

## 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:

1 **SEC. 208. DISTRIBUTION OF ADDITIONAL RESIDENCY POSI-**  
2 **TIONS TO HELP COMBAT OPIOID CRISIS.**

3 (a) IN GENERAL.—Section 1886(h) of the Social Se-  
4 curity Act (42 U.S.C. 1395ww(h)) is amended—

5 (1) in paragraph (4)(F)(i), by striking “para-  
6 graphs (7) and (8)” and inserting “paragraphs (7),  
7 (8), and (9)”;

8 (2) in paragraph (4)(H)(i), by striking “para-  
9 graphs (7) and (8)” and inserting “paragraphs (7),  
10 (8), and (9)”;

11 (3) in paragraph (7)(E), by inserting “para-  
12 graph (9),” after “paragraph (8),”; and

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

1           “(9) DISTRIBUTION OF ADDITIONAL RESIDENCY  
2 POSITIONS TO HELP COMBAT OPIOID CRISIS.—

3           “(A) ADDITIONAL RESIDENCY POSI-  
4 TIONS.—For each of fiscal years 2021 through  
5 2025 (and succeeding fiscal years if the Sec-  
6 retary determines that there are additional resi-  
7 dency positions available to distribute under  
8 subparagraph (D)), the Secretary shall increase  
9 the otherwise applicable resident limit for each  
10 qualifying hospital that submits a timely appli-  
11 cation under this subparagraph by such number  
12 as the Secretary may approve for portions of  
13 cost reporting periods occurring on or after  
14 July 1 of the fiscal year of the increase. Except  
15 as provided in subparagraph (B)(iv) or (D), the  
16 aggregate number of increases in the otherwise  
17 applicable resident limit under this subpara-  
18 graph shall be equal to 500 over the period of  
19 fiscal years 2021 through 2025, distributed in  
20 accordance with the succeeding subparagraphs  
21 of this paragraph.

22           “(B) DISTRIBUTION FOR FISCAL YEAR  
23 2021.—

24           “(i) IN GENERAL.—For fiscal year  
25 2021, the positions available for distribu-

1                   tion with respect to the fiscal year as de-  
2                   scribed in subparagraph (A) shall be dis-  
3                   tributed to hospitals that have existing es-  
4                   tablished approved programs in addiction  
5                   medicine, addiction psychiatry, or pain  
6                   medicine as determined by the Secretary.  
7                   The Secretary shall establish standards  
8                   and a process for ensuring additional resi-  
9                   dency positions under this subparagraph  
10                  are used to increase the number of resi-  
11                  dents studying in the fields specified in the  
12                  previous sentence.

13                  “(ii) NUMBER OF POSITIONS HOS-  
14                  PITAL ELIGIBLE TO RECEIVE.—Subject to  
15                  clauses (iii) and (iv), the aggregate number  
16                  of positions a hospital may receive under  
17                  this subparagraph with respect to fiscal  
18                  year 2021 is equal to the sum of the fol-  
19                  lowing:

20                  “(I) The number of full-time-  
21                  equivalent residents that will be train-  
22                  ing in addiction medicine, addiction  
23                  psychiatry, or pain medicine as deter-  
24                  mined by the Secretary with respect  
25                  to the fiscal year.

1                   “(II) The associated number, as  
2                   defined by the Secretary, of residents  
3                   training in a pre-requisite program,  
4                   such as internal medicine, necessary  
5                   for the number of full-time residents  
6                   for the programs described in sub-  
7                   clause (I).

8                   “(iii) ADDITIONAL POSITIONS FOR EX-  
9                   PANSION OF EXISTING PROGRAM.—If a  
10                  hospital demonstrates to the Secretary that  
11                  the hospital is planning to increase the  
12                  number of full-time-equivalent residents in  
13                  existing programs described in clause (i),  
14                  the Secretary may increase the number of  
15                  positions a hospital is eligible to receive  
16                  under clause (ii) in order to accommodate  
17                  that expansion, as determined by the Sec-  
18                  retary.

19                  “(iv) CONSIDERATIONS IN DISTRIBU-  
20                  TION.—The Secretary shall distribute addi-  
21                  tional residency positions under this sub-  
22                  paragraph based on—

23                         “(I) in the case of positions made  
24                         available under clause (ii), the dem-  
25                         onstrated likelihood, as defined by the

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

3 “(II) in the case of positions  
4 made available under clause (iii), the  
5 demonstrated likelihood, as so defined,  
6 of the hospital filling such positions  
7 within the first three cost reporting  
8 periods beginning on or after July 1,  
9 2021.

