SAFEGUARDING AMERICA'S PHARMACEUTICALS ACT OF 2013 (H.R.1919)
FACT SHEET

Securing Pharmaceutical Distribution Supply Chain

- Establish lot-level tracing requirements for drug manufacturers, wholesale distributors, pharmacies, and repackagers based on changes in ownership.
- Establish a waiver process to grant an authorized manufacturer release from bill's requirements.
- Affiliates of the supply chain, including third party logistics providers, must participate in the verification and notification of suspect or illegitimate products. Records from a suspect drug investigation must be kept by the manufacturer for 3 years.
- Members of supply chain required to transact only with licensed or registered entities.
- Manufacturers required to affix a prescription drug identifier on each package of prescription drugs prior its distribution.

Enhanced Drug Distribution Security

- The Food and Drug Administration (FDA), in conjunction with manufacturers, required to establish pilot programs to evaluate:
    - Accessibility of necessary drug distribution technologies;
    - Affordability to obtain, install, and maintain these technologies, and;
    - Ability to easily integrate the technologies into the business practices of all drug product manufacturers.
- If the results of the pilot program are determined to hinder small businesses, then alternative means to meet the act's requirements will be provided.
- FDA is required to have bi-annual public meetings to improve collaboration with stakeholders regarding moving to unit-level traceability.
- Implementation of enhanced interoperable electronic systems to assist detection of suspect drug products.

Uniform National Policy

- No state or political subdivision will be permitted to establish or continue requirements for tracing drugs through the distribution system.

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