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# **CIT-PART: Report Case Study Sweden**

**Kristofer Hansson, Susanne Lundin**



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**Research Report**

**CIT-PART:  
Report Case Study Sweden**

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**September 2011**

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## 1 Introduction

In the early 1990s xenotransplantation (XTP) was a promising biotechnology, with many countries prepared to take this research to clinical trials. It was also a technology associated with so many problems and risks that the researchers sought financial support to continue their XTP research. This was, in many ways, an international concern, as the researchers tried to collaborate to overcome those problems and risks. But despite this international effort, the situation became a national policy process in many countries where researchers, politicians and stakeholders tried to find a solution and take the next step in XTP research. In this case study, we take a closer look at Sweden and how the national policy process took shape in the 1990s.

As we will see in this case study, Swedish XTP researchers and politicians were involved in various international networks, but when it came to initiating a more formal policy process, the discussion became more or less national. Swedish law needed to change so that the country's XTP researchers could continue with their research and take it to clinical trials. The policy process was closely linked to the idea that Sweden as a nation could gain an advantage, both for the researchers and for the state. The new biotechnology could benefit the citizens and provide future funding for the welfare society. To achieve this, Swedish researchers needed to be the first to clinically introduce this technology. So this case study is about how a nation tries to gain advantages in an international research arena.

It is also a case study of what role the citizens have in the policy process. Biotechnology that is problematic and risky, for various reasons, needs the approval of the general public, because they will be the end users. In this case study, we take a closer look at how researchers and politicians interacted with the citizens in the policy process.

### 1.1 Material and method

For this study we conducted 15 interviews ranging from 40 minutes to two hours in length with persons involved in XTP policy-making (see below). Six interviews are with people who were active on the Swedish XTP committee and nine are with people working in the field.

Those interviewed were:

- Two persons from the Swedish Green Party, both politically active in biotechnology and XTP.
- Four medical scientists who in various ways worked with XTP and/or transplantation in the 1990s. Two of them were also members of the committee on XTP.
- One clinical immunologist.

- Three researchers in the field of humanities and social sciences, all of whom had worked with the scientists presented above.
- One person representing the Animal Rights Movement in Sweden.

All the interviews were conducted in Swedish using a list of questions. This list was constructed from the common list of research question the CIT-PART team shared. The interviewees were free to construct their own narrative about what they remember happening in the XTP field in the 1990s. This means that sometimes an interviewee will share material that goes beyond the common issues, while also discussing new material that could not be foreseen before the interview.

There are two things worth mentioning about the interviews. First, we contacted around 25 people; among those who for various reasons decided not to participate, some would contribute important knowledge and perspective to this study. We tried to compensate for this loss in the interviews, but there are some knowledge gaps to fill. Second, the policy process regarding XTP occurred in the 1990s, meaning that most people had difficulties remembering exactly what happened and how they reasoned at the time. In this case study, we compared their statements with each other and with written text from that time. We comment on those parts in the case study where there is an uncertainty.

We also used articles written by the interviewees and published in magazines and newspapers. Various documents from the parliament and the government are central to this case study. We have also collected answers from the consultation on the committee report. We collected an excerpt from an application for XTP research made at the University of Gothenburg in 1990s. Earlier we collected media material that was reported in an article (c.f. Hansson, 2003). In this case study the documents (texts) are seen as artefacts that can create facts in a collective process (c.f. Latour, 1987b).

## 1.2 Some analytic points

Luigi Pellizzoni and Marja Ylönen had an important discussion that pointed out that experts and elites have difficulty understanding the citizens' perspectives on biotechnology (Pellizzoni and Ylönen, 2008; see also Clark and Murdoch, 1997). This lack of understanding creates an allocation of responsibility where some experts and elites frame the issue concerning biotechnology as controversial and risky. Luigi Pellizzoni pointed this out in an article from 2001 where he analyses which actors are able to talk and raise questions about biotechnology. He writes: "*By stating who is entitled to have a say, it implicitly defines who is not*" (Pellizzoni, 2001b: 212). In this perspective, it is important to discuss who has the privilege to formulate problems. Pellizzoni relates this closely to the dynamics of power when he writes:

“Power signifies establishing not only who may speak but also how they may speak; not only the legitimacy of the interlocutors but also the language and arguments that they may use. It is this that constitutes power in communication. When it is impossible or difficult to exclude someone from dialogue, I may refuse to acknowledge what s/he says, or the way in which s/he says it. This is not always intentional. Sometimes, the obstacle to dialogue is that what the other has to say is meaningless to me (Lyotard 1983). Experts, for example, are often incapable of understanding laymen’s insights into a problem: the languages and knowledge styles are too different (Clark and Murdoch 1997, Pellizzoni 1999). A classic British case is the conflict between scientists and Cumbrian sheep farmers on the measurement and handling of soil contamination following the Chernobyl accident (Wynne 1996). (Pellizzoni, 2001a: 61)”

In this case study, we use this perspective to discover different practises that in one way or another exclude citizens from biotechnology policy-making processes. It is a perspective to help us understand how exclusion practises in decision-making processes work and how allocation of responsibility can develop.

