Comments of the Pew Charitable Trusts
To House Committee on Energy and Commerce
On a Proposal to Improve Drug Distribution Security
May 8, 2013

Dear Chairman Pitts and Ranking Member Pallone,

We would like to offer the following comments on the proposed legislation to secure drug distribution in the United States. We thank you for your continued interest in this important issue.

Counterfeiting and drug diversion, while thankfully far less common in the U.S. than in other parts of the world, remain matters of serious concern. The United States lacks strong baseline standards for licensure of pharmaceutical wholesalers, and we lack a standard system for companies to keep track of our pharmaceuticals during distribution. There is currently no way to check whether an individual vial or bottle is authentic or counterfeit. Despite the strength of laws in states such as California, multiple state requirements on drug traceability are not ideal either for companies or for consumers. The United States lags behind other countries that have already put in place serialization and verification requirements.

Pharmaceutical manufacturers are already making investments in drug serialization technology. To justify the expense – and the preemption of strong state laws – it is essential that any federal law achieve the following within a reasonable time frame:

- Participation of all members of the supply chain
- Traceability of drugs at the package / unit level, and
- Routine checking of drug serial numbers.

As currently drafted, this legislation does not guarantee that there will be a national drug distribution security system that will involve all members of the supply chain and will track drugs at the unit level within a reasonable time frame. We urge the committee to amend this legislation to establish a clear path to a unit-level traceability system, as called for by a majority of the witnesses who testified at your April 25th hearing.

MAJOR RECOMMENDATIONS

Include a self-effecting statutory requirement for an electronic, unit-level traceability system. Statutory clarity on unit-level traceability will ensure better patient protection and reduce the challenging regulatory uncertainty now faced by many companies. Without a clear, assured path to a unit-level system, passage of this legislation would create uncertainty for supply chain stakeholders and would harm public health by removing robust state standards and replacing them with a weaker system. As currently drafted this bill does not create a clear path. It allows for the potential to achieve a unit-level traceability system by directing the FDA to issue a proposed regulation, but a final rule is never required by a specific date. The bill puts in place a lot-level traceability system that is fully in place 2 years post-enactment, but a lot-level traceability system is not sufficient to protect patients. A lot may contain thousands of

individual bottles or packs of vials. Each unit may be sold separately, and tracking by lot does not allow industry or regulators to know who bought and sold a given drug throughout distribution. Maintaining data about lots would fail to catch unsafe drugs in many scenarios. For example, if regulators identify counterfeit vials of expensive injectables, they will not be able to find out what legitimate players bought and sold those vials before they were diverted.

Achieve unit-level traceability 7 years post-enactment. This bill does not require a proposed regulation until 2027, and does not set a timeline for a final rule. The soonest an enhanced distribution security system could possibly be in place is 2029—assuming FDA could propose and finalize the regulations in one year. This prolonged timeline will eradicate momentum in the supply chain towards unit-level traceability, will halt progress on serialization and data sharing system development, and will seriously undermine investments already being made by stakeholders. Companies have been preparing for California drug tracking requirements for several years, and have publicly affirmed their ability to comply with current implementation dates, which would see a full electronic traceability system in effect in 4 years' time. Establishing a system in 7 years' time allows extra time for compliance without sacrificing momentum and implementation planning already underway.

Public meetings, studies, and pilot programs should inform, but should not be conditions or precedents to a unit-level traceability system. The bill does not establish a clear requirement for a unit-level system in statute, or even require a final rule. The bill requires regulations to take into consideration at least 23 public meetings and multiple studies. This will create years of regulatory uncertainty that will impede progress and development of workable systems by supply chain stakeholders

A unit-level traceability system must allow for enhanced product verification. This bill contains some initial requirements for verification of drug packages after manufacturers have applied serial numbers. Specifically, members of the supply chain would have to check package identifiers when investigating suspect products. This is a helpful first step, but this bill contains no explicit requirements for enhanced verification in the future. This lack of clarity is a concern. Serialization should not be simply a tool for investigation; it should support proactive routine checking to identify products that need to be investigated. Without proactive verification steps a criminal could sell recycled or counterfeit bottles of HIV medicine, and unless the product appeared suspect for some other reason, no one would detect it because no one would be required to check it. Patients were put at risk – and the New York NY Medicaid program defrauded – through just such a large-scale diversion scheme last year. Congress should clarify that FDA has the scope to specify enhanced verification expectations under the unit-level electronic system established by this bill.

