

What Really Happened During the Collet Study: An Interview with Dr. Pierre Marois

By David Freels

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Without Dr. Pierre Marois the two Canadian studies on Hyperbaric Oxygen Therapy for cp children would have never happened. In a private meeting during 2003's 3rd Symposium, Dr. Pierre Marois of Quebec, Canada spoke on the record about what really happened during the Collet trial, within the context of an impending class-action lawsuit for medical fraud to be filed by the parents against the Canadian government. Besides Dr. Marois, those in attendance included Dr. Ignacio Fojgel of Argentina, Dr. Philip James of the UK, Dr. William Maxfield of the US, Hyperbaric Medicine Today editors Ken Locklear and David Freels, Tom Fox CHT, and Claudine Lanoix CHT. In 1998 Claudine took her twin sons to the United Kingdom where they received HBOT through the Multiple Sclerosis Therapy Centres (www.ms-selfhelp.org). Dr. Marois is in private practice and the twins's physiatrist. Upon returning from the UK, Claudine Lanoix went straight from the airport to Dr. Marois's office accompanied by TV journalists. Dr. Marois's astounded reaction to the changes in the twin boys was nationally broadcast on Canadian television.

Dr. Marois: This [class-action suit] is not being done to put one against another one. This is because what was published in the journals and what they are doing with it. They are saying completely different things themselves. They publish one thing because it was published by the government in the Lancet and they change, complicate, what they say publicly all the time—just to mislead the scientific community

HMT: So it's deliberate?

Dr. Marois: If you just put the two things together, and they are two completely different things.

This all started when Claudine came back from England with her two children. One was less spastic, better movement. One was starting to walk without his braces for the first time, and we saw changes in the other kids too--holding his sitting position better.

The journalists asked me what I thought of the treatment, but I didn't want to say it was a miracle treatment, but that we needed to do research. But this was on Canada coast-to-coast television next day, and I received calls from all over. But about 15 of the families--I follow about 1500 children with cerebral palsy--I didn't want to get involved in research at all at that time—we were expecting a daughter two weeks after.

The families wanted to go to England the next week. Took a mortgage out on their house. So I told them, don't go there. We might do

a little meeting in the next few weeks, we might think about doing a research project, but things got worse and [then] 30 families wanted to get to England. So we contacted McGill University and the hyperbaric center near the ocean in Quebec.

We expected 30 parents or so at the meeting, and we had 100 parents and all were hoping for a miraculous treatment. And we just told them, “So far we don’t know anything about the treatment, some results for some children. We don’t have any proof that it’s working. We’ll just do a pilot study.”

In two months we raised \$250,000. We trained therapists to do the evaluations before and after. We trained doctors and everything. We did a pilot study with 25 children. Twenty treatments only and they were treated at 1.75 ATA [*Effects of hyperbaric oxygen therapy on children with spastic diplegic cerebral palsy: a pilot project*. Undersea Hyperb Med. 1999 Winter;26(4):235–42.]. Nobody expected anything from that research, but we were very surprised because most of the children improved quite substantially.

And we measured changes in GMFM, but we didn’t use anything to measure speech or other obstacles to their changes, but we saw changes. Some children started to speak and things like that—[that’s] the reason why in the second research, we included a lot of other tests. And so we were very surprised by that, and we didn’t want to, even at that time, to tell the parents that it was proof that it was working, that it was just a pilot study.

And we really decided to do a double-blind study at that time and we met with the government, saying that ‘in three days we’ll meet with the parents to tell them the results and we want to be able to tell them at the same time that you’re willing to put forward for the double-blind study,’ and they agreed to just give \$250,000. It was not enough, but still it was a first step.

So we met with the parents. Told them the results. Told them not to go to England, and that we would do—quickly—a double-blind study, which was a bit crazy because it usually takes a year or two or more than that.

So we are to raise 1.5 million dollars. We are to build a protocol that would be approved by five ethics and scientific committees. We are to build a center because there were only three places in province Quebec where we could treat children. We had to create a private clinic so we could, that would be open just for the research, and so I opened the clinic myself because nobody wanted to do it.

Dr. James: And why Collet then attacked you for doing that—

Dr. Marois: He knew it was just for the purposes of the study, and we lost all our shirts with that, all our money, because the government never paid for what they were supposed to.

Dr. James: So the two \$250,000 they promised was never paid?

Dr. Marois: The government in fact paid 1.7 million dollars, but Collet did what he wanted with that money. He paid some centers, he paid a little bit to our center too, but he still owes a quarter of a million dollars, and we'll never see it. And so all the people, there were therapists and nurses that invested in that center because they knew the government would pay and they believed so much that the research should be done, and they lost all their money.

Dr. James: Collet was in control of the finances? The cost of running the study was never properly reimbursed?

Dr. Marois: That's right.

HMT: You were due to be reimbursed by him and he refused to do that?

