

**Peter Gøtzsche, 19 April 2013**

**Just for the record, do you want to tell me a little bit about your background?**

First I became a biologist, then I worked in the drug industry and I very quickly realized that I could not stay there for long, so I started to study medicine. I know what people do in the drug industry.

**Who did you work for?**

Astra, later Astra Syntex, which was a joint venture with the California-based company Syntex. And our major product was naproxen.

I have written in my book that comes out later this year what was wrong with the research and marketing of naproxen, because I remember that very clearly. The company had done some dose-response studies, where they for example gave nothing, 250 mg, 750 and 1500 mg, and then they claimed in the article that there was a linear dose-response relationship, which comes close to fraud. A dose-response relationship looks like a hyperbola, and naproxen is dosed very highly, already 500 mg a day is a high dose. If you draw a curve based on the averages, which were tabulated in the article that had no such curve, you can see very clearly that in the whole spectrum of doses from 250 mg to 1500 mg, you gain virtually nothing. Actually, you gain less than the minimal clinically important difference. So you don't get any benefit from using higher doses. What you do get are harms, which are linearly related to dose in contrast to the benefit. So you get a lot more gastric ulcers. This was not the only dose-response study. There were several such studies, also from other companies, and they were about equally fraudulent.

**What was this used for?**

This was used for telling general practitioners and arthritis doctors (rheumatologists) that they should double the dose and give 1000 mg rather than 500 mg of naproxen daily. That meant a lot more ulcers and kidney problems and whatever you get from that increase in dose. I already knew that when I worked for the company because I could see through its tricks. I wasn't responsible for them, however. I did my own trials on naproxen, so that is just my experience.

**When was that?**

That was from 1977 and onwards. Actually, right up till I became a doctor in 1984, I worked for that company.

**So it was the time that Astra was bringing the first SSRI on the market?**

Yes. The drug was zimelidine and it caused Guillain-Barré's syndrome. There were also arthritis drugs that were withdrawn, so I saw early on just how harmful research and marketing of drugs are.

**Okay, so you studied medicine and qualified in 1984. And what type of medicine did you go into?**

Virtually everything. But I spent most time in departments of gastroenterology and hepatology, because Denmark had a tradition that people who were strong in methodology ended up in these professions. So I looked actively for these departments, not because I was particularly interested in gastroenterology, but because that was where the clever people worked. Later, I came into infectious diseases, but my thesis was about non-steroidal anti-inflammatory drugs (NSAIDs), because I had worked with that in the drug industry. After the thesis, I started in rheumatology and thought I would become a professor of rheumatology, but then The Cochrane Collaboration was about to start. I joined it immediately realizing that as a doctor you can help one patient at a time, but if I do a good review, I might help hundreds of thousands of patients.

**So this has been very rewarding. Start with explaining, when did you join Cochrane?**

When it started in 1993. I had defended my thesis in meta-analyses three years earlier, and I believe there wasn't anybody in the Nordic area that had done this, I'm pretty sure about that. At that point in time, there were only about 150 meta-analyses in the medical literature, and I had done three of them. So I came very early into this and had to look up obscure references to find out how to do meta-analyses. Some of what I found wasn't particularly good, which I realized afterwards, so the science of meta-analysis has improved tremendously after doctors took over. In the beginning, it was the psychologists and social scientists, and the way they did them, wasn't really good. But when doctors and medical statisticians came on board, it became much better.

**So, you hooked up with Cochrane. You became in essence an epidemiologist, now into screening?**

Yes, but I never called myself an epidemiologist. I'm a researcher, that's it. I have done research in so many different areas and ways, so you cannot put me in a box, and put a label on me.

**I'm not trying to put you in a box.**

No, but it is like an art critic who once asked Pablo Picasso: "You have painted in so many different styles, what are you looking for?" And Picasso said, "I'm not looking, I'm finding." That's what I do, too.

**That's an interesting comment on research these days, because most research groups want to distinctly do one thing, and if you do more than one thing, you're a dilettante.**

Yes. And this academia is so funny many times. When I got my professorship, I became very annoyed by the evaluation of my merits, because it said something about my line of research being somewhat narrow, but I have done research in all sorts of ways and areas. I was very annoyed, also because the evaluation went on criticizing me for this and that, although I'm pretty sure I'm the only Dane that has ever published more than 50 articles in the big five (BMJ, Lancet, JAMA, Annals of Internal Medicine and the New England Journal of Medicine). So, how can people tell me it isn't good enough?

But that's how academia is. You know how it is. No matter what you do, you are told that it isn't really good.

**Okay, what with the big things you did, Peter, before you got involved in screening and the whole mammography screening affair?**

I did some meta-analyses early on that I still find quite interesting. For example, I documented in my thesis how much bias and fraud there were in the randomized trials where one NSAID had been compared with another NSAID. These trials were done for marketing purposes and they were terrible, basically, most of them. Then I went on and did some revealing analyses that told us that what the companies had published – that the new drugs were better than the old drugs and had less harms – just couldn't be true. I got the idea to look at the cross-over trials that had compared a new drug with an old one, and where the patients had been asked which drug they preferred after having tried both of them. They should of course prefer the new one, if the industry's trials were to be believed. I analyzed the cross-over trials with indomethacin, which is an old drug that people have said have many adverse effects. What I found was that the patients didn't prefer the new drugs more than indomethacin. So, I used data that the drug industry never thought should be used for anything of this nature. In particular, I think they didn't bias these data, and I used them to show that it's all a hoax. It's not true. I published this meta-analysis in The Lancet.