A unit-level traceability system must include participation by all supply chain sectors. Pharmacy requirements established by this bill are more limited than those applied to other sectors, and the bill contains no explicit requirements for more robust pharmacy participation at future dates. This system cannot meaningfully protect patients unless all members of the system participate; particularly pharmacies, which are at the front lines of patient care. As with verification systems, the FDA must have the scope to ensure meaningful pharmacy participation under the unit-level electronic system established by this bill.

Preemption of state pedigree laws should not occur until transaction history requirements go into effect. The bill requires full preemption of state laws upon enactment, but does not put new transaction history requirements into place until around 2 years later (when dispensers would be required to accept traceability information). This creates a 2-year window during which there would be no pedigree protections in place in the United States at all. This bill should not remove these important patient protections and law enforcement tools until interim measures are in place.

A strong system would also capture the physical movement of a drug. It is important to note that the risks to drug distribution relate not only to ownership – as envisioned in this bill – but to a drug's physical location. For example, a company with multiple distribution centers might retrospectively identify a cold-chain problem in just one location, but would have no way of knowing which units of drug had been affected. Similarly, the physical possession of a drug during transport might create opportunities for diversion that are independent of ownership. A robust electronic unit-level tracking system would capture changes in physical possession as well as ownership.

DETAILED RECOMMENDATIONS

Definitions

- **The definition of illegitimate and suspect product includes an overly burdensome requirement to show public health harm.** These definitions are contingent upon whether an adulterated or otherwise unfit product WOULD result in serious health consequences or death. However, a company is unlikely to know with absolute certainty that a serious harm will occur. A known risk of serious health consequences must be sufficient to trigger these categorizations, and the related activities driven by them. These definitions should encompass adulterated or otherwise unfit product that COULD result in serious health consequences or death.
- **Entities that can confirm an illegitimate product should not be limited to a manufacturer.** The definition of illegitimate product should include product so confirmed by repackagers, wholesale distributors, third-party logistics providers, or dispensers as well. If, for example, a wholesaler or pharmacy discovers drugs in their possession that have clearly been tampered-with, such as might happen with drug diversion schemes in the downstream distribution chain, they should be able to confirm that these products are illegitimate. A manufacturer would not be able to confirm this based on checking the validity of a serial number.
- **The definition of transaction should not broadly exempt transfers between affiliated groups.** The term affiliated group is broad. In its potential to encompass co-owned pharmacies and wholesalers it would undermine the intent of transaction history requirements. In addition, to ensure flexibility and maintain the effectiveness of the system in future the Secretary must have the authority to make additions or subtractions to the list of transaction exemptions
- **Package-level verification <u>must be clarified</u> to mean checking the standard numerical identifier.** The current definition of verification is determining whether the product identifier corresponds to the standardized numerical identifier OR lot number and expiration date assigned to the product by the manufacturer. The bill includes some requirements for package-level verification, but it must be made clear that such package-level verification means checking a

product's SNI, and not simply the lot number on a package. Without this clarification, the definition creates a loophole to unit-level verification. We propose adjusting the definition to clarify that subsequent references in the text to package-level verification mean checking the package SNI.

General requirements

- **Waivers, where permitted, should only be for individual companies and should be annually reviewed.** We support the creation of a waiver system, but are concerned that waivers for economic hardship could become a sweeping exemption for certain classes of supply chain partners, undermining the intent of legislation to increase standards to improve supply chain security. We do recognize that individual companies may need short-term waivers for reasons of economic hardship, but language should be clear that such waivers apply to individual entities that are structurally different from the rest of the sector to which they belong, and not to entire sectors of the distribution supply chain. Any such waivers should be subject to annual review and renewal. Once implementation of a serialization and traceability system begins, scale and efficiencies may rapidly reduce implementation costs. Therefore, a hardship exemption one year may no longer be necessary the next.