## 2 XTP background for the Swedish case

The aim of this chapter is to frame the background for XTP research in Sweden in the 1990s. Central to this is the XTP research that was done and how it developed in this period. The background does not give a full picture of that development; instead it gives a number of empirical examples in the form of interview quotes from the researchers. This is complemented with how the Swedish media reported on XTP research. In this presentation we focus on how the XTP research was framed as both an opportunity and a problem in the 1990s. We end the chapter by discussing the public's general attitude towards XTP.

In the early 1990s, Sweden had one of the world's best xenotransplantation science projects. Between 1990 and 1993, researchers at Karolinska University Hospital, Huddinge, carried out clinical trials in which ten patients with diabetes underwent transplant surgery with pig cells that produced insulin. Two years later, in 1995, researchers at Sahlgrenska University Hospital, Gothenburg, connected a pig kidney to a patient. Human blood streamed through the kidney for one hour and fifteen minutes. At this time Sweden had between 10 and 15 groups of scientists working with xenotransplantation. A project called "Xenotransplantation in Gothenburg before year 2000" was established in Gothenburg. At the University of Lund, researchers were planning a project to transplant pig cells to patients with Parkinson's disease.

### 2.1 XTP research in Sweden in the 1990s

Transplanting organs from animals was an old dream that is linked to the shortage of human organs in hospitals. XTP was seen as a technique that could solve this problem, in whole or in part. Although clinical attempts were first made in the early 1990s in Sweden, there were enthusiasts who had dreams much earlier. One of those enthusiasts was Professor Carl-Gustav Groth, who was the first researcher in Sweden to conduct clinical XTP trials transplanting diabetic patients with insulin-producing pig cells at Karolinska University Hospital. Professor Erna Möller collaborated extensively with Carl-Gustav Groth and she remembers when he first discussed XTP with her.

Erna Möller: "It all started with a thought. Carl-Gustav Groth and I were waiting for a plane home from Helsinki, when he said, 'what if we could have access to an unlimited number of donors from animals, instead of these difficulties in finding suitable organs from deceased or living donors.' So the idea goes way back."

Kristofer Hansson: "When was this?"

Erna Möller: "Mid-70s, maybe."

In the latter half of the 1980s, laboratory studies were initiated in Sweden. Cell biology and immunology scientists conducted the first XTP studies. In a previous article, we describe this early development:

“Nevertheless, in the latter half of the 1980s, XTP research was initiated in Sweden. To begin with, this research consisted mainly of laboratory studies using research animals, conducted by scientists in fields such as cell biology and immunology. Diabetes and research on insulin and the pancreas were the principal targets of such studies. At the Department of Medical Cell Biology at Uppsala University, nude mice – laboratory mice with a genetic mutation – were transplanted with porcine pancreatic islet-like cell clusters. In cooperation with the Swedish University of Agricultural Sciences in Uppsala, the foetuses of 11 pregnant sows that had been killed with a slaughtering mask were used as the basic organic material of the islet-like cell clusters (Korsgren et al., 1988: 509f.). At Sahlgrenska University Hospital in Gothenburg, a research group specialising in carbohydrates and blood groups was approached by a British research group. Here the focus was on the potential use of the porcine kidney in humans. The British group, which had already performed an in-vivo link between a porcine kidney and a human kidney, asked for support and studies regarding the phenomenon of hyperacute rejection. By the end of the 1980s the Gothenburg and British groups had begun a close cooperative association, which led to the publication of several scientific papers (Hellerström et al., 1988; Holgersson et al., 1990) and became the foundation for the clinical trials that were performed on patients in Sweden in the 1990s.

Researchers had already begun to envisage clinical trials of XTP at the end of the 1980s (Hellerström et al., 1988). At the time, this goal was seen as quite unproblematic from a societal perspective, in the sense that there was no knowledge about, or discourse on, a possible risk of virus transmission from animals to human populations through XTP. Instead, concerns about the potential risks of the technology centred primarily on the individual research patients (type 1 diabetics and/or patients with kidney failure) who were to receive future experimental xenografts (*Hansson et al., 2011*).”

This dream was linked to a reality that had grown when transplantation of human organs improved. The shortage was a reality in the hospitals and something that chief physician Nils H Persson at Malmö University Hospital (UMAS) in Sweden, working as a transplant surgeon points out:

Nils H Persson: “All this time we have had an organ shortage. An important part of the work has been to attempt to obtain organs for transplantation. Because it is limited and likely to remain limited, we have looked at other ways and thus to transplants from animal to human. In the 90s there was a

feeling that we were close. We even had people calling us and saying that they had a farm and could produce pigs to take organs from. It was long before we had begun to discuss what risks would be associated with this. So for us it is been a thought that, it was interesting but not yet.”

