

There was a time when it might not have seemed particularly noteworthy that a presidential nominee was competent and sane. But we do not live in those times. So it is actually worth taking notice of the fact that Scott Gottlieb, Trump's nominee to head FDA, is competent and sane. And unlike some other Trump nominees like Ben Carson, he actually has [relevant expertise](#), having taken his medical training at Mt. Sinai in New York, served as Deputy Commissioner for Medical and Scientific Affairs at the FDA from 2005 to 2007, and earlier as a senior advisor to the FDA Commissioner and as the FDA's Director of Medical Policy Development. That doesn't necessarily make him a good appointment, as I'll discuss below. But it does count for something.

I've read a couple of Gottlieb's writings. In [one](#), he argues that Epi-Pens are so overpriced because an FDA policy relating to generic drugs makes it difficult for competitors to enter the market. In particular, he says, a drug with a different delivery system can't qualify, so the competitor would have to work very much like the Epi-Pen, which would infringe Epi-Pen's intellectual property rights. I'm in no position to provide an independent assessment of the validity of this argument. But it's obviously located in a completely different intellectual space than Scott Pruitt's nonsensical misstatements of climate science. In another [paper](#), he argues that drug pricing is irrational because of a practice of disguised rebates that were originally aimed at large HMOs but were then offered to pharmacies in a convoluted form due to an antitrust settlement. It's hard to assess this argument without a deep understanding of the economics of the industry, but it's a rational policy claim that invites reasoned discussion. That's also a welcome shift from some of the science denial and fact avoidance we've seen in this Administration.

Nevertheless, there are some serious concerns about Gottlieb. He's got very close industry ties, allegedly [having received](#) over \$400,000 in just the past few years. He's also a partner in New Enterprise Associates, a life sciences venture fund. That gives me some reason to worry that he'll be too quick to identify the interests of the industry with the interests of patients. He now says that he'll recuse himself from decisions involving about 20 companies for his first year. His connection with the American Enterprise Institute may also suggest that he's too ideological rather than science driven. He clearly thinks that the FDA is overemphasizing drug safety at the expense of the potential benefits of innovative drugs. But there's some real evidence behind the FDA's reluctance to fast-track drugs, as an [LA Times](#) story explains.

Trump has proposed doubling the user fees that drug companies and others pay for pre-marketing review. Trump has also promised to "reform the Food and Drug Administration, to put greater focus on the need of patients for new and innovative medical products." This apparently means cutting back on FDA review of the efficacy of drugs. Interestingly drug

companies aren't enthusiastic about this, because they are worried that insurance companies won't cover drugs without proof that they work. We'll have to see how much of Trump's agenda Gottlieb will try to accomplish.

Everything is relative. As the [Times](#) reported last Thursday, while there is considerable concern about his ties to industry, "others who know Dr. Gottlieb, including Democrats, praise his intellect and independent thinking, even as they acknowledge that he is likely to bring a more industry-friendly worldview to a sprawling agency of more than 16,000 employees." Under other circumstances, I would be very worried about Gottlieb's selection due to his industry ties. Compared to Scott Pruitt, however, he's a real gem, in that he doesn't actually hate the agency he'd be heading.