- **Temporarily recognizing a third-party logistics provider as licensed without any assessment introduces system risk.** As written, this provision could have the deleterious effect of deeming a third-party logistics provider licensed even if a state recently found the company in violation of existing state law. It also creates a significant loophole that bad actors may abuse. At a minimum, State regulators must be able to assert a third-party logistics provider is non-compliant and prevent them from being licensed. Under the current bill, only the FDA may make such an assertion. States may have much greater familiarity with these companies than the FDA, and could more readily identify these abuses in the course of standard State oversight activities.

Additional regulatory safeguard needed: high risk of suspect product

- **The Secretary must be able to alert all sectors to a high risk of illegitimate product, and trigger relevant investigations and notifications.** If the Secretary informs a manufacturer, repackager, wholesale distributor or dispenser of a high-risk of a suspect product, these entities must initiate a suspect product investigation. It is important that the FDA be able to alert all supply chain partners of high risk of illegitimate product, not just manufacturers. A manufacturer could alert affected trading partners, but a pharmacy that received diverted drugs with a fake transaction history from an unauthorized source would not receive a notice as they would not be a known trading partner for that drug.

Manufacturer Requirements

- **Manufacturers should be required to pass traceability information to third-party logistics providers.** Third party logistics providers should receive traceability information and keep these records in order to participate in activities to secure the distribution chain.

- **Regulators should be able to request transaction information from manufacturers to perform routine monitoring for compliance, not only when investigating a suspect product or during a recall. Regulator information requests should be fulfilled in 24 hours, not 2 business days.** In this bill, regulators can only request a transaction history or transaction

statement in the event of a recall or for the purposes of investigating a suspect or an illegitimate product. This is limiting language that would prevent routine monitoring by federal or state regulators. A regulator must be able to request transaction information to ensure compliance as in current practice, for example, with requirements that supply chain partners accept products only from licensed entities.

- **It is critical that manufacturers be required to respond to requests for verification. Without this requirement even limited verification will not function.** This bill requires manufacturers to place serial numbers on their products, and requires wholesalers and pharmacies to verify those numbers in certain cases, but includes no provision requiring manufacturers to respond to a verification request from a trading partner. This means wholesalers and pharmacies have no assurance that they will be able to comply with the law. To allow verification to function, manufacturers must be required to respond to verification requests, ideally in real time but no later than 24 hours. Swift verification by a manufacturer is critical. The need to quarantine inventory pending verification could place an unnecessary burden on supply chain stakeholders, particularly dispensers and, in some circumstances, could result in treatment delays.
- **Manufacturers should be required to notify all affected trading partners, not just the Secretary, when an illegitimate product is discovered.** Requiring the Secretary to assess whether trading partner notification is needed is an unnecessary step that may delay removing harmful product from the supply chain. Identifying an illegitimate product, as defined, requires a high degree of certainty. There is no reason a company that identifies such a product should not alert its trading partners.
- **Manufacturers should be required to respond to notifications of illegitimate product not just by the Secretary, but by trading partners as well.** Such notifications should trigger appropriate investigative activities.
- **All record-keeping requirements should be 6 years, not 3.** This is consistent with recordkeeping recommendations of the Inspector General of Health and Human Services.

Wholesale Distributor Requirements

- **Transaction information, history, and statements should each be provided in a consolidated record.** Allowing wholesalers to provide downstream trading partners with any random combination of paper, electronic data, or even manufacturer packaging places a large and unnecessary burden on downstream trading partners. At a minimum each of these items must be provided in a consolidated document, whether paper or electronic.
- ***We support the inclusion (or lack of exclusion) of lot numbers in traceability requirements for wholesalers that purchase drugs directly from a manufacturer.*** Ensuring that primary wholesalers pass lot numbers to purchasers is necessary to achieve even interim lot-level traceability. Without this, Secondary wholesalers, who are required to include lot numbers in transaction histories, would have to capture this information ostensibly by reading the lot numbers off manufacturing packaging. This would be burdensome and may create an uneven playing field akin to the one that resulted in a stay of the Prescription Drug Marketing Act.

