Medical Drug Regulations  
Opposition Brief by Drew Magness   


Drugs designed to help people shouldn’t kill people.

That’s the key thesis behind two of the strongest affirmative arguments this year:

1. We need safety regulations on drugs
2. Drug patents cause companies to want to hike their drug prices and bar people from buying the drugs due to an inability to afford them.

Luckily, both of these arguments can be answered through another simple argument: FDA limitations do more harm than good.

Your argumentation here is twofold. First off, you argue that the FDA is an ineffective way to regulate drugs because of the very nature of the incentives behind the behemoth of FDA red tape. These incentives make FDA people overly cautious. They get bad press if a dangerous drug gets through the program, but don’t get any bad publicity if thousands of people die without access to the drug. Not only that, but FDA safety regulations are archaic and ineffective because they oftentimes approve unsafe drugs and don’t let safe ones get through.

Beyond that, argue that patents aren’t what causes price hikes, but rather the obstinate inflexibility of FDA regulations and rising costs cause the costs of producing drugs to skyrocket which is why some producers must raise prices. Also, we need patents because they ensure that companies will make a profit to cover the insane costs of producing and researching new drugs.

In essence, the FDA is an ineffective agency and the very idea of drug regulation will always do more harm than good. Don’t forget your alternative! Private certification and advisory boards help consumers make better decisions while still protecting their private property rights.

Opposition Brief: Medical Drug Regulations

Regulations Caused Shkreli Price Hikes

Nick Stockton September 23rd 2015 (A general assignment science reporter, has covered everything from mass spectrometry to military tech, global warming to gene editing. He also has a background in defense, finds geopolitics fascinating, knows his way around boats, and likes building stuff.) “How Prescription Drugs Get So Wildly Expensive” Wired <https://www.wired.com/2015/09/prescription-drugs-get-wildly-expensive/>

How can that be? Drug companies and greed are supposed to go together like bankers and um, greed. Shkreli recently capitulated to the public outrage and said he’d drop his drug’s price. But he hasn’t backed down from his rationale for the original price hike: This is what it takes to do research, to be profitable, to be successful in his highly regulated industry. And in a way, he’s right. Long before you ever have a chance to balk at drug prices, the companies that make the medicine rack up billion-dollar tabs from research, development, and clinical trials. Insurance companies negotiate for distribution, and whittle more money away from a company’s bottom line. Not to mention that without profits, investors won’t invest in pharma, and drugs won’t get made. So is Shkreli really an excessive rogue actor, or is he merely playing by the same rules as the rest of the pharmaceutical industry?

FDA Interpretation of Patents At Fault. Not Patents Themselves.

Alfred Engelberg October 29th 2015 (Alfred B. Engelberg is a retired intellectual property lawyer and philanthropist. During his legal career he was a Patent Examiner in the United States Patent Office, a patent trial attorney in the United States Department of Justice, and a member of the New York City law firm of Amster, Rothstein & Engelberg. As counsel to the generic drug industry, he played a major role in drafting the Hatch-Waxman Act of 1984 which created the modern generic drug industry. Subsequently, he specialized in litigation challenging the validity of patents claiming a number of commercially important prescription drugs. In recent years, Mr. Engelberg has been active as a writer, advisor, and speaker on policy issues related to affordable medicines and intellectual property rights in the United States and around the world.) “How Government Policy Promotes High Drug Prices” Health Affairs Blog <http://healthaffairs.org/blog/2015/10/29/how-government-policy-promotes-high-drug-prices/>

In contrast, Federal law prohibits the Food and Drug Administration (FDA) from approving a copy of a new drug for a period of seven to 12 years *even if there are no patents*. The FDA is also prohibited from approving a generic drug anytime a claim of patent infringement is alleged — a policy that has encouraged many frivolous patent claims just to delay competition.

15 Years to Get Through FDA

Dr. Lee Hieb December 31st 2012 (Dr. Lee Hieb is an orthopedic surgeon specializing in spinal surgery. She is past president of the Association of American Physicians and Surgeons) “How many have died because of the FDA” World Net Daily <http://www.wnd.com/2012/12/how-many-have-died-because-of-the-fda/#9fQZD4Sc8DuvSRzW.99>

Notice it took less than two years to get aspirin from bench studies to worldwide distribution. Today, on average it takes 15 years of a drug company’s time and research and development resources to pass through the sphincter of the FDA. What is the result of this long, drawn-out process? Are we – as they claim – safer? I think just the opposite.

