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Cross-Capitalism, Health Care, Politics

The Regulatory Capture Of The FDA

The mega-profit pharmaceutical industry relies on connections with the agency tasked with regulating it.

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Ever heard of Aducanumab? Probably not. It's a monoclonal antibody intended to treat Alzheimer's disease. It's also a product of the Food and Drug Administration's (FDA) approval process. Aducanumab was approved by the agency despite the fact that both private trials were dropped early because it was not clear that it was better than a placebo and could actually exacerbate the negative cognitive processes. One of these companies is Karuna Therapeutics, which was recently purchased by Bristol-Myers Squibb for $14 billion. Karuna's CEO Paul Friedman whose leadership is heavily weighted toward pharmaceutical industry profiles and connections, was a former senior FDA official who helped approve Prozac, Viagra, and Celebrex. Karuna's "neuroscience" focus sounds dangerous to me.

Regulatory capture is defined when a supposedly objective regulatory agency ends up promoting the ends of the industries they are regulating. Pharmaceuticals, I suppose, for quite a while, in the FDA's jurisdiction is the Bristol-Myers example. The majority of FDA officials are not corrupt, but the agency's mission is to promote the pharmaceutical industry and the government's connections to and influence on regulatory agencies. Full RCP disclosure: I was involved in an FDA drug approvals and subsequently worked for a company and lobbying on behalf of the company before my retirement.

For example, Dr. Thanos Lagakos, a former director of psychiatric products for the FDA, was a consultant to Bristol-Myers Squibb and Janssen Pharmaceuticals. Dr. Lagakos's FDA and pharma connections to mega-companies focused on treatments for schizophrenia, manageable for a regulatory processes. One of these companies is Karuna Therapeutics, which was recently purchased by Bristol-Myers Squibb for $14 billion. Karuna's CEO Paul Friedman, who was a former senior FDA official who helped approve Prozac, Viagra, and Celebrex. Karuna's "neuroscience" focus sounds dangerous to me

The fact that it's only approved provisionally, and still needs to be confirmed beneficial by phase 4 trials, makes the FDA's decision a little less horrible than I thought it was, but it's still horrible. They should modify the AAP to require that the phase 4 trials be complete, and show benefit, within a certain time frame. Deadlines, that's what we need. And if the benefit is too slow to meet the deadlines, too bad for the manufacturer. We shouldn't let them market the stuff if we're more than a certain limited time away from really knowing if it's gonna help anyone.

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YT14 → HandsomeMrToad · 6 months ago · edited

Phase 4 trials are by definition trials after preliminary or not so preliminary approval has been granted. Alzheimer's dementia is the biggest insititutional problem facing developed nations, so I guess FDA decided to try out phase 4 to prove or disprove the amyloid protein plaque hypothesis.

Specifically, with very mild cases... Or even someone who is 50+ without ANY symptoms but is homozygote for say apoE4. I know, I know, the first and second historic Alzheimer cases (very early onset) were both actually E3/E3. Still, E4/E4 is a known configuration that confers substantial predisposition.

In terms of how long? If one starts with very mild cases, or even a genetic predisposition without symptoms I would guess it will be at least a decade. The current Covid-19 vaccines give a sufficient cover for such an experimental approach. The currently running, decade-long phase 4 trials in multiple sclerosis are also quite informative.

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Wait and see what happens if and when Biogen completes the obligatory study. FDA could pull approval, or they could be pressured to do more studies. It depends a bit on whether the Alzheimer's community buys that the drug works. If you get enough testimonials from people who think it does, that translates to a lot of political pressure.

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A problem with the accelerated approvals is that a lot of companies fall behind in their commitments. There is a website for tracking that at FDA, but how many people know or care about that?

Further, if the drug is out in the market and approved, then no patient wants to be part of a randomized study because the drug is...FDA approved. So the trials are hard to do, take forever, and the manufacturers eventually tell the FDA that they can't fulfill their commitments. Oh, well.

Then, when the FDA sees a confirmatory study that shows no benefit or worse outcomes with the drug (as occurred with bevicizumab after accelerated approval for breast cancer) and the advisory committee recommends rescinding the approval then the patient advocacy groups line up to complain that the FDA is taking away their mother/father/grandfather/daughter's "only hope".