- **Regulators should be able to request transaction information from wholesale distributors to perform routine monitoring for compliance, not only when investigating a suspect product or during a recall. Regulator information requests should be fulfilled in 24 hours, not 2 business days.** In this bill, regulators can only request a transaction history or transaction statement in the event of a recall or for the purposes of investigating a suspect or an illegitimate product. This is limiting language that would prevent routine monitoring by federal or state regulators. A regulator must be able to request transaction information to ensure compliance as in current practice, for example, with requirements that supply chain partners accept products only from licensed entities.

- **Wholesalers must take additional steps to secure the returns process**
    - **Once drugs bear the product identifier, wholesalers must be required to associate saleable returns with their original transaction information.** Returns have been identified as one of the major risk areas for the insertion of illegitimate product into the legitimate pharmaceutical supply system. This required association will help prevent the introduction of illegitimate product through the returns process.
    - **Saleable returned drugs must not be re-sold with a false attestation that they were purchased directly from the manufacturer.** This bill allows wholesalers to re-sell returned product without providing a transaction history. However, the bill should make clear that these products may not be re-sold with an attestation or implication that they were purchased directly from the manufacturer. Erasing a product's prior transaction history when it is returned and re-sold diminishes a purchaser's ability to determine that drug's provenance, and makes it easier for criminals to introduce counterfeit, diverted or stolen drugs. Multiple drug returns can also be an indicator of reimbursement fraud, and this information is useful to regulators looking to identify this. Under current Florida law, a company must track returns on a pedigree if they happen outside of a 14-day window. This bill would remove this important provision currently protecting patients in Florida.

- **Wholesalers (and all sectors) should be able to determine suspect products, not just manufacturers**. If a wholesaler discovers drugs in its possession that have clearly been tampered-with, such as might happen with drug diversion schemes in the downstream distribution chain, it should be able to independently confirm that these products are illegitimate, and take the required action under this bill. A manufacturer would not be able to confirm this based on checking the validity of a serial number.

- **Wholesalers should be required to notify all affected trading partners, not just the Secretary, when an illegitimate product is discovered.** Requiring the Secretary to assess whether trading partner notification is needed is an unnecessary step that may delay removing harmful product from the supply chain. Identifying an illegitimate product, as defined, requires a high degree of certainty. There is no reason a company that identifies such a product should not alert its trading partners.

- **Wholesalers should be required to respond to notifications of illegitimate product not just by the Secretary, but by trading partners as well.** Such notifications should trigger appropriate investigative activities.

- **All record-keeping requirements should be 6 years, not 3.** This is consistent with recordkeeping recommendations of the Inspector General of Health and Human Services.

Dispenser Requirements

- **Dispensers must be ultimately responsible for meeting requirements, even if they have a third party managing their data.** The current bill allows pharmacies to use a third party to maintain their transaction information and states that dispensers shall not be relieved of *other* obligations placed upon them. This implies that dispensers would no longer be accountable for meeting transaction information requirements. A pharmacy should not be absolved of its responsibility to meet the requirements set forth by this bill simply because it has a written agreement with another entity to help it comply. The pharmacy must still be responsible, just as a drug manufacturer is ultimately responsible for its products, even when they are made by contractors.

- **Regulators should be able to request transaction information from dispensers to perform routine monitoring for compliance, not only when investigating a suspect product or during a recall. Regulator information requests should be fulfilled in 24 hours, not 2 business days.** In this bill, regulators can only request a transaction history or transaction statement in the event of a recall or for the purposes of investigating a suspect or an illegitimate product. This is limiting language that would prevent routine monitoring by federal or state regulators. A regulator must be able to request transaction information to ensure compliance as in current practice, for example, with requirements that supply chain partners accept products only from licensed entities.

- **Dispensers (and all sectors) should be able to determine suspect products, not just manufacturers**. If a dispenser discovers drugs in its possession that have clearly been tampered-with, such as might happen with drug diversion schemes in the downstream distribution chain, it should be able to independently confirm that these products are illegitimate, and take the required action under this bill. A manufacturer would not be able to confirm this based on checking the validity of a serial number.

