



STATISTICS

by Thomas Lumley

Faulty powers

It's what you're not looking for that may provide evidence of a defective product.

One of the problems in developing drugs is detecting serious side effects. People who need medication tend to be unwell, so it's hard to find a reliable comparison. That's why the roughly threefold increase in heart-attack risk among Vioxx users took so long to be detected. Many of the people who take prescription arthritis drugs are people who have a high risk of heart attack anyway.

It's why the roughly twofold increase in death risk for New Zealand kids using Fenoterol for asthma control, back in the 80s, took Neil Pearce's efforts and years of fighting the manufacturers to establish. Kids with severe asthma sometimes die of it, even without drug side effects.

An exception to this difficulty is very rare events: cases where you expect to see nothing and start seeing something. The diet drug combination fen-phen caused, rarely, the sort of heart-valve damage you don't see in young women without some obvious explanation. The antihistamine Teldane occasionally caused weird heart-rhythm disturbances. Less seriously, but more weirdly, Viagra sometimes causes blue-tinted vision.

Because these effects are rare even in people taking the drug, they don't get noticed until it is widely used, and they have to be reported by doctors and patients. As you can imagine, the quality and quantity of reporting is variable, but the NZ Pharmacovigilance Centre says New Zealand does well by international standards.





The current recall of some General Motors cars in North America is a good illustration of the statistical issues. From 2005 to 2007, some GM models had a defective ignition switch. A heavy key chain could provide enough force to turn the switch from "On" to "Accessories", which would shut off the engine and could disable the front air bags. At highway speeds, this is not helpful.

The recall affects about two million cars, adding up to about 14 million vehicle-years of driving. At the time of writing, there had been 31 crashes and 13 deaths attributed to the switch, about one death per million vehicle-years. Using the average US rates, that would be less than 2% of the expected number of deaths in crashes of these models, so the defect didn't actually make these models much less safe. It's just that your car shouldn't shut down and disable its air bags while you're driving, and it's the sort of thing you notice.

According to the Insurance Institute for Highway Safety, which measures this sort of thing, one set of models involved in the recall, the

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Driver error? 2007 Chevrolet Cobalt.

2005-2007 Chevrolet Cobalt, did have an unusually high rate of fatal crashes. At 117 driver deaths per million vehicle years, it ranked fourth for driver deaths per million vehicle-years from 2006 to 2009, and worst among small cars. The Cobalt had nearly twice the average driver-death rate for all cars, and its rate was 66% higher than that for other cars of the same size. The higher crash rate is probably due mostly to differences in drivers, and certainly almost none of it is due to the faulty ignition switch. Against that background, though, a less dramatic defect might never have been found. ■

DRIVER DEATHS PER MILLION CAR-YEARS

