While Law struggles to fend off criticisms of his science from colleagues, he must also contend with questions about his Cell Therapy Research Foundation and its practices. While patients are not charged for his experimental therapies, the families are asked to help raise money—a practice that is unusual among foundations. And because Law is outside the university system, he is not required to have the institutional review board (IRBs) that universities must have. Instead, he set up two "independent review boards" to approve his human experiments. Who are the members? Law refuses to say. "We decided not to talk about [the board membership] because the [members] are very worried that pressure will be put on them because [myoblast transfer therapy] is so much in the limelight," Law said.

Concerns about the foundation's activities caused families of children receiving treatment, and some physicians, to complain to the FDA. An FDA investigator inspected the Memphis foundation in May. A preliminary report from the FDA site visit, obtained by *Science*, included at least two allegations that experts think are potentially serious, if true: a selection of data that could introduce bias into the results and conducting experiments with more subjects than Law's own review board gave permission for.

After *Science* showed the FDA findings to Don Wood, MDA science director, Wood said: "It is obvious to me that [Law] is doing a lot of data selection. It calls into question all the conclusions he is making. If you had all the data, maybe the conclusions would be totally different. Maybe not. The problems [FDA found] suggest that we are not seeing the true picture on whether or not the kids are getting stronger from the treatment. This is serious."

Law strongly denied that he is biasing the results but acknowledged that some data are discarded. "When a child is undergoing manual testing of strength, sometimes a muscle cramp would develop. The muscle cannot generate as large a force because the patient is hurting. The result is registered on the [testing machine's] screen. If you take that data into consideration, knowing full well that the patient is having a muscle cramp, the data would not represent maximum force development. When that happens, we exclude that data." He added: "None of the FDA observations goes to the fundamental validity or reliability or the quality of our research." He rejected the FDA allegations as a failure of the FDA investigator to understand the foundation's research.

After reviewing Law's files, the FDA's investigator does conclude that Law's team may have treated more boys with myoblast therapy than had been approved by the two "independent review boards" that reviewed his work. This is a potentially serious infraction of ethical standards, said John C. Fletcher, head of biomedical ethics at the University of Virginia Medical Center, Charlottesville, Virginia; Fletcher was a pioneer in establishing IRBs at research universities in the 1970s. "The number of subjects is very important, particularly with more risky research. It is very common for an IRB to limit the number of subjects in difficult or controversial research to a small number at first, and then increase it. But you may not exceed the number that the IRB limits you to."

Law denies he exceeded his approved limits. Initially, he said, the independent review boards approved a Phase II trial with 30 children. At Pittsburgh he reported treating 32 subjects, but, he says, the additional patients had also been approved by the review boards. "There is an approval letter in the file for an additional five subjects."

Even if the Memphis scientist is able to show that he complied with the dictates of his independent review boards, ethicist Fletcher criticized those very boards. "If he wanted to have a good review, he could have gone to a university IRB and asked them to do it as a service," Fletcher said, adding that "some private organizations do this."

Law has hired a lawyer to formulate his response to the FDA's preliminary report. Government officials refuse to comment on the FDA investigation or when it will conclude. FDA will not say whether it plans any action against the Cell Therapy Research Foundation. The matter is complicated by the fact that the FDA itself is only now struggling to define its role in regulating cellular therapies. In the past, such biological treatments have not been regulated, and Law was not required to file the equivalent of an investigative new drug application to conduct his studies. In the future, however, that may change—particularly if the agency's review of Peter Law's controversial foundation takes on a higher profile.

–Larry Thompson

Larry Thompson is a science writer living in Bethesda, Maryland.

COLD FUSION

Where There's Heat There's Yen

TOKYO—Officials at Japan's Ministry of Trade and Industry (MITI) this week announced that they hope to launch a 5-year program next year to study the systems in which the University of Utah's Stanley Pons and his British colleague Martin Fleischmann claimed they saw evidence of cold fusion. Sheer folly, given that most of the world's physicists have written off cold fusion as impossible? Not so, says MITI—it's just Japanese pragmatism. All MITI is interested in is the continuing reports of excess heat generated in the hydrogen-palladium cells studied by Pons and Fleischmann and the possibility of putting any new phenomenon—even if chemical rather than nuclear in origin—to industrial use.

An official from MITI's National Resources and Energy Agency, who spoke on condition of anonymity, explained that MITI has no intention of joining the debate over whether "cold fusion" really occurs. "We are not concerned with that kind of effect and leave this argument to the academic field," the official said. "We are more interested just in the fact that something is happening that is producing heat, and this might have some practical applications." Improved fuel cells and new types of batteries are possibilities the official mentioned.

Despite their official indifference to the "academic" debate, MITI officials took advice from Pons and Fleischmann as they put the finishing touches on their program. Last week, MITI held a closed seminar on cold fusion in Sapporo, the regional capital of the northern island of Hokkaido. Pons and Fleischmann were present, along with researchers from Japanese universities and private companies as well as cold fusion researchers from other countries.

Barring last-minute objections by the Japanese Ministry of Finance, the new project will begin in April of next year with an initial budget of $1 million to $3 million. Scientists from universities and from about 10 leading Japanese utility, electronics, and metallurgical companies—many of which already have their own cold fusion programs—will participate in the program, according to Osaka University professor of engineering Akito Takashashi, Japan's leading cold fusion researcher (*Science*, 24 April. p. 438). Initial efforts in the new program will involve the collection of data from around the world and a series of small-scale research projects.

Whatever MITI's intentions, Takashashi is confident that the project will vindicate Pons and Fleischmann. In his own experiments he claims he is seeing both heat and neutrons. "I don't believe that this is a chemical reaction, but actual cold fusion," he says. But if he turns out to be right, the National Resources and Energy Agency may have to end its official disinterest in the cold fusion debate. The anonymous official there points out that his division has responsibility for energy sources such as fuel cells, solar power cells, or wind machines. Nuclear energy, he says, is not within his jurisdiction.

–Frederick S. Myers

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