- **Dispensers should be required to notify all affected trading partners, not just the Secretary, when an illegitimate product is discovered.** Requiring the Secretary to assess whether trading partner notification is needed is an unnecessary step that may delay removing harmful product from the supply chain. Identifying an illegitimate product, as defined, requires a high degree of certainty. There is no reason a company that identifies such a product should not alert its trading partners.

- **Dispensers should be required to respond to notifications of illegitimate product not just by the Secretary, but by trading partners as well.** Such notifications should trigger appropriate investigative activities.

- **All record-keeping requirements should be 6 years, not 3.** This is consistent with recordkeeping recommendations of the Inspector General of Health and Human Services.

Repackager requirements

- **Regulators should be able to request transaction information from repackagers to perform routine monitoring for compliance, not only when investigating a suspect product or during a recall. Regulator information requests should be fulfilled in 24 hours, not 2 business days.** In this bill, regulators can only request a transaction history or transaction statement in the event of a recall or for the purposes of investigating a suspect or an illegitimate product. This is limiting language that would prevent routine monitoring by federal or state regulators. A regulator must be able to request transaction information to ensure compliance as in current practice, for example, with requirements that supply chain partners accept products only from licensed entities.
- **Repackagers (and all sectors) should be able to determine suspect products, not just manufacturers**. If a repackager discovers drugs in its possession that have clearly been tampered-with, such as might happen with drug diversion schemes in the downstream distribution chain, it should be able to independently confirm that these products are illegitimate, and take the required action under this bill. A manufacturer would not be able to confirm this based on checking the validity of a serial number.
- **Repackagers must associate the product identifiers the place on products with the original product identifiers applied by manufacturers.**
- **Repackagers should be required to notify all affected trading partners, not just the Secretary, when an illegitimate product is discovered.** Requiring the Secretary to assess whether trading partner notification is needed is an unnecessary step that may delay removing harmful product from the supply chain. Identifying an illegitimate product, as defined, requires a high degree of certainty. There is no reason a company that identifies such a product should not alert its trading partners.
- **Repackagers should be required to respond to notifications of illegitimate product not just by the Secretary, but by trading partners as well.** Such notifications should trigger appropriate investigative activities.
- **It is critical that repackagers be required to respond to requests for verification. Without this requirement even limited verification will not function.** This bill requires repackagers to place serial numbers on their products, and requires wholesalers and pharmacies to verify those numbers in certain cases, but includes no provision requiring manufacturers to respond to a verification request from a trading partner. This means wholesalers and pharmacies have no assurance that they will be able to comply with the law. To allow verification to function, manufacturers <u>must</u> be required to respond to verification requests, ideally in real time but no later than 24 hours. Swift verification by a manufacturer is critical. The need to quarantine inventory pending verification could place an unnecessary burden on supply chain stakeholders, particularly dispensers and, in some circumstances, could result in treatment delays.
- **All record-keeping requirements should be 6 years, not 3.** This is consistent with recordkeeping recommendations of the Inspector General of Health and Human Services.

Third-party logistics provider requirements

- **Third-party logistics providers should participate in the initial product tracing system.** They should not accept possession of products without transaction history, information and statements, and should be required to maintain copies of this information.
- **Third-party logistics providers should be required to notify all affected trading partners, not just the Secretary, when an illegitimate product is discovered.** Requiring the Secretary to assess whether trading partner notification is needed is an unnecessary step that may delay removing harmful product from the supply chain. Identifying an illegitimate product, as defined, requires a high degree of certainty. There is no reason a company that identifies such a product should not alert its trading partners.
- **Third-party logistics providers should be required to respond to notifications of illegitimate product not just by the Secretary, but by trading partners as well.** Such notifications should trigger appropriate investigative activities.
- **All record-keeping requirements should be 6 years, not 3.** This is consistent with recordkeeping recommendations of the Inspector General of Health and Human Services.

