''(D) DISTRIBUTION OF REMAINING POSITIONS.—If the aggregate number of positions distributed under subparagraphs (B) and (C) during the period of fiscal years 2021 through 2025 is less than 500, the Secretary shall distribute the remaining residency positions in succeeding fiscal years according to criteria consistent with this paragraph until such time as the aggregate amount of positions distributed under this paragraph is equal to 500.

''(E) NOTIFICATION.—The Secretary shall notify hospitals of the number of positions distributed to the hospital under this paragraph as a result on an increase in the otherwise applicable resident limit by January 1 of the fiscal year of the increase. Such increase shall be effective for portions of cost reporting periods beginning on or after July 1 of that fiscal year.

''(F) APPLICATION OF PER RESIDENT AMOUNTS FOR PRIMARY CARE AND NONPRIMARY CARE.—With respect to additional residency positions in a hospital attributable to the increase provided under this paragraph, the approved FTE per resident amounts are deemed to be equal to the hospital per resident amounts for primary care and nonprimary care computed under paragraph (2)(D) for that hospital.

''(G) PERMITTING FACILITIES TO APPLY AGGREGATION RULES.—The Secretary shall permit hospitals receiving additional residency positions attributable to the increase provided under this paragraph to, beginning in the fifth year after the effective date of such increase, apply such positions to the limitation amount under paragraph (4)(F) that may be aggregated pursuant to paragraph (4)(H) among members of the same affiliated group.

''(H) DEFINITIONS.—In this paragraph:

''(i) OTHERWISE APPLICABLE RESIDENT LIMIT.—The term 'otherwise applicable resident limit' means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) of

paragraph (4) on the resident level for the hospital determined without regard to this paragraph but taking into account paragraphs (7)(A), (7)(B), (8)(A), and (8)(B).

"(ii) RESIDENT LEVEL.—The term 'resident level' has the meaning given such term in paragraph (7)(C)(i).".

(b) IME.—

(1) IN GENERAL.—Section 1886(d)(5)(B)(v) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(B)(v)), in the third sentence, is amended by striking "and (h)(8)" and inserting "(h)(8), and (h)(9)".

(2) CONFORMING PROVISION.—Section 1886(d)(5)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(B)) is amended—

(A) by redesignating clause (x), as added by section 5505(b) of the Patient Protection and Affordable Care Act (Public Law 111–148), as clause (xi) and moving such clause 4 ems to the left; and

(B) by adding after clause (xi), as redesignated by subparagraph (A), the following new clause:

''(xii) For discharges occurring on or after July 1, 2021, insofar as an additional payment amount under this subparagraph is attributable to resident positions distributed to a hospital under subsection (h)(9), the indirect teaching adjustment factor shall be computed in the same manner as provided under clause (ii) with respect to such resident positions.''.

Page 95, after line 21, insert the following:

SEC. 304. ACTIONS FOR DELAYS OF GENERIC DRUGS AND BIOSIMILAR BIOLOGICAL PRODUCTS.

(a) DEFINITIONS.—In this section—

(1) the term ''commercially reasonable, market-based terms'' means—

(A) a non-discriminatory price for the sale of the covered product at or below, but not greater than, the most recent wholesale acquisition cost for the drug, as defined in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B));

(B) a schedule for delivery that results in the transfer of the covered product to the eligible product developer consistent with the timing under subsection (b)(2)(A)(iv); and

(C) no additional conditions are imposed on the sale of the covered product;

(2) the term ''covered product''—

(A) means—

(i) any drug approved under subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or biological product licensed under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262);

(ii) any combination of a drug or biological product described in clause (i); or

(iii) when reasonably necessary to support approval of an application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), or section 351 of the Public Health Service Act (42 U.S.C. 262), as applicable, or otherwise meet the requirements for approval under either such section, any product, including any device, that is marketed or intended for use with such a drug or biological product; and

(B) does not include any drug or biological product that the Secretary has determined to be currently in shortage and that appears on the

drug shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e), unless the shortage will not be promptly resolved—

(i) as demonstrated by the fact that the drug or biological product has been in shortage for more than 6 months; or

(ii) as otherwise determined by the Secretary;

(3) the term ''device'' has the meaning given the term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321);

(4) the term ''eligible product developer'' means a person that seeks to develop a product for approval pursuant to an application for approval under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or for licensing pursuant to an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k));

(5) the term ''license holder'' means the holder of an application approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or the holder of a license under subsection (a) or (k) of section 351 of

the Public Health Service Act (42 U.S.C. 262) for a covered product;

