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From the New York Times, I'm Sabrina Tavernisi, and this is The Daily.
For decades, drug companies have argued that patents are critical to bringing new drugs to market. Today, my colleague Rebecca Robbins, on a case that suggests they can also create perverse incentives to hold new drugs back. It's Thursday, September 7th.
So Rebecca, you report on the pharmaceutical industry, and you've been reporting on a case involving a big name American drug company. Tell me about that reporting.
Yeah, Sabrina. So we all know that prices are really high for many drugs in the United States, and in some respects, that is by design. So the way the system works is we rely on for-profit companies to spend a lot of money to develop and bring to market new drugs. And in return for spending that money for taking all those risks, they get to have a monopoly the last four years. And that allows them to sell their medications for lots of money and keep those prices high. And there are actually laws and regulations that protect that monopoly. And part of the rationale for this system is that the promise of these profits creates incentives for the company to produce new and better drugs to help more people. But recently, my colleague Cheryl Gay Stolberg and I came across a case that I think raises serious questions about whether this system is always getting the best medications to patients as quickly as possible. And where does that story start? So I want to start with the story of a patient named David Swisher. Hi, Rebecca. How are you? I'm good. Thank you so much for your- So today, David is a 66-year-old retiree. He's living in Florida after retiring from a long career in the airline industry that took him all over the country for different jobs. And so back in 1997- I was living in Texas, South of Houston. And I just turned 40. David started feeling ill. And it was very intense. I mean, it was like you're aching from head to toe. I kept going into the emergency room like for a week telling him, I feel bad. Something's wrong. I have the flu. After the third time I went in there, really, really not feeling good. Someone was smart enough to send me upstairs and say, let's do a workover on this guy and see what's going on. And finally, after two nights in the hospital, one of the young interns, she came in and she just says, well, we figured out what's wrong with you. It turned out that he had HIV.
What was going through your head at that moment?
That I was going to drop dead.
And when he got his diagnosis, his mind immediately turned to his worst fears.
I'd lived through all that epidemic from December 6th from 1978 until 1984. And it just got so gloomy and dark.
He had a huge number of friends that he lost. It was a really, really painful time.
Like 80% of my friends had died in a six-year period and all of them were under 30.
They'd call me on Friday and say, David, I parked my car in a bad spot. I left the keys in your desk. Can you move my car so I can just doesn't get towed away and then bring it up to me in the hospital on Monday? Okay, so no problem.
I would go move the vehicle, go up on Sunday night to see him and find out they were dead.

So when David got his HIV diagnosis in the mid-1990s, he thought it was a death sentence.
But it turns out it wasn't. And that's because, by that point, drug companies were making huge strides in treating HIV with powerful new medications. But the first versions of these drugs had some really tough side effects. They were really challenging for patients to take.
In my mind, I'm thinking, that's fine. I'll be alive. You know, I'd much rather be alive than option, which wasn't good. But I was allowed to go back to work and I was pretty much, you know, I'd lost some weight and I didn't look really healthy, but I was able to regain the weight.
But over time, the medications became easier to take, fewer side effects, more convenient.
I went from a cocktail of a bunch of pills to one pill a day. And in 2004, a drug company called Gilead released a drug called Truvada. You may have heard of it today. It's used for both preventing HIV and treating it. I remember it was a big deal when it came out.
Exactly. It was a huge deal. And that's because it was really effective. Many patients had less severe side effects on Truvada. And it was more convenient to take. It really became a game changer in the fight against AIDS. And the key ingredient in Truvada is a version of something called Tenafavir. It prevents the HIV virus from replicating. This doctor said to me, he says, well, you're doing well on the three medications you're on, but the drug rep has really been pushing this, touting it really as the miracle medication. It's all about convenience. It's one pill. All you got to do is take one pill. So I started taking the Truvada. That's where it started.
So David did well on this pill for a while, but then something started to change for him.
He felt different. I would say between 2006 and 2011, it had gotten progressively worse.