Not a good position to be in.

Approvals should be, as former FDA Commissioner Scott Gottlieb recommended "easy on/easy off" meaning not so exorbitantly expensive to obtain (to keep prices down) but easy to remove (to protect patients when things go wrong). Currently, it is very, very hard to pull an approval of a drug unless it is causing huge adverse events that cost the company money and they take the drug off the market due to lawsuits. Merck took Vioxx off the market for this reason, once the thrombotic risks were known to the public. FDA did not pull the drug, because there were people for whom it had a good risk-benefit analysis.

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I don't think it is regulatory capture. It looks more like FDA trying out a softer, EUA-like regime on other experimental treatments. The data on aducanumab are indeed very very soft. But I think FDA reasoned that the problem of how to treat Alzheimer will not be resolved without a mass-experiment, including therapeutic leakage to very early cases. After 40 years of research there is still no consensus on whether beta-Amyloid is the primary pathogen in Alzheimer. Studies like the current one will pave way to such a consensus one way or the other.
For example, if geriatric psychiatrists know for sure reducing Alzheimer plaque size won't help, they'll turn to other targets like tau tangles. Lot's of them in Alzheimer brains too...

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Les Brunswick · 6 months ago

Over the years, I have noticed conservatives switch back and forth on the question of regulatory agencies. Most of the time they complain that they are far too harsh in their regulations, and by doing so greatly damage the economy and society in many different ways.

But then once in a while a disaster will happen because a regulatory agency is too lax, and gives industry what it wants even though it is clearly wrong. When that happens, conservatives change their story 100% and tell us that regulatory agencies have all been corrupted by capture by industry. And then a month or two later conservatives will go back to complaining regulatory agencies are far too strict.

This all makes sense when you realize that both stories lead to the same conclusion, namely that regulatory agencies are a bad idea and should be done away with, because they inevitably either regulate too much or not at all.

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HandsomeMrToad → Les Brunswick · 6 months ago

It might be interesting to see whether there's a correlation between how people feel about this decision and how they feel about "right-to-try" laws.

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Les Brunswick → HandsomeMrToad · 6 months ago

What are right-to-try laws? I have never heard that phrase before.

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HandsomeMrToad → Les Brunswick · 6 months ago · edited

Here, this explains it just as well as I could. It's partisan anti-Trump (like much, probably most, of the medical profession) but the facts in it are correct and clearly presented. Including, the fact that the Federal right-to-try law created great photo-ops and opportunities for speeches and hype, but actually changed almost nothing.

https://undark.org/2020/09/...

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Right to try specifies terminally ill patients have the right to try an experimental drug before approval. But that has always been true, in fact for patients with any condition or any degree of severity (not just cancer or terminally ill).

This was a feel good ploy to make people think Trump was cutting red tape. I voted for Trump but this was not any real achievement so don't start on me.

If you contact a drug manufacturer about using their drug before it is approved you will be told to enroll in a clinical trial or if you are not eligible they likely will let you use it under expanded access or what used to be called compassionate use. You just have to fill out a request (2-3 pages) and the FDA approves them 99% of the time.

Most people have no idea what the FDA permits and what it forbids. Most doctors are too busy to find out. A lot of times doctors tell their patients the FDA won't let them use Wonder Drug X to get out of finding out how to get Wonder Drug X through expanded access, which is pretty routine for drugs in development.

On the other hand, a company may decide not to allow you to have their drug outside a clinical trial; it is possible that the supply is limited or your bad reaction will jeopardize their approval. In the end, it is their private property, and they get to make that decision. We don't (usually) appropriate some company's experimental drug and make them give it away (yet). That is a conservative position.

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Easy on/easy off approvals as advocated by Scott Gottlieb could be a better approach, but the agency should be rescinding bad approvals at a rate that indicates they are serious about it. So far, it is a rare event. Once the patient community concludes it "works" then conservatives say "let them try it". Only thing is, 3rd party reimbursement is usually tied to FDA approval. When bevacizumab was unapproved for breast cancer a lot people complained that FDA was taking away a therapeutic option, but the real issue is that bevacizumab was approved and on the market for other things, but once it no longer had approval for breast cancer, patients would have to pay out of pocket for it. Which is a conservative position, but many conservatives railed against pulling the approval.

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