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Whistleblower on Medical Research Fraud: 'Positive Results Are Better for Your Career'

By Rafaela von Bredow and Veronika Hackenbroch



Andrew Fox/ DER SPIEGEL Cardiologist Peter Wilmshurst at his home in Atcham, Britain. He blew the whistle on malpractice by US pharmaceutical company NMT Medical.

In an interview, whistleblower Peter Wilmshurst discusses how pressure from Big Pharma corrupts research into new medicines and leads companies to cover up fraudulent data. He says he has no regrets about taking on an entire industry.

Semi-retired British cardiologist Peter Wilmshurst -- described in 2012 by the *British Medical Journal* as a "successful and cheerful whistleblower" -- began his crusade against dishonesty in medical research in 1986. In the course of the 66-year-old's career, he conducted studies for pharmaceutical and medical devices companies, and unlike many of his colleagues, never hesitated to publish negative results. He's been the subject of multiple cases of legal action and risked bankruptcy and his reputation to expose misconduct in the pharmaceutical industry. Today he advises and supports other whistleblowers with the organization "Patients First."

He sat down with SPIEGEL to discuss mistruths and fraud in medical research and why he decided to challenge the pharmaceutical industry.

SPIEGEL: In your early years as a researcher, a pharmaceutical company offered you a bribe equivalent to two years of your salary: They wanted to prevent you from publishing negative study results. Were you disappointed that you weren't worth more?

Peter Wilmshurst: (laughs) I was just a bit surprised to be offered any money, really. I was a very junior researcher and doctor, only 33 years old, so I didn't know that sort of thing happened. I didn't know that you could be offered money to conceal data.

SPIEGEL: How exactly did they offer it to you? They probably didn't say: "Here's a bribe for you."

Wilmshurst: No, of course not! Initially we were talking about the results that I'd obtained: That the drug that I had been testing for them did not work and had dangerous side effects. Then the company representatives asked me to leave some of the patients out of the data analysis. Without these patients, the study result would have been positive. When I said I couldn't do that, they asked me not to publish the data. And to compensate me for the work I had done in vain, they said, they would offer me this amount of money.

SPIEGEL: What went through your head at that moment?

Wilmshurst: Well, I thought it was wrong. If you've got the data, you have got to publish it. That's the imperative. I mean, that's one of the big issues in pharmaceutical research, that the data we're basing our treatments on are actually only part of the data, because industry conceals the unfavorable bits.

SPIEGEL: So it didn't take you long to make up your mind?

Wilmshurst: No. Also because the patients that took part in our research did this on the expectation that their data would be used. In this study the participants had had cardiac catheterization. They had risked their lives for the study! So you cannot hush up the results!

SPIEGEL: How did the company react?

Wilmshurst: They terminated the trial prematurely, and to prevent us from doing more research with the drug, a representative from the pharmaceutical company came to the hospital pharmacy and asked for the stocks. The pharmacist noticed that something was wrong and tried to call me. While he was on the phone the drug rep picked up the box with the drug in it and left.

SPIEGEL: They stole the drug?

Wilmshurst: Well, it was theirs, so they didn't really steal it. But it was very unorthodox. Later other scientists who were associated with the company attempted to publicly discredit our results. And then we learned that three other groups that had tested the drug had also had negative results. But they had been persuaded not to publish them. Each of them had been told that they were the only ones with negative results and that their reputation would suffer if they published.

SPIEGEL: Is research fraud like this widespread?

Wilmshurst: I can't tell you exactly what percentage of the trials are flawed. But I think the problem is far bigger than you imagine. And it is getting worse.

SPIEGEL: Why?

Wilmshurst: Because research is getting more important for a doctor's career, and it is so easy to manipulate data, conceal it or fabricate it. Or make unimportant research look like a huge success.

A Trillion Dollar Industry Global annual pharmaceutical industry Average profit margins revenues, in billions of dollars by industry, in percent 10 15 20 1.043 Pharma Media Oil/gas 499 Auto Current as of 2013 2014 Source: Forbes

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Graphic: The Trillion Dollar Pharmaceuticals Industry

SPIEGEL: Are studies about drugs with dangerous side effects also systematically hushed up?

Wilmshurst: Yes, absolutely. And often the scientists don't even have to be offered bribes or threatened to conceal data. Some do it without any industry pressure. It is much better for a researcher's career to publish positive results. And that is what it's about: to climb up the ladder a bit more.

SPIEGEL: How exactly do the strategy managers of big pharmaceutical companies go about bringing a drug to the market? You know the tricks ...

Wilmshurst: Indeed. I could probably advise aspiring managers in the pharmaceutical industry (laughs).

SPIEGEL: Okay, let's play a little game. Let's pretend to be these managers. What would you advise us to do?

Wilmshurst: Well, I think the way you should do it is to get eminent doctors on your side by paying them a lot of money. Officially they are still independent consultants or university professors, but the truth is, they lose their independence the moment they are on your payroll. What these opinion-leaders say has a lot of weight among other doctors.

SPIEGEL: Is money enough?

Wilmshurst: I think for many of them enough money is all they need, really. I mean, most people have a price. But of course you have to be very friendly with them, you have to go and talk to them, have lunch with them, discuss the research. They have to forget that it is your aim to make the maximum amount of money.

SPIEGEL: And what if the professor produces results in a trial that we don't like?

Wilmshurst: You have made the principal investigator sign a confidentiality agreement beforehand, so that you have control over the data. And you may put into the contract arrangements for a bonus in case of a positive result. (grins) This may help the researcher interpret the data in a more favorable way for you.