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

15 “(vi) POSITIONS NOT DISTRIBUTED  
16 DURING THE FISCAL YEAR.—If the number  
17 of resident full-time-equivalent positions  
18 distributed under this subparagraph is less  
19 than the aggregate number of positions  
20 available for distribution in the fiscal year  
21 (as described in subparagraph (A)), the  
22 difference between such number distrib-  
23 uted and such number available for dis-  
24 tribution shall be added to the aggregate

1 number of positions available for distribu-  
2 tion under subparagraph (C).

3 “(C) DISTRIBUTION FOR FISCAL YEARS  
4 2022 THROUGH 2025.—

5 “(i) IN GENERAL.—For the period of  
6 fiscal years 2022 through 2025, the posi-  
7 tions available for distribution with respect  
8 to such period (as described in subpara-  
9 graph (A), including after application of  
10 subparagraph (B)(vi)) shall be distributed  
11 to hospitals which demonstrate to the Sec-  
12 retary that the hospital—

13 “(I) will establish an approved  
14 program in addiction medicine, addic-  
15 tion psychiatry, or pain medicine; and

16 “(II) will use all of the additional  
17 positions made available under this  
18 subparagraph in such program or a  
19 prerequisite residency program for  
20 such program within the first four  
21 cost reporting periods after the in-  
22 crease would be effective.

23 “(ii) REQUIREMENTS.—Subject to  
24 clause (iii), a hospital that receives an in-  
25 crease in the otherwise applicable resident

1 limit under this subparagraph shall ensure,  
2 during the 10-year period beginning after  
3 the date of such increase, that the hospital  
4 uses the positions received under clauses  
5 (i)(I) and (i)(II) for the programs for  
6 which the positions were distributed, or  
7 similar programs (as determined by the  
8 Secretary). The Secretary may determine  
9 whether a hospital has met the require-  
10 ments under this clause during such 10-  
11 year period in such manner and at such  
12 time as the Secretary determines appro-  
13 priate, including at the end of such 10-  
14 year period.

15 “(iii) REDISTRIBUTION OF POSITIONS  
16 IF HOSPITAL NO LONGER MEETS CERTAIN  
17 REQUIREMENTS.—In the case where the  
18 Secretary determines that a hospital de-  
19 scribed in clause (ii) does not meet the re-  
20 quirements of such clause, the Secretary  
21 shall—

22 “(I) reduce the otherwise applica-  
23 ble resident limit of the hospital by  
24 the amount by which such limit was

1 increased under this subparagraph;  
2 and

3 “(II) provide for the distribution  
4 of positions attributable to such re-  
5 duction in accordance with the re-  
6 quirements of this paragraph.

7 “(D) DISTRIBUTION OF REMAINING POSI-  
8 TIONS.—If the aggregate number of positions  
9 distributed under subparagraphs (B) and (C)  
10 during the period of fiscal years 2021 through  
11 2025 is less than 500, the Secretary shall dis-  
12 tribute the remaining residency positions in suc-  
13 ceeding fiscal years according to criteria con-  
14 sistent with this paragraph until such time as  
15 the aggregate amount of positions distributed  
16 under this paragraph is equal to 500.

17 “(E) NOTIFICATION.—The Secretary shall  
18 notify hospitals of the number of positions dis-  
19 tributed to the hospital under this paragraph as  
20 a result on an increase in the otherwise applica-  
21 ble resident limit by January 1 of the fiscal  
22 year of the increase. Such increase shall be ef-  
23 fective for portions of cost reporting periods be-  
24 ginning on or after July 1 of that fiscal year.

1           “(F) APPLICATION OF PER RESIDENT  
2 AMOUNTS FOR PRIMARY CARE AND NONPRI-  
3 MARY CARE.—With respect to additional resi-  
4 dency positions in a hospital attributable to the  
5 increase provided under this paragraph, the ap-  
6 proved FTE per resident amounts are deemed  
7 to be equal to the hospital per resident amounts  
8 for primary care and nonprimary care com-  
9 puted under paragraph (2)(D) for that hospital.

10           “(G) PERMITTING FACILITIES TO APPLY  
11 AGGREGATION RULES.—The Secretary shall  
12 permit hospitals receiving additional residency  
13 positions attributable to the increase provided  
14 under this paragraph to, beginning in the fifth  
15 year after the effective date of such increase,  
16 apply such positions to the limitation amount  
17 under paragraph (4)(F) that may be aggre-  
18 gated pursuant to paragraph (4)(H) among  
19 members of the same affiliated group.