The FDA Kills Because of Failing Incentives

Dr. Lee Hieb December 31st 2012 (Dr. Lee Hieb is an orthopedic surgeon specializing in spinal surgery. She is past president of the Association of American Physicians and Surgeons) “How many have died because of the FDA” World Net Daily <http://www.wnd.com/2012/12/how-many-have-died-because-of-the-fda/#9fQZD4Sc8DuvSRzW.99>

But the real truth is more one of human nature. As Mr. Kazman points out, the most devastating problem to an FDA regulator is not some silent death in Kansas due to lack of a new cardiac drug, but rather injured patients lined up before a congressional committee testifying about a drug that *was* passed. As a variant on the principle that if you do nothing you can never be wrong, FDA regulators’ self-interest is best served by passing the fewest drugs possible. During one 10-year period, not one new cardiac drug was approved – and this from the world’s leading pharmaceutical industries. So, the next time you hear an FDA honcho at a press conference bragging how they will be saving 35,000 lives each year with the new cardiac drug they just passed, remember the 35,000 people who died each year waiting 15 years for that FDA approval.

FDA is Ineffective Bureaucracy

Dr. Lee Hieb December 31st 2012 (Dr. Lee Hieb is an orthopedic surgeon specializing in spinal surgery. She is past president of the Association of American Physicians and Surgeons) “How many have died because of the FDA” World Net Daily <http://www.wnd.com/2012/12/how-many-have-died-because-of-the-fda/#9fQZD4Sc8DuvSRzW.99>

And it is important to realize that the FDA is not a team of crack researchers – although it does incestuously employ former drug company people – nor is it a group of actively practicing physicians. They are paper pushers. When the anti-inflammatory drug Vioxx came out, as an orthopaedic surgeon seeing a high volume of patients, I tried using it. It had undergone “extensive testing” and “FDA approval.” Within *three weeks*, I advised my patients to get off the drug, told my office manager not to refill any prescriptions, and had her call all of our patients we gave the drug to and suggest they switch to another brand. Within *three weeks* of observing patients, I had seen too many side effects, the same side effects that caused the FDA to withdraw the drug from market *three years later*.

FDA Causes Prices to Skyrocket

Dr. Lee Hieb December 31st 2012 (Dr. Lee Hieb is an orthopedic surgeon specializing in spinal surgery. She is past president of the Association of American Physicians and Surgeons) “How many have died because of the FDA” World Net Daily <http://www.wnd.com/2012/12/how-many-have-died-because-of-the-fda/#9fQZD4Sc8DuvSRzW.99>

And then there is cost. It has been estimated that 25 percent of the cost of any drug is due to the FDA. I suspect it is higher. If aspirin is any indication, what the FDA drags out into 15 years could be done in two or three. Between 1994 and 2004, according to a study from the FDA itself, the utilization of NMEs – new molecular entities (i.e. new drugs) – went down by nearly half while the cost of research nearly doubled. And this in an age of computerization, sequencing of the human genome and efficient chemical engineering. The lost opportunity and costs are staggering.

FDA Incentivizes Hiding Problems

Dr. Lee Hieb December 31st 2012 (Dr. Lee Hieb is an orthopedic surgeon specializing in spinal surgery. She is past president of the Association of American Physicians and Surgeons) “How many have died because of the FDA” World Net Daily <http://www.wnd.com/2012/12/how-many-have-died-because-of-the-fda/#9fQZD4Sc8DuvSRzW.99>

There is another result of the long FDA approval: dishonesty. Again, consider human nature. When raising children to be honest, does it help to punish them severely for being honest about mistakes? Or does it cause them to hide their mistakes? When the cost of honesty is too high, there is a tendency to dishonesty. In a free market, such as the environment for the creation of aspirin, when a line of research proves unsafe, it is easy to drop it and move on – because the research and development costs are relatively low company expenditures. But when the major company budget is sunk into a product now 13 or 14 years into the FDA approval pipeline, what will the company do if problems are noticed? Obviously if serious life-threatening issues arise, they cannot avoid withdrawing the drug. But how about lesser problems that may be “under the radar”? It would only be natural for companies heavily invested in a drug to minimize problems toward the end of development so as not to lose their considerable investment.

