

Good afternoon.

My name is Jim Waters, and I'm privileged to serve as president of the Bluegrass Institute for Public Policy Solutions, Kentucky's first and only free-market think tank, which was founded in 2003.

Whether we're talking about manufacturing, education or health care, it's vital that we understand that the free market works -- when allowed to do so. Competition drives innovation. Perhaps nowhere is innovation more important than in the area of researching and developing medicines that save lives.

I'd like to tell a short story to illustrate:

Once upon a time, an eagle's egg was knocked loose from its nest and rolled down the mountain into a barnyard full of chickens. Intending compassion, these chickens committed to protecting this egg until it hatched, after which they raised this creature -- not as a beautiful eagle -- but as just another chicken who scratched for grub and worms and flittered around the barnyard.

One day, a neighbor convinced the farmer who owned these chickens to let him take that eagle up the mountain to see if he could fly. When that man released him, that innate desire to live free and soar took over. That majestic bird stretched his wings and flew into the sky.

But what if he hadn't? What if he'd fallen to the ground and died? Would anyone dare claim the neighbor had done evil in giving that eagle the opportunity to try?

Should we really have a rope-a-dope drug-approval system that says "no" even to terminally ill human beings' right to try every option to save their lives -- even if -- in the end -- some of those lives do cease?

What if medical missionary Dr. Kent Brantly had died of the humiliating, wasting disease of Ebola even after taking Zmapp while in Liberia -- six thousand miles away from family and utterly alone?

Sure, he had a right to know that no human had ever been tested and that it hadn't fully passed FDA safety review, which have been going on for years. But who should have told him that he had no such right to try it until some government agency finally got around to approving it, even as he stood close enough to death's door at age 33 to push it open?

Who had the right to deny Kalamazoo College sophomore Emily Stillman the opportunity to try a vaccine against meningitis that was available but not yet approved by America's drug bureaucracy -- even after years of testing and trial?

Too often that bureaucracy has cried in chicken-little fashion: "the sky might fall" while denying the Emily Stillmans of our world the right to try and save a life -- her life ... as if that life belonged to a government agency.

Yet no government agency blocked Dr. Brantly's access to the experimental Zmapp and the ensuing miracle, which finds him today fully healed and still serving the world's poor and downtrodden.

It's a moving story. Don't misunderstand. I'm very happy for him and his family. But what about all the others that also had a right to at least try? Who also could have lived a miracle?

Twelve-hundred people make it through the FDA's "compassionate use" application each year. But the process is complicated, time-consuming and expensive. The FDA keeps no record of the many, many people who try but are denied such application.

The process is complicated, time-consuming and expensive. The first step in the process requires a doctor to complete an application to the FDA that takes around 100 hours to complete, after which the manufacturer must also submit lengthy documentation requirements. The FDA then has a month to review the submission and either grant or deny the request. If there are any questions, that one-month clock starts over.

After the FDA approves a request, a separate committee not affiliated with the FDA -- called an Institutional Review Board -- also must approve the patient's use of the drug. This board can also take up to a month to reach a decision.

Sadly, there are many documented cases of patients dying while their application is being considered.

It seems like our government's experimental drug policy has been more about control ... about picking and choosing. Epipen, for instance, is a wonderful drug. But without the heavy-handed regulatory process currently enforced by the FDA, I'm convinced other manufacturers could not only create similar -- but better -- products.

Perhaps most disturbing about the Epipen situation is that the FDA has limited the manufacturing of the lifesaving anti-allergic reaction device to a single company under the guise of ensuring safety. Yet this regulatory overreach has not only dramatically increased the price of the product, it has discouraged other manufacturers from developing even better products.

This is cronyism at its worst -- favoring a single company while shutting out other firms who want to participate and discouraging the research and development that would bring new and better drugs to market.

Where's the compassion in forcing drug manufacturers through what amounts to be a seven-to-10-year, \$2 billion process while people die who were willing to accept the risk of drugs that may not have completely jumped through all FDA hoops? It's not compassionate, and it certainly doesn't seem fair.

What if Dr. Brantley had taken Zmapp and then died anyhow? What if Emily Stillman had died even if she had taken the vaccine? Should that risk outweigh the potential of life restored? Should some government agency even be taking the temperature of such a risk?

An alternative ending to that parable that's often been used tells about how the eagle died in that chicken coop, having never been given the opportunity to try ... never knowing he could fly. Who knows the miracles that await by giving those even at death's crossing the right to know, the right to try, the right to see if they just might soar once again? -*Jim Waters, Bluegrass Institute for Public Policy Solutions*