July 10, 2009

Bill Comparison

The Pew Prescription Project promotes consumer safety through reforms in the approval, manufacture, and marketing of prescription drugs

"FDA needs additional tools to move our oversight capabilities into the 21st century. FDA needs to access regulatory information quickly, hold all parties responsible for the quality of products in the supply chain, and have reasonable and reliable options for enforcement." (Principal Deputy Commissioner Joshua M. Sharfstein, 2010)

At least 80% of the active ingredients in U.S. prescription drugs now originate overseas. (US Government Accountability Office, 2007)

Regulatory demands placed on the Food and Drug Administration far exceed its ability to respond. (FDA Advisory Board, Subcommittee on Science and Technology, 2007)

Regulation of overseas drug manufacturing: H.R.759 v S.882

	Provision	H.R. 759: FDA Globalization Act of 2009. Mr. Dingell, Mr. Pallone & Mr. Stupak	S.882: Drug and Device Accountability Act of 2009. Mr. Kennedy & Mr. Grassley
FDA Regulatory Capacity and Authorities	**New information systems for risk-based targeting**	Secretary shall establish IT capacity for risk-based surveillance of GMP compliance.	Not explicit
	Electronic registration and drug listing	—	Electronic registration and drug listing information. Database will link entities within a supply chain; will integrate with inspection histories and other FDA databases.
	Unique identifier / site tracking	Registration numbers	Registration numbers: D-U-N-S (will also be ID for importers)
	Inspections	All sites every 2 years, but Secretary may impose risk-based schedule. Risk based inspections not less than every 4 years. Mandatory inspection before a new or significantly altered drug enters into interstate commerce. Risk assessments may reference type of drug or device, inspection history, shipping and volume history.	All sites every 2 years, but Secretary may impose risk-based schedule. Risk based inspections may be as frequent as needed, not less than every 5 years. May include excipient sites. Risk assessments may reference type of drug or device, country of manufacture, record of inspections by FDA and other governments, inspections by 3rd parties for excipients. Annual reports on inspections must be publicly posted.
	Dedicated inspectorate	Secretary shall establish a dedicated foreign inspectorate	Secretary shall establish a dedicated foreign inspectorate
	Testing	—	Secretary shall identify assays that are no longer sound, prioritize assays for revision based on health risk, assess whether assays can distinguish between drug and possible contaminants.

FDA Regulatory Capacity and Authorities	**International information-sharing**	—	Secretary may share confidential information with foreign government officials when safe and necessary, and may receive confidential information from said governments
	Recall	Secretary may order cessation of distribution or recall when necessary, if manufacturer does not take recommended action. Hearings on orders will be granted.	Secretary may order cessation of distribution or recall when necessary. Informal hearings on orders will be granted.
	Subpoena Power	Subpoena power for witnesses and documents	Subpoena power for witnesses and documents
	Hold / destroy products at border	Secretary may hold or destroy at the border products that pose a health risk. For articles valued greater than $2,000, Secretary shall provide the opportunity for an informal hearing before destruction.	Secretary may hold or destroy at the border products that pose a health risk.
	Whistleblower protections	Included	Included
Manufacturing Sites	**Registration**	Any product not required to be registered under any other section must be registered with FDA prior to import.	Registration to include all "precursor ingredient" sites. Both domestic and foreign sites must include payments of inspection fees at registration, and D-U-N-S number for all manufacturing sites.
	Legal responsibility	Submission of false and misleading data under the Act is prohibited for drugs and medical devices.	Manufacturers must certify under penalty of perjury that they have knowledge of this Act's requirements, knowledge of their submission (new product application, product report), knowledge that their submission complies with the Act and is not false or misleading, that all required clinical trial information has been submitted to FDA. If secretary determines violations, subsequent inspection costs will be assessed of submission sponsor.
	Fee structure	Required for registration, set by Secretary. Will increase each year at minimum of inflation. Other appropriations must increase by same amount.	Required for registration, set by Secretary. Cannot be greater than other appropriations or difference between other appropriations and needed funding. Fees for foreign sites will cover travel, lodging and translation in addition to the standard fee. Fees will be proportionally greater/less for sites that under a risk-based schedule are inspected more/less than every two years.
	Fee coverage	Inspections & compliance: Personnel, IT, facilities & maintenance, accounting	Registration and Inspection activities
	Upstream supply chain / ingredients tracking	All manufacturing establishments must be able to provide electronic documentation of entire supply chain including suppliers and raw material manufacturers.	Manufacturers shall submit lists for all finished dose drugs containing identity of all establishments involved in their preparation including active, inactive, and precursor ingredient preparation. Drugs without correct purity and source information will be deemed adulterated.
	Quality assurance	All manufacturing establishments must have Quality Risk Management Plans which shall provide for assessments of suppliers (raw material on), explain the quality control process and monitor and review supplier compliance, provide for effective testing specifications.	—

Manufacturing Sites	**Excipient mfrs**	Not subject to fee. Secretary may create risk-based inspection schedule separate from other sites.	Secretary may eliminate exemption of excipient manufacturers from registration after review.
	Generic mfrs	Separate fee assessed at submission of an Abbreviated New drug application (ANDA) to cover generic drug pre-approval inspection costs.	—
	Small businesses	Fees may be waived if they would impose financial hardship	Fees may be waived or reduced for small drug companies and may be reduced to 1/4th of the normal fee for small device companies
	Distribution	Repackagers only required to document establishment immediately preceding them in the supply chain	Drug is adulterated if not conveyed under good distribution and import practices
	Country of origin labeling	Manufacturers must list country of origin of their products and product APIs on their website	Manufacturers must list country of origin of their products and product APIs on their website
Importers	**Registration / certification**	Importers must register if they are not already registered with FDA as a manufacturer.	Required importer registration and licensing. Registration includes name, places of business, D-U-N-S number.
	Fees	$10,000 importer registration fee	Importers must post a bond (amount to be set by Secretary) subject to forfeiture upon violation of the Act.
	Documentation	Importers must provide documentation of product identity, quality, safety, approval and registration.	Importers must provide D-U-N-S number, new drug application number, and other tracking numbers, records of inspections, for all drugs, APIs, API precursors. Excipients must provide the same as well as a 3rd party quality certification when secretary deems acceptable. Not required for imports subject to further manufacturing for export.
Penalties	**General violations**	Max: $100,000 initial, $200,000 subsequent violation of same requirement.	Max: $100,000 per violation, assessed each day violation continues
	False data at import	Max: $200,000	Max: $150,000
	Failure to comply with orders (recall)	Max: $250,000/day	Falls under general violations
	False certifications of compliance	Not applicable	False certifications of compliance: Submission sponsors: max: $1 million. Responsible person (director of submission sponsor): max: $1 million, 10 years imprisonment. Willful false certification of compliance: Submission sponsors: max: $5 million. Responsible person: max: $5 million, 20 years imprisonment.
	Counterfeit	Max: fines in accordance with title 18, US Code, 20 years imprisonment. Max life imprisonment if counterfeit results in death.	Special penalties for counterfeit not discussed