Dr. Marois: Yes, and we have letters to prove that. So. We also had to select more than 100 children. We had to recruit or teach therapists to do the evaluation, and psychology, physical, occupational, and speech therapists. And all of this in four months.

We had to recruit doctors to supervise and do the evaluations. We had close to 20 doctors. About 40 therapists. Almost 80 professionals involved and a lot of clinicians. So the protocol was built by Michel Vanasse and myself. We were calling the government every day to be sure they would get involved financially. We were calling all the time, The Ministry of Research, everyday. And one day they told us we will pay for this research if the FRSQ (The Quebec Health Research Fund) approved the project.

So they built an expert team composed of all people that were against the hyperbarics, and coming from all parts of Canada—even if it was a Quebec project. And they said first that there was absolutely no logic behind the treatment and it was a dangerous treatment and they did not recommend the government to pay for that. Their report was like the report of a 10-year old child. It was crazy. It was really easy to destroy, and we gave a 20-page report that destroyed this completely dead, and the government was now with two reports.

One was crap, saying they should not fund the research, and one by scientific people were saying why it should be done. And the parents came out in the media. The television. One of the parents was there with a child in a wheelchair in the Prime Minister's office and the cameras were there. So next day I receive a phone call from the government saying, "Dr. Marois we have good news for you. Just come to Quebec, and we'll tell you about everything."

The next day I go there and they give me a letter saying the government will pay for the research, but at the same time they give me another letter signed by the president of the College of Physicians, by the Secretary General of the College of Physicians, the FRSQ president and general manager of FRSQ, and by two other people—saying that this research should not be done, that Pierre Marois and Michel Vanasse are in

conflicts of interest, ethical problems, things like that. And already the research had already been approved by five ethics committees, knowing that we were opening the hyperbaric center for the research. And I received that the day before I flew to the first symposium on HBOT for cp, so while I was at that symposium, I called the college of physicians and said, "If you are not in my office when I come back, I will file a lawsuit against you." And they all come, all the people that signed the letter, came and said, suddenly, "It was an error. We should not have ever, ever signed that—"

HMT: All of them? They all made a mistake?

Dr. Marois: All of them, they all made a mistake. And they never explained to me why they did that, but I know they just want us to step aside. Finally we stood up, and they retract themselves—not in the letter. And they expected us to be in the research project—under conditions that if they could select a new person to direct this research—so they named Collet, and we accepted that because it was supposed to be a neutral person doing that research.

HMT: What's Collet's background?

Dr. Marois: Mostly in research with pharmaceuticals. He's a pediatrician, but he does not have license to work as pediatrician in Canada because he was from France—

HMT: Ah-hah!

Dr. Marois: But he has the right to do research, and he's in charge of the research centers of the Jewish Hospital in Montreal and most of his research is pharmaceuticals for pharmaceutical companies. First thing he did, when we did the protocol, we had three groups. One was 1.75 ATA with 100% oxygen. One was 1.3 ATA with 21% oxygen—air, but we were afraid this would induce changes in the children, and we had a third, a control group that was receiving nothing—

HMT: Nothing?

Dr. Marois: Nothing. At least we could compare with natural evolution and things like that—was not a placebo group, but at least a control group. And he removed that, this group—for absolutely no, no reason—

Dr. James: It was his instruction that that group was removed—Collet's instruction?

Dr. Marois: Yeah, and we tried to oppose that, but he decided himself to remove it anyway. They were to get evaluations at exactly the same time: before, at mid-intervention, after intervention, and three months after.

Dr. James: Would they have had the same withdrawal of drugs and physical therapy?

Dr. Marois: Yes.

Dr. James: They would?

Dr. Marois: Yes.

Dr. James: So it would have been a very good control?

Dr. Marois: Yes. They would have had the same things, evaluations. So. They removed that.

Dr. Fojgel: So--after the acceptance by the five ethics committees--

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Dr. Marois: Now, so we had to—

Dr. James: To re-submit it?

Dr. Marois: Re-submit it, exactly.

Dr. James: A delaying tactic?

Dr. Marois: Might be a delaying tactic, but it was more than that. It was more brilliant than that because without that [control] group you could say anything. Finally the study starts in October, 1999, but they tried to close down our center three times, saying we had to have inspections—

HMT: Who tried to close you down?

Dr. Marois: Who tried to close us down? Collet. Collet was in charge of everything in the research, but he knew if this center was closing we could not do the research because we had such limited facilities in Quebec to do it.

HMT: Collet's trying to close down one of the centers where the study's actually taking place?

Dr. Marois: Yes.

Claudine Lanoix: Can I clarify where the facilities were? One, McGill University where they have a Perry Sigma Plus monoplace chamber—

Dr. Marois: They could treat four children a day.

