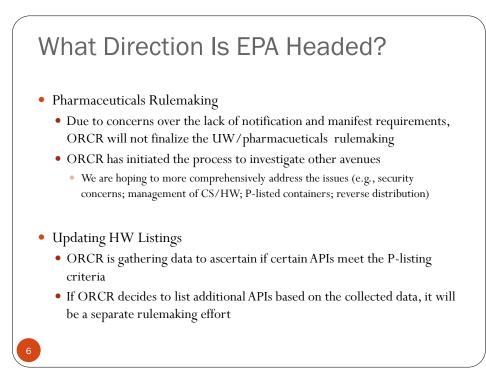
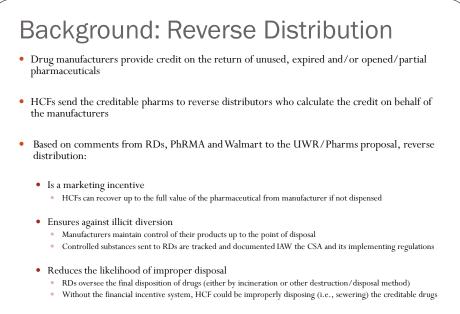


## Background: 2008 Proposal (cont.) Other ORCR priorities prevented progress on the issue during 2010 In the Fall of 2010, new ORCR Office Director gave the go-ahead and explore other options Explore viable regulatory options, other than UW, to address issues: UW program was deemed too inflexible to address manifest concerns

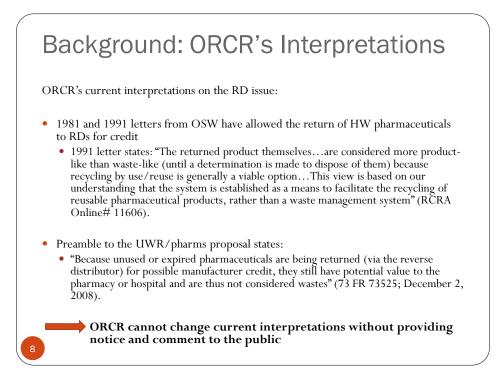
- Other pharmaceutical issues would not be addressed with the UW rule
  - Reverse distribution
  - P-listed containers
  - Out-of-date listings

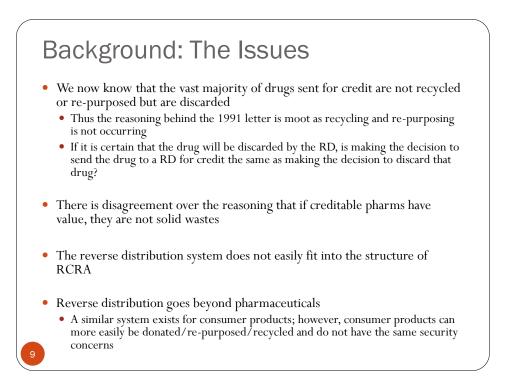
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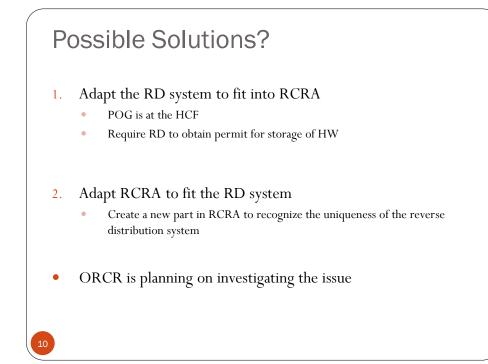




• Manufacturers use the data collected by reverse distributors on returned drugs to help plan for future production







## Questions? Comments?

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