

AMENDMENT TO H.R. 1919
OFFERED BY MR. PALLONE OF NEW JERSEY

Strike section 3 of the bill and insert the following:

1 SEC. 3. ENHANCED DRUG DISTRIBUTION SECURITY.

2 (a) IN GENERAL.—Section 582 of the Federal Food,
3 Drug, and Cosmetic Act, as added by section 2, is amend-
4 ed by adding at the end the following:

5 “(h) ENHANCED DRUG DISTRIBUTION SECURITY.—

6 “(1) IN GENERAL.—On the date that is 10
7 years after the date of enactment of the Safe-
8 guarding America’s Pharmaceuticals Act of 2013,
9 the following interoperable, electronic tracing of
10 product at the package level requirements shall go
11 into effect:

12 “(A) The transaction information and the
13 transaction statements as required under this
14 section shall be exchanged in an interoperable,
15 electronic manner in accordance with the stand-
16 ards established under the guidance issued pur-
17 suant to paragraphs (3) and (4) of subsection
18 (i), including any revision of such guidance
19 issued in accordance with paragraph (5) of such
20 subsection.

1 “(B) The transaction information required
2 under this section shall include the product
3 identifier at the package level for each package
4 included in the transaction.

5 “(C) Systems and processes for verification
6 of product at the package level shall be required
7 in accordance with the standards established
8 under the guidance issued pursuant to sub-
9 section (a)(2) and the guidances issued pursu-
10 ant to paragraphs (2),(3), and (4) of subsection
11 (i), including any revision of such guidances
12 issued in accordance with paragraph (5) of such
13 subsection, which may include the use of aggre-
14 gation and inference as necessary.

15 “(D) The systems and processes necessary
16 to promptly respond with the transaction infor-
17 mation and transaction statement for a product
18 upon a request by the Secretary (or other ap-
19 propriate Federal or State official) in the event
20 of a recall or for the purposes of investigating
21 a suspect product or an illegitimate product
22 shall be required.

23 “(E) The systems and processes necessary
24 to promptly facilitate gathering the information
25 necessary to produce the transaction informa-

1 tion for each transaction going back to the
2 manufacturer, as applicable, upon request by
3 the Secretary (or other appropriate Federal or
4 State official), in the event of a recall or for the
5 purposes of investigating a suspect product or
6 an illegitimate product shall be required.

7 “(F) A wholesale distributor shall maintain
8 systems and processes to allow the wholesale
9 distributor to accept saleable returns from dis-
10 pensers only if the wholesale distributor can as-
11 sociate returned product with the transaction
12 information and the transaction statement asso-
13 ciated with that product.

14 “(2) COMPLIANCE.—

15 “(A) INFORMATION MAINTENANCE AGREE-
16 MENT.—A dispenser shall be permitted to enter
17 into a written agreement with a third party, in-
18 cluding an authorized wholesale distributor,
19 under which the third party shall confidentially
20 maintain any information required to be main-
21 tained under this section. If a dispenser enters
22 into such an agreement, the dispenser shall
23 maintain a copy of the written agreement and
24 shall not be relieved of the other obligations of
25 the dispenser under this subsection.

1 “(B) ALTERNATIVE METHODS.—The Sec-
2 retary, taking into consideration the assessment
3 conducted under paragraph (3), shall provide
4 for alternative methods of compliance with any
5 of the requirements set forth in paragraph (1),
6 including—

7 “(i) establishing timelines for compli-
8 ance by small businesses (including small
9 business dispensers with 25 or fewer full
10 time employees) with such requirements, in
11 order to ensure that such requirements do
12 not impose undue economic hardship for
13 small businesses, including small business
14 dispensers for whom the criteria set forth
15 in the assessment under paragraph (3) is
16 not met, if the Secretary determines that
17 such requirements under paragraph (1)
18 would result in undue economic hardship;
19 and

20 “(ii) establishing a process by which a
21 dispenser may request a waiver from any
22 of the requirements set forth in paragraph
23 (1) if the Secretary determines that such
24 requirements would result in an undue eco-
25 nomic hardship.

1 “(3) ASSESSMENT.—

2 “(A) IN GENERAL.—Not later than the
3 date that is 18 months after the Secretary
4 issues the final guidance required under sub-
5 section (i), the Secretary shall enter into con-
6 tract with a private, independent consulting
7 firm with expertise to conduct a technology and
8 software assessment that looks at the feasibility
9 of dispensers with 25 or fewer full-time employ-
10 ees conducting interoperable, electronic tracing
11 of products at the package level. In no case
12 may such assessment commence later than 7.5
13 years after the date of enactment of the Safe-
14 guarding America’s Pharmaceuticals Act of
15 2013.