Just really achy, like achy inside my bones and just really like someone to kind of beat me up, you know, just that achy all over. And so after a long time trying to figure out what was going on, David's primary care doctor had an idea. He suggested ordering a scan of David's bones.
Okay, so we did it. And so I sat there and he came in and he says, well, it's like bones of a 90-year-old woman. I've never seen anyone at your age have such severe osteoporosis.
So at this point, your man who's 62 being told you have the bones of a 90-year-old, how did it feel to hear that? Frightening. All that the primary care said was, it's quite possible that it's toxicity from some of the medications that you may be taking.
The conclusion he and his doctors came to was that even though Truvada was treating David's HIV and keeping him alive, it also appeared to be the most likely cause of the side effects, the weakness in his bones, and also some kidney issues he was experiencing.
So what does he do? Well, fortunately for David, in 2016, Gilead released a new HIV drug.
This new drug contained a newer version of tenofovir. Again, that's the active ingredient in Truvada, the medication that appeared to be making David sick. But this new formulation of tenofovir was different. The tweak in the formulation of tenofovir turned out to be a big deal. It ended up meaning that the medication didn't carry the same side effects that David had been experiencing. So David switched over to Gilead's newer version of the drug, and his health began to improve. But David had spent years suffering from side effects he attributes to Truvada. He even took an early retirement because he felt he wasn't able to work anymore. So he wanted to know what exactly had gone wrong with Truvada.
So I googled kidney decline and severe osteoporosis.
David did some googling, and he came across an advertisement from lawyers who were looking for patients, patients who had experienced side effects like the ones he had. These lawyers

were suing Gilead. And David was eligible to join the lawsuits.
And I thought about it really reluctantly. I had never seen anybody, so I was thinking that first of all, I wouldn't really know how to go about it. And is that something that I wanted to get into, you know, or did I just want to let the medicines do their work? And David was reluctant at first to reach out to these lawyers. He was taking the new drug. It seemed to be working much better for him. But it just really got me mad.
But he was also angry that Truvada, this drug he'd taken for years and years, appeared to have hurt him so much. And he was also angry at Gilead. So David ultimately decided to join the lawsuits. He became one of some 26,000 patients who were suing Gilead.
And what are they arguing in the lawsuit? Like on what grounds are they suing Gilead?
Lawyers for these patients have put together a number of claims. They're arguing the usual sorts of things you see in personal injury lawsuits that Gilead was aware of the problems and did not adequately warn patients about these potential side effects. But they're also making a more unusual claim. They say that the newer version of T'Nolfavir, that's the one David eventually switched over to, that didn't have the same bone and kidney side effects, could have been made available to patients about a decade earlier than it was.
So what does that mean? There was a newer version that's better and they just held it?
That's right. They say that Gilead had been working on this newer version in the early 2000s. They also claim that even though there was good reason at the time to think that the newer version would turn out to be safer, that it wouldn't have those same kidney and bone side effects, Gilead still decided to delay bringing it to market.
So they're arguing that the company actually had a newer version that was safer that they withheld. But why would they do that? Well, the theory is that it was all about maximizing profits.
Okay, so explain what you mean by that. Well, it all goes back to the system that I was talking about, this for profit system of drug development. A central part of that is patents, which protect a drug company's intellectual property. Patents are really the lifeblood of the pharmaceutical industry. So the way it works is when a drug company develops a product, they can and do file for lots of patents. And together, these patents create a monopoly which lasts for years. That means other companies cannot sell a generic version of the same drug. And so prices stay high because whichever company controls the patents faces no competition.
And what's the rationale for that? The thinking is if you were to do all this research and spend all this money to bring a drug to market, and then immediately your competitors could just come in and sell knockoff copies of your hard work so you couldn't make money.
Well, then you wouldn't have much of an incentive to do that innovation in the first place.
And I think there's broad agreement that a lot of times that system works really well.