Then there was this thing about doctors saying that it's better to use non-steroidal anti-inflammatory drugs than plain painkillers like paracetamol, if you have an inflammation, because they work against the inflammation. So I thought: How can you document that they have an effect on inflammation, because if they work on pain, people will move around more, and if they do that, I will expect the oedema to go down because of that. What I did was that I used trials that had a

placebo control, and which had measured the size of the inflamed finger joints with jeweller's rings very precisely. I found out that these drugs didn't reduce the size of the swollen joints, the ring size, so I couldn't see an effect.

Some years later I did a large study with orthopaedic surgeons on ankle distortions. A beautiful study, where we randomized the patients twice: once to naproxen or placebo, and once to crutches or no crutches; a factorial design. I was very interested in seeing whether naproxen decreased the oedema, which we measured by emerging the foot in water and noting how big it was compared with the other foot. Naproxen didn't reduce the oedema the slightest bit whereas mobilising the patient by not providing crutches had a large effect! So again, I had demonstrated that this so called anti-inflammatory effect is a hoax. People in sports medicine give these pills to footballers and others, because they think they work on the inflammation, but it's a very bad idea, as we know these drugs decrease the body's ability to heal. It's very bad, also because the pills can kill the sportsmen by causing myocardial infarction or a bleeding stomach ulcer.

There is another twist to our study. I was on the editorial board of the BMJ at the time, and I went to London and could hardly walk. I walked in great pain, and Paul Glasziou from Australia asked me that, since I had injured my ankle, then why didn't I use crutches, as I could hardly walk? I told him that I had done a large randomized trial that showed that I would recover faster, if I forced myself not to use crutches.

This inspired Paul Glasziou to do a meta-analysis of bedrest where he concluded that bedrest is not good for anything; it looked like bedrest was a bad thing. But our large, very important study was not understood by people. We submitted it to the BMJ that rejected it, and we submitted it to a humble Nordic orthopaedic journal that didn't understand it either and rejected it. Then my co-authors got tired, and we translated it into Danish and published it in the Journal of the Danish Medical Association. Many years later, a researcher told me that our study was the best of all such studies in the world! So he wanted me to translate it into English, that's really ironic. But, well, that's academia again, there are many failures in academia. It's such a beautiful study.

### **So, when did screening come into your life?**

It was enforced upon me in 1999 because a study in the Swedish Medical Journal had shown that it wasn't possible to see any effect of mammography screening in Sweden, although they had screened for 14 years. This made the Danish Medical Association contact the Danish National Board of Health to ask them what they should believe, the Swedish observational study or the randomized trials? That was a very hot potato, indeed, because we had only had screening in 20% of the country, and there would be a voting in parliament in 5 weeks' time about introducing it in the whole of Denmark. The hot potato quickly ended in my lap and I was asked to review the trials. We worked like hell, my statistician and I, because we wanted to finish our work before the vote. In just 4 weeks time, we produced a report that more or less tells us the same as the very extensive Cochrane review we did later. So you can work fast, if you need to.

We concluded that we didn't know if screening did more good than harm, and that it was also possible that it did more harm than good because there is overdiagnosis. Our report was shelved at the National Board of Health; it never made it to the ministry. It was shelved for political reasons, so that our minister of health, who was against screening, never learned about our results. People voted in parliament and they decided to introduce screening. But then a colleague leaked our report to the press and there were devastating articles in major newspapers about the Machiavellian methods in the Danish National Board of Health. Then we were asked to do a full Cochrane review and the National Board of Health funded it, so that's how I came into this. But the politicians in the rest of the country were still sceptical, in fact so sceptical towards screening that they didn't introduce mammography screening despite the decisive vote.

### **How were they sceptical?**

Well, the leading politician in Danish healthcare said that he had great respect for the National Board of Health that had produced a heavy report recommending screening, but also that he had great respect for the work of the Nordic Cochrane Centre. So he didn't know what to believe. For the next 17 years, the politicians didn't introduce screening because of our work.

### **Why did you say the first vote went to favour screening, so was that undone?**

No, the parliament decided that we should screen in the whole country, but the local politicians resisted this for the next 17 years, which is quite remarkable.

And this had the result that Denmark is the only country in the world that has a concomitant control group that was not screened. We have of course taken advantage of that and have shown that we cannot see any effect of screening in Denmark, in fact breast cancer mortality has gone down equally much in the non-screened areas as in the screened areas. But people won't listen, it's a religion.

### **What is causing the rise in breast cancer incidence? The instruments were thought to detect breast cancer, not to increase the incidence of breast cancer?**

Yes, but they do. Screening increases the incidence dramatically. In a way, you could say that screening causes breast cancer, but this needs some explanation. What screening does is that it detects a lot of cancers that are harmless. Many of these would have disappeared by themselves without any treatment, which we also know can happen for several other cancers. So in a way you can say that screening causes breast cancer, not because of the little radiation women get when they are screened, but because it unravels cancers that it's not beneficial to detect.