16 “(B) CONDITION.—As a condition of the
17 award of the contract under subparagraph (A),
18 the private, independent consulting firm shall
19 agree to consult with dispensers with 25 or
20 fewer full-time employees when conducting the
21 assessment under such subparagraph.

22 “(C) CONTENT.—The assessment con-
23 ducted under subparagraph (A) shall assess
24 whether—

1 “(i) the necessary software and hard-
2 ware is readily accessible to such dis-
3 pensers;

4 “(ii) the necessary software and hard-
5 ware is not prohibitively expensive to ob-
6 tain, install, and maintain for such dis-
7 pensers; and

8 “(iii) the necessary hardware and
9 software can be integrated into business
10 practices, such as interoperability with
11 wholesale distributors, for such dispensers.

12 “(D) PUBLICATION.—The Secretary
13 shall—

14 “(i) publish the statement of work for
15 the assessment conducted under subpara-
16 graph (A) for public comment prior to be-
17 ginning the assessment;

18 “(ii) publish the final assessment for
19 public comment not later than 30 calendar
20 days after receiving such assessment; and

21 “(iii) hold a public meeting not later
22 than 180 calendar days after receiving the
23 final assessment at which public stake-
24 holders may present their views on the as-
25 sessment.

1 “(4) PROCEDURE.—Notwithstanding section
2 553 of title 5, United States Code, the Secretary, in
3 promulgating any regulation pursuant to this sec-
4 tion, shall—

5 “(A) provide appropriate flexibility by—

6 “(i) not requiring the adoption of spe-
7 cific business systems for the maintenance
8 and transmission of data;

9 “(ii) prescribing alternative methods
10 of compliance for any of the requirements
11 set forth in paragraph (1) or set forth in
12 regulations implementing such require-
13 ments, including timelines—

14 “(I) for small businesses to com-
15 ply with the requirements set forth in
16 the regulations in order to ensure that
17 such requirements do not impose
18 undue economic hardship for small
19 businesses (including small business
20 dispensers for whom the criteria set
21 forth in the assessment under para-
22 graph (3) is not met), if the Secretary
23 determines that such requirements
24 would result in undue economic hard-
25 ship; and

1 “(II) which shall include estab-
2 lishing a process by which a dispenser
3 may request a waiver from any of the
4 requirements set forth in such regula-
5 tions if the Secretary determines that
6 such requirements would result in an
7 undue economic hardship; and

8 “(iii) taking into consideration—

9 “(I) the results of pilot projects,
10 including pilot projects pursuant to
11 this section;

12 “(II) the public meetings held
13 and related guidance documents
14 issued under this section;

15 “(III) the public health benefits
16 of any additional regulations in com-
17 parison to the cost of compliance with
18 such requirements, including on enti-
19 ties of varying sizes and capabilities;

20 “(IV) the diversity of the phar-
21 maceutical distribution supply chain
22 by providing appropriate flexibility for
23 each sector, including both large and
24 small businesses; and

1 “(V) the assessment pursuant to
2 paragraph (3) with respect to small
3 business dispensers, including related
4 public comment and the public meet-
5 ing, and requirements under this sec-
6 tion;

7 “(B) issue a notice of proposed rulemaking
8 that includes a copy of the proposed regulation;

9 “(C) provide a period of not less than 60
10 days for comments on the proposed regulation;
11 and

12 “(D) publish the final regulation not less
13 than 2 years prior to the effective date of the
14 regulation.

15 “(i) GUIDANCE DOCUMENTS.—

16 “(1) IN GENERAL.—For the purposes of facili-
17 tating the successful and efficient adoption of se-
18 cure, interoperable product tracing at the package
19 level in order to enhance drug distribution security
20 and further protect the public health, the Secretary
21 shall issue the guidance documents as provided for
22 in this subsection.

23 “(2) SUSPECT AND ILLEGITIMATE PRODUCT.—

24 “(A) IN GENERAL.—Not later than 180
25 days after enactment of the Safeguarding

1 America's Pharmaceuticals Act of 2013, the
2 Secretary shall issue a guidance document to
3 aid trading partners in the identification of a
4 suspect product and notification termination.
5 Such guidance document shall—

6 “(i) identify specific scenarios that
7 could significantly increase the risk of a
8 suspect product entering the pharma-
9 ceutical distribution supply chain;

10 “(ii) provide recommendation on how
11 trading partners may identify such product
12 and make a determination if the product is
13 a suspect product as soon as practicable;
14 and

15 “(iii) set forth the process by which
16 manufacturers, repackagers, wholesale dis-
17 tributors, dispensers, and third-party logis-
18 tics providers shall terminate notifications
19 in consultation with the Secretary regard-
20 ing illegitimate product pursuant to sub-
21 sections (b)(4)(B), (c)(4)(B), (d)(4)(B),
22 (e)(4)(B), and (f)(B).

