

STAT

A supplement maker tried to silence this Harvard doctor — and put academic freedom on trial

By [Rebecca Robbins](#) @rebeccadrobbins

January 10, 2017



Kayana Szymczak for STAT Dr. Pieter Cohen at his home in Brookline, Mass.

The dietary supplements had ominous names, like Black Widow and Yellow Scorpion. They contained an illegal and potentially dangerous molecule, similar in structure to amphetamines.

But when a Harvard researcher dared to point that out, in a scientific, peer-reviewed study and in media interviews, the supplement maker sued him for libel and slander.

STAT has conducted the first detailed look at the legal showdown that followed by interviewing key players and reviewing hundreds of pages of trial transcripts and other court documents. The jury trial had momentous

implications for the future of research into the safety of weight-loss and muscle-building pills; for the freedom of academics to speak out about matters of public health; and for our ability to learn what's in the supplements on our kitchen counters.

In case things weren't interesting enough, swirling in the backdrop was a bizarre backstory involving a slew of sensational allegations against the wealthy founder of the supplement company — who [dreamed up](#)¹¹ the business while in prison on a charge stemming from selling ecstasy.

The Harvard researcher, Dr. Pieter Cohen, won the defamation trial in federal court in Massachusetts in November.

But the man who sued him, Jared Wheat, the owner and CEO of Hi-Tech Pharmaceuticals, doesn't see the jury verdict as a loss: He's openly hopeful that the long and costly legal battle will scare away other academics from investigating the supplement industry.

If that doesn't work, he's counting on President-elect Donald Trump to follow through on vows to to "[open up](#)²²," the nation's libel laws to make it easier for parties who feel they have been defamed to win lawsuits. Trump has discussed this goal in the context of his grievances against the news media. But it could also have ramifications for published research.

Asked whether Trump should make easing libel laws a priority, Wheat told STAT: "Absolutely."

Meanwhile, the six adulterated supplement brands from Hi-Tech are still on the market, despite alarms raised not just by Cohen, but by the Food and Drug Administration. The FDA has ordered Hi-Tech to recall several such products. Wheat has refused, though he said the company has voluntarily made minor tweaks to the formulas for some of them to satisfy distributors.

The entire episode opens a window into the Wild West world of supplements. Unlike drug companies, supplement manufacturers don't have to show that their formulations are safe or effective before putting a product on the market. They don't have to run clinical trials. They don't have to consult federal regulators.

With little oversight, they can jump right into a highly lucrative industry: Wheat, a convicted felon, said his company brings in more than \$100 million a year in annual revenue. His company's [social media](#)³³ pages are lined with images of bodybuilders with veins bursting out of their biceps.

And Wheat has no regrets about spending what he estimated as between \$300,000 and \$400,000 in corporate funds to go after an academic who challenged the safety of his products in a meticulously documented study.

"I spent a lot of money, but hopefully it will deter others from going out there and making baseless allegations," Wheat said in a phone interview from his company's headquarters in Georgia. His advice to other academics: "Think twice and do better research, knowing you can get sued if you do this."



A hidden danger in weight-loss pills

Pieter Cohen was browsing an email newsletter when he learned he was being sued for [\\$200 million](#)⁴⁴.

Sitting at his computer that day in the spring of 2015, he stumbled upon a report of the lawsuit in a supplement industry trade publication. He wasn't even sure at first if it was real.

It was. Hi-Tech was suing him and his three coauthors in federal court in Georgia over the [study](#)⁵⁵ they had published a few weeks earlier in the scientific journal Drug Testing and Analysis.

Cohen had launched that study with the goal of prodding the FDA to enforce the law by cracking down on supplements illegally containing a compound known as BMPEA. Chemically similar to amphetamines, BMPEA has never been demonstrated to be safe or effective in humans.

And there are plenty of reasons to suspect it can be dangerous. It's been shown to send blood pressure and heart rate soaring in dogs and cats. It's been [linked](#)⁶⁶ to a stroke in a Swedish woman. Such evidence prompted Canadian health officials to [call it](#)⁷⁷ a "serious health risk."

Supplement makers often claim that BMPEA is a natural botanical product that comes from a Southwestern shrub called *Acacia rigidula*. In fact, it has never been shown scientifically to come from that shrub, or from any other natural source. And the shrub itself is illegal to include in supplements because no manufacturer has gone through the necessary steps to prove that it's safe for humans to ingest.

There are a number of theoretical reasons that companies might want BMPEA in their products. It's possible that it might have weight-loss effects similar to those of amphetamines, which decrease appetite and increase metabolism. It may also aid in athletic performance. In other words: BMPEA might be more potent than natural botanical ingredients.

