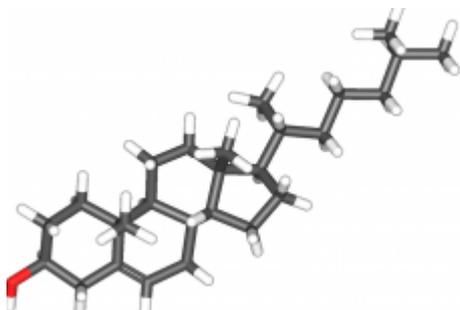


Hey pharma critics, have a heart

By ACSH Staff — November 24, 2014



Today we give a shout out to Dr. John LaMattina, the former

president of R&D at Pfizer and now regular commentator at *Forbes*.

His November 21 [commentary](#) [1] on Merck's efforts to develop a new heart drug speaks volumes about the difficulty and expense of new drug discovery, but also addresses less obvious issues faced by companies, especially the risk of navigating areas that have had mixed results, and the benefit of the ensuing clinical trials to medical knowledge, regardless of whether the drug succeeds or not.

ACSH's Dr. Josh Bloom, also a Pfizer graduate says, Lost in the argument over drug prices is exactly what John discusses that most drugs fail in the clinic and sometimes spectacularly so. This has to be factored into drug pricing and this is rarely understood or acknowledged by industry critics.

It would be difficult to come up with a much better example of spectacular failure than what happened to Pfizer's torcetrapib, an experimental drug designed to raise HDL (the good cholesterol).

It did just that, but in 2006, after Pfizer spent \$800 million, clinical trials showed that there were significantly more deaths in the group taking Lipitor plus torcetrapib than the group that took Lipitor alone. The entire program was dropped.

This catastrophic failure is explained very clearly by chemistry uber-blogger Derek Lowe in his 2007 [opinion piece](#) [2] in *Chemistry World*, which is published by the very prestigious Royal Chemistry Society. Lowe concludes, The largest drug company in the world [Pfizer] just lost what could have been their biggest-selling drug ever, and only time will tell whether the clinical disaster was avoidable. But for now, everyone in the field is holding their breath, because nothing's obvious and nothing's for certain.

Roche suffered a similar fate in 2012 when their Dalcatrapib a drug that works by the same mechanism cholesteryl ester transfer protein (CETP) failed to show any effect.

Does this mean that all cholesteryl ester transfer proteins (CETP) are doomed? Apparently not,

since Merck is now conducting another huge clinical trial (called REVEAL), of their own CETP inhibitor anacetrapib plus Lipitor, which will run through 2017 (it began in 2011), and is estimated to cost Merck \$500 million.

Risky? You bet.

LaMattina says, Does this mean that REVEAL will be as positive as IMPROVE-IT? That s not easy to predict since it is hard to gauge the impact that anacetrapib s HDL elevation will have. To date, experimental drugs that raise HDL have not shown long-term benefits.

He also points out that, Merck has a lot to gain if REVEAL is successful, as anacetrapib will become a major new drug. However, in the IMPROVE-IT and REVEAL studies, Merck probably invested close to a billion dollars with no assurance that either study would have a favorable outcome.

Yet, even if REVEAL fails to show any benefit, LaMattina notes, [T]he knowledge gained in understanding the consequences of lipid modulation is invaluable to cardiologists and the patients that they are treating.

This is just more evidence that the pharmaceutical industry, which relies primarily on new drug discovery, is the riskiest industry in the world, says Dr. Bloom. The business model is based on failure, with an occasional success. This is the main reason why new drugs cost so much.

So, why can t this type of research be done outside of the industry?

LaMattina has a simple answer: It must be stated that such studies can only be done by a big pharmaceutical company like Merck. These type of studies cannot be funded by the NIH nor small to midsize companies. They simply can t afford them.

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Links

[1] <http://www.forbes.com/sites/johnlamattina/2014/11/21/do-the-improve-it-results-offer-promise-for-another-merck-heart-drug-anacetrapib/>

[2] <http://www.rsc.org/chemistryworld/Issues/2007/January/OpinionInpipeline.asp>