

PEDIGREE LEGISLATION and the Effect on the Pharmaceutical Supply Chain
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Learning Assessment Questions

1) The PDMA...

- a) Regulates wholesale distributors
- b) Was written by the FDA
- c) Is a set of FDA regulations encompassing 4 broad topics
- d) Was signed into law by President Reagan in 1987

2) Pedigree regulations...

- a) Are being handled exclusively on a state level
- b) Are being handled exclusively on a federal level
- c) On a Federal level have been subjected to numerous delays in the effective date
- d) Attempt to control drug sample distribution

3) If a counterfeit batch of drugs is introduced into the U.S. drug distribution system...

- a) Your wholesaler will be able to identify the problem because the wholesaler has been tracking lot numbers in the absence of pedigree regulations.
- b) The drug will likely be a low priced generic
- c) Patients may receive suboptimal doses, inactive ingredients, or even toxins instead of active ingredient.
- d) There will not be a problem because the pharmacist will notice that the drug is counterfeit.

4) Drug pedigree is expected to improve patient safety because...

- a) It will completely eliminate the problem of counterfeits
- b) It will shut down secondary wholesalers, the root of the problem.
- c) It will provide a history of who has owned the drug so that one can make informed decisions about the integrity of the product
- d) Drug pedigree does not address patient safety.

5) The FDA's pedigree regulation, 21CFR 203.50 is set to take effect....

- a) 7/1/2006
- b) 1/1/2007
- c) 12/31/2006
- d) 12/1/2006

6) Implementation of Pedigree regulations were delayed by the FDA because...

- a) of the severe economic impact on over 4,000 small businesses, largely the secondary wholesale market
- b) of the severe economic impact on drug manufacturers
- c) on pharmacies
- d) FDA did not delay regulations, congress did

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- 7) Pedigree regulations represent the first time a wholesaler and pharmacy will be able to track...**
- a) their own purchase records
 - b) the DEA registration number of their supplier
 - c) lot numbers
 - d) price changes for a drug
- 8) The biggest point of initial entry for counterfeits into the US drug distribution system is through....**
- a) manufacturers
 - b) primary wholesalers
 - c) secondary wholesalers
 - d) pharmacies
- 9) Salvaged pharmaceuticals ...**
- a) cannot be sold in a manner consistent with PDMA
 - b) can be sold in a manner consistent with PDMA through salvage wholesale dealers
 - c) can be reintroduced by primary wholesaler into the drug distribution system
 - d) are issued a new pedigree by the last wholesaler to own them
- 10) Pedigree regulations will secure the US drug distribution system by...**
- a) shutting down the secondary wholesale market
 - b) providing a recorded purity and transaction history of each sale
 - c) completely eliminating counterfeiting in the US
 - d) minimizing the number of sales a drug can move through