PHARMAPHOBIA

HOW THE CONFLICT OF INTEREST MYTH UNDERMINES AMERICAN MEDICAL INNOVATION

THOMAS P. STOSSEL
“Pharmaphobia is a blunt, honest, smart, frightening, and unvarnished look at why we need to stop thinking in terms of ‘good guys and bad guys’ and start thinking about allies and partners. It’s the only way to save American healthcare.”

—Peter J. Pitts, former FDA associate commissioner; president, Center for Medicine in the Public Interest

“A distinguished Harvard hematologist and basic researcher, Thomas Stossel is passionately interested in ensuring that scientific progress is translated into tangible benefit for patients. In Pharmaphobia, Stossel embraces a nuanced and integrative vision that values both innovative science and market forces. Patients are fortunate to have a determined and relentless clinical champion like Stossel in their corner.”

—David A. Shaywitz, MD, PhD, chief medical officer, DNAnexus; co-founder and west coast innovation lead, MGH/MIT Center for Assessment Technology and Continuous Health (CATCH)

“At last, someone willing to challenge the Zeitgeist. In Pharmaphobia, Thomas Stossel . . . makes clear how America’s obsession with hidden motives and imagined conspiracies has deprived us of the kind of advice and products that could save our lives.”

—Paul A. Offit, MD, professor of pediatrics, The Children’s Hospital of Philadelphia

“At last, a scholarly treatise on excessive conflict-of-interest regulations that impede the interaction of academic scientists with companies that can turn their discoveries into therapeutic triumphs. This book is a must-read for all who believe that one day they will need a medicine or device to relieve their pain, or to forestall death.”

—Michael Brown, MD, professor of medicine and director of the Jonsson Center for Molecular Genetics at UT Southwestern; recipient of the 1985 Nobel Prize in Physiology or Medicine

“Only a skeptic who has spent a half-century inside the belly of the academic medicine beast would have the knowledge and experience to write this brilliant, take-no-prisoners expose of what Thomas Stossel dubs the ‘conflict-of-interest narrative.’ This book will prove to be a landmark in the counter-revolution that aims to improve both the medical and legal systems.”

—Harvey Silverglate, criminal defense and civil liberties trial lawyer; author of Three Felonies a Day: How the Feds Target the Innocent (2009)
1. Why did you decide to write PHARMAPHOBIA: How the Conflict of Interest Myth Undermines American Medical Innovation?

I wrote the book for two principal reasons.

The first is to convey four poorly appreciated facts.

1. Over the nearly 50 years I’ve been a physician health care has improved. As examples, our lifespan has increased by 10 years, we’re half as likely to die of a heart attack or stroke, and suffer a lot less from arthritis as we age.

2. The basis of these improvements is the incredible tools health care professionals have at their disposal: for example, statins for preventing heart attacks and strokes, colonoscopes to prevent cancer and arthritis drugs and artificial joints to preserve mobility.

3. These tools predominantly originate from the private drug and medical device industries and from health care professionals partnering with those industries.

4. We acquire those tools with great difficulty and at great expense.

The second reason is to expose how for the past 30 years opportunists have been responsible for minimizing industry’s contributions to health improvements and denying the costs of achieving them. These individuals claim that if health care professionals or researchers take payments from those industries, they become corrupt and risk their reputations by performing flawed research or harming patients for money. The code slur for this alleged behavior is “conflict of interest.” I define these critics as “conflict-of-interest narrative instigators.”

These instigators are wrong, and I wrote the book to set the record straight. The book collates the facts and arguments that can be used to rebut the confident but false assertions of the conflict-of-interest instigators.

2. You contend that doctors and academic researchers contribute to medical progress—but private industry is the great engine of American medical innovation. Why is this the case? And why does private industry require partnerships with doctors and researchers to drive innovation?

I’ve done medical research for most of my career, and people say that I’ve been successful at it. I hope that this research will save lives someday, but only drug and device companies can make that happen. Physicians and academic researchers by themselves certainly make contributions, but they lack the resources and the skill sets that do the job. Only industry can do it.

3. In PHARMAPHOBIA, you argue that an ideological crusade has used distortion and flawed logic to make medical innovation even more difficult and expensive in a misguided pursuit of theoretical professional purity. Please explain.