23 “(B) REVISED GUIDANCE.—If the Sec-
24 retary revises the guidance issued under sub-

1 paragraph (A), the Secretary shall follow the
2 procedure set forth in paragraph (5).

3 “(3) UNIT LEVEL TRACING.—

4 “(A) IN GENERAL.—In order to enhance
5 drug distribution security at the package level,
6 not later than 18 months after conducting a
7 public meeting on the system attributes nec-
8 essary to enable tracing of product at the pack-
9 age level, the Secretary shall issue a final guid-
10 ance document that outlines and makes rec-
11 ommendations with respect to the system at-
12 tributes necessary to enable tracing at the pack-
13 age level as required under the requirements es-
14 tablished under subsection (h). Such guidance
15 document shall—

16 “(i) define the circumstances under
17 which the sectors within the pharma-
18 ceutical distribution supply chain may, in
19 the most efficient manner practicable, infer
20 the contents of a case, pallet, or other ag-
21 gregate of individual packages or con-
22 tainers of product, from a product identi-
23 fier associated with the case, pallet, or
24 other aggregate, without opening each
25 case, pallet, or other aggregate or other-

1 wise individually scanning each package;
2 and

3 “(ii) identify methods and processes
4 to enhance tracing of product at the pack-
5 age level, such as enhanced verification ac-
6 tivities, the use of aggregation and infer-
7 ence, processes that utilize the product
8 identifiers to enhance tracing of product at
9 the package level, or package security fea-
10 tures.

11 “(B) PROCEDURE.—In issuing the guid-
12 ance under subparagraph (A), and in revising
13 such guidance, if applicable, the Secretary shall
14 follow the procedure set forth in paragraph (5).

15 “(4) STANDARDS FOR INTEROPERABLE DATA
16 EXCHANGE.—

17 “(A) IN GENERAL.—In order to enhance
18 tracing of a product at the package level, the
19 Secretary, not later than 18 months after con-
20 ducting a public meeting on the interoperable
21 standards necessary to enhance the security of
22 the pharmaceutical distribution supply chain,
23 shall update the guidance issued pursuant to
24 subsection (a)(2), as necessary and appropriate,

1 and finalize such guidance document so that
2 the guidance document—

3 “(i) identifies and makes rec-
4 ommendation with respect to the standards
5 necessary for adoption in order to support
6 the secure, interoperable electronic data
7 exchange among the pharmaceutical dis-
8 tribution supply chain that comply with a
9 form and format developed by a widely rec-
10 ognized international standards develop-
11 ment organization;

12 “(ii) takes into consideration stand-
13 ards established pursuant to subsection
14 (a)(2) and section 505D;

15 “(iii) facilitates the creation of a uni-
16 form process or methodology for product
17 tracing; and

18 “(iv) ensures the protection of con-
19 fidential commercial information and trade
20 secrets.

21 “(B) PROCEDURE.—In issuing the guid-
22 ance under subparagraph (A), and in revising
23 such guidance, if applicable, the Secretary shall
24 follow the procedure set forth in paragraph (5).

1 “(5) PROCEDURE.—In issuing or revising any
2 guidance issued pursuant to this subsection or sub-
3 section (h), except the initial guidance issued under
4 paragraph (2)(A), the Secretary shall—

5 “(A) publish a notice in the Federal Reg-
6 ister announcing that the draft or revised draft
7 guidance is available;

8 “(B) post the draft guidance document on
9 the Internet Web site of the Food and Drug
10 Administration and make such draft guidance
11 document available in hard copy;

12 “(C) provide an opportunity for comment
13 and review and take into consideration any
14 comments received;

15 “(D) revise the draft guidance, as appro-
16 priate;

17 “(E) publish a notice in the Federal Reg-
18 ister announcing that the final guidance or final
19 revised guidance is available;

20 “(F) post the final guidance document on
21 the Internet Website of the Food and Drug Ad-
22 ministration and make such final guidance doc-
23 ument available in hard copy; and

1 “(G) provide for an effective date of not
2 earlier than 1 year after such guidance becomes
3 final.

4 “(j) PUBLIC MEETINGS.—

5 “(1) IN GENERAL.—The Secretary shall hold
6 not less than 3 public meetings to enhance the safe-
7 ty and security of the pharmaceutical distribution
8 supply chain and provide for comment. The Sec-
9 retary may hold the first such public meeting not
10 earlier than 1 year after the date of enactment of
11 the Safeguarding America’s Pharmaceuticals Act of
12 2013. In carrying out the public meetings described
13 in this paragraph, the Secretary shall—

14 “(A) prioritize topics necessary to inform
15 the issuance of the guidance described in para-
16 graphs (3) and (4) of subsection (i); and

17 “(B) take all measures reasonable and
18 practicable to ensure the protection of confiden-
19 tial commercial information and trade secrets.