### **What does this mean for the women?**

Only a few months ago, Michael Baum in London calculated that any positive effect of mammography screening on breast cancer mortality is neutralized by the harms caused by radiotherapy when this is used in healthy overdiagnosed women. It increases the risk of dying from heart disease and lung cancer and several other things. So, one of the big fat lies about mammography screening is that it saves lives. It doesn't.

### **So you got engaged in mammography screening and it became a major controversy. When did this start?**

Oh, that's a very interesting story, because - when the National Board of Health wanted to bury our report, so that no one in Denmark would ever learn about it - I decided that the whole world should learn about it. We worked for another month and submitted a paper to The Lancet, which made the editors' heads turn round, as we were told. We corresponded with the people who had done the trials and got more information from them that we put into the revised paper after it had been peer reviewed. That's how, only half a year later, we published in Lancet what Danes were not supposed to know about, and it created an enormous fuss. I think our paper has been cited some 700 times.

We published another Lancet paper, only one year later, because - when we had finished our Cochrane review - the Cochrane Breast Cancer group censored the review. They didn't want us to write about the harms of screening, although this was anticipated in our protocol that the same group had approved and published. In that protocol we talked about the number of operations and so on, but we were not allowed to publish this information. There were conflicts of interest. I believe there were several editors in the Cochrane Breast Cancer Group who were in favour of mammography screening. But it was outrageous. We have always said in The Cochrane Collaboration that harms are equally important as benefits. The Cochrane editors offered us to publish the benefits and said that they would think more about the harms, but they had already thought about the harms for a full year! So why think more about them? Our results were very

clear. We got so intensely frustrated that we submitted the full report to Lancet, and we were supported very much by Richard Horton, the editor, who published a harsh editorial where he outlined that the Cochrane Breast Cancer Group had not adhered to the principles of the Cochrane Collaboration.

### **And what then?**

I didn't become the most popular man in Cochrane, of course, because some people thought that we should have kept this behind closed doors. But, come on, how could we? We had done everything we could; we had negotiated with these editors repeatedly and thought we were approaching a mutual understanding. But then they suddenly turned their thumbs down, just before the review was coming out and said that they wouldn't publish the harms. That was when we turned to Lancet that acted incredibly quickly. We submitted our full review to Lancet, including the harms; we received extensive peer reviews; we responded to the peer reviews; we updated the review; and we published it. The whole process took just took five weeks! Journals can be very fast when they want to.

### **When was that?**

In 2001.

### **Okay, and your mammography screening book? When was that?**

In 2009, I attended a conference in London about women's health, and a professor in cancer screening, Stephen Duffy, gave a lecture about breast screening where what he said was so absurdly wrong that I decided that now I had just had enough. I started writing my book at the hotel while still participating in the conference and I document in it that Stephen Duffy has lied about his own research. After I had pointed out a serious error in his research, both to himself and in a letter I published in Lancet, he lied about his research in his reply. It was really over the top, so I wanted to expose these people for what they are, which is why I wrote the book.

### **What happened between 2001 and 2009, I mean, the screening issue balanced back and forth and a growing number of people agreed with you?**

There's still a lot of opposition but the whole field has moved a good deal in our direction, and one of the clearest signs of that was when the leader of the Norwegian Breast Screening Programme, breast surgeon Mette Kalager, started to study the effect of screening. She discovered by herself that screening doesn't work and that it creates harm. Just as we had said. She abandoned her job but was now accused of scientific misconduct by the Norwegian Cancer Registry, which is like Cancer Research UK. There was no scientific misconduct or any substance in this allegation, it was an outrageous *ad hominem* attack. But that was not all. When she has submitted her PhD, it was rejected by Elsebeth Lynge, the person who was behind the National Board of Health's report that recommended introduction of screening in Denmark. Her thesis was rejected because of a paper on overdiagnosis, which I had peer reviewed. It was a good paper, and it was later published in *Annals of Internal Medicine*. She also had a paper in *New England Journal of Medicine*, and yet her PhD wasn't considered good enough. So there you can see again just how unfair academia can be. Kalager got another committee assembled after having had to go through a lot of trouble, and she did get her PhD, but the whole process was scandalous.

I should say one more thing about people like Elsebeth Lynge and Stephen Duffy who believe strongly in screening. They bury the data in complicated statistical models, often of such a type that they will tell you anything you want to hear. You can put the assumptions into the model that you need and you will get the results you want to see. Elsebeth Lynge has, for example, published a paper where she claims - this time not based on a model - but she claims that we can screen in Denmark without overdiagnosis.

Which is ridiculous because it is biologically impossible. I mean, you advance the time of diagnosis, and if a woman gets killed in the traffic before she would have had a clinically detectable cancer, this is by definition an overdiagnosed case. You cannot screen without overdiagnosis and yet Elsebeth Lynge has postulated this in a paper that lended no support to this idea. We have written many letters to the editors where we have pointed out all the errors our opponents have made, it could be a whole textbook about how not to do research.