But critics say there are also downsides to this system. For one, it keeps drug prices higher for longer. And in David's case, his lawyers are arguing that the system created an incentive for Gilead to delay bringing its innovation to the market. That was the newer drug that would have been safer for David. So Gilead had a monopoly on the older version of the drug. That's the one that was in the medication that David took. And that monopoly was due to expire in 2017. So that meant that Gilead had full protection against competition until then and could keep prices high. And the plaintiffs lawyers argue that Gilead intentionally decided not to release the newer, potentially safer version of the drug so that it could make more money.
Okay, so the plaintiffs are saying that, you know, we've been suffering from these side effects,

which you, Gilead, knew about. And all the while, you had a new drug that didn't have those side effects. But you didn't release it because you didn't want to effectively eat into the profit that the first drug was still bringing in. That's right. And what did Gilead say? And what was their response about this allegation that they intentionally withheld the drug for profit?
So Gilead denies the allegation completely. The company acknowledges that they did delay the drugs
development. In fact, they publicly acknowledged in 2004, when they made the decision, they put out a press release announcing that they had decided to stop developing the drug. But the company says that had nothing to do with profit. The real reason they said at the time, and they say now, is that the newer version wasn't sufficiently different from the older version to justify moving it forward. And on its face, that's a completely reasonable reason to not move forward with a drug. It doesn't make sense to bring to market two virtually identical versions of the same thing. But as this lawsuit has unfolded and moved through the court system, the lawyers for the patients who are suing have as part of the normal discovery process managed to get their hands on internal company documents from around the time in the early 2000s, when Gilead executives
were making decisions around the development for this newer version of the drug. And those documents give a really rare view of what was going on behind the scenes of what the company executives were considering. And I think they suggest that Gilead's version of events doesn't reflect a whole story. We'll be right back.
Imagine if past tech choices didn't hold you back. If no single IT vendor told you no, if you knew that you could harness complexity, not be overcome by it, what would you do if you could see what's possible at redhat.com slash options? Redhat's objective experts, flexible technologies, and dedicated partners provide the options you need today to go wherever tomorrow leads. No matter the cloud, environment, app, or vendor, visit redhat.com slash options to keep your options open.
We apply the same journalistic standards to everything we write about, whether it's the gut microbiome or how to get a good night's sleep, even if we're talking about something like, is it bad for me to drink coffee on an empty stomach? Everything that our readers get when they dig into a well article has been vetted. Our reporters are consulting experts calling dozens of people doing the research it can go on for months so that you can make great decisions about your physical health and your mental health. We take our reporting extra seriously because we know New York Times subscribers are counting on us. If you already subscribed, thank you. If you'd like to subscribe, go to nytimes.com slash subscribe. So Rebecca, you told us that the plaintiffs in this case are arguing that Gilead withheld a safer drug from the market in order to maximize their profits. Gilead denies this. But now the plaintiffs' lawyers have their hands on all of these internal documents. So what do we actually know about what happened here?
So the documents give us a really fascinating look inside this drug company at a time when executives were making decisions about these medications. So let's go back to the year 2001. That was the year that the FDA approved the original version of Tanassavir. And in those early years, the evidence began to accumulate that some patients, very small fraction of the overall number, but some patients did develop side effects, typically problems with their bones, their kidneys, that appear to be caused, at least in part, by the older version of Tanassavir.
But Gilead was not just banking on the original formulation of this drug. Like companies typically do, Gilead scientists were tinkering in the lab with other very similar compounds. The idea was

that if you make small changes, tinker with molecules, you might find some dramatically improved drug or learn something important or have a backup in case the product that was being prioritized didn't pan out. Okay. And one of those molecules stood out pretty quickly. The company's scientists identified this newer version as having potential in its own right.
Maybe it should be developed on its own merits as a new potential blockbuster in the drug company's
pipeline. And I assume this is the version of the drug that the lawsuit talks about, right?
So what was so exciting about this new version?
