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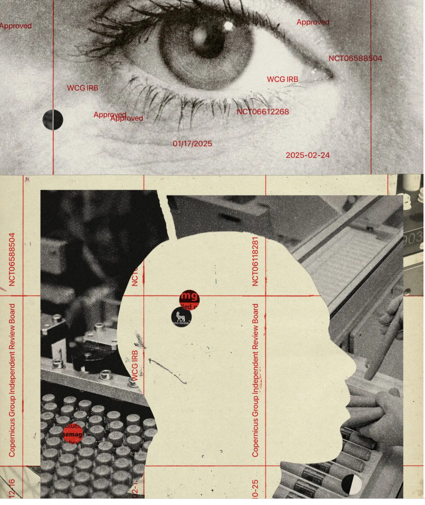

Blake Cale

How Private Equity Oversees the Ethics of Drug Research

Many drug trials are vetted by companies with ties to the drugmakers, raising concerns about conflicts of interest and patient safety.

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By Walt Bogdanich, Carson Kessler and Jeremy Singer-Vine

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When the Danish drugmaker Novo Nordisk wanted to test whether the main ingredient in Ozempic, its wildly popular weight-loss and diabetes drug, could also treat liver disease, it first needed approval from an ethics panel to ensure the safety of trial volunteers in the United States.

Such panels, called institutional review boards, have the power to reject drug trials or order modifications if participants face unreasonable risks. They are supposed to be independent watchdogs — counterweights to Big Pharma and overzealous researchers.

Yet Novo didn't have to venture far to hire an ethics panel for its liver-disease trial in May 2024: It chose WCG Clinical, a review board partly owned by its own corporate parent, The New York Times found.

Novo declines to discuss the review boards it selects; their names are scrubbed from a federal online database, because the information is deemed proprietary. But documents obtained by The Times reveal that the liver study was hardly an outlier: In the six years since its parent company invested in the private-equity-controlled panel, Novo has selected WCG to review at least 46 trials, a sharp increase over previous years.

Most of those trials grew out of Novo's efforts to find new uses — and markets — for semaglutide, the primary ingredient in Ozempic, Wegovy and Rybelsus, the company's top-selling drugs for diabetes or obesity.

OZEMPIC
PRESCRIPTION ONLY MEDICINE
1 mg

The maker of Ozempic sought approval for a drug trial from a review board partly owned by its own corporate parent. Carsten Snejbjerg/Bloomberg

What happened during those reviews remains confidential, hidden behind the ethics panel's closed doors. But the financial ties between the drugmaker and its ethics panel highlight how private-equity investors are transforming this obscure but vital corner of American health care — and the questions that raises about the panels' independence and rigor.

The first ethics panels, created in response to testing scandals in the 1960s and '70s, were nonprofits based at universities and hospitals. But in recent years, private-equity investors have increasingly reshaped them as for-profit endeavors.

For drug companies racing to develop the next blockbuster, private equity promised quicker, more efficient reviews. At the same time, private-equity ownership has driven the boards' expansion far beyond their original watchdog role.

Both WCG and its chief competitor, the private-equity-controlled Advarra, have close corporate relationships with drugmakers. And both have become part of multipronged enterprises selling pharmaceutical companies a wide range of drug-testing services — blurring the line between the reviewer and the reviewed, introducing potential conflicts of interest that threaten the review boards' mission, a Times investigation has found.

Any weakening of the ethics panels' oversight, industry critics say, is particularly dangerous today, amid widespread mistrust of scientific research and the Trump administration's slashing of the government's foremost pharmaceutical gatekeeper, the Food and Drug Administration.

"It looks like there is not much in place that will robustly protect people who want to participate in research," said Jill A. Fisher, a professor at the University of North Carolina's Center for Bioethics. The result, she and other experts fear, will be less protection for trial participants, and for the public at large.

Jill Fisher, a social scientist at the University of North Carolina's Center for Bioethics, raised concerns about patient protections. Justin Cook for The New York Times

In interviews, several prominent bioethicists expressed concern upon learning that WCG had approved trials for one of its owners, a relationship not previously reported. "That sounds like a grave conflict of interest," said Sarah Babb, a Boston College professor who has studied the review boards' evolution.

Today, more than half of all U.S. drug trials are reviewed by for-profit panels. WCG and Advarra accounted for all but a small fraction of those, according to a 2023 report by the Government Accountability Office.