In 2014, FDA scientists had [reported](#)⁸⁸ detecting BMPEA in a handful of supplement products labeled as containing *Acacia rigidula* — but they couldn't find any evidence of BMPEA in the actual shrub. That research made a minor splash, but the FDA team hadn't named names.

Cohen — who's known as perhaps the most dogged detective scrutinizing supplements — wanted to see if he could replicate some of those findings and publicize the specific brands containing BMPEA.

So his team chemically analyzed 21 popular supplements, made by a handful of manufacturers and labeled as containing *Acacia rigidula*. Eleven of them turned out to contain BMPEA — including six of the 10 Hi-Tech

products in the study. (All six were marketed for weight loss.)

Hi-Tech's "Fastin-XR" pills, for example, contained 82 milligrams of BMPEA in the maximum daily dose recommended on the label. The maximum recommended dosage of "Yellow Scorpion" pills contained 69 milligrams, and "Black Widow," 56 milligrams. Because BMPEA has not been studied in humans, it's hard to compare the strength of these pills to, say, ADHD medication, but it was clear this was more than a trace.

Such pieces of evidence "strongly suggest" that BMPEA is synthetically produced and used to spike the products, Cohen's paper concluded.

People in the supplement industry "were hoping that we were able to silence this guy."

Jared Wheat, CEO of Hi-Tech Pharmaceuticals

The study immediately made waves: Cohen went on "CBS This Morning" and was quoted in an article that appeared [on the front page](#)⁹⁹ of some editions of the New York Times. Two senators issued a [stern statement](#)¹⁰¹⁰ urging the FDA to keep such products off the shelves.

And within two weeks, the FDA issued [warning letters](#)¹¹¹¹ to Hi-Tech and four other companies, ordering them to recall products containing BMPEA.

Cohen's study listed products and their manufacturers in the table of results. That's the only place in the paper where Hi-Tech is named. Cohen did not mention Hi-Tech by name in any of his media interviews.

Still, all the attention was giving Hi-Tech's customers cold feet. Distributors and retailers, including Rite Aid, sent back Hi-Tech products. A few other supplement companies that paid Hi-Tech to manufacture their products took their business elsewhere. So Wheat sued. He would later blame Cohen for costing Hi-Tech an immediate \$14 million in lost business.

News about the suit spread quickly in the dietary supplement industry. Wheat said he got "hundreds" of supportive calls and emails from people "hoping that we were able to silence this guy."



A watchdog becomes a target

The guy the supplement industry wants to silence speaks thoughtfully, punctuating his points with emphatic hand gestures. Cohen is friendly and informal, at one point rolling up his pant leg to show a large skin graft on his left calf, a battle scar from a fall during a hiking expedition with his wife and their three school-aged children.

"He's the kind of person you want as your doctor," said Dr. Joshua Sharfstein, a former principal deputy FDA commissioner and now a professor of public health at Johns Hopkins. "He's not a clock-puncher by any stretch of the imagination."

Cohen, 46, is an assistant professor at Harvard Medical School and an internist at Cambridge Health Alliance, a network of hospitals and clinics just north of Boston. He first got interested in studying supplements after seeing Brazilian immigrant patients with alarming symptoms, such as palpitations, panic attacks, and even kidney failure.

It turned out they had been taking a Brazilian weight-loss supplement spiked with amphetamines, antidepressants, and benzodiazepines.

With hardly any research funding, Cohen has turned out study after high-impact study identifying hidden synthetic stimulants in popular weight-loss products. And he's repeatedly called for tighter regulation. He's become the most widely recognized critic of the supplement industry, in part because he's very media-savvy, boosting the reach of his studies by pitching them to journalists. (He also pitched STAT on writing about this lawsuit.)

Cohen's well regarded, even among some people who disagree with him. Steve Mister, president of the Council for Responsible Nutrition, a trade group for dietary supplement makers, praised him for performing an "important watchdog function" and added that he does "some very good research" — even though Mister generally doesn't think it should translate to policy changes. (Hi-Tech has never been a member of the trade group.)

Cohen had dealt with supplement companies unhappy with his research before, but it had never gone anywhere. And Hi-Tech's suit seemed destined for the same fate last spring when a judge in Georgia dismissed it because Cohen didn't do any of his work there.

But then Hi-Tech refiled in Massachusetts, with a few small changes. Cohen's coauthors were no longer named as defendants. The demand for precisely \$200 million in damages was dropped, too.

And this time, Cohen's Harvard lawyers couldn't get the suit dismissed. Last summer, a federal judge [ruled](#)¹²¹² that the company had a 7th Amendment right to a jury trial.

"How many people can continue in the field if this is what it takes — if one paper leads to this?"

Dr. Pieter Cohen

Academics around the country have come under similar threats, said Hank Greely, a law professor who heads the Center for Law and the Biosciences at Stanford University.