(6) the term ''REMS'' means a risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1);

(7) the term ''REMS with ETASU'' means a REMS that contains elements to assure safe use under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1);

(8) the term ''Secretary'' means the Secretary of Health and Human Services;

(9) the term ''single, shared system of elements to assure safe use'' means a single, shared system of elements to assure safe use under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1); and

(10) the term ''sufficient quantities'' means an amount of a covered product that allows the eligible product developer to—

(A) conduct testing to support an application—

(i) for approval under subsection (b)(2) or (j) of section 505 of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 355); or

(ii) for licensing under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)); and

(B) fulfill any regulatory requirements relating to such an application for approval or licensing.

(b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFICIENT QUANTITIES OF A COVERED PRODUCT.—

(1) IN GENERAL.—An eligible product developer may bring a civil action against the license holder for a covered product seeking relief under this subsection in an appropriate district court of the United States alleging that the license holder has declined to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms.

(2) ELEMENTS.—

(A) IN GENERAL.—To prevail in a civil action brought under paragraph (1), an eligible product developer shall prove, by a preponderance of the evidence—

(i) that—

(I) the covered product is not subject to a REMS with ETASU; or

(II) if the covered product is subject to a REMS with ETASU—

(aa) the eligible product developer has obtained a covered product authorization from the Secretary in accordance with subparagraph (B); and

(bb) the eligible product developer has provided a copy of the covered product authorization to the license holder;

(ii) that, as of the date on which the civil action is filed, the product developer has not obtained sufficient quantities of the covered product on commercially reasonable, market-based terms;

(iii) that the eligible product developer has requested to purchase sufficient quantities of the covered product from the license holder; and

(iv) that the license holder has not delivered to the eligible product developer sufficient quantities of the covered product

on commercially reasonable, market-based terms—

(I) for a covered product that is not subject to a REMS with ETASU, by the date that is 31 days after the date on which the license holder received the request for the covered product; and

(II) for a covered product that is subject to a REMS with ETASU, by 31 days after the later of—

(aa) the date on which the license holder received the request for the covered product; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with subparagraph (B).

(B) AUTHORIZATION FOR COVERED PRODUCT SUBJECT TO A REMS WITH ETASU.—

(i) REQUEST.—An eligible product developer may submit to the Secretary a written request for the eligible product developer to be authorized to obtain suffi-

cient quantities of an individual covered product subject to a REMS with ETASU.

(ii) AUTHORIZATION.—Not later than 120 days after the date on which a request under clause (i) is received, the Secretary shall, by written notice, authorize the eligible product developer to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU for purposes of—

(I) development and testing that does not involve human clinical trials, if the eligible product developer has agreed to comply with any conditions the Secretary determines necessary; or

(II) development and testing that involves human clinical trials, if the eligible product developer has—

(aa)(AA) submitted protocols, informed consent documents, and informational materials for testing that include protections that provide safety protections comparable to those pro-

vided by the REMS for the covered product; or

(BB) otherwise satisfied the Secretary that such protections will be provided; and

(bb) met any other requirements the Secretary may establish.

(iii) NOTICE.—A covered product authorization issued under this subparagraph shall state that the provision of the covered product by the license holder under the terms of the authorization will not be a violation of the REMS for the covered product.

(3) AFFIRMATIVE DEFENSE.—In a civil action brought under paragraph (1), it shall be an affirmative defense, on which the defendant has the burden of persuasion by a preponderance of the evidence—

(A) that, on the date on which the eligible product developer requested to purchase sufficient quantities of the covered product from the license holder—

(i) neither the license holder nor any of its agents, wholesalers, or distributors

was engaged in the manufacturing or commercial marketing of the covered product; and

(ii) neither the license holder nor any of its agents, wholesalers, or distributors otherwise had access to inventory of the covered product to supply to the eligible product developer on commercially reasonable, market-based terms; or

(B) that—

(i) the license holder sells the covered product through agents, distributors, or wholesalers;

(ii) the license holder has placed no restrictions, explicit or implicit, on its agents, distributors, or wholesalers to sell covered products to eligible product developers; and

(iii) the covered product can be purchased by the eligible product developer in sufficient quantities on commercially reasonable, market-based terms from the agents, distributors, or wholesalers of the license holder.