**You have worked very intensively on the breast cancer screening issue. Do you think the same errors, the same motivation, occur in all screening programs?**

What I can say is that what we have uncovered about breast screening, I find everywhere. It is very common that researchers deliberately use substandard methods to “prove” their point.

**What about prostate cancer screening?**

Well, there are only a couple of randomised trials, and it is not the same problem. No, I am talking more generally about that people everywhere, far too many people, are prepared to sacrifice what they know are sound scientific principles and use unsound scientific principles instead in order to sustain their beliefs. This is one of the biggest threats against a rational health care that we have. If engineers had been like that, we would never have been able to land people on the Moon.

I just don't understand why so many researchers and health care people can be so dishonest. I don't get it. I have shown in many of my papers that people are deliberately dishonest, because even after I pointed out to them that what they did was clearly wrong, they continued doing it.

**What are the forces, I mean, they get away with this, so what are the forces and why do the regulators, for instance, refuse to warn about the hazardous screenings and the hazards of drugs?**

That is a very complicated story, but at least we know that drug regulators are often the last ones to detect and warn against dangers of drugs, and this is partly because warning against a drug is the same as admitting that they weren't careful enough when they approved the drug, and partly because they deal with the drug industry every day. The drug industry meets with them, they call them up on the phone, they consult with them about what they should do in this and that situation. They don't consult with patients; they don't consult with doctors really, so they become more and more on the same wavelength as the drug industry. Further, many people go back and forth between a drug agency and a drug company, that's the revolving door phenomenon, and if a high ranked person in a drug agency is very kind to the drug industry and ignores the harms of their drugs, he can look forward to a highly paid job in a major company if he wants to.

The whole history of the US Food and Drug Administration (FDA) is one that is riddled with scandals where higher-ups overrule their scientific officers again, and again, and again, for no good reason apart from cultivating their own interests. Drug regulation doesn't ensure we have safe drugs.

**What is it in terms of screening and our approach to drugs, which involves not recognizing the harms? What are the common factors?**

First of all, National Boards of Health behave like in the BBC “Yes Minister” series. When politicians have said mammography screening is a good thing and that now we should screen, then they say “Yes Minister,” and they downplay the harms and exaggerate the benefits. It's terrible, but they are not neutral. With doctors, it's more the human dimension. Doctors don't like to face the harms they create, they deny them, they overlook them, and they explain them away.

**Turning to antidepressant drugs, what would happen, if on TV or radio, you asked one of your opponents, “Lars Kessing, why do you have so many difficulties acknowledging the harms that you cause?” What would he say?**

I am pretty sure he would say that I exaggerate; that the harms are minor; and that these drugs don't cause suicide although this is a lie. He actually said on television that these drugs *protect* against suicide. I was the next speaker and said that these drugs can cause suicide.

**What is it that motivates these experts to take the approach they do, that they cannot be doing any harm? And how do you turn them around, have you ever in debates been able to get them to stop doing harm?**

Yeah, it does happen that I shock people so much that they start thinking, but a good number of them are beyond reach. You can't do anything, no matter how hard you try, so you need to work on those in the middle who can be influenced by good arguments. I have given up trying to find out what goes on in people's minds, it's just too complicated and it's too irrational many times. Emotions play a huge role in how humans think and behave, you know that.

**Can you think of any good examples that you can give me on how to lead an academic debate where things change?**

They are so rare that they are hard to remember. I have debated twice with psychiatrist Lars Kessing on live TV where he said things that weren't true. He came up with this horrendous argument, which the drug industry also uses, that although antidepressants increase the risk of suicidal thoughts and behaviour in children and adolescents, they somehow don't increase suicides. If you produced a new car that is dangerous and you could see that it increases the amount of personal injury in the traffic, would you then say "Oh, but it hasn't been shown that it increases deaths, so we believe that it doesn't increase deaths." This is ridiculous.

In FDA's material of one hundred thousand people in randomized trials there were just 8 suicides, and we know that the companies have cheated because they have held back many suicides. It has been documented that there were many more suicides than what the FDA reported. It is doubly outrageous for the psychiatrists to say such nonsense because it has been documented - which cannot surprise anybody - that there is a relation between suicide attempts and suicides. Of course there is. If more people try to kill themselves, more will succeed.

**When did you get into psychiatric drugs and why, I mean screening was your big thing, so when did you get into the antidepressives?**

This was about 5 years ago. A person who had worked in the Danish Consumer Council came to me and wanted to do a PhD, which she called "Is history repeating itself, a comparison of benzodiazepines and SSRIs." I thought it was a brilliant idea. She did three nice studies and is now defending her PhD. The most important part of her work was that she found out that 37 of 42 symptoms when people stop taking a drug were the same in people on SSRIs as in people on benzodiazepines. But the psychiatrists try to tell me that this is very different and that we have misunderstood the issues. They have argued that patients can get convulsions when stopping benzodiazepines, but there are actually also reports of convulsions when people stop SSRIs, so it is more or less the same that happens.