Claudine Lanoix: The other one was at Hôpital du Sacré-Coeur de Montreal where they have a multi-place, but there were chances that treatment would be delayed or canceled for the day because they also have to keep their chamber available for--

Dr. Marois: They could only treat five children a day.

Claudine Lanoix: That's the only place in Montreal to treat emergencies. Then there was—

Dr. Marois: Centre hospitalier régional de Rimouski could treat five children a day. There was a center in Lévis that could treat three children a day—it's a monoplace chamber. And there was a center in Institut Maritime du Québec à Rimouski that could treat about 25 children a day, but we had 110 children to treat. So in Longueuil, we were treating 67 children a day—

Claudine Lanoix: This was the center that was created for this whole purpose of the research--

Dr. Marois: And it closed—we rented the chambers, and it closed down the day the research was done.

HMT: Is there any proof, documentation, that Collet was working to get the center closed?

Dr. Marois: Yes. All the time he was, the reasons were—the chamber is not lighted enough--just stupid things. And it's not even

right because he even chose the inspectors to come from Toronto and everywhere, and all these people told him, “It’s perfectly fine. It’s one of the best places we have seen so far”. And finally the last patient was treated I think the 15th of January.

Tom Fox: There are a couple of things I wanted to ask. First, who is Dr. Boyle?

Dr. Marois: Dr. Boyle was the general manager of the Quebec Health Research Fund. He is the worst of all, a career bureaucrat--and a puppy.

Dr. James: This man, Boyle, what’s his training?

Dr. Marois: I think, he was also a statistician before, but I’m not sure.

Dr. James: But he’s not an MD?

Dr. Marois: No, he’s not an MD. In January, 2000 the research is finished, and we want to see the raw data that’s with Dr. Collet. Collet writes to us saying that he wants to have some of his friends—he’s not saying friends, but some of his colleagues that will interpret the results. You know we are already 18 people in that research, we are kinnisons, we built the protocol, things like that, and he says ‘You know, I will have a group of people interpret the results’, and I reacted to that with a letter.

And asked why do you want to bypass us? We did the research, we are the clinicians in the research. We should look at the results and to print them. And he said, “By no means do I want to bypass anyone” and things like that.

And finally he just completely bypassed us, and we never have any news from him. He had lunch with the Prime Minister, I’m sorry, the Health Minister of Quebec, saying it’s a placebo effect, and we should do research on psychological factors only.

And so we are rushing and sending letters and calling Collet to have a meeting with him—all the researchers. Finally it’s in April--a month and a half after he has met with the Minister of Research—that we finally have a meeting.

And he arrives with the article already printed to send for publication with the conclusion saying that it’s a placebo effect and that it proves that three-fourths who showed results [in Montgomery] were poor science, and we have to sign this. So, we were about 20 people around the table, saying, “Are you crazy? We want to see the real data. We want to analyze this. You cannot say that--it’s scientifically dishonest to say that.”

He tells us, “I’m willing to do all the changes you want. Just give a signature so I can change, send corrected text for publication. So next day he doesn’t change anything. He sends the text like that for publication. We reacted with letters. There was even a letter signed by the four main researchers besides Collet. This is not a neutral way to do things. It’s not fair, it’s a fraud. Finally we sent all this mail to the

government. We don't have any news from them. It's two full weeks after that we are called for a half hour meeting. They say they don't have anything to do with that research. It's a placebo effect. They asked us if we'd agree to have a scientific committee that would analyze all the hypotheses because they were all putting forth hypothesis psychological effect, training effect, and natural evolution. But they were saying it was a placebo effect—they were convinced of that—so nobody agreed to have a scientific committee before them.

We wanted to see the raw data files and do our homework and analyze those results.

HMT: You did not get to see the data at all?

Dr. Marois: No. We've never seen the data.

HMT: You've never seen the data?

Dr. Marois: I've never seen the raw data. I've seen the results as published.

HMT: So everybody is truly blinded, then?

Dr. Marois: Yeah, more than double-blind. It's triple-blinded. Anyway, they created a scientific committee composed mostly of the people that had rejected the research the first time [before we started] and they came out three weeks after. We did not know anything. They say, "We have created this scientific committee. They have come also to conclude that it is a placebo effect. We have nothing to say, and we will present the results tomorrow to the parents."

So I ask, "Okay, can we be there just to look at the results?"

They said, "You don't have the right. It is not your meeting. Your meeting is today. Tomorrow is the meeting with the parents. You don't have any right to be there.

HMT: Are you kidding me?

Dr. Marois: No, no. I am not kidding you. Just like that. You don't have any right to be there, to be there while we are presenting the results.

And they [Collet] went to Sainte-Justine hospital, which is the biggest pediatric hospital in Quebec, the second largest in Canada. Toronto. And they met with the chief of the department of pediatrics of neurology and rehabilitation and asked them to be there the next day and support their presentation. They refused completely, saying that, "It should be done by the researchers that did the research, and they did not accept."