20           “(H) DEFINITIONS.—In this paragraph:

21           “(i) OTHERWISE APPLICABLE RESI-  
22 DENT LIMIT.—The term ‘otherwise appli-  
23 cable resident limit’ means, with respect to  
24 a hospital, the limit otherwise applicable  
25 under subparagraphs (F)(i) and (H) of

1 paragraph (4) on the resident level for the  
2 hospital determined without regard to this  
3 paragraph but taking into account para-  
4 graphs (7)(A), (7)(B), (8)(A), and (8)(B).

5 “(ii) RESIDENT LEVEL.—The term  
6 ‘resident level’ has the meaning given such  
7 term in paragraph (7)(C)(i).”

8 (b) IME.—

9 (1) IN GENERAL.—Section 1886(d)(5)(B)(v) of  
10 the Social Security Act (42 U.S.C.  
11 1395ww(d)(5)(B)(v)), in the third sentence, is  
12 amended by striking “and (h)(8)” and inserting  
13 “(h)(8), and (h)(9)”.

14 (2) CONFORMING PROVISION.—Section  
15 1886(d)(5)(B) of the Social Security Act (42 U.S.C.  
16 1395ww(d)(5)(B)) is amended—

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

22 (B) by adding after clause (xi), as redesign-  
23 ated by subparagraph (A), the following new  
24 clause:

1           “(xii) For discharges occurring on or after July  
2           1, 2021, insofar as an additional payment amount  
3           under this subparagraph is attributable to resident  
4           positions distributed to a hospital under subsection  
5           (h)(9), the indirect teaching adjustment factor shall  
6           be computed in the same manner as provided under  
7           clause (ii) with respect to such resident positions.”.

Page 95, after line 21, insert the following:

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

10           (a) DEFINITIONS.—In this section—

11                   (1) the term “commercially reasonable, market-  
12           based terms” means—

13                           (A) a non-discriminatory price for the sale  
14                           of the covered product at or below, but not  
15                           greater than, the most recent wholesale acquisi-  
16                           tion cost for the drug, as defined in section  
17                           1847A(c)(6)(B) of the Social Security Act (42  
18                           U.S.C. 1395w–3a(c)(6)(B));

19                           (B) a schedule for delivery that results in  
20                           the transfer of the covered product to the eligi-  
21                           ble product developer consistent with the timing  
22                           under subsection (b)(2)(A)(iv); and

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

1 (2) the term “covered product”—

2 (A) means—

3 (i) any drug approved under sub-  
4 section (b) or (j) of section 505 of the Fed-  
5 eral Food, Drug, and Cosmetic Act (21  
6 U.S.C. 355) or biological product licensed  
7 under subsection (a) or (k) of section 351  
8 of the Public Health Service Act (42  
9 U.S.C. 262);

10 (ii) any combination of a drug or bio-  
11 logical product described in clause (i); or

12 (iii) when reasonably necessary to  
13 support approval of an application under  
14 section 505 of the Federal Food, Drug,  
15 and Cosmetic Act (21 U.S.C. 355), or sec-  
16 tion 351 of the Public Health Service Act  
17 (42 U.S.C. 262), as applicable, or other-  
18 wise meet the requirements for approval  
19 under either such section, any product, in-  
20 cluding any device, that is marketed or in-  
21 tended for use with such a drug or biologi-  
22 cal product; and

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

1 drug shortage list in effect under section 506E  
2 of the Federal Food, Drug, and Cosmetic Act  
3 (21 U.S.C. 356e), unless the shortage will not  
4 be promptly resolved—

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

8 (ii) as otherwise determined by the  
9 Secretary;

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

13 (4) the term “eligible product developer” means  
14 a person that seeks to develop a product for ap-  
15 proval pursuant to an application for approval under  
16 subsection (b)(2) or (j) of section 505 of the Federal  
17 Food, Drug, and Cosmetic Act (21 U.S.C. 355) or  
18 for licensing pursuant to an application under sec-  
19 tion 351(k) of the Public Health Service Act (42  
20 U.S.C. 262(k));

21 (5) the term “license holder” means the holder  
22 of an application approved under subsection (c) or  
23 (j) of section 505 of the Federal Food, Drug, and  
24 Cosmetic Act (21 U.S.C. 355) or the holder of a li-  
25 cense under subsection (a) or (k) of section 351 of

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

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

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

11 (8) the term “Secretary” means the Secretary  
12 of Health and Human Services;

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

18 (10) the term “sufficient quantities” means an  
19 amount of a covered product that allows the eligible  
20 product developer to—

21 (A) conduct testing to support an applica-  
22 tion—

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

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

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

6 (B) fulfill any regulatory requirements re-  
7 lating to such an application for approval or li-  
8 censing.