This is a very important contribution to the literature she made there. And then I met you in 2010, which only increased my interest in this, particularly after I had read your book, "Let them eat Prozac."

**Okay, but when did you really get deep into it, the whole SSRI affair.**

That was about 2 or 3 years ago. We asked the European Medicines Agency (EMA) about unpublished clinical study reports of SSRIs, so we are now working with these reports in order to find out the extent to which the companies have cheated by underreporting hostile reactions and suicide attempts and behaviour. We wish to find out if these drugs increase the risk of suicide in all age groups.

### **What about old people?**

During the work with my book, I went through a huge amount of literature and I found a very good cohort study, very carefully done, in people on SSRIs that were above 65 years of age. This study found that for every 28 old people you treat for just one year, you kill one of them.

### **Is this all suicide?**

No, it's not suicide. These drugs are so harmful for old people that it's difficult to believe, but we know what the mechanism is. They often lead to falls, and when people break their hip, one quarter of them die. We knew already that elderly people are very susceptible to the effects of brain active drugs, so it is not surprising that SSRIs kill old people. Maybe we should do some research on this. Because I heard yesterday on television that every third or fourth elderly person was on an SSRI; this is terrible. They are not depressed to this extent. They are just sad because life is soon over and all that sort of thing. We should not give them an antidepressant that kills them.

### **Okay, just to come back then, what was it that made you ask the European Medicines Agency about unpublished data?**

I actually can't remember how I got the idea. It was in 2007 that I decided that the pervasive secrecy in drug regulation was just too much. We have so many Cochrane reviews on drugs, and what we do is that we repeat what the drug industry has carefully selected for us and published, and we know that this isn't the truth. So in a way we are acting like the drug industry's lapdog.

### **Hmm, it's marketing department?**

Yes, but this is not what we want. I know a lot about how much the drug industry is cheating with its research, so I decided that I would try to get hold on unpublished trials in the European Medicines Agency on two anti-obesity drugs, because these drugs are quite dangerous, and the effect is small. I wanted to find out whether we could get access to the data, and since I never thought we would succeed, my plan was that I would expose all the foolish arguments for not releasing these data to us in the British Medical Journal, when we were done. However, to my big surprise we got access, but only after we had complained to the European Ombudsman.

### **Did you write to him or go to a meeting?**

No, I sent a letter. Nikos Diamandouros, a fantastic person from Greece who took our case very seriously. Because the European Union is built on some wonderful principles that allow the citizens to get access to documents that are important for them, and where it is also said that it gives legitimacy to the administration that the citizens can see what is happening. Our case took three years. There was a lot of correspondence between the Ombudsman, the director of the EMA and us.

### **The director of EMA was?**

Thomas Lönngren from Sweden who, after the Ombudsman had accused the EMA of maladministration because they wouldn't give us access to the data, left the agency a few months later and went directly into a company that consulted for the drug industry. He had built it up while he was still a director of the EMA, in clear violation of EMA's own rules, which say that you cannot work for the drug industry for a quarantine period of two years. He already started with that while he was still at the EMA. It was scandalous. After we had gotten access to these reports, I quite quickly asked for access to SSRI drug reports, which are far more interesting than those for anti-obesity drugs.

### **So, you got access to the reports when? When did that come through?**

It came through in 2010 and we got the first reports about six months later.

It was a major, major breakthrough. A couple of years ago, the European drug regulators, all the national ones, met in Copenhagen and I was invited to give a talk about our breakthrough at the EMA. The national regulators started to discuss between them what they should do, now that the EMA had offered – or rather had been forced to offer through the Ombudsman’s intervention - public access. I believed they couldn’t go on saying to people, you can’t get access with us, particularly since some drugs are registered locally, which means that the EMA doesn’t have the documents. However, when we went to the UK drug agency to get data on fluoxetine, which the EMA didn’t have, it was like contacting the MI5. They weren’t prepared to give us anything. The emails I received even didn’t had a name on them, they were anonymous.

So I complained several times and finally told them that although some British people might think that Britain is outside the European Union, it was still a member of the European Union. I therefore argued that the agency couldn’t go on with the old style now that the EMA had changed. Then we got some documents, but very little. The agency told us that they had destroyed all the early documents on fluoxetine because they had a rule that after 15 years they can destroy everything “unless there is a legal, regulatory, or business need to keep them, or unless they are considered to be of lasting historic interest.” This is deeply ironic, because certainly, drug trials have both historic and legal interest. This outraged several members of the European Parliament. How can a European drug regulator just destroy everything after 15 years?

### **You talk about the European Parliament, when did you start making links there?**

In 2010. It was very funny really, because I was contacted by a Danish MEP who had heard that I would be a good speaker to talk about genetic screening at birth. I told her that I knew absolutely nothing about this, but that if she was interested, I could talk about mammography screening and our breakthrough with the EMA. She accepted this and I went to Strasbourg and gave my talk, but there were almost no people, just around 20.