Yeah. So early studies conducted in animals and in the laboratory indicated that this new formulation was much better than the original version at delivering Tanassavir to the cells in the body it was targeting. And that meant that way less of it was leaking into the bloodstream, where it would travel to kidneys and bones and cause this toxicity. And the early studies showed also that it could be given at a lower dose. Now, it's important to say the Gilead scientists did not have definitive proof at this point that the newer formulation of the drug was safer in humans. You would have to run bigger clinical trials to know for sure. But there was some pretty strong early evidence that this was promising. That was echoed in an internal memo from 2002 that said the newer version, quote, may translate into a better side effect profile and less drug-related toxicity, end quote. That's huge, right? I mean, that would mean that this new formulation was likely not to cause those awful side effects we heard David and so many others had. Right. So at the time, there was a lot of optimism within the company about this newer version. It appeared to be full steam ahead with this drug. Company scientists were updating the research community at conferences. Executives were keeping investors abreast. The company was running projections looking at how much money the drug could make. And in 2002, the company began
the first human clinical trial of the newer version to evaluated safety. In that same year, you can see in the documents that a Gilead employee mapped out a development timeline for the newer version. And the timeline projected that the company could get the newer version to market as quickly as 2006. So that would have been just a few years after David had started on the old version of the drug. Exactly. But that's not what ended up happening.
Even though there had been all this excitement among Gilead scientists about the newer version of the drug, at some point around 2003, company executives started to sour on rushing it to market. And Gilead did not follow through on those plans that could have brought it to market by around 2006. Why? So these internal documents indicate that executives started to worry that releasing the newer version of the drug would eat into the market share for the older version of the drug. Okay. Now, the phrase they used was cannibalize. As in the new drug would ultimately cannibalize and quote the market for the older drug. Gilead would essentially be competing with itself. So that's pretty explicit. That's right. And remember, Gilead at this time knew it had a monopoly on selling the older version of the drug that would last until 2017.
So there was still a lot of runway, still a lot of time for Gilead to earn money from this franchise.
Right. This is a rare golden ticket. They want to keep it as long as it'll go.
Exactly. So instead of pushing forward on this newer version of the drug, the documents indicate that the company was formulating a plan. It was called a patent extension strategy. And it's repeatedly referred to that way in the documents. What the company wanted to do was find a way to maintain its monopoly, to maintain sales beyond the expiration of the monopoly on the first drug.

And the internal documents from 2003 showed that the company ultimately planned to time the release of the newer version of the drug right when it would be optimal to switch patients over from the older drug. This is right before the patent was expiring. One memo says the development
of the newer version, quote, is timed such that it is launched in 2015, end quote. Notice that back, you know, a drug like that isn't going to take 12 years to develop. So this is a business analyst at the company proposing delaying the release of the newer version. And so in 2004, Gilead halted the development of the newer version of the drug.
Okay. So to recap, these documents suggest that company executives didn't want to squander any of this precious patent. They wanted to be able to keep prices high for as long as possible to maximize profits. And so they halted the development of a new potentially better drug, which is really the opposite of what the whole patent system is meant to do.
That's the allegation. Now, the documents don't explicitly say that the reason for halting development was because the company was following any sort of strategy to try to maximize profits. But the documents do provide context around the business considerations Gilead was thinking about at the time. And the plaintiffs say that the way the chronology ultimately played out, the way things ended up unfolding validates their accusation. What we know is that the newer version of the drug sat on a shelf for years, despite those early signs that it might turn out to be safer for some patients. Gilead kept selling the older version. It became a blockbuster, bringing in billions of dollars and keeping millions of patients alive. And then in 2010, Gilead decided to resurrect the newer version of the drug. They did the clinical trials, they went through the regulatory process, and they released it in 2015.