"Some threats come through litigation, some of them come through legislative requests or demands, and we don't really have any good ways of dealing with them," Greely said. "There are lots of ways that scientists are getting harassed."

And faculty members can't always count on their university to provide legal assistance; it depends on a number of factors, including the kind of research they're doing, according to Robert O'Neil, former general counsel for the American Association of University Professors.

Cohen was lucky to have Harvard in his corner. Still, the several months leading up to the trial were grueling for him. He had to put aside all his research projects. He was deposed for an intense six and a half hours. And he worried about the financial hit he could take, should the jury decide against him. It took months for Harvard's insurer to commit to covering a jury award for Hi-Tech, and even then it would only cover up to \$5 million. The trial started out with Hi-Tech demanding more, though by the end, the company's demands were whittled to below \$5 million.

Worst of all, Cohen was required to turn over hundreds of pages of his notes, peer-review feedback, and his written correspondences with the journal, coauthors, and journalists.

"That's when I really just had a new sense of what we were talking about here," Cohen said.



An antagonist with a checkered past

The seven-day trial, which started last October, wasn't about whether Hi-Tech's supplements actually contained BMPEA.

Hi-Tech admitted they did in the initial lawsuit — in fact, a few of the products in question actually listed it on their labels — but claimed, without evidence, that it had naturally extracted the substance from *Acacia rigidula*.

Instead, the case hinged on what Cohen had said about BMPEA: Had it really never been tested for safety or efficacy in humans? Was it really potentially dangerous? Was it really synthetic, not derived from *Acacia rigidula*?

These are not controversial questions in the scientific community. (The answers are yes, yes, and yes.) But they are scientifically complex questions, and it was far from certain how the jury would assess the evidence.

“There are lots of ways that scientists are getting harassed.”

Hank Greely, law professor

Hi-Tech's lawyers and witnesses claimed, without evidence, that BMPEA had been evaluated in proprietary studies that have never been published. They also tried to persuade the jury that the compound had been tested by pointing to studies of molecules that are chemically similar to, but ultimately distinct from, BMPEA.

By contrast, Cohen's lawyer, Brian Sullivan, focused on the high stakes for public health. In his opening statement, Sullivan urged the jury to consider the evidence “in the context of Dr. Cohen's ability and his right to speak the truth to powerful interests and the interests of his patients and people in general ... [who are] putting things in their bodies without knowing really what's in there.”

The trial and its preparations also aired unsavory details about Hi-Tech's checkered past.

First convicted for selling ecstasy while still a teenager, Wheat went on to violate the terms of his release and spent several years in prison, where he conceived of Hi-Tech.

The business was rolling by 1998, but Wheat didn't stay out of trouble for long. In 2003, the FDA forced his company to destroy supplements spiked with an unapproved erectile dysfunction drug. In 2006, the agency seized \$3 million worth of his company's products containing ephedra, a banned and potentially dangerous stimulant.

Later that year, Wheat and several Hi-Tech associates were arrested for running an illegal online pharmacy based out of Belize. Federal prosecutors later alleged that Wheat had been involved in discussions about killing an FDA agent and blackmailing a federal prosecutor.

Wheat denied knowledge of these alleged and unrealized schemes, and the government didn't pursue them. He pleaded guilty to the illegal pharmacy charge and was sentenced to four years in prison. (He did another two-month stint behind bars in 2014 for not complying with a court order to recall Hi-Tech products.)

Asked about the conviction, Wheat said, "it would take hours to explain, and I just don't have time to deal with it, and nobody ever tells the accurate side of the story." He also told this reporter to "go write your slander piece all you care to — that's what all y'all do."

"You have enemies? Good. That means you stood up for something in your life."

Brian Sullivan, attorney for Pieter Cohen

In his opening statement, Sullivan framed Hi-Tech's clashes with the law as important context for the jury to consider.

Hi-Tech's lawyer, by contrast, made a point in his closing statement to note that the company had "rebuilt [its] reputation" after "coming back from those setbacks."

The trial was tough on Cohen. At one point, he had to rush to the emergency room when the lymphatic system in his leg got infected, stemming from the hiking injury. And he knew that his own research career — and the whole field of independent research into the safety of supplements — hung in the balance. After all, if Hi-Tech could successfully sue over research it didn't like, what would stop other companies from trying the same?

In his closing statement to the jury, Sullivan turned to a quote often (perhaps erroneously) attributed to Winston Churchill. "'You have enemies? Good. That means you stood up for something in your life.' Dr. Cohen has enemies because he stood up sometimes in his life," he declared.

Two and a half hours after they left to deliberate, the jurors returned a verdict in Cohen's favor.

Cohen was still too wound up to feel anything. It wasn't until a few days later, when it dawned on him that the trial was really, finally, over, that he felt relief.