### **What’s her name?**

Margrete Auken. One of the listeners was very important, a highly influential German politician who is also a doctor. He had been elected four times to the European Parliament and was very interested in our breakthrough with the EMA. He was also at that time the rapporteur for the Parliament in relation to the European Commission’s proposed revision of the clinical trials directive about how to do trials in the European Union. He asked me whether I could prepare a background paper for him about why we needed access to study reports and data from the trials, one of the obvious reasons being that many of them never get published, so we never learn about them. This assignment developed into a large paper that is much cited and downloaded, where I describe that we have a moral obligation to make available all results from all trials and patients. It’s pretty obvious according to the Helsinki Declaration, but that’s not how the world is. I called the paper “Why we need easy access to all data from all clinical trials and how to accomplish it.” That was my starting point as a scientific lobbyist in the European Parliament.

### **Who was that?**

Peter Liese. I was invited to more meetings in Parliament and I quickly came in contact with a huge consumer organization, Transatlantic Consumer Dialogue, that has some 20 to 30 million people as members. I gave talks about why we needed access to data, and the last six months I’ve been heavily involved on the sideline in political negotiations about the clinical trials directive.

One incident was rather funny. Auken was visited by three people from a drug company around a time when I gave one of my talks in Brussels. She said I should participate in the meeting, as it could be fun for me to listen to industry lobbyists. It surely was. One of them said, “We in the drug industry very much favour transparency about our clinical trials,” which made both Auken and me jump out of our seats and she told him bluntly that it was bullshit. She also called it window dressing and told him that he didn’t mean anything of what he had said and that we could

document this. So this is what the industry does, they try to tell people that they are on our side, which they are definitely not. They are fighting tooth and nail in the European Parliament to prevent independent researchers from getting access to the data and their unpublished studies, because they don't sell drugs, they sell lies about drugs. And if we can see what the truth is, it would be much more difficult for them to sell drugs.

**Industry, at the moment, seems to be split. There are the good guys, like GSK, talking about access to data, and then there are the companies trying to take legal action against the European cause. What is your view on this?**

They are all playing games, because if they were really serious about this, they would say, hey, we will behave just like the EMA and provide access with no conditions. It would be very easy but this is not what they are doing. They are setting up obstacles all the time. They construct their own committees, sometimes populated by friends of industry, who are going to judge whether a research project is "good enough" to warrant access to the data. But it's completely ridiculous, you can just ask yourself the question, would a drug company really provide access to data, if a guy like me comes along and wants to study the harms of a blockbuster, and if the company knows that it has deliberately cheated and concealed the harms, and if that the blockbuster might run a risk of getting deregistered if I did my research, and if also the blockbuster was essential for this drug company's survival? Do you really think that I would be allowed to see what they have behind closed doors? Of course it wouldn't happen – I would then be told that my project wasn't good enough, that there was something wrong with it or whatever. It just wouldn't work. I mean, how stupid can you be, how can anyone believe in this? That's what I wonder the most.

**But all sorts of people want to believe in this. The BMJ thought this was a wonderful idea.**

This is crazy. Why don't people learn from history? Why don't they learn from simple financial considerations? Which drug company would run a risk of going bankrupt if people like me were allowed to peep into their archives? Why would they? I mean, Ely Lilly, as you know, was in serious financial trouble and could "go down the tubes" if Prozac failed, as they wrote themselves in internal emails. Prozac is such a terrible drug, I don't understand why it was ever approved by anybody.

**So, who are the good guys, which you think are the people that could wake medicine up and realise that it needs access to the data if it is going to be proper medicine? Can you stop medicine to be fooled by people like the BMJ that thinks the GSK approach is wonderful. Ben Goldacre also thinks it is wonderful, how do you stop doctors to be stupid?**

That's not possible, is my first answer. You can stop some of them from being foolish, but it is very, very difficult because the industry buys everybody who has an influence and when you get nice money without having to do much to earn them, if anything, then you will be difficult to persuade. I call it corruption when the drug industry is paying thousands of doctors in my little country to sit on their advisory boards or to be a consultant for them or whatever, it is all about buying people, so how do you fight against this? You can't even turn to patients because they are dominated by patient organisations that more or less say the same as the industry does, and are often financed by the industry, so where to start?

**Do you think the reason they haven't tried to buy you is that it is very useful for them to have a person like you who seems to be the critic?**

No, that is not the case; they know very well that I can't be bought.

**But hang on. It is useful for them to have a Peter Gøtzsche so that they can controversialise. They build up the image of Che Guevara so he helps to sell t-shirts, helps sell mugs, helps sell everything in the same kind of way, I mean, industry loves controversies about Prozac and the birth defects caused by Paxil or whatever. They can use controversy to sell drugs, they get the name of the drug out in the media. It is wonderful to**

**have people arguing and they hear you talk and people on the other side talk, and all they hear is the name of the drug. They don't hear the argument.**

No, that is not how it is, I think. They tried to quiet me some years ago when they accused me of scientific misconduct.

**Go on, who accused you?**

The Danish drug industry, the whole industry association accused me of scientific misconduct.

**On the basis of what?**

Nothing. We had published a research letter in JAMA where we showed that trial protocols very often contained clauses about the drug industry owning the data and needing to approve manuscripts and all that sorts of thing. It was a rather innocuous paper but it hadn't been demonstrated before, so they became furious and said that "we cannot recognise what these guys wrote in JAMA," which is nonsense because they know very well what they write in their protocols. So they accused me of scientific misconduct and it took 18 months, after which I exposed the whole affair in the BMJ.

