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**Poor FDA** **drug approvals**

Poor drug approvals by the US FDA have cost thousands of lives, reinforcing the need for expert medical data and assessments of drugs

1. **Vioxx**, an anti-inflammatory medication intended to treat arthritis, was the subject of one of the largest recalls in history. After it was approved in 1999, it was prescribed to over 20 million people and was one of the most widely prescribed drugs of 2003. The following year, it was recalled. While original clinical trials showed no increased risk of heart attack or stroke, later studies revealed a large number of heart attacks associated with the drug. FDA later estimated that Vioxx had been associated with more than 27,000 heart attacks or deaths linked to cardiac problems.
2. **Cylert**, first released in 1975, was intended to treat ADHD/ADD by stimulating the central nervous system. Geared towards children, it proclaimed it had minimal cardiovascular effects. And, indeed, there were no heart problems — just liver toxicity. There were 13 cases of acute liver failure reported to the FDA, 11 of which resulted in death or liver transplant. While this number may seem relatively low, the reported figure is based on the ability to positively recognize the connection between the drug and the health problem. According to the nonprofit group Public Citizen, who petitioned for the removal of Cylert from the market in 2005, as well as the reported cases of liver failure, there were 193 “adverse drug reactions involving the liver in patients younger than 20 years old” between 1975 and 1996.
3. **Darvon / Darvocet** was on the market for 55 years as an opioid pain reliever. And while the “non-narcotic analgesic with the potency of codeine!” may have gotten rid of that headache, it was awful for your heart. In creating serious cardiac abnormalities, Darvon / Darvocet was responsible for 2,110 deaths between 1981 and 1999 alone.
4. **DES**, a synthetic form of estrogen, was marketed to expecting mothers as a drug to prevent spontaneous abortion, miscarriage, and premature labor. It was actually extremely unsuccessful at accomplishing any of the above. Instead, it created a slew of other problems that affected multiple generations, including:
	1. Cervical and Vaginal Cancer
	2. Birth defects and developmental abnormalities
	3. Increased risk of breast cancer (and a high risk to die of breast cancer)
	4. Risk of cancer in the child
	5. Increased risk in fertility and pregnancy complications
	6. Early menopause
	7. Testicular abnormalities

Approximately 5-10 million mothers and female fetuses were exposed to DES, and although the number of users fell in the 1960s (when it became widely understood that the drug was not doing what it was intended to do), studies soon showed that mothers who took DES during the first five months of pregnancy were more likely to suffer from complications with their reproductive systems. The FDA finally banned it in 1971.