Then he got back to work.



More research is on the way

Wheat explains away his loss in part by pointing to the makeup of the Massachusetts jury pool: They probably had a hometown bias for a local university professor — not to mention the fact that "they're liberal people up there," Wheat said. He insists he would have won had the trial been in Georgia, where the company is based.

Meanwhile, consumers are still buying the supplements in question. Wheat claimed his company altered several

of them by slightly tweaking the chemical structure of BMPEA to satisfy distributors who refused to carry the products otherwise. He likened it to making green tea decaffeinated.

He insists those changes didn't come in response to the FDA's April 2015 warning to recall several products containing BMPEA. FDA spokesperson Lyndsay Meyer said the agency is "continuing to work with each of the companies [warned about BMPEA] to ensure that their products comply with federal law."

But Wheat characterized those letters as toothless — an attitude that exposes the FDA's limited ability to police potentially unsafe supplements.

After Wheat lost the suit against Cohen, he said, "a few dozen" people in the industry called to say they hoped it had at least "deterred" Cohen from actively publicizing his critical research.

They might be unwise to count on it.

Cohen submitted a new study for publication just days after he won his trial, and has three new projects in motion in the new year. He believes it will be more important than ever under the new Trump administration to hold the FDA responsible for enforcing the law.

"My experience," Cohen said, "has really reinforced to me why it is so important to not only continue the research we're doing but to be very aggressive about speaking out about it."

He said he hopes his experience will spur discussion about legal protections for academic researchers. "How many people can continue in the field if this is what it takes," he said. "If one paper leads to this?"

Correction: A previous version of this story misstated the TV show that Cohen went on to talk about his supplement study.

Links

1. <http://www.myajc.com/news/despite-checkered-history-norcross-supplement-maker-avoids-fda-crackdown/OjbFr9il9nMJOpSk9xKxPM/>
2. <http://www.politico.com/blogs/on-media/2016/02/donald-trump-libel-laws-219866>
3. <https://www.instagram.com/hitechpharma/?hl=en>
4. <https://www.truthinadvertising.org/wp-content/uploads/2015/04/Hi-Tech-v-Cohen-complaint.pdf#page=28>
5. <http://onlinelibrary.wiley.com/doi/10.1002/dta.1793/full>
6. <http://annals.org/aim/article/2293221/hemorrhagic-stroke-probably-caused-exercise-combined-sports-supplement-containing-methylphenyl>
7. <http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2014/43087r-eng.php>
8. <http://www.sciencedirect.com/science/article/pii/S0731708513004378>
9. http://well.blogs.nytimes.com/2015/04/07/study-warns-of-diet-supplement-dangers-kept-quiet-by-f-d-a/?_r=0
10. <https://www.blumenthal.senate.gov/newsroom/press/release/blumenthal-durbin-statement-on-new-study-highlighting-dangers-posed-by-ineffective-regulation-of-supplement-industry>
11. <http://www.fda.gov/Food/DietarySupplements/ProductsIngredients/ucm443790.htm>
12. <http://masslawyersweekly.com/2016/09/29/federal-judge-weighs-anti-slapp-burden/>

Links

1. <http://www.myajc.com/news/despite-checkered-history-norcross-supplement-maker-avoids-fda-crackdown/OjbFr9il9nMJOpSk9xKxPM/>
2. <http://www.politico.com/blogs/on-media/2016/02/donald-trump-libel-laws-219866>
3. <https://www.instagram.com/hitechpharma/?hl=en>
4. <https://www.truthinadvertising.org/wp-content/uploads/2015/04/Hi-Tech-v-Cohen-complaint.pdf#page=28>
5. <http://onlinelibrary.wiley.com/doi/10.1002/dta.1793/full>
6. <http://annals.org/aim/article/2293221/hemorrhagic-stroke-probably-caused-exercise-combined-sports-supplement-containing-methylphenyl>
7. <http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2014/43087r-eng.php>
8. <http://www.sciencedirect.com/science/article/pii/S0731708513004378>
9. http://well.blogs.nytimes.com/2015/04/07/study-warns-of-diet-supplement-dangers-kept-quiet-by-f-d-a/?_r=0

10. <https://www.blumenthal.senate.gov/newsroom/press/release/blumenthal-durbin-statement-on-new-study-highlighting-dangers-posed-by-ineffective-regulation-of-supplement-industry>
11. <http://www.fda.gov/Food/DietarySupplements/ProductsIngredients/ucm443790.htm>
12. <http://masslawyersweekly.com/2016/09/29/federal-judge-weighs-anti-slapp-burden/>

Rebecca Robbins can be reached at rebecca.robbins@statnews.com

Follow Rebecca on Twitter [@rebeccadrobbins](https://twitter.com/rebeccadrobbins)