(4) REMEDIES.—

(A) IN GENERAL.—If an eligible product developer prevails in a civil action brought under paragraph (1), the court shall—

(i) order the license holder to provide to the eligible product developer without delay sufficient quantities of the covered product on commercially reasonable, market-based terms;

(ii) award to the eligible product developer reasonable attorney fees and costs of the civil action; and

(iii) award to the eligible product developer a monetary amount sufficient to deter the license holder from failing to provide other eligible product developers with sufficient quantities of a covered product on commercially reasonable, market-based terms, if the court finds, by a preponderance of the evidence—

(I) that the license holder delayed providing sufficient quantities of the covered product to the eligible product developer without a legitimate business justification; or

(II) that the license holder failed to comply with an order issued under clause (i).

(B) MAXIMUM MONETARY AMOUNT.—A monetary amount awarded under subparagraph (A)(iii) shall not be greater than the revenue that the license holder earned on the covered product during the period—

(i) beginning on—

(I) for a covered product that is not subject to a REMS with ETASU, the date that is 31 days after the date on which the license holder received the request; or

(II) for a covered product that is subject to a REMS with ETASU, the date that is 31 days after the later of—

(aa) the date on which the license holder received the request; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in ac-

cordance with paragraph (2)(B); and

(ii) ending on the date on which the eligible product developer received sufficient quantities of the covered product.

(C) AVOIDANCE OF DELAY.—The court may issue an order under subparagraph (A)(i) before conducting further proceedings that may be necessary to determine whether the eligible product developer is entitled to an award under clause (ii) or (iii) of subparagraph (A), or the amount of any such award.

(c) LIMITATION OF LIABILITY.—A license holder for a covered product shall not be liable for any claim under Federal, State, or local law arising out of the failure of an eligible product developer to follow adequate safeguards to assure safe use of the covered product during development or testing activities described in this section, including transportation, handling, use, or disposal of the covered product by the eligible product developer.

(d) NO VIOLATION OF REMS.—The provision of samples of a drug pursuant to an authorization under subsection (b)(2)(B) shall not be considered a violation of the requirements of any risk evaluation and mitigation strategy that may be in place under section 505–1 of the Fed-

eral Food, Drug, and Cosmetic Act (21 U.S.C. 355–1) for such drug.

(e) RULE OF CONSTRUCTION.—

(1) DEFINITION.—In this subsection, the term ''antitrust laws''—

(A) has the meaning given the term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12); and

(B) includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such section applies to unfair methods of competition.

(2) ANTITRUST LAWS.—Nothing in this section shall be construed to limit the operation of any provision of the antitrust laws.

SEC. 305. REMS APPROVAL PROCESS FOR SUBSEQUENT FILERS.

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

(1) in subsection (g)(4)(B)—

(A) in clause (i) by striking ''or'' after the semicolon;

(B) in clause (ii) by striking the period at the end and inserting ''; or''; and

(C) by adding at the end the following:

''(iii) accommodate different, comparable approved risk evaluation and mitigation strategies for a drug that is the subject of an abbreviated new drug application, and its reference drug product.'';

(2) in subsection (i)(1), by striking subparagraph (B) and inserting the following:

''(B) Elements to assure safe use, if required under subsection (f) for the listed drug.

''(i) Subject to clause (ii), a drug that is the subject of an abbreviated new drug application may use—

''(I) a single, shared system with the listed drug under subsection (f); or

''(II) a different, comparable aspect of the elements to assure safe use under subsection (f).

''(ii) The Secretary may require a drug that is the subject of an abbreviated new drug application and the listed drug to use a single, shared system under subsection (f), if the Secretary determines that no different, comparable aspect of the

elements to assure safe use could satisfy the requirements of subsection (f).''; and

(3) by adding at the end the following:

''(l) SEPARATE REMS.—When used in this section, the terms ''different, comparable aspect of the elements to assure safe use'' or ''different, comparable approved risk evaluation and mitigation strategies'' means a risk evaluation and mitigation strategy for a drug that is the subject of an application under section 505(j) that uses different methods or operational means than the strategy required under subsection (a) for the applicable reference drug, or other application under section 505(j) with the same such reference listed drug, but achieves the same level of safety as such strategy.''.

SEC. 306. FUNDING FOR OPIOID GRANT PROGRAM FOR STATE RESPONSE TO OPIOID ABUSE CRISIS.

Section 1003(c) of the 21st Century Cures Act (42 U.S.C. 290ee–3 note) is amended by adding at the end the following new paragraph:

''(3) For purposes of carrying out this subsection, there is appropriated, out of any funds in the Treasury not otherwise appropriated, $995,000,000 for each of fiscal years 2019 through 2021.''.

Page 98, strike line 20 and all that follows through page 99, line 9.