9 (b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFI-  
10 CIENT QUANTITIES OF A COVERED PRODUCT.—

11 (1) IN GENERAL.—An eligible product developer  
12 may bring a civil action against the license holder  
13 for a covered product seeking relief under this sub-  
14 section in an appropriate district court of the United  
15 States alleging that the license holder has declined  
16 to provide sufficient quantities of the covered prod-  
17 uct to the eligible product developer on commercially  
18 reasonable, market-based terms.

19 (2) ELEMENTS.—

20 (A) IN GENERAL.—To prevail in a civil ac-  
21 tion brought under paragraph (1), an eligible  
22 product developer shall prove, by a preponder-  
23 ance of the evidence—

24 (i) that—

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

3 (II) if the covered product is sub-  
4 ject to a REMS with ETASU—

5 (aa) the eligible product de-  
6 veloper has obtained a covered  
7 product authorization from the  
8 Secretary in accordance with sub-  
9 paragraph (B); and

10 (bb) the eligible product de-  
11 veloper has provided a copy of  
12 the covered product authorization  
13 to the license holder;

14 (ii) that, as of the date on which the  
15 civil action is filed, the product developer  
16 has not obtained sufficient quantities of  
17 the covered product on commercially rea-  
18 sonable, market-based terms;

19 (iii) that the eligible product developer  
20 has requested to purchase sufficient quan-  
21 tities of the covered product from the li-  
22 cense holder; and

23 (iv) that the license holder has not de-  
24 livered to the eligible product developer  
25 sufficient quantities of the covered product

1 on commercially reasonable, market-based  
2 terms—

3 (I) for a covered product that is  
4 not subject to a REMS with ETASU,  
5 by the date that is 31 days after the  
6 date on which the license holder re-  
7 ceived the request for the covered  
8 product; and

9 (II) for a covered product that is  
10 subject to a REMS with ETASU, by  
11 31 days after the later of—

12 (aa) the date on which the  
13 license holder received the re-  
14 quest for the covered product; or

15 (bb) the date on which the  
16 license holder received a copy of  
17 the covered product authorization  
18 issued by the Secretary in ac-  
19 cordance with subparagraph (B).

20 (B) AUTHORIZATION FOR COVERED PROD-  
21 UCT SUBJECT TO A REMS WITH ETASU.—

22 (i) REQUEST.—An eligible product de-  
23 veloper may submit to the Secretary a  
24 written request for the eligible product de-  
25 veloper to be authorized to obtain suffi-

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

3           (ii) AUTHORIZATION.—Not later than  
4           120 days after the date on which a request  
5           under clause (i) is received, the Secretary  
6           shall, by written notice, authorize the eligi-  
7           ble product developer to obtain sufficient  
8           quantities of an individual covered product  
9           subject to a REMS with ETASU for pur-  
10          poses of—

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

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

19                           (aa)(AA) submitted proto-  
20                           cols, informed consent docu-  
21                           ments, and informational mate-  
22                           rials for testing that include pro-  
23                           tections that provide safety pro-  
24                           tections comparable to those pro-

1 vided by the REMS for the cov-  
2 ered product; or

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

6 (bb) met any other require-  
7 ments the Secretary may estab-  
8 lish.

9 (iii) NOTICE.—A covered product au-  
10 thorization issued under this subparagraph  
11 shall state that the provision of the covered  
12 product by the license holder under the  
13 terms of the authorization will not be a  
14 violation of the REMS for the covered  
15 product.

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

20 (A) that, on the date on which the eligible  
21 product developer requested to purchase suffi-  
22 cient quantities of the covered product from the  
23 license holder—

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

1 was engaged in the manufacturing or com-  
2 mercial marketing of the covered product;  
3 and

4 (ii) neither the license holder nor any  
5 of its agents, wholesalers, or distributors  
6 otherwise had access to inventory of the  
7 covered product to supply to the eligible  
8 product developer on commercially reason-  
9 able, market-based terms; or

10 (B) that—

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

14 (ii) the license holder has placed no  
15 restrictions, explicit or implicit, on its  
16 agents, distributors, or wholesalers to sell  
17 covered products to eligible product devel-  
18 opers; and

19 (iii) the covered product can be pur-  
20 chased by the eligible product developer in  
21 sufficient quantities on commercially rea-  
22 sonable, market-based terms from the  
23 agents, distributors, or wholesalers of the  
24 license holder.