Drop Shipments

- **The carve-out for drop shipments should be clarified.** As currently written, the drop shipment provision broadly exempts any entity that does not take physical possession of the drug. However, requirements under this bill are generally based on ownership and not possession. This creates a large potential loophole. For example, if a wholesaler purchases a product and sells it to a pharmacy, but uses a separate company to ship the drugs from the manufacturer to the pharmacy, this wholesaler could be exempt from product tracing requirements. As a consequence, the information provided by the manufacturer upon change of ownership to the wholesaler would never make it to the pharmacy. Entities that take ownership of a product but not physical possession must still be involved in receipt and passage of transaction information, history, and statements. The drop shipment exemption should be constrained to entities that exclusively provide administrative services but do not take ownership.

Enhanced Drug Distribution Security

- **Include a self-effecting statutory requirement for an electronic, unit-level traceability system.** Statutory clarity on unit-level traceability will ensure better patient protection and reduce the regulatory uncertainty now faced by many companies. Without a clear, assured path to a unit-level system, passage of this legislation would create uncertainty for supply chain stakeholders and would harm public health by removing robust state standards and replacing them with a weaker system. As currently drafted this bill does not create a clear path. It allows for the potential to achieve a unit-level traceability system by directing the FDA to issue a proposed regulation, but a final rule is never required by a specific date.
    - **Require a unit-level traceability system 7 years post-enactment.** This bill does not require a proposed regulation until 2027, and does not set a timeline for a final rule. The soonest a final rule, if written, could possibly go into effect is 2029. This prolonged timeline will eradicate momentum in the supply chain towards unit-level traceability and will seriously undermine investments already being made by stakeholders. Establishing a

system in 7 years' time allows extra time for compliance beyond California dates without sacrificing momentum and implementation planning already underway.

- **Specify that the unit-level traceability system must allow for enhanced product verification.** This bill currently does not require any *proactive* verification of drugs at the package level. Serialization should not be simply a tool for investigation; it should support proactive routine checking to identify products that need to be investigated. Without proactive verification steps a criminal could sell recycled or counterfeit bottles of HIV medicine, and unless the product appeared suspect for some other reason, no one would detect it because no one would be required to check it.
- **Specify that the unit-level traceability system must include participation by all supply chain sectors.** Pharmacy requirements established by this bill are more limited than those applied to other sectors, and the bill contains no explicit requirements for more robust pharmacy participation at future dates. This system cannot meaningfully protect patients unless all members of the system participate; particularly pharmacies, which are at the front lines of patient care.

- **Public meetings, studies, and pilot programs should inform, but should not be conditions or precedents to a unit-level traceability system.** The bill does not establish a clear requirement for a unit-level system in statute, or even require a final rule. The bill requires regulations to take into consideration at least 23 public meetings and multiple studies. This will create years of regulatory uncertainty that will impede progress and development of workable systems by supply chain stakeholders. Congress should be explicit in legislation that public meetings, studies and pilots cannot delay or be considered conditions to a required unit-level traceability system.

- **Studies and meetings required by this bill are duplicative.** These multiple studies and meetings all cover cost impact to supply chain stakeholders and/or small businesses in various forms. One study assessing cost impact is sufficient. Further, requiring public meetings every 6 months beginning 6 months post-enactment and lasting until the Secretary reports to Congress 12 years later is unnecessary.

Uniform National Policy

- **Preemption of pedigree laws should not begin until new transaction history requirements take effect, currently 2 years following enactment.** A federal law should not leave Americans unprotected for two years.

- **National standards for wholesaler licensure should create a floor for state regulation, but states should be allowed to go further.** This legislation must not undermine the ability of the states to protect public health by requiring safe and secure practices by the wholesalers. For example, states currently may establish sanitary and security standards for wholesalers to ensure that medical products have not been contaminated or tampered with while under the wholesalers control. A state could require that a wholesaler storage facility maintain a certain level of security in order to deter theft and diversion of drugs. A state may also determine what constitutes adequate temperature control for storage so that proper cold chain can be maintained for drugs that require refrigeration. By establishing federal standards as a strict maximum for state enforcement the result could be the gutting of nuanced state regulation and guidance on issues such as those described above.

Thank you again for your commitment to crafting legislation that will protect patients from counterfeit, diverted, and potentially unsafe drugs.