Private equity's growing domination of the panels is just one facet of its powerful role in health care. With private-equity backing, WCG and Advarra have bought up competitors, as well as companies that provide an array of services to drugmakers running clinical trials — all with little government oversight or transparency, according to internal corporate records; government reports; and interviews with bioethicists, former review board employees and clinical trial experts.

WCG now receives more revenue from helping drug companies conduct trials — including designing the trials and finding volunteers — than from policing them on behalf of those patients, records show.

WCG declined to be interviewed or answer emailed questions. In a statement, WCG's chief marketing officer, Carmin Gade, said company policy forbade commenting on "client-related matters or specifics of their clinical trials," as well as internal company matters. But in a 2021 Securities and Exchange Commission filing, the company denied having a conflict of interest, asserting that its commercial interests were separate from its ethics reviews.

Advarra, too, declined to be interviewed, but said in a statement that it "maintains strong safeguards and internal policies to ensure the independence of its Institutional Review Board." The company also said it had recommended changes to a vast majority of the protocols it reviewed.

The pressure for quicker reviews came not just from drugmakers but from patient-advocacy groups seeking faster approvals for new treatments. But the promise of speed brought certain risks. Several former Advarra employees said the company had imposed daily quotas on reviewing informed-consent forms for trial volunteers.

"If you are just focused on turnaround time, that doesn't tell you really anything about quality," said Holly Fernandez Lynch, a lawyer and bioethicist at the University of Pennsylvania. She added: "It inhibits people from saying, 'Wait, we need to pause on this. Is this the right thing to do?'"

"Our system is based on the assumption that people are going to follow the rules," said Holly Fernandez Lynch, who teaches medical ethics and law at the University of Pennsylvania. Caroline Gutman for The New York Times

Waving through a poorly designed testing protocol could lead to patients taking a drug with unexplored side effects. Yet an ethics panel is largely a black box, offering no effective way to judge the quality of individual reviews — or whether they might have been compromised by intertwined corporate interests.

What's more, federal oversight of institutional review boards, or I.R.B.s, is piecemeal and limited, with little to no assessment of whether they actually conduct rigorous reviews. The industry instead has opted for self-regulation.

"Our system is based on the assumption that people are going to follow the rules," Ms. Lynch said. She added: "There's nothing in the regulations that says you can't have a quota, for example. There's nothing in the regulations that says, here's what high-quality deliberations look like."

Federal watchdogs have repeatedly called for reform, emphasizing the importance of independence. "We warned that the effectiveness of these boards was in jeopardy," the Department of Health and Human Services' inspector general wrote in 2000. "Few of our recommended reforms have been enacted."

Two decades later, researchers wrote in the Annals of Internal Medicine that the private-equity model was "particularly susceptible to approaches that could undercut the ethical mission of I.R.B.s."

Birth of an Industry

The 1966 report in The New England Journal of Medicine shocked the scientific world.

Participants in 22 clinical trials had been subjected to sometimes lethal tests without their consent. Live cancer cells had been injected into patients. Experiments had been performed on babies less than 48 hours old.

These disclosures began a reckoning over the ethics of medical research that intensified in 1972 after news of the Tuskegee study, in which researchers followed Black men who had syphilis without offering penicillin to treat it. Two years later, Congress passed the National Research Act, mandating that I.R.B.s be used in federally funded trials.

Rules requiring ethics boards came on the heels of the Tuskegee Syphilis experiments, which observed — but didn't treat — Black men with the disease. National Archives

The panels were to be independent, with at least five members, a mix of scientists and nonscientists. They would review the trial protocols, assessing whether the drug's potential benefits outweighed any reasonable risks to participants. And they would ensure that the consent forms presented to volunteers clearly stated the risks. The F.D.A. would then examine trial results and determine whether the drug could be marketed.

Ethical review panels were incubated at universities, hospitals and medical schools, where academic volunteers were pressed into service with little incentive to review studies quickly. And at first, those academic settings remained the primary venue.

But the seeds of a new system were planted in Olympia, Wash., where Dr. Angela Bowen, an endocrinologist and researcher, formed the first independent ethics panel, Western Institutional Review Board. She set up a fee-for-service model, using local doctors, lawyers and other experts to review human research.

As the pharmaceutical industry expanded, with new discoveries and increased competition, drugmakers sought faster turnaround times. Commercial ethics panels were ready to oblige.

As for-profit review boards grew, so did concerns that they might be inclined to sacrifice patient protection for greater profits. Those concerns came to a head in a scandal over an experimental antibiotic, Ketek.

The F.D.A. approved Ketek in 2004, and within two years, reports of liver failure and deaths linked to the drug began rolling in. Only then did it emerge that F.D.A. approval had come despite reports of fraudulent research and concerns within the agency over the drug's safety.