The next day there is the presentation with the parents, and suddenly one parent called me. I was at home, and they knew everything about this. The parent called me and said all the parents were asking where are all the researchers—because we were known by everybody. Collet told the parents they [the researchers] were invited, but they didn't want to come.

We have all this on cassettes. It was taped all the time. Said, “We didn’t want to come.”

When I heard that I jumped into my jeep, and I drove to the hospital. There were bouncers all around—

HMT: They had what—bouncers?

Dr. Marois: Strong arm men. All the windows of the place were taped. Journalists were there, but nobody could get in—

Claudine Lanoix: And let me tell you, inside it was complete pandemonium because a lot of the parents knew of some of the politics of what was going on, and when they stood up and said, ‘This was a placebo effect’—some parents, this was the first time some of them were finding out what group their child was in. Up until that point they didn’t know.

HMT: Had there been any complaints that ‘my child did not gain anything’, ‘waste of time’, anything like that?

Claudine Lanoix: No, none of that.

HMT: Everybody was happy and just wanted to know what group they were in?

Claudine Lanoix: Some of the parents, because their child had made so much evolution, were convinced their child was in the treatment group but it wasn’t always the case. Some of them had been in the low hyperbaric group. It was total total pandemonium in that room. There were parents outraged because they had stood there and said Dr. Marois and Dr. Vanasse were clearly in conflict of interest and had financial gain.

Dr. Marois: When I arrived there, most of the parents were saying, “We want to hear from Dr. Marois.” In front there was Dr. Boyle, Dr. Collet, the president of the scientific committee that they formed, and also the president of the Quebec Health Research Fund.

They didn’t want me to come at all, and I didn’t want to be there at all with those people, but finally the parents were asking all the time for me to go there and talk with them, and when I came in the room they were just saying to the parents it’s a placebo effect, but we won’t publicize anything right now. We will analyze further this information—but they just had a press release, and they met with the journalists half an hour before, and I had the press release in my hands where it was saying that it was a placebo effect, and they were publishing that in the newspapers the next day.

And finally I went there with the parents. I told them first—I read them the press release, and they were just furious. I told them that we were not invited, that we were told we had no right to be there so they were even more furious.

And they showed a slide that said ‘researchers can have a conflict of interest, saying that I was the owner of the center and things like that, but this was written in the protocol. All the parents knew that. All the ethics committees knew that. All the scientific committees knew that. So I

just went again before parents and said, 'Is there anyone in the room who did not know?'

I was not paid in that research for anything. It was all volunteer's work. I put about 1000 hours volunteer work in that research. Collet got paid, but we never received a penny for that.

The parents were just furious. Finally the four people just go away, and I'm just there with the parents .

In October or so, three months after, there was a meeting of the American Academy of Cerebral Palsy in Toronto. This was a big meeting. This was the start of the turnover of everything. There was a presentation that was supposed to be made by Dr. Collet and Michel Vanasse. Michel Vanasse is my colleague.

HMT: He was here at the last symposium--2001.

Dr. Marois: Yes. He stands with me all the time, but he doesn't like to fight at all. He's a very laid back person. The presentations were supposed to made by Dr. Collet, Michel Vanasse, and the College of Physicians—who had nothing to do with that research. We didn't know why they would be there. I didn't go to the meeting at all. Michel Vanasse did.

Dr. Collet agreed to not emphasize any hypothesis and let the physiological effect, psychological effect, things like that—let the scientific committee there [at AACPD] to decide. Just presenting the datas like they were.

During the meeting Collet changed completely and presented only placebo effect. Michel Vanasse was taken by surprise, and being a quite laid back guy did not want to start a on fight there. So everybody went out of this big meeting, 1000 people there, waiting for the results with the conviction that it was a placebo effect and that research proved there was not any effect at all.

Tom Fox: Pierre, let me interject something there, too. I was at that meeting It was a four-day meeting of the American Academy of Cerebral Palsy and Developmental Medicine, and it was in Toronto.

HMT: That's Dr. Oppenheim's group.

Dr. James: Oh really?

Tom Fox: They had scheduled the scientific presentations for the third day of the conference, which was a Saturday. Saturday morning at 7 o'clock in the morning. The room was absolutely full. Like he said, there could have easily been 1000 people there. A 1000 physicians, and Dr. Collet got up and he just hammered that it was a placebo effect.

Clearly Dr. Vanasse was taken by surprise. You could see the startle in his face. He sat back and presented his side which no longer complemented the slides that Collet used. Later on that day they broke the groups into two.

Everybody in the professional side gets up and they start their comments to Dr. Collet by saying, 'I want to thank you for a most

magnificent study that has really contributed to the field—.' And then they went on to expound upon what they wanted to expound upon.

