



The Role of the Supply Chain in Combatting Counterfeits

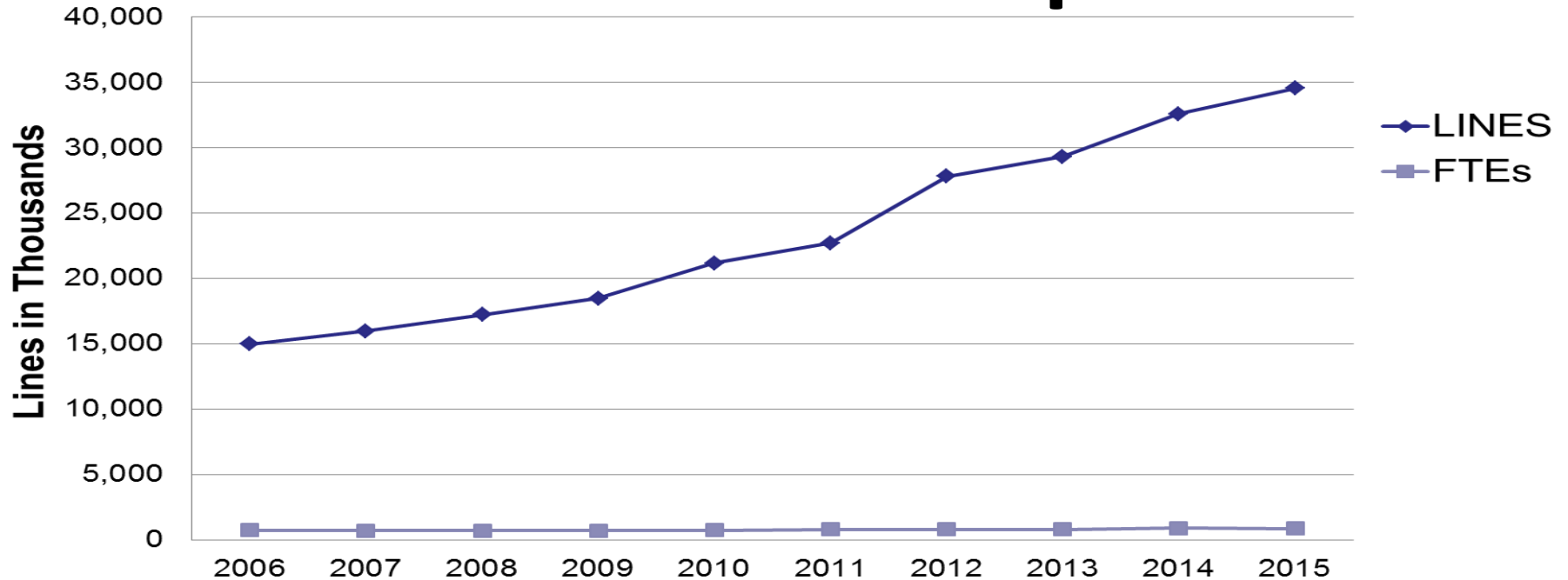
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Growth of FDA Imports



Core Traditional Approaches

- Factory Inspection (21 U.S.C. § 704)
- Enforcement Actions
 - Prosecution – deterrence (21 U.S.C. § § 331, 333)
 - Injunction -- control of manufacturing process (21 U.S.C. § 332)
 - Seizures – control of product (21 U.S.C. § 334)
- Imports – Proceed or refusal based on appearance of violation (21 U.S.C. § 801)

Difficulties of Overseas Prosecutions

- Subpoena power in investigations
- Cooperation of foreign authorities
- Compulsory power at trial
- Evidentiary Issues
- Jurisdictional Issues: extradition and extraterritoriality

Supply Chain Approaches

- Registration, Listing, and Self-Identification
- Supply Chain Integrity Programs
- Track and Trace
- CGMP Focus on Supply Chain Issues
- Good Distribution Practices / PDMA
- Mutual Reliance
- Administrative Destruction

Imported Teddy Bear...



...stuffed with counterfeit Viagra