So they followed through on their plan to extend the patent, the one they talked about in the documents. It appears that way. Now, Gilead said this had nothing to do with following through on any sort of patent extension strategy. They said the reason they changed their mind about whether the newer drug made sense to move forward with is that the situation for patients had changed by then. One consideration was that long-term HIV survivors were getting older. They were more susceptible to bone and kidney problems, and it made sense to have a safer option for them. And when the newer version came out, Gilead positioned it as just as effective as Travada, but gentler on the bones and kidneys. In other words, it doesn't have the same side effects David suffered from. So when the patent on the older version expired in 2017 and drug makers
offering generic versions were able to come in with their own products, the price of Travada ultimately went way down from about $22,000 a year to under $400 a year. But Gilead successfully switched a lot of patients from the older version to the newer version. And those patients are still exposed to the higher price. That's a sticker price of $26,000 a year. And the switch to the newer version was really, really successful. Today, Gilead drugs containing the newer version account for half the market for HIV treatment and prevention.
And it makes sense that people switched over, right? Because this new version of the drug has fewer side effects. Well, it's a little more complicated, actually. The newer version doesn't have the old side effects, but it does have its own side effects. It can cause weight gain and elevated cholesterol levels in some patients. So I think the reality is that the older version is safer for some patients and the newer version is safer for other patients. But the lawyers in David's case say that if both versions of the drug had been available on the market, at least patients and

their doctors would have had the option to choose which version would best suit their needs based on those risks. So you might switch patients who were experiencing kidney and bone issues over to the newer version. Okay. So whatever the motive, what happened in the end was that the company did
make enormous profits because the release of the new drug ended up being perfectly timed, right? So how common is this? Is this a strategy that you see a lot in the pharmaceutical industry?
So under the current system, there are a ton of complicated ways that companies essentially extend their monopolies and maximize their profits. So the phenomenon that we saw play out with Gilead's versions of Tenafavir is called product hopping. And that's because you're hopping patients from the older version of the drug over to the newer version of the drug just before the patent for the older drug runs out. But there are other common strategies too. One is called patent thickening. Patent thickening? That's right. The idea here is to file so many patents on all sorts of things, the dosage, the delivery method, even things like a safety program to ensure that the drug is safely distributed. And the idea is to make it as hard as possible for generic competitors to find their way through like a thicket. It's hard to navigate a thicket. Like a thick and actual thicket of patents. That's right. The idea is that it's so costly, so time consuming for a smaller company to wade through that thicket of patents that they might give up, they might decide it's too risky that they would face lawsuit or not be able to keep the product on the market.
And companies do all sorts of things to try to fight off generic competition. They'll reach deals with generic competitors to minimize the impact of generic competition or sometimes sue them claiming
that companies are infringing on their patents. So these strategies you're describing,
they don't seem to have that much to do with creating new treatments. They seem more about using pretty powerful legal and financial muscles to flood the zone in a way that blocks competition. But in the case of Gilead and Tanafavir, that meant not just blocking another company from entering the market but actually hitting pause on developing a new drug, their own drug, that could be less harmful. That feels ethically squishy. That's right. There are definitely legal questions here, but there's also an ethical question. Oftentimes when you see product topping, there's not a ton of consequence about when the newer version is released. Oftentimes, it's even criticized for being a tiny tweak, something that isn't important, something that doesn't improve outcomes, doesn't improve quality of life for patients. But I think what's distinctive about this case is the allegation that the timing of the release of the newer version of the drug resulted in harm to patients. The stakes here had an impact for patients' health.
Not only for their pocketbooks.
And I think that's one of the questions that's going to be addressed as the courts decide whether or not these lawsuits can move forward. But it seems like the argument, both in court but also ethically, rests on whether Gilead, way back in the early 2000s, actually knew that this newer drug would come out ahead when weighing the pros and cons. They had reason to believe it might turn out
to be gentler on the bones and kidneys, but it was still really early days in the research.
So you could, at the time, reasonably conclude that the signal just wasn't strong enough for Gilead to have an ethical imperative to put the drug on a fast track.
Yeah, that's really the question, isn't it? How much evidence was enough evidence for Gilead to have a responsibility to move the drug forward?