The “purity” pitch is a moral bullying campaign pitched by the conflict-of-interest instigators that is based on no longer relevant remnants of the history of medicine. For thousands of years, physicians, such as they were, had little influence on healthcare and
had very low status. To try and elevate it, they pretended to be like priests, wearing robes and spouting Greek and Latin. But priests never had to prove they got you into heaven, whereas it was obvious that physicians were ineffective – so the ploy didn’t work. When finally, thanks to science, doctors could help patients, they had to compete with a thriving mail order “patent medicine” business. So then medical leaders countered by claiming that real – as opposed to patent – medicine wasn’t a business – it was a “calling.” But that’s ridiculous. Medicine is a business. Nevertheless, the conflict-of-interest instigators have revived those antiquated ideas and browbeat physicians and researchers who accept industry payments as lacking altruism and being untrustworthy.

4. What regulations have been adopted as a result of this conflict-of-interest narrative?

There have been two sets of impediments to medical progress. The first was for medical schools to establish nanny oversight of researchers who receive funding from industry for their work. The nannies waste researchers’ time and, in some cases, arbitrarily and inappropriately restrict the type of research that can be done. The idea for such oversight was that industry payments encourage researchers to lie and cheat to sustain corporate sponsorship. In fact, it’s never happened.

The second regulation set spread into the entire healthcare system. Activities considered perfectly normal in our economy such as product marketing, providing product samples for patients, allowing professionals to educate one another about new drugs and devices, not to mention handing out trivial items like pens and refreshments got restricted or banned outright. No evidence exists that these activities ever harmed anyone.

5. Are there legitimate conflict-of-interest concerns that should be addressed by policymakers?

The answer is “no.” Of course, in an enormous enterprise like healthcare, bad behavior occurs and should be punished. But essentially all the alleged adverse effects of conflicts of interest regarding medicine’s interaction with drug and device companies are non-existent.

6. How have bureaucrats, reporters, politicians, and lawyers benefitted by attacking the medical products industry?

Corruption sells whether it’s real or not. Politicians get attention and lawyers profit no matter which side of controversies they’re on.

7. What impact has this conflict-of-interest movement had on medical innovation? How has it diverted resources from medical research to compliance? What impact have regulations had on interactions between industry, researchers, physicians, and patients?

Regulations always slow things down, and compliance and enforcement divert precious funds from research and development. It takes on average 16 years and costs over $2 billion to get a new drug approval by the FDA. For patients desperate for new treatments and cures, such delays can be lethal. Marketing restrictions mean doctors don’t learn about drug and device advances. Delays or prevention of potentially innovation-promoting relationships between researchers and industry have been
documented. The myth that device and drug development isn’t difficult and expensive encourages enactment of taxes on companies and calls for price controls. Both inhibit innovation.

8. **Looking ahead, without reform should Americans still anticipate revolutionary drugs and medical devices to prolong our lives and improve our quality of life?**

Without reform, innovation will continue to be slower than it should, and patients will suffer.

9. **How has your career as a physician-researcher with experience working in the biotechnology industry influenced your perspective?**

It totally repaired the inverted reality imparted by medical schools that all the good ideas come from universities and that companies exploit them and profiteer. Experience is a great teacher.

10. **What solutions and reforms do you advocate? What can average citizens and leaders in government do to promote reform?**

As I’ve watched the conflict-of-interest myths grow from strength to strength over the past 30 years, it’s been obvious that medical practitioners and drug and device companies have been passive and accommodated those myths. A sure-fire formula for losing respect is to give away credit for the good things you do and taking the blame for crimes you don’t commit. I urge healthcare providers and drug and device companies wake up and fight back, but I look to the general public, especially patients, as our best hope. For example, citizens or their loved ones, especially those with presently poorly treatable diseases, should question a 2.3% tax on medical devices that is part of the Affordable Care Act. The tax can make barely profitable companies unprofitable and put startups at the cutting edge of innovation out of business. People also be aware of another part of the Act known as “The Sunshine Law” that requires companies to report to the government payments to health care providers of as little as $10. This law is not only insulting, insinuating that such trivial payments can corrupt, but diverts scarce resources for R&D to payment reporting.