I got up to ask questions, and they turned off my mike. I was hammering him and Wayne Evans. Wayne Evans came in later that day, and he presented to the parents. There must have been at least 500 parents sitting there waiting to hear about this. Wayne Evans did things like took pictures of dolls and put shunts in plastic doll heads and said, 'these don't belong in these.' Plastic dolls with shunts in their heads in hyperbaric chambers. He said, 'clearly this is unsafe.' Then he talked about 25 minutes about the explosion in Japan and fire, and he went on, and I got up, and I said, "Sir. I have been doing this for a certain amount of time, and you have totally misrepresented the safety record in the North American field of hyperbarics, and I think it's done a disservice to the people that are waiting here to hear what you have to say about this study. Most of his talk was about Japan. He's also a member of the UHMS.

Dr. Marois: He was a member of the scientific advisory committee that destroyed everything.

Dr. James: He's a technician?

Dr. Marois: No, he's a doctor.

Tom Fox: An anesthesiologist.

Dr. Fojgel: We have been listening to a pile, a heap of slandering, and libel, and hijacking of your research. What I'd like to know is, what are the motives?

Dr. Marois: Let me finish. I'm not over yet, but I will talk about it later.

Dr. James: This is electrifying--

HMT: Were there any complaints from the parents?

Dr. Marois: Oh they wrote letters—

HMT: Were there ever any complaints that "my kid got worse?"

Dr. Marois: No. Never.

HMT: What about "I thought they got better, but now that I've heard the results, maybe they didn't really get better."

Dr. Marois: No.

HMT: Any complaints from the parents about the condition of their child?

Dr. Marois: I never heard that, I never heard anything. All the parents were willing to go into the research, and they knew they could get no results at all. The only complaint was that, if the research was positive with 1.75 ATA and not with 1.3, all the parents would get the 1.75 treatment

HMT: That was an agreed upon thing?

Dr. Marois: Yes.

HMT: Prior—

Dr. Marois: Yes, it was.

HMT: So it's never happened?

Dr. Marois: It's never happened because they say the research is negative.

Tom Fox: At that AACPDMD meeting, when Collet's sitting there describing the protocol, he went on and on about the barotrauma experienced by the oxygen group. In their process of blinding the two groups, they actually decided to go to 9 feet and 25 feet in the same amount of time. Then they wondered why they've got a difference in barotrauma in the 1.75 group and the 1.3 group.

HMT: Obviously then you don't have blinded groups—either the people doing the treatment or the people receiving the treatment.

Tom Fox, Dr. Maxfield: That's true.

HMT: So it's obviously not a controlled study.

Claudine Lanoix: The only people that weren't blinded were us, the technologists—who were running the treatments.

Dr. Marois: Wait, wait. Everybody was blinded. The people inside the chambers, the parents were—even the physicians were. It was only the technicians operating the machines, following the protocol. You cannot be more blinded than that.

Dr. Fojgel: To do a really blinded study would take two technicians.

Dr. James: You cannot blind it.

Dr. Fojgel: Yes, it would be too expensive.

HMT: So there's no complaints about the therapy?

Dr. Marois: No, never because most of the children have big changes. So, just after, the article was still not published, and it was sent to Lancet for publication, and the chief editor—Butcher—has heard about what's happening in Quebec. I think the parents wrote to him.

Dr. James: Yes, I did.

Dr. Marois: He wrote to me, wanting some clarification about this research and what's going on. I agreed to sign this research because we removed the placebo, but at that time it was still the placebo. So I wrote to Dr. Butcher saying it wasn't a placebo at all. Finally, Dr. Collet—there was a letter that was just crazy. Here, I'll read it. He says, "The huge expectation of the parents in the benefit of HBO Therapy has led to heated and unfortunately acrimonious exchanges when the results showed that there was no effect. This great false hope has been fuelled by misleading publicity posted on the web by hyperbaric centers and because of the personal conviction of physicians like Dr. Pierre Marois, who are also owners of hyperbaric centre (as acknowledged in the article). In their letter, parents refer to the position of Dr. Marois who "could not stand back and watch this travesty in medical study go unanswered." This statement is also a distortion of the truth. You will note that Dr. Marois accepted to sign the authorship agreement and is a co-author of the article. The present conflict stems from a situation where parents and a few physicians are unable to accept the results of the study that

unequivocally indicate that HBO Therapy for cerebral palsy is ineffective." The article doesn't say that at all! So I wrote Dr. Butcher—

HMT: Where was that letter written?

Dr. Marois: It was written to Dr. Butcher, who is the chief editor of The Lancet—

HMT: Who wrote that?

Dr. Marois: Dr. Collet. Dr. Collet wrote that.

So. One week after, we had the parents—Michel Vanasse and myself—have the press conference with the journalists to give them (this) and the press release from the government so they could do something with that. Almost nothing came out from the journalists.