**You say it took 18 months, what happened?**

The process took that long 0 the committee that deals with allegations of scientific misconduct.

**So if things had gone wrong, what could have happened to you?**

Drummond Rennie, one of my good friends and a deputy editor of JAMA, was very worried about me, because he said that even though you are acquitted, it can damage your reputation, because they can talk about it and say that "We have a process against this man" and all that. It was at smear technique, harassment and intimidation, and I tried to tell the committee in the beginning that they had the possibility of dismissing a case if it is unfounded. I told them that it was completely unfounded because there was nothing of substance in the letter from the Danish drug industry, just something about "We cannot recognise the conclusions." They could have looked in the same protocols as we had used and said that our numbers were wrong, but they didn't do anything of that kind, it was just insinuations.

**Did it cause you worry?**

No, I am rarely worried about anything.

**Which drug did you say you're taking? This could be a very good advert for some drug!**

I don't take any drugs but I am not the worried type of guy. And my exposure of their misbehaviour in the British Medical Journal gave them bad PR. I also exposed them in our Danish medical journal where I wrote that this was all about intimidation and harassment, and not about an honest suspicion of scientific misconduct.

**But don't you think that even this could have been useful for them? Without this affair, all sorts of people might think they could speak up as well, but now lots of people know that the price for speaking up is that they are going to be harassed.**

I can see what you mean, but what happened in my case seemed to put an end to it all. Before this, whenever I gave interviews to journalists criticising the drug industry, they were often on my back the next day and said it was wrong; that I could not document what I said; and that there were all sorts of problems, which there weren't of course, but even so, they had been chasing me for many years. After this, they stopped. I have not had problems with the Danish drug industry since this happened, so maybe they finally came to the conclusion that they couldn't stop me.

**Oh, they can get at you but let's forget it. Maybe it is because you are useful for them. So, what is going to happen about access to data? It looks like we are going to be worse off in the near future than we were a few years ago.**

No, it is pretty clear that the summary of the data will be a reality, so we will get summaries of all drug trials.

### **Summaries.**

Yes, but these are not summaries like in a scientific publication, these are quite detailed summaries according to a template where you are going to write about all your outcomes with standard deviations, etc. Of course this is not enough but it is far better than the situation we have now, so what we are still struggling for is to get access to the full study reports and even the raw data, that is where the battle is right now. Things are moving in the right direction and I have talked to the Ombudsman about the court case against the EMA, and they think that maybe the Court will stop access to EMA documents as long as the court case is running, that could happen, but no one really thinks that these companies will prevail. The Ombudsman is a strong institution in the European Union and his ruling is in accordance with the basic principles of the European Union. I don't think they will succeed.

### **But you can turn it around and say: what if they succeed?**

Then I think there will be a public uproar. I will do what I can to contribute to that.

### **I know, but I still don't think the public will care.**

There are quite many politicians in the European Parliament now that really do care about this. And the Ombudsman, not Diamandouros himself but one of his staff, visited me here in Copenhagen and he said that our case is the most important one they have handled for the last ten years, and they are dealing with an incredible amount of cases, in all sorts of areas, also the car industry, for example. Of course they cannot say officially that our case is the most important one, but he told me unofficially that it was. Because life and death is what matter most to every one of us, I feel pretty sure that there are so many politicians now that know so much about this that it would have consequences if the court case favours the companies.

### **Industry has a lot of strong cards to play, they have jobs, for example, and investment.**

I know, but there is a limit to everything, I mean, we wouldn't introduce the growing of opium in the European Union because it creates jobs like in north Afghanistan, would we?

### **But there is not really a limit to everything, as the industry is very much in the businesses of managing risks, and what risks mean is the public's perception of risk, and they are masters of this; they are better than the Nazis ever were.**

Yes, they are pretty good at this game, but we also have very good people on our side, e.g. the British Medical Journal. A couple of weeks ago in Oxford, its editor, Fiona Goodlee, asked me what we should do next and then she said, "We should perhaps start pressing the idea that industry should not be allowed to do any trial on people," and I said, "Of course they shouldn't, this has always been wrong." So you and I don't agree on this and I am sometimes pretty optimistic about it. What I think I see is that we have built up a momentum and a degree of shame about the current status quo, which means that whatever happens in the coming months it will go on, we will achieve more. You can see how much Ben Goldacre has achieved with his book, and I believe that I will achieve something with my book, and there will be more writings and more books and more articles and more meetings.

### **And you don't think that it's like the screening thing, that the screening guys think they can do no harm? A little bit of motivation has to be because they just cannot see how screening could do harm, do you know what I mean?**

Yeah.

### **And do you not think yourself and Ben, and the other people in this field, think you can't do harm, we can't make things worse, but of course, you can make things worse?**

I can't see the risk because we are improving all the time, now we have access to documents from the EMA, that's a clear improvement. How could it be worse?