SPIEGEL: But there's one obstinate researcher who keeps insisting on publishing negative results. And he doesn't accept the bribe that we offer him. What now?

Wilmshurst: Well, you can try and discredit him, you can try to ruin his reputation and cast doubts on his results. That's what was done with me. And then in the end you can sue him. The threat is often enough to keep him quiet.

SPIEGEL: Later, long after the first attempt at bribery, you also declined a $\pm 50,000$ ($\pm 69,000$) consultancy fee that was offered to you by another company. Are you a hero?

Wilmshurst: (laughs) I don't know. I'm not actually the only doctor who doesn't take bribes! And why is this seen as a heroic deed? Nobody says: Great, that you didn't rob this bank! I see it the other way around: How can anyone accept this money?

SPIEGEL: Most young people start medical school with very high ideals ...

Wilmshurst: ... yes, at the beginning they all want to work for Doctors without Borders. Then, five or six years later when they leave medical school, they want to be a cosmetic surgeon.

SPIEGEL: And how are they pulled into the system?

Wilmshurst: I think it starts in a very innocent way. You go to a lecture and the pharmaceutical industry provides sandwiches for lunch. You don't think of a sandwich as a bribe, do you? And then you see other people taking more -- money for lectures, tickets to conferences. Gradually you accept bigger and bigger bribes.

SPIEGEL: So many senior doctors are not very good role models?

Wilmshurst: Unfortunately not. As a junior doctor what you see is that money is very, very important. Many doctors judge their value to society by how much they earn. Like bankers. If they haven't got enough to drive a Porsche, then they're not a very good doctor.

SPIEGEL: Ambition and envy must play a role, too. Why do so few doctors speak up when they notice one of their colleagues is manipulating data?

Wilmshurst: I absolutely agree that research fraud seldom goes unnoticed. Colleagues know that someone has not used as many animals or as much radioactive isotope as written in a publication. But there is almost a code of silence not to speak about it.

SPIEGEL: But why do the honest doctors keep silent?

Wilmshurst: It could end your career. Maybe your boss knows about it? And condones it?

SPIEGEL: So you better not risk it?

Wilmshurst: Well, maybe I shouldn't say this, but it's a bit like speaking up in Nazi Germany, isn't it? It's so much in the system, you don't know who is involved and whom to turn to. Although obviously the consequences of speaking up in medical science are not so extreme -- one can end up unemployed rather than dead.

SPIEGEL: But most publications have coauthors. How can someone agree to have his name on a paper if he suspects the research could be fraudulent?

Wilmshurst: You are absolutely right. Take the case of Joachim Boldt, the German anaesthetist from Ludwigshafen Hospital. He published a phenomenal amount of articles until it became known that he didn't have the consent of the ethical committee and fabricated data in about 90 of them. How could his coauthors not have noticed a fraud of this size? Even if he did not ask them if they wanted their name on the paper, once the paper was published they must have seen it.

SPIEGEL: A few years ago the medical devices company NMT Medical sued you for libel. You had conducted a study for the company and then pointed out some severe problems with the security of a device. There were several legal actions against you. In the end the company went bankrupt, and you lost £25,000. Was it worth it?

Wilmshurst: Oh yes. Yes, of course.

SPIEGEL: Why?

Wilmshurst: Why? Because it has helped to get the true results of the study out: that this medical device did not work and led to some life-threatening complications. The first publication was sugarcoated. After the trial a correction had to be published. And although this correction is still not 100 percent correct, it is better than the first version.

SPIEGEL: During the almost four years of the legal actions you spent almost all your spare time work on your defense. Does your wife agree that it was worth it?

Wilmshurst: Yes, absolutely. And my two daughters, too. Of course, it was a difficult time for me and my family. But that doesn't mean you can do what's wrong, does it?

SPIEGEL: Did you celebrate when the legal actions were over?

Wilmshurst: Oh yes! All along we had thought we were going to go bankrupt and lose our house. When we realized, we would only lose $\pounds 25,000$, my wife and I opened a bottle. So losing $\pounds 25,000$ can be a good reason to celebrate! (laughs)

SPIEGEL: Do you know other cases where things ended well for a whistleblower?

Wilmshurst: No, almost none.

SPIEGEL: Why?

Wilmshurst: Colleagues and superiors don't trust whistleblowers, because they think it could be their turn to be reported next. Also, the reputation of the medical institution they work for is at risk if a whistleblower reports fraud, so loyalty to your employer is valued higher than the truth. But I think as a doctor your loyalty should be primarily to your patients. And as a scientist it should be to the truth of your research. But I think some people have forgotten what it means to be a doctor and a scientist.

SPIEGEL: What in your view are the most important changes that should be made to prevent fraud?

Wilmshurst: I think there should be routine controls in labs and during clinical studies. Research should be independently checked.

SPIEGEL: That's unlikely to scare the pharmaceutical industry.

Wilmshurst: Yes, so there also have to be more fundamental changes. Since it's the money of the pharmaceutical companies that controls the researchers, it would be important to put a barrier between the company and the scientific investigators. The company could pay the money that is needed to do a study to an independent body, e.g. the Department of Health. The Department of Health then suggests which researcher could do the study, and when the company agrees, pays out the money. So there is no direct contact between the company and the researcher.

SPIEGEL: Where would you be today, if as a young doctor you had decided to accept the bribe from the pharmaceutical company?

Wilmshurst: I don't know. Well, you never know, do you? I might be in prison! (laughs)

SPIEGEL: Dr. Wilmshurst, we thank you for this interview.