



## FDA in Bed With the Drug Boys on Deadly Propulsid

### Why We Missed the Warning Signs of an Unreliable Drug System



It has long been suspected that mega-drug makers were negotiating behind-the-scene deals to keep their potentially toxic drugs on the market. According to corporate and government documents, the Food and Drug Administration (FDA) may have an inadvertent hand in facilitating that behavior.

#### Case in point: Propulsid

The fatal side effects evoked by Johnson & Johnson's popular heartburn medicine Propulsid and the desire to make a profit at the expense of the public's health. For example, when federal officials informed Johnson & Johnson that Propulsid might be withdrawn from the market altogether, the government and the company negotiated new warnings for the drug's label rather than looking out for the public's best interest and immediately removing the drug from the market.

And it wasn't until two years later with mounting reports of heart injuries and deaths that Johnson & Johnson finally pulled the drug from the market. At that time, a government hearing threatened to highlight the drug's long and concealed record of trouble. It's that hidden record in conjunction with newly obtained corporate and government documents that allowed the public to see:

- A pharmaceutical company focused on saving a profitable drug despite growing evidence of harmful effects.
- A drug agency with an inability to monitor and regulate pharmaceuticals effectively once they hit the market.

Though Johnson & Johnson eventually made five significant changes to Propulsid's warning label and sent five letters to doctors across the country, for many innocent patients it was simply too late.

#### Propulsid's Horrific History

The history behind Propulsid has many eerie similarities with some of the painkillers currently at the heart of controversy. For example, just as Pfizer failed to publish an early study of Celebrex that indicated a heart risk, dozens of studies on Propulsid sponsored by Johnson & Johnson that might have warned doctors away were also never published. Moreover, Johnson & Johnson was able to delay and soften some proposed label changes, just as Merck later did with Vioxx.

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But let's start at the beginning ...

The first signs of trouble regarding Propulsid emerged soon after the drug was approved in 1993 for the treatment of nighttime heartburn in adults. Then, in January 1995, the FDA received reports of 18 patients using Propulsid who developed serious heart arrhythmias; one infant died. Johnson & Johnson executives claimed such side effects occurred only in patients who took Propulsid with other drugs or who had heart problems.

By July 1996, regulators received reports of 57 Propulsid patients (including seven children) who had developed serious arrhythmias or other heart problems. In August 1997, a top FDA official wrote to Johnson & Johnson stating that Propulsid's increasing number of cardiac problems among infants and children suggested that younger patients may be at a greater risk. Regardless, by 1998, doctors were writing more than half a million prescriptions a year for children and infants.

Finally, in May 1998, the FDA proposed major changes to Propulsid's label. Yet throughout the negotiations and label changes, the company kept up its support of physician and patient groups that were promoting the drug as safe for use in children.

The company and the government negotiated for five years before Propulsid was finally pulled from the market. But clearly that wasn't soon enough; by January 2000, the FDA had reports of 80 heart-related deaths and 341 injuries among patients taking the drug. And just last year Johnson & Johnson agreed to pay some \$90 million to settle lawsuits that eventually involved claims that 300 people died and as many as 16,000 were injured from taking Propulsid.

[New York Times June 10, 2005](#)

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#### **Dr. Mercola's Comment:**

The above article provides strong evidence that the debacle involving COX-2 inhibiting drugs like [Vioxx, Celebrex and Bextra](#) had important historical precedents. Unfortunately, the evidence appears very strong that this is [typical behavior for many drug companies](#).

Perhaps you may not be surprised to learn that [those who are paid to protect your health](#) frequently cooperate, and some might say conspire, with the very companies they are mandated to monitor. When the fox starts protecting the henhouse, you can bet that your long-term interests are not at the forefront of the fox's intentions.

**When will our country begin to fully appreciate that the drug companies and the FDA are typically forced to action after large numbers of people pay the price for corporate greed with their lives?**

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