**I think this is a great achievement but how do you remain aware that what you are trying to do could produce a worse outcome? It's a bit like 1962 when the efforts to reform the drug industry did what seemed like perfectly reasonable things, put controlled trials in there, but that produced the mess we have now. Could you do the same thing? CEO Andrew Witty from GlaxoSmithKline will help you do the same thing.**

No.

**He is saying yes. Peter Gøtzsche and Ben Goldacre are right, we are going to sign up, we are going to fit in with them and of course if he gets his way the access we have will make things worse, not better.**

I just cannot imagine that, because if we get access to the data and the narratives of serious harms, then...

**Ah, if you get access to the narrative. What he is offering you is, you know, you are not going to get the data, you will be able to go on a site where he can monitor every move of your cursor.**

True, and we have been on Glaxo's website and found out that they had not filed study 329. Peter Doshi had to ask Glaxo for the missing studies. We decided to study some of these reports on Glaxo's website and it's heartbreaking when you look at the narratives for study 329 and see what really happened to these children when they were treated with paroxetine. It's just so heartbreaking that Glaxo could pretend in the publication that nothing really bad happened to the children in the trial. We do have narratives now on duloxetine, an Eli Lilly drug, from the EMA, so I have difficulty seeing how it could make matters worse.

**But I am sure the guys in 1962 thought exactly the same thing.**

Yes, but this is different. This is the difference between systematically cheating with the data because you know that no one will ever be able to detect this and then now, when people can check for cheating. Wouldn't you expect this to lead to more honesty in the drug industry when they know that we can actually reveal their tricks?

**I have always been saying that, yes, but are you going to be able to detect this? That still remains to be seen.**

If we get access to these very long clinical study reports we can detect a lot of bias. The main problem is one of capacity, it take years every time and the industry might make the reports five times as long in the future to prevent us from ever arriving at the goal.

**But unless you see that you could make things worse, you might be used. Ben Goldacre did his book and all of a sudden Ben Goldacre became a tool of a GSK press release.**

That is true.

**I mean, he is there thinking how could I do any harm and all of a sudden he makes GSK look good, he makes them look very good. Do you see what I mean?**

Yes, that's where we can end up producing a worse outcome. We have to remain very sceptical, not just sceptical of industry but particularly sceptical when industry agrees with us.

**Why did you do your health check review?**

Well, we had done research on cancer screening for quite some years so I thought why not look at general health checks? It is very popular politically to offer something to the citizens that seems to be good for them, so we did a review of regular health checks and were very surprised that there were actually 16 trials and 14 of them had useful data. Although there were very many patients and

many deaths, we couldn't see any positive effect of health checks and the harms were poorly described. Of course, when you screen for various things, you will make more diagnoses, but this was also very poorly described in these studies. Our take on this is that health checks are harmful. They don't lower mortality but they create more patients and more overtreatment.

We published our review both in the Cochrane Library and in the British Medical Journal in the autumn of 2012 and I have just been told that our review was the Cochrane Review in 2012 that received the most media attention. To our big surprise, it has been very well received almost everywhere, apart from in the UK where the National Health Service has some section that deals with kidney diseases and they came up with a completed misguided criticism of our health check review on their website. Obviously, they wanted to protect the idea that everybody should get health checks in the UK. We sent a reply explaining the errors they had made but they refused to publish it with the foolish argument that their website was not a forum for a public debate. But if it wasn't, then why did they attack our review so fiercely? Thereby allowing themselves to participate in a public debate where dissenting voices are not allowed.

Instead, we submitted a paper to the BMJ exposing the fact that the National Health Service does not want to be evidence based. But everywhere else our review was very well received and when I informed the Danish Minister of Health about our results a year before they were published, she decided to abandon her new government's plan to introduce health checks saying that this was the first time the new government had run away from one of their promises in an evidence based fashion.

Our review spared Denmark from spending billions on an intervention that doesn't work. But the believers didn't give up. They continued to defend their hobby horses and wrote, for example, in the Danish medical journal that we should screen for diabetes because it is so good for people. We replied that many of our trials also screened for diabetes and yet we couldn't see any effect.

**One of the people who used to warn about the hazards of screening in the UK is Muir Gray. He is almost an advocate of screening now, do you have any comment?**

Muir Gray is also a political figure, so what he really thinks deeply inside I cannot tell. He is now Sir Muir Gray, and you don't become a Sir if you go against the stream.

After our review had come out, JAMA wrote a positive and nice editorial about it and later JAMA wanted something in their patient information series about what our review meant. That was "funny" for us because the editor required that, although we had said in our review that this *causes* that, we were not allowed to say so in our JAMA paper. We should say that this is *associated* with that. We were told that it is only in a randomised trial that you can say A causes B!

**You know that this is wrong.**

Of course it is wrong, it is completely wrong. Randomised trials are done for exactly that reason - to allow us to say something about cause and effect, and a meta-analysis is just a compilation of randomised trials, so of course we can talk about cause-effect relationships also there. I urged the editor to take it up with all of the JAMA editors including Drummond Rennie who has been active in the Cochrane Collaboration for many years and must be dissatisfied with JAMA's editorial policy on these issues. But to no avail. The failure of academia again.