20 “(2) CONTENT.—Each of the following topics
21 shall be addressed in at least one of the public meet-
22 ings described in paragraph (1):

23 “(A) An assessment of the steps taken
24 under subsections (b) through (f) to build ca-
25 pacity for a unit-level system, including the im-

1 pact of the requirements of such subsections
2 on—

3 “(i) the ability of the health care sys-
4 tem collectively to maintain patient access
5 to medicines;

6 “(ii) the scalability of such require-
7 ments, including as it relates to product
8 lines; and

9 “(iii) the capability of different sec-
10 tors and subsectors, including both large
11 and small businesses, to affix and utilize
12 the product identifier.

13 “(B) The system attributes necessary to
14 support the requirements set forth under sub-
15 section (h), including the standards necessary
16 for adoption in order to support the secure,
17 interoperable electronic data exchange among
18 sectors within the pharmaceutical distribution
19 supply chain.

20 “(C) Best practices in each of the different
21 sectors within the pharmaceutical distribution
22 supply chain to implement the requirements of
23 this section.

24 “(D) The costs and benefits of the imple-
25 mentation of this section, including the impact

1 on each pharmaceutical distribution supply
2 chain sector and on public health.

3 “(E) Whether electronic tracing require-
4 ments, including tracing of product at the pack-
5 age level are feasible, cost-effective and needed
6 to protect public health.

7 “(F) The systems and processes needed to
8 utilize the product identifiers to enhance tracing
9 of product at the package level.

10 “(G) The technical capabilities and legal
11 authorities, if any, needed to establish an inter-
12 operable, electronic system that provides for
13 tracing of product at the package level.

14 “(H) The impact that such additional re-
15 quirements would have on patient safety, the
16 drug supply, cost and regulatory burden, and
17 timely patient access to prescription drugs.

18 “(I) Other topics, as determined appro-
19 priate by the Secretary.

20 “(k) PILOT PROJECTS.—

21 “(1) IN GENERAL.—The Secretary shall estab-
22 lish 1 or more pilot projects, in coordination with
23 authorized manufacturers, repackagers, wholesale
24 distributors, third-party logistics providers, and dis-
25 pensers, to explore and evaluate methods to enhance

1 the safety and security of the pharmaceutical dis-
2 tribution supply chain. Such projects shall build
3 upon efforts, in existence as of the date of enact-
4 ment of the Safeguarding America's Pharma-
5 ceuticals Act of 2013, to enhance the safety and se-
6 curity of the pharmaceutical distribution supply
7 chain, take into consideration any pilot projects con-
8 ducted prior to such date of enactment, and inform
9 the draft and final guidance under paragraphs (3)
10 and (4) of subsection (i).

11 “(2) CONTENT.—

12 “(A) IN GENERAL.—The Secretary shall
13 ensure that the pilot projects under paragraph
14 (1) reflect the diversity of the pharmaceutical
15 distribution supply chain and that the pilot
16 projects, when taken as a whole, include partici-
17 pants representative of every sector, including
18 both large and small businesses.

19 “(B) PROJECT DESIGN.—The pilot
20 projects under paragraph (1) shall be designed
21 to—

22 “(i) utilize the product identifier for
23 tracing of a product, which may include
24 verification of the product identifier of a

1 product, including the use of aggregation
2 and inference;

3 “(ii) improve the technical capabilities
4 of each sector and subsector to comply
5 with systems and processes needed to uti-
6 lize the product identifiers to enhance trac-
7 ing of a product;

8 “(iii) identify system attributes that
9 are necessary to implement the require-
10 ments established under this section; and

11 “(iv) complete other activities as de-
12 termined by the Secretary.

13 “(l) SUNSET.—The following requirements shall have
14 no force or effect beginning on the date that is 10 years
15 after the date of enactment of the Safeguarding America’s
16 Pharmaceuticals Act of 2013:

17 “(1) The provision and receipt of transaction
18 history under this section.

19 “(2) The requirements set forth for returns
20 under subsection (c)(1)(B)(i).

21 “(m) RULE OF CONSTRUCTION.—The requirements
22 set forth in subsections (h)(4), (j), and (k) shall not be
23 construed as a condition, prohibition, or precedent for pre-

1 cluding or delaying the provisions becoming effective pur-
2 suant to subsection (h).”.