The next morning I receive a call for me to go to St. Joseph's hospital for a meeting with the president of the medical board, the director of research center at St. Joseph's hospital, and the director of professional services of _____ system. And they wore all white. And they met with me and saying, 'You know Dr. Marois, we know the work you have done and everything, but we want you just to shut up your mouth right now because we received a phone call from the Quebec Health Research Fund, saying they were cutting millions of dollars in research funding for children—because you were talking. So if you talk anymore they will cut off even more fundings for research.

At that time, what could I do? If I was still talking in province of Quebec, I was going against what I wanted to do--help children. I was shutting my mouth in Quebec. Right now, two years have gone by, I never have the right to present the results to my colleagues in my own hospital. We don't have the right to talk about this research project—

HMT: Still don't?

Dr. Marois: No. Well, I have the right, but you know, the next thing there's probably a bomb under my car. I would prefer a bomb under my car than loss of money for research for children. This I do not have any documents on.

Tom Fox: What you don't understand, and what he's not saying a lot to, and I found this out when I went up to put the chamber in. When he's talking about the college of physicians is very powerful, and they can actually sanction a physician—so that he loses his license to practice—

Dr. Marois: They really tried to scare me three times, and each time I was there and they went away, and there was really nothing they could do against me.

Tom Fox: But, not only did they threaten him, when we went in and we set this clinic up to have two physicians co-located so we could have them supervising the therapy, the College of Physicians came in and wrote a sanctioning letter to our supervising physicians telling them they were to have no part in supervising our therapy.

Claudine Lanoix: I want to backtrack one more time to right after the first trial [Montgomery], where we did the pilot project with the 25

children. We used the chamber at McGill University. Well right after that, the results were quite good. Parents were lining up at the door to have treatment, and they were taking children in for treatment—and that study finished in November—

Dr. Marois: The results were out in January. It was published eventually a year after. We had a meeting with 1000 parents, the results were out in the newspapers and everywhere at that time.

Claudine Lanoix: The word had been spreading among the parents and everybody, but when it happened, and McGill was treating children privately, the government came in—the College of Physicians specifically—came in and closed it down. They threatened all of the physicians in the hyperbaric program at McGill University—that they were not allowed to treat children. If they did they would all be sanctioned and they would lose their license to practice.

Dr. Marois: Because it was not a recognized indication. Treating sports injuries is also not a recognized indication, but they were treating—and are still treating sports injuries over there.

HMT: When they say that in Canada—unrecognized conditions—what do they reference?

Dr. Marois, Claudine, Tom Fox: The UHMS.

HMT: So they made UHMS [indications] law in Canada?

Dr. Marois: Yes—the College of Physicians, but it's only in Quebec they could do that this way [not treat children], but at the same time they never enter into restriction on treating sports injuries—

HMT: Pick and choose.

Dr. Maxfield: Not do as I do, but do as I say.

Claudine Lanoix: You would know the names—Dr. Montgomery and Dr. Lacroix.. These were the two physicians they threatened to sanction. By mid-April McGill had to close their doors. They were no longer able to treat children. Nor have they ever treated children again—up until they did the second research project, and that was it. Never anything after that.

HMT: Have they ever treated a child for any of the approved indications?

Claudine Lanoix: No, not at McGill

HMT: The approved indications? Crush?

Claudine Lanoix: They don't have hospital capabilities.

Dr. Marois: McGill is mainly a sports injury clinic. For the hockey players, the Alouettes, the ball players

HMT: Wasn't it the College of Physicians and Surgeons that issued the order of no hyperbarics for pediatrics under age 18.

Claudine Lanoix: That was in the province of British Columbia only.

Dr. Marois: Everything was pretty calm after that. I shut my mouth in province Quebec. I did a conference here and San Francisco and Chicago and many places. And I thought with time the current would

change and we're presenting the real results, would be enough—until I got this Dr. Essex's paper in *Developmental Medicine and Child Neurology* [*Hyperbaric oxygen and cerebral palsy: no proven benefit and potentially harmful*. *Dev Med Child Neurol*. 2003 Mar;45(3):213–5.]. And this guy is coming from nowhere, never did any studies on hyperbarics. It's just plan bullshit in there.

So I think the only way things can get real now is if the parents go against the government in class-action for scientific fraud. The parents are getting together now to do that. They have the biggest medical law firm in Quebec.

HMT: Could they sue to seize the data?

Dr. Marois: They could do that, but even--

Dr. James: Who has the data now?

Dr. Marois: Dr. Collet.

Dr. James: Still has the data?

Dr. Marois: Yes.

HMT: He's got the money. He's got the data.

Dr. Marois: After the study he was promoted to be an advisor of the Quebec Health Research Fund. It was a conflict of interest, but everybody had a promotion in that research. So I answer to the [Essex] article, and it will be published next month. There was another article in the *Perinatology Journal* (*Hyperbaric oxygen therapy for a neurologically devastated child: whose decision is it?* [Paris JJ, Schreiber MD, Reardon FE, *J Perinatol*. 2003 Apr–May;23(3):250–3.]), and we answered that one and co-signed the letter. We hope that it will be published also. About the [near-drowning] child that was treated.

