# Summary

Montana is launching a risky experiment in which untested medical treatments will be sold freely inside the state. The moving force behind the legislation was provided by tech bros interested in longevity treatments.

Montana’s SB 455 throws caution to the wind. To qualify, a treatment must have gotten through the earliest stages of the FDA test process, involving tests on small groups to ensure that doses of drugs aren’t toxic to humans.  If a drug passes those minimal hurdles, it can be sold in the state, subject to safeguards that may or may not prevent unethical conduct. In the meantime, biotech firms will be making money from sick people for dubious treatments.

Montana has adopted a bold new law (according to advocates) or a reckless one (according to critics).  The new law allows experimental drugs and medical devices to be used on anyone–or at least anyone with enough cash–once treatments have passed very basic safety testing.  Whether the treatments work is apparently not something Montanans care about it. The moving force behind the legislation was provided by tech bros interested in longevity treatments.

To qualify, a treatment only has to get through the earliest stages of the FDA test process, involving tests on small groups to ensure that doses of drugs aren’t toxic to humans.  If a drug passes those minimal hurdles, it can be sold in the state, despite the lack of any evidence about effectiveness or possible side-effects. Considering that the treatments probably won’t be covered by health insurance or Medicare, it’s likely that the primary customers will be affluent, although it’s possible some less affluent people will use up their savings to get them. There’s a somewhat complicated set of requirements that are supposed to maintain some level of medical ethics, but how well that will work is anyone’s guess.  The first of the review boards required under the statute seems slanted in favor of “anything goes” libertarians.

Essentially, Montana is running an experiment on what happens to people’s health in a world  without FDA regulation. It’s hard to imagine that any ethics board would give a researcher permission to run this policy experiment on human subjects. Still, despite the ethics issues, Montana has gone ahead with it.  If nothing else, he experiment should produce some interesting legal, sociological, and medical information.

On the legal side, it's going to be instructive to see if firms can evade FDA jurisdiction, which would require avoiding any connection with interstate commerce. Ideally, the drugs or medical devices would be manufactured in Montana, there would be no interstate marketing, and transactions (as with marijuana dispensaries) would be in cash. (OK, that last part probably isn't required, although I do imagine a lot of the transactions will be in crypto.) But from what I can tell, the FDA generally does feel strongly about interstate advertising and transportation of unlicensed drugs and medical devices.

The tech bros who lobbied for this law are apparently hoping the FDA will look the other way while they openly violate federal law by using interstate commerce for their operations. This may be well true under the current Administration, which has little or no interest in evidence-based health protection. (Actually, the Administration seems to think shooting basically anything into your system is fine if it isn't a vaccine.) But future Administrations may be less blithe about gambling with patients' health and could even bring criminal prosecutions for intentional violations of federal law like shipping unlicensed drugs into Montana for sale.

There are likely to be other legal issues. If anything does go wrong in an individual case, there will surely be some interesting product liability claims. Others have mentioned the possibility of lawsuits against firms by other states' governments if their own citizens become guinea pigs.

Besides the opportunity to explore new legal issues, it will be interesting to see whether privatizing safety and effectiveness will work. I'm dubious about whether the state of Montana has the resources, expertise, or political will to police the private efforts. Given the fact that firms stand to profit by peddling untested drugs in Montana, there's good reason to question pious declarations of ethical intentions. And of course the more firms take advantage of the invitation, the more business Montana stands to gain, so it has an incentive to let firms do whatever they want.

If there's no effective outside policing, even putatively honest firms are likely to feel pressure to start cutting ethical corners in the interest of profits. Less honest firms may outright cheat. Still, I might be wrong, and Montana's privatized ethics requirements might be unexpectedly effective.

Finally, there's the question of whether any useful treatments emerge. The FDA has complex rules intended to get rigorous information about whether drugs and devices work and avoid serious side-effects. I don't see how one of these Montana

efforts would get a big enough sample to mean anything, and they certainly wouldn’t qualify as randomized control tests. But I suppose if the (statistically meaningless) results look promising, it might help a start-up get enough funding to undertake serious drug testing within the FDA process. So we *might* end up with a useful treatment we might otherwise have missed.

On the other hand, an adverse selection effect is at play. The most promising treatments are the most likely to use the existing FDA regulatory processes, so the ones that resort to Montana’s backdoor process will be disproportionately those with lower prospects for FDA approval. In effect, “going to Montana” is a signal that a treatment isn’t super promising, much like opening a musical in Bozeman rather than Broadway. So even if the system does help identify some treatments that are safe and effective, the proportion is likely to be lower than the FDA process.

Another adverse selection effect is that the firms that can make the most money from less rigorous oversight are the least ethical ones. This certainly doesn’t mean most firms will be unethical, only that they will be a disproportionate presence.

As you may have gathered from my tone, I have great doubts about this whole idea. But I could always be wrong. If nothing else, health policy experts may get some interesting data from Montana’s experiment in eliminating regulatory safeguards.