25 (4) REMEDIES.—

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

4 (i) order the license holder to provide  
5 to the eligible product developer without  
6 delay sufficient quantities of the covered  
7 product on commercially reasonable, mar-  
8 ket-based terms;

9 (ii) award to the eligible product de-  
10 veloper reasonable attorney fees and costs  
11 of the civil action; and

12 (iii) award to the eligible product de-  
13 veloper a monetary amount sufficient to  
14 deter the license holder from failing to pro-  
15 vide other eligible product developers with  
16 sufficient quantities of a covered product  
17 on commercially reasonable, market-based  
18 terms, if the court finds, by a preponder-  
19 ance of the evidence—

20 (I) that the license holder delayed  
21 providing sufficient quantities of the  
22 covered product to the eligible product  
23 developer without a legitimate busi-  
24 ness justification; or

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

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

9 (i) beginning on—

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

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

19 (aa) the date on which the  
20 license holder received the re-  
21 quest; or

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

1 cordance with paragraph (2)(B);

2 and

3 (ii) ending on the date on which the  
4 eligible product developer received suffi-  
5 cient quantities of the covered product.

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

13 (c) LIMITATION OF LIABILITY.—A license holder for  
14 a covered product shall not be liable for any claim under  
15 Federal, State, or local law arising out of the failure of  
16 an eligible product developer to follow adequate safeguards  
17 to assure safe use of the covered product during develop-  
18 ment or testing activities described in this section, includ-  
19 ing transportation, handling, use, or disposal of the cov-  
20 ered product by the eligible product developer.

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

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

3 (e) **RULE OF CONSTRUCTION.**—

4 (1) **DEFINITION.**—In this subsection, the term  
5 “antitrust laws”—

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

9 (B) includes section 5 of the Federal  
10 Trade Commission Act (15 U.S.C. 45) to the  
11 extent that such section applies to unfair meth-  
12 ods of competition.

13 (2) **ANTITRUST LAWS.**—Nothing in this section  
14 shall be construed to limit the operation of any pro-  
15 vision of the antitrust laws.

16 **SEC. 305. REMS APPROVAL PROCESS FOR SUBSEQUENT**  
17 **FILERS.**

18 Section 505–1 of the Federal Food, Drug, and Cos-  
19 metic Act (21 U.S.C. 355–1) is amended—

20 (1) in subsection (g)(4)(B)—

21 (A) in clause (i) by striking “or” after the  
22 semicolon;

23 (B) in clause (ii) by striking the period at  
24 the end and inserting “; or”; and

25 (C) by adding at the end the following:

1           “(iii) accommodate different, com-  
2           parable approved risk evaluation and miti-  
3           gation strategies for a drug that is the  
4           subject of an abbreviated new drug appli-  
5           cation, and its reference drug product.”;

6           (2) in subsection (i)(1), by striking subpara-  
7           graph (B) and inserting the following:

8           “(B) Elements to assure safe use, if re-  
9           quired under subsection (f) for the listed drug.

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

13                   “(I) a single, shared system with  
14                   the listed drug under subsection (f);  
15                   or

16                   “(II) a different, comparable as-  
17                   pect of the elements to assure safe use  
18                   under subsection (f).

19           “(ii) The Secretary may require a  
20           drug that is the subject of an abbreviated  
21           new drug application and the listed drug to  
22           use a single, shared system under sub-  
23           section (f), if the Secretary determines  
24           that no different, comparable aspect of the

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

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

4 “(1) SEPARATE REMS.—When used in this section,  
5 the terms “different, comparable aspect of the elements  
6 to assure safe use” or “different, comparable approved  
7 risk evaluation and mitigation strategies” means a risk  
8 evaluation and mitigation strategy for a drug that is the  
9 subject of an application under section 505(j) that uses  
10 different methods or operational means than the strategy  
11 required under subsection (a) for the applicable reference  
12 drug, or other application under section 505(j) with the  
13 same such reference listed drug, but achieves the same  
14 level of safety as such strategy.”.

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

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

20 “(3) For purposes of carrying out this sub-  
21 section, there is appropriated, out of any funds in  
22 the Treasury not otherwise appropriated,  
23 \$995,000,000 for each of fiscal years 2019 through  
24 2021.”.

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

