

## In Search of a Direction Finding Duck in the Vaccine Debate

Written by The Conversation

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I love [Michael Leunig's](#) cartoons, their whimsy speaks to me, and I always felt myself a Mr. Curly type, in need of a direction finding duck sometimes in the storms of life. I was therefore saddened by his [recent cartoon](#) depicting a mother running from flying needles, with anti-vaccination overtones.

Leunig has always been on the “spiritual” side of any debate, however, in this case his vision has potential to cause adverse real world outcomes.

Leunig recently was interviewed on [ABC News Breakfast](#), in which [he compared vaccination to Thalidomide](#), the drug responsible for severe birth defects in the late 50's early 60's. The interviewer tried to say the Thalidomide example didn't count as there was a cover up by the drug manufacturer.

Well, no. The story is more complicated, and tells us about why modern vaccines are safe (and why new drugs are so expensive these days).

It's worth remembering that the Thalidomide disaster happened in the late 50's early 60's, Thalidomide was withdrawn in 1961, 54 years ago. Medicine was almost unrecognisable then. The majority of drugs we use today were not invented yet, there was a handful of antibiotics, the first diuretics being used as anti-hypertensives turned up in the mid 50's (beta blockers would not be available until the 1963 and the others much later), Valium was invented in 1963, [vaccines for measles](#), mumps, oral polio and many others all lay in the future.

And drug regulation was very, very different. In the UK and many other places while drugs were monitored for good manufacturing, there was no [requirement for support of claims for safety and efficacy](#). In the US, after an incident where [cough syrup containing diethylene glycol](#) poisoned hundreds of children, laws regulating the composition of medicines tried to control the safety of medicines.

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Thalidomide was discovered in 1954, after a series of animal tests and human clinical trials, it was introduced as a sedative and anti-emetic commercially in 1957. It had the advantage that it was safer than the barbiturates used as sedatives, with less potential for overdose. Studies in rats showed it was very non-toxic.

Shortly after the introduction of Thalidomide there was a rise in the occurrence of a rare form of birth defect, [phocomelia](#). Suggestions for the rise ranged from nuclear fallout to a poisoning campaign in West Germany by East Germany.

It was only in 1961 that two clinicians, Australian Dr. William McBride and Dr. Widukind Lenz in Germany separately came to the conclusion that it was Thalidomide taken by pregnant women that was the cause. Part of the reason that Thalidomide was so hard to pin down was that it produced malformation only during a [window 20 and 36 days after fertilisation](#). Thalidomide taken after 36 days post fertilisation had no effect, and it took astute observation to associate Thalidomide intake with the birth defects.

In November 1961, [Dr. Lenz contacted the German manufacturers of Thalidomide](#) about the effects, but the manufacturers claimed the risk was unproven. In November 1961, Dr. McBride also contacted the British manufacturers of Thalidomide with his results, which were also dismissed. Dr. Lenz then presented his results at a pediatric conference, while Dr. McBride's observations were published in [the Lancet](#). By December 1961 the drug was withdrawn from sale in Germany, the UK and Australia. Given the slower pace of communication in the 1960's, and different regulatory environments, it took until 1963 until the last country withdrew it.

As a result of the Thalidomide disaster, world-wide drug testing regulations changed. Proof of efficacy and safety were now required, with a range of animal models required before clinical trials, with careful attention to reproduction and birth defects. Thalidomide was never tested in rodent models of pregnancy, but [rodents are resistant](#) to the effects of thalidomide, and it would have been passed as safe in a rat or mouse test. Which is why we now use multiple animal models. Clinical trials are now longer with greater numbers of subjects. And we have post-marketing surveillance, to pick up rare side effects that may be missed in even large clinical trials.

These extensive safety testing trials, while not perfect, have meant that our new medicines are

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much safer than they were back in the 1950's to 60's. It also means it costs a lot more to bring a drug to market (nearly \$1 billion dollars per drug, with most of the cost in clinical trials).

The safety regime that we test vaccines under, including the long term follow up, is a **direct** result of the lessons learned from thalidomide. We now have decades of evidence that vaccines are safe, and [do not cause autism](#) or allergies, or any of the other maladies that have been claimed to be associated with them.

Indeed, measles vaccination is associated with a significant **fall** in [all cause mortality](#) , [Haemophilus influenzae](#) Type b (Hib) vaccine not only reduces death from Hib but also reduces the risk of leukaemia.

Maternal instincts, as in [Leunig's cartoon](#) , are important, but counter-intuitively [instincts can be dangerous](#) . The instinctive reaction of a drowning person to grasp onto objects has killed over [100 attempted-rescuers](#) from Australia and New-Zealand.

We have direct and long-term evidence that vaccines are safe and save more lives than just from preventing the disease they are targeted against. We should not let instinct override these facts and, like a drowning person grasping something to cling to, cause a fatal outcome.

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