So what kind of impact could a decision in this case have?
So Gilead's lawyers say in legal filings that this could set a dangerous precedent,
this argument that the plaintiff's lawyers are making. They are saying that if any company can be held liable for not releasing a product on a specific timetable, that could jeopardize innovation. The concern here is that if drug companies could be sued for not releasing products immediately, then they would be less likely to take the risk, spend huge amounts of money to run clinical trials if they could get in trouble if they didn't get the timing just right.
Right. I mean, when you think about it, it is kind of strange, like a court ordering a company to release its product before it wants to.
Exactly. For instance, you probably wouldn't see Apple being held liable for not releasing its latest iPhone quickly enough. And I think there's precedent in past cases suggesting Gilead has a pretty strong defense here. You know, when these sorts of patent strategies are challenged in court, drug companies often end up winning.
On the other hand, this isn't an iPhone. It's a drug, right? Kind of different category.
Right. The critics here of Gilead say that drugs can't be treated like other products, that it's a matter of life and death, not just a question of when people get the newest version of the iPhone. So is there a way to change the incentives for companies?
Well, one avenue is cases like David's, which could set a precedent for
better or for worse, depending on your perspective. We'll see how that plays out in the courts. But as for policy changes, federal lawmakers regularly introduce bills that aim to crack down on various aspects of patent gaming. But those haven't gained much traction so far.
And there are lots of reasons for that. The industry lobbies hard against regulation.
But another consideration is that policymakers are worried about interfering with the system that we have set up. The system that, in a lot of cases, has been extraordinarily successful at producing breakthrough therapies. And I think this is what is so hard about regulating the pharmaceutical industry. We want to strike a balance between the benefits the system brings and the ways that it can sometimes harm patients. We don't want to create incentives that discourage
companies from coming up with breakthrough therapies. We want to create the space where companies will take the risks to bring the next truvada to market. But we also don't want to have a system where companies prioritize profits over patients, where safer medications get delayed for business reasons and patients suffer. We want to discourage companies from gaming the system.
Rebecca, thank you. Thank you.
We'll be right back.
Support for this podcast comes from the International Rescue Committee. For almost 90 years, the IRC has helped people affected by humanitarian crises survive, recover, and rebuild their lives. Founded in 1933 to assist refugees fleeing Europe, the IRC has always been powered by ingenuity, fortitude, and optimism. Your help is urgently needed to fuel programming as the IRC works to meet the world's record levels of need. You can support families in crisis at rescue.org slash rebuild. Here's what else you should know today. The Biden administration announced it would prohibit
drilling in 13 million acres of the National Petroleum Reserve and cancel all existing leases in the Arctic National Wildlife Refuge. It was Biden's most aggressive move yet to protect millions of acres of pristine Alaskan wilderness from oil and gas exploration. But it would not stop the

enormous Willow Oil Drilling Project in the same vicinity that Biden approved earlier this year and that climate activists oppose. And the Special Counsel investigating Hunter Biden said on Wednesday
that he planned to indict the president's son on a gun charge before the end of the month. In a three-page update filed in federal court in Wilmington, Delaware, David Weiss laid out plans to bring charges related to Biden's purchase of a pistol in 2018 when prosecutors say he lied on a federal form by stating that he was not using drugs at the time. The move was prompted by the acrimonious collapse of a clean deal between Biden and federal prosecutors in July.
Today's episode was produced by Eric Krumke and Will Reed. It was edited by Liz O'Balen and Paige Cowett. Fact checked by Nicole Pasalca and Susan Lee. Contains original music by Rowan Nymesto, Dan Powell, Alicia Beytupe, and Marion Lozano, and was engineered by Alyssa Moxley.
Our theme music is by Jim Brunberg and Van Lansverk of Wonderly. Special thanks to Cheryl Stolberg.
That's it for the Daily. I'm Sabrina Tevron, you see. See you tomorrow.