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## Dangerous Prescription - Talking Points

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## Frontline's Dangerous Prescription

By Derek Wilmott

**There are three broad issues that this documentary presents. Please think of these issues and the accompanying questions while viewing the film. Afterwards, we will talk about these and other issues that the film examines.**

- 1) Dangerous Prescription investigates the integrity of America's drug safety system. It investigates the FDA's handling of several drugs that were approved but later were pulled from the market after causing injuries and even deaths. The program also examines the role that drug companies play in the approval and monitoring of prescription drugs and questions whether the FDA's current system is adequate for protecting the public.
- 2) This documentary recounts the biggest safety disaster in the FDA's history: the approval and the removal of the diet drug known as Fen Phen. This drug is a combination of fenfluramine (also sold under the brand name Pondimin) and phentermine. Redux was another, slightly modified version of fenfluramine called dexfenfluramine. Critics say that the FDA had evidence of the dangers of Redux before the drug was released but chose to approve it anyway.
- 3) The documentary also examines the impact of the "Prescription Drug User Fee Act." This piece of legislation, passed by Congress, allows drug companies to pay a fee of more than \$500,000 with each drug application so that the FDA can hire more drug reviewers, thereby speeding up the drug approval process. Critics say that the law has created a too cozy relationship between the FDA and the Pharmaceutical companies that they are supposed to be regulating.

### **Some questions to consider:**

- When the FDA approves a drug, does that mean it is "safe and effective?"
- Where does the FDA get its funding for drug safety?
- How does the FDA find out about adverse events?
- How does the FDA decide to pull a drug from the market?
- What role does the FDA play in the drug development and approval process?