Dr. James: You've met Jeffery Weiss, here?

Dr. Marois: Yes. I met him this morning. It's not over yet. In May [2003] there was a big meeting in Quebec, the International Conference on Cerebral Palsy. It was the beginning of May, and this was published (supplemental publication) by *Developmental Medicine and Child Neurology*. It's the abstracts, and Collet was speaking there. We have a transcript here of Collet's speech. It was just crazy. I know some doctors that were there, and we never saw that in our lives. There was no science at all, and he was just bullshitting everyone. I have the transcript here. It was just crazy.

Dr. James: Collet did not do any good for himself in doing that—

Dr. Marois: No, not at all. There was a hidden camera that taped everything. He didn't know about it.

HMT: Do you have a copy of that presentation?

Dr. Marois: It's on the CD. The video, all the documentation. The letters. Some things are sometimes hard to read but it's all there. (much of the contents from this CD can also be downloaded from http://www.hyperbare.ca/fr/dossiers/complot_oth_web.html)

But even here, he changed again the title. “Results of multi-center double-blind placebo-controlled study.” He removes my name and Michel Vanasse’s name. In his references, he changes the titles. “A multi-centered, placebo-controlled randomized clinical trial for *The Lancet* paper. And in the Developmental Medicine paper (Hardy) “A double-blind placebo-controlled randomized clinical trial.” He’s changed completely the titles of the two articles in the reference that is published in the supplements to Developmental Medicine just to prove his point of placebo. But he’s talking about placebo in this conference. He’s talking about placebo all the time.

Tom Fox: Pierre, hasn’t the Hardy paper re-evaluated the same data, changed the sample size—

Dr. Marois: No, in fact the sample size was those who were evaluated by their own psychologists. It’s the same study, they just took apart the study and tried to—

Dr. Fojgel: From another point of view?

Dr. Marois: Not even from another point of view. It’s just taking the whole study and taking a part of it, and analyzing it a little further.

Tom Fox: But if you look at it, it’s a different sample size so it appears to be a separate study.

Dr. Marois: But it’s the same study, and it was published in all the journals in Quebec that it was a placebo effect and the journal at the University of Montreal that it was a placebo—

HMT: But you know, there’s never been a placebo-controlled trial for anything in cerebral palsy where the placebo group ever had any improvement.

Dr. Marois: I’d say you are right. It’s never happened.

HMT: This is the first one, and that’s what ought to be making history here—if this is really a placebo.

Dr. Marois: Dr. Fojgel, you were asking what is the reason. I don’t think there is a single reason—

Dr. James: There’s a simple reason. It relates to the fact that the word “hyperbaric” is emotive. Essentially, your study has criticized their standard of care in the most emotive area of medicine—that is the care of children. It’s a black/white issue. This is ‘The Exorcist’ phenomenon. The head turns around on the neck and looks the other way. It’s not acceptable. From that point on everything they do is all predicated on the fact that they do not want this to succeed, and they’re prepared to lie. Medicine is riddled with stories like this.

Dr. Marois: I agree with you. This is one of the main reasons. There are other reasons also. There are fiscal reasons. From the industry of pharmaceuticals, but also there was a big reason in Quebec. When we decided to do that research project. There was no way we could get funding from the FRSQ. We were given only \$100,000 a year after years

of asking. We were not a part of the establishments of research, and we just got by them to get \$1.5 million dollar. Everybody was—

Claudine Lanoix: They were jealous.

Dr. Marois: They were jealous. And they said if this way of doing things is functioning, ‘everybody will just go around us, and the whole structure of research in Quebec will fall apart.’ It was a tremendous test for them. And it was also an ego problem, you know all the fights we had with them in the beginning—when they refused. So they really wanted to put the hammer on the nail and kill everyone.

Dr. James: But if hyperbarics had been kosher—

Dr. Marois: If it was a pill, my goodness, it would make billions.

Dr. James: Of course. Then there’s no problem. But that’s what it starts from. From that point on, the fact that you were able to go around them. Parents were involved. There’s parental criticism of their standard or care. Everything is a negative for them. From a professional standpoint, all negative.

Claudine Lanoix: Imagine for a moment if they came out in favor of the study, and said ‘this treatment has possibilities for children with cerebral palsy’, where would they find funding? There were 3,000 or 4,000 parents at the doorstep looking to treat their kids in hyperbarics. Where were they going to get the money, and how were they going to put in all these centers, find and train technicians to run them, and the physicians to supervise them? Where’s the money going to come from?

Dr. Maxfield: Where’s the money to pay for the care they’re already getting?