Congress investigated, and it wasn't only the F.D.A. that came under criticism. There was also a for-profit ethics panel, Copernicus, which would later become part of WCG.

At a 2008 hearing, Copernicus's chief executive, Sharon Hill Price, acknowledged that the company had failed to inform the F.D.A. after receiving 83 notices of testing protocol violations. "So protocol violations, no matter the number, wasn't alarming to your organization, to Copernicus?" asked Representative Bart Stupak, Democrat of Michigan.

"Not at the time," Ms. Price responded. "No."

(Ketek's manufacturer, Sanofi, ceased production in 2016.)

Dr. David B. Ross, who evaluated new drugs for the F.D.A., offered a harsh assessment of ethics reviews. "The I.R.B. system nationally is broken," he testified.

Private Equity Moves In

As the oldest and biggest independent review board, Western attracted attention from private-equity investors expanding their health care footprint. In 2007, Boston Ventures bought Dr. Bowen's company and her reputation.

Boston Ventures quickly recruited as chief executive Dr. Stephen Rosenfeld, a veteran of the National Institutes of Health.

"I really thought we could have made it into something great," he said.

The next year, Dr. John Ennever, former medical director in the clinical trials office at Columbia University's medical center, signed on as vice president of medical affairs.

Boston Ventures, as befits a private-equity firm, wanted Western to grow, and that brought a cultural change, the two men recalled.

Dr. Rosenfeld said he was asked to do marketing and leave some operational decisions to others. That was inconsistent, he said, with his responsibilities as chief executive. "There was a tension between how a company can run when it is owned by someone who founds it to serve a purpose, versus when it's owned by private equity," he said. After two years, he was asked to leave.

Dr. Stephen Rosenfeld was tapped to lead Western after it was bought by private-equity investors, but he wasn't given as much authority as he expected. Ryan David Brown for The New York Times

When another private-equity firm, Arsenal Partners, bought Western in 2012, "the first thing they did is they laid off 30 percent of the work force," Dr. Ennever said.

They also replaced outside review-panel members with Western employees, according to Dr. Ennever. With private equity, he added, “anything you can do to improve the bottom line, you do it, and I think that leads to less rigorous reviews.” Dr. Ennever left, too.

Boston Ventures and Arsenal declined to comment.

That same year, Arsenal bought Copernicus, which had weathered the Ketek controversy, and merged it with Western to form the Western-Copernicus Group — WCG.

WCG quickly began a buying spree, acquiring 31 companies that recruit research subjects; plan research studies; train trial investigators; and provide management consulting, data monitoring and medical imaging. WCG also bought competing review boards.

WCG frequently describes itself as a “servant to mankind.” In promotional materials, it pitches the virtues of working both sides of the street: “Strategically positioned at the very center of the clinical trial ecosystem, we act as the key point of connectivity among our various clients.”

(Conflicts of interest also exist in academe, where universities sometimes profit from drugs developed by faculty members.)

WCG doesn’t identify its clients, but says it uses “appropriate disclosure” to manage potential conflicts.

But in its 2021 S.E.C. filing, WCG cautioned that others could see it differently: “Governmental or regulatory authorities may assert that the combination of these services for a client compromises the integrity of the I.R.B. decisions or the data or analyses generated during any trials.”

WCG, Novo and Ozempic

For decades, Novo Nordisk was known for making insulin to treat diabetes. Then, in the 2010s, it developed semaglutide, first sold as Ozempic, an injectable drug that causes the body to produce its own insulin while also satiating hunger.

Ozempic went on sale in late 2017 and became a cultural touchstone, promoted as a life-changing wonder drug by celebrities, influencers and a bountiful advertising budget that, until recently, made Novo Europe’s most profitable company. Novo later used semaglutide to make Wegovy, specifically targeting obesity, and Rybelsus, a diabetes pill.

In late 2019, Novo’s parent, Novo Holdings, joined Arsenal and another private-equity firm in recapitalizing WCG in advance of a public stock offering. (The offering never happened.) Two Novo Holdings officials would take seats on WCG’s board; WCG’s former chief executive would join Novo’s advisory board.

Between 2012, when WCG was incorporated, and late 2019, it was tapped 17 times to review interventional drug trials for Novo, according to records obtained through a Freedom of Information request. That figure surged to 46 trials in the years since the drugmaker’s parent invested in WCG.