A system that values Private Property Rights is Preferable

Dr. Lee Hieb December 31st 2012 (Dr. Lee Hieb is an orthopedic surgeon specializing in spinal surgery. She is past president of the Association of American Physicians and Surgeons) “How many have died because of the FDA” World Net Daily <http://www.wnd.com/2012/12/how-many-have-died-because-of-the-fda/#9fQZD4Sc8DuvSRzW.99>

So what is the answer? Remember when the Good Housekeeping Seal of Approval meant something? Or name brands? Manufacturers were free to produce products, and you as the consumer were free to choose name brands you trust over white labels, Seal of Approval items over those not-so-blessed. If we can’t disband the FDA – which would be my first choice to save untold taxpayer dollars – let’s at least make it an advisory board. You can choose to take unapproved (and thus cheaper) drugs, or you can pay more for the FDA-approved variety. Keep in mind, in our litigious environment it is certainly not in the best interest of any drug company to produce a bad drug. And in my hypothetical system, cancer victims are free to seek “unapproved” treatments, not having the luxury to await 30-year clinical trials. Drug prices would come down, not only for the big companies, but because now little companies could compete, and competition always reduces price. Most importantly, the marvels of today’s science, instead of being throttled by overregulation, will be unleashed to create a marvelous new world of medicine.

Costs 2.6 Billion Dollars to Produce a New Drug

The Tufts Center on Drug Development November 8th 2014 (The study was authored by DiMasi, Henry G. Grabowski of the Duke University Department of Economics, and Ronald W. Hansen at the Simon Business School at the University of Rochester. The Tufts Center for the Study of Drug Development (http://csdd.tufts.edu) at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. Tufts CSDD, based in Boston, conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums, and publishes Tufts CSDD Impact Reports, a bi-monthly newsletter providing analysis and insight into critical drug development issues) “Cost to Develop and Win Marketing Approval for a New Drug Is $2.6 Billion” Tufts Center for the Study of Drug Development <http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study>

Developing a new prescription medicine that gains marketing approval, a process often lasting longer than a decade, is estimated to cost $2,558 million, according to a new study by the Tufts Center for the Study of Drug Development. The $2,558 million figure per approved compound is based on estimated:

* Average out-of-pocket cost of $1,395 million
* Time costs (expected returns that investors forego while a drug is in development) of $1,163 million

Estimated average cost of post-approval R&D—studies to test new indications, new formulations, new dosage strengths and regimens, and to monitor safety and long-term side effects in patients required by the U.S. Food and Drug Administration as a condition of approval—of $312 million boosts the full product lifecycle cost per approved drug to $2,870 million. All figures are expressed in 2013 dollars. The new analysis, which updates similar Tufts CSDD analyses, was developed from information provided by 10 pharmaceutical companies on 106 randomly selected drugs that were first tested in human subjects anywhere in the world from 1995 to 2007.

**Analysis:** Drug patents are needed in order to cover the 2.6 billion it takes to create a drug. The costs of creating a new drug are MASSIVE. If companies know that someone is just going to swoop in and sell a generic version of their drug for a cheaper price and drive them out of business, they’re going to be less incentivized to actually produce new drugs.

We spend more money and produce fewer drugs

Matthew Herper in Forbes August 11th 2013 (I believe this is biology's century. I've covered science and medicine for Forbes from the Human Genome Project through Vioxx to the blossoming DNA technology changing the world today.) <https://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/#7b54215713c3>

A 2012 article in Nature Reviews Drug Discovery says the number of drugs invented per billion dollars of R&D invested has been cut in half every nine years for half a century. Reversing this merciless trend has caught the attention of the U.S. government. Francis Collins, the director of the National Institutes of Health, in 2011 started a new National Center for Advancing Translational Sciences to remove the roadblocks that keep new drugs from reaching patients.