Claudine Lanoix: But see, if the standard of care in a system that’s been put in place where nothing changes, if you add another element-- that would have been a very big element, and it would have changed things drastically.

Dr. Marois: Dr. Collet had a presentation in Quebec two months ago, and he said, “The hyperbaric center is in fact not a good practice because there is no regulation, and I wanted to prevent them from practicing.”

HMT: So he’s trying to eliminate Hyperbaric Medicine altogether?

Tom Fox: Yeah, but you’ve got to wonder about the status quo, when at 7 o’clock in the morning there are 1000 physicians standing tall on the third day of a conference. That’s pretty impressive.

HMT: What do you think the international implications or pressures are on Canada to come up with these findings?

Dr. James: I doubt if it’s organized at that level. But it doesn’t need to be. It doesn’t need to be. You see, *The Lancet* really didn’t come out too strongly about this. Mildly pressurized? A whole third of an atmosphere? Mildly pressurized? What a joke.

Dr. Marois: But it’s just as bad, if not worse, to publish letters like the Paris letter. And Essex letter. It’s crazy.

HMT: And this is the transcript from the camera that nobody knew—

Dr. Marois: Yes, exactly.

HMT: When will the parents be moving forward, the lawsuit.

Dr. Marois: It's just starting. The parents will need two experts that will say the way things were done were unethical and it was a fraud. I won't find anybody in Quebec who will do that. If you know anyone who is not involved in hyperbarics who will be straightforward enough—

HMT: Like an ethicist or something?

Dr. Marois: An ethicist or a researcher that would be quite reknown, but that would be honest and willing—

Tom Fox: Would you want somebody to speak to the placebo effect--

Dr. Marois: We don't even need to do that. I don't think we need to put interpretation--confrontation. Just what they did, what was published, and all the changes they have done. They are killing themselves—

HMT: But like you said, there's never been a placebo group to make gains before.

Dr. Marois: This would start a new discussion. But just the way they change the articles—it's a fraud. The titles, the way they do things. It will just put the old thinking, the public--

HMT: Who's the official point of contact on this? You or the parents?

Dr. Marois: The lawyer, if anybody's willing to file a lawsuit at the same time, could put that together.

HMT: When can this information be released?

Dr. Marois: I think the best way to do this is to wait until everybody receives their letter that a lawsuit has been filed against them. And then it will get blown out in the newspapers. It will be mostly against Dr. Collet and Dr. Boyle and government--

Tom Fox: Are you going to use that statement you just read that Collet made?

Dr. Marois: Yes. The only thing we could not really use because we don't have any proof of that on paper was when they asked me to shut up my mouth—

Dr. James: But you could give a deposition, personally. You don't need anybody medical involved in your case because you've got all of the evidence. Seriously.

Dr. Marois: The lawyer was preferring to have someone not necessarily medical but someone in the research field who would say that the way they proceeded was completely off.

Dr. James: In terms of methodology, you don't need an MD. In fact, you're probably better not having an MD because you'll have a bias. In this situation, the facts are very, very clear. They've committed an

unpardonable sin in actually putting things on paper which allows a back-tracking. Like for example, using the wrong title for *The Lancet* paper. It's a very, very deliberate falsification, which obviously The Lancet position—

HMT: They involved The Lancet. It's a copyright issue.

Dr. James: They agreed to publication on one condition, and that was on editorial review, this was not a placebo-controlled study. So to actually falsify that is a very foolish mistake. Because nobody reading through the references would really care, having had the main emphasis on the fact that 'this was a placebo effect' in the meeting. He's stupid to do that because he's actually now put on paper something--the fact that you were not party to the initial writing, nor were you given access to any of the results. And imagine the public response to having a paper on a clinical subject where the first author has never seen a patient. That must be unique in the history of medicine.

HMT: And the ones who participated in the study have never seen the data. Talk about blindedness. Is the letter from The Lancet where Collet was asked to remove the placebo reference, is that on the CD as well?

Dr. Marois: Oh, yeah. Here, you can keep that. I'm just afraid that this CD will go out too quickly—

Dr. James: Yes. I was unaware of the fact that there was a legal case now being finalized, which is actually much more effective. The CD is like a newspaper. It's much too ephemeral. It doesn't change anything. What changes things is when specific information is made public, because it affects the politicians who are looking at the next election—which affects the people at the head who are embarrassed.

Dr. Marois: So the bigger the blow will be, it will be, if everything is slowly leaking everywhere. It could change some things, but I think the biggest effect would be if everybody was in a class action together, coming from the States and Quebec. You just have to join the class-action.

The class-action lawsuit described here was never filed. All the lawyers involved thought the parents would have won, but they were also afraid the government would have done everything to show the problem was a conflict between researchers and that "the poor parents would simply not accept the fact that HBOT does not work." It's anticipated that the full story of Jean Paul Collet and the Canadian study will emerge soon through a very surprising and quite unexpected medium.