Wegovy, a sister medication to Ozempic, features the same active ingredient. Hollie Adams/Reuters

The trials examined semaglutide’s effect on obesity, diabetes, and certain types of liver and kidney disease; it was effective in treating them, and in lowering the risk of cardiovascular disease.

Evaluating these testing protocols was no small matter. Laboratory rats developed cancer after taking it, and even though the F.D.A. approved the drug, it must carry a boxed warning, indicating the highest level of risk. No evidence has emerged linking the drug to cancer in humans.

More than 2,300 federal lawsuits accuse Novo Nordisk of failing to properly alert patients to possible harm from semaglutide, including intestinal paralysis, gallbladder injury and bowel blockages. “We have significant questions on what was evaluated during the course of clinical trials,” said Jonathan Orent, co-lead counsel on those lawsuits.

The drugmaker has denied the allegations.

Novo Nordisk declined to be interviewed or answer written questions for this article. But in a statement, a spokeswoman, Liz Skrbkova, said, “We expect all our partners, including WCG Clinical, to comply with strict regulatory and ethical standards, in line with our unwavering commitment to patient safety, data integrity and transparency.”

Advarra also underwent a transformation, advertising that it could provide “an end-to-end solution for managing all aspects of a clinical trial.”

Watching this was Blackstone, the world’s biggest private-equity firm. In 2018, it bought Clarus, a company that funded trials of experimental drugs.

Four years later, Blackstone and another fund announced they had made “a majority investment” in Advarra, laying the groundwork for potential conflicts of interest like those at WCG. The Times’s analysis of federal data found that Advarra was hired to review the trials of at least 10 drugs in Blackstone’s Clarus portfolio. (In a statement, Blackstone said it did not make operational decisions for those drug companies. Separately, Advarra said Blackstone “has never attempted to influence the review of a clinical trial.”)

Inside the I.R.B.s

Speed is the reason drug companies have turned increasingly to commercial ethics panels. Instead of waiting a month or more for a university or hospital to render an assessment, a commercial panel might take a week. With private equity, the imperatives of speed only intensified.

“And they very, very rarely ask questions,” said Lisa Shea, a former manager at a company that provides research help for pharmaceutical and medical-device companies.

Ms. Shea said she had worked on 80 to 100 industry trials. “Protocols are not written perfectly, even if it’s the final protocol.”

Nor are all consent forms — a vital element of protocol reviews. “They too often appear to be designed more for protecting the legal interests of institutions conducting research,” three researchers wrote in 2017 in The New England Journal of Medicine.

In interviews, four former Advarra employees spoke of pressure to process consent forms faster. Three told of quotas for processing those forms.

Falling short means “you get a warning,” said Alana Levy, a former consent form development editor. She added, “You could get a bonus if you did over a certain number.”

Another former consent form editor described a dashboard that measured the amount of time workers took to edit each form.

In its statement, Advarra said it did not impose quotas or give bonuses based on volume or speed.

A Times investigation last year showed the consequences of one trial approved by Advarra. Among the trial volunteers were 274 whom genetic tests had shown to be predisposed to brain injuries if they took the drug, but the protocol stipulated that the patients not learn those test results. Two high-risk volunteers died, and more than 100 others suffered brain bleeding or swelling.

A form from a drug trial saying that genetic testing results would not be shared with trial participants.

Advarra said in a statement that ethics panels outside the United States had also approved the protocol.

At WCG, the pressure to maximize profits contributed to internal discord, according to former employees. Testifying in 2024 in an employment dispute, a former WCG vice president, Michael Demo, said one executive took disfavored employees to the back of a local Cracker Barrel restaurant to “scream at an appropriate volume.”

In the same lawsuit, another former employee, Ericka Atkinson, said “the morale was terrible.” To calm the waters, she said, WCG called a senior leadership meeting in 2024 in Princeton, N.J., assisted by a consulting group led by the retired Army general Stanley A. McChrystal.

Restoring order at WCG proved elusive. Ms. Atkinson, who attended the session, said it devolved into small groups attacking one another. “The meeting in and of itself was toxic,” she said. She, too, left WCG.

Walt Bogdanich joined The Times in 2001 as investigative editor for the Business desk. Since 2003, he has worked as an investigative reporter. He has won three Pulitzer Prizes.

Carson Kessler is an investigative reporter and a member of the 2023-24 Times Fellowship class, a program for journalists early in their career.

Jeremy Singer-Vine is a data editor at The Times, leading a team of journalists who combine programming, data analysis and traditional reporting skills.

See more on: Novo Nordisk A/S, Blackstone Group, The, Food and Drug Administration

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