In this way, XTP should be contextualised as a technique closely connected to the transplant surgery that rapidly developed in the latter half of the 20th century. While the transplant surgery showed promise in improving the health and lives of many people, there has always been a shortage of organs. In the 1990s, XTP was not the only technique that held the promise of overcoming the shortage. At the same time, Stig Steen, professor in thoracic surgery at Lund University, was doing research on non-heart-beating donors: *“Non-heart-beating donor – transplantation from people whose hearts have stopped – and xenotransplantation, both things were kind of desperate solutions to try to give hope to those who were on the waiting list”*. Stig Steen was not doing any XTP research at this time, but worked with the same problems as XTP researchers. The interview quotes show the main problem that the researchers felt that this was and still is.

Nils H Persson and Stig Steen were not involved in XTP research, and their answers should be seen from this perspective. The scientists working with XTP research also saw the organ shortage as the main reason for developing XTP. At the same time, the scientists also had other visions. Professor in transfusion medicine Bo Samulesson was the head of the experiment at Sahlgrenska University Hospital in Gothenburg in the 1990s.

Bo Samulesson: “I became interested in the shortage of kidneys. I saw those patient lists that were increasing with new patients, and I started to think what alternative there was. I became more and more aware that xenotransplantation was something promising. This was one reason. The other reason was that Michael Breimer and I had previously looked at glycolipids in pig kidneys. We already had a lot of data about how the antigenic picture looked in pig organs. Then we connected this and started thinking about how to run a project with an aim to test it. In connection with this, we came in contact with Ken Welsh and David Tobe, who operated in Oxford and made the first connection between a pig kidney and a human. We collaborated with them on research and they were interested in our carbohydrate knowledge.”

The researchers in XTP worked in different networks than the doctors in the clinics, and therefore they also had other reasons for getting involved in XTP (c.f. Idvall, 2003a, 2003b). For Bo Samulesson, XTP afforded the possibility of developing the knowledge he and Michael Breimer had on glycolipids and carbohydrates. The Swedish researchers were also building up international networks with researchers in the two countries that were at the forefront: the United States and the United Kingdom (c.f. Persson & Welin, 2008). But the

network was also expanding in other directions. Bo Samuelsson and his team came to work with research groups in Paris and Nantes in France. Nationally the network expanded with connection to the research groups at Karolinska Institut in Stockholm and Uppsala University that were working with this research. Thus, XTP research expanded in many different directions. The research group at Sahlgrenska University Hospital was also expanded with specialist researchers.

Bo Samulesson: "There was a group that grew quite large. I could say that we were between 20 and 30 people that were pushing this development. We had a broad group, including people from the blood bank and tissue typing laboratory and transplant surgeons. There were anaesthetists, people from renal medicine, immunologists and we had Stellan Welin for the ethical perspective. We had a large group and we had meetings quite frequently with this big group."

The group expanded with research that could develop the different problems that had arisen from the research and thus expand knowledge about XTP (c.f. Knorr Cetina 1999; Latour, 1987b). In this report we have a special interest in Stellan Welin and the perspectives he brought into the group, and we will therefore return to him and his associates in chapter 4.

There were other groups doing XTP research in Sweden in this period. Two different groups were working with transplanting cells from pigs to humans. Researchers at Karolinska University Hospital, Huddinge, carried out clinical trials in which ten patients with diabetes underwent transplant surgery with pig cells producing insulin. At the University of Lund, neurology professor Håkan Widner had a group that was planning a project to transplant pig cells to patients with Parkinson's disease. Clinical testing was never realized, but they did prepare for animal testing.

Håkan Widner: "We did animal testing to prepare for doing it on patients."

Kristofer Hansson: "What animals did you use?"

Håkan Widner: "We were transplanting immature pig cells into mice and rats. We also took part in a pig-to-pig transplant. The embryos came from normal pig strains here, the Piggham variety, from which we took embryos. It was immature pig foetuses that were transplanted in the first place. Then we made some cell cultures. We also had access to some of the transgenic pigs that were in Cambridge."

Kristofer Hansson: "When was this done?"

Håkan Widner: “We probably started in 1997 to 2001 with EU funding, and then we had some extra resources until 2004. We had two PhD students.<sup>1</sup> The goal was to examine the feasibility of doing this with patients and to understand the mechanisms behind rejection, and to understand the biology, how the nerve cells fit, so to speak.”

In 1995, a research group under the direction of David White managed to insert a gene into a pig to alleviate hyper-acute rejection immediately after transplantation. For the researchers in Sweden this was promising progress, and as Håkan Widner points out, the researchers had access to these pigs. Bo Samuelsson and his team at Sahlgrenska University Hospital also had ambitious plans to use the transgenic pigs, and they had contact with David White.

Bo Samuelsson: “Michael and I had contact with David White, who had made the transgenic pig. The intent was to do the identical coupling that we had done with ordinary pig kidneys, using kidneys from transgenic pigs instead. We created a budget and developed a plan to fly the kidney to Gothenburg. But, if I remember correctly, he was bought up by a major US company and they interfered with this process. Michael and I were over in the US and were examined by their scientific committee. It turned out that there was a strong resistance to our plans.”

It was not obvious that the scientific networks would expand freely (c.f. Pickstone, 2000). In the 1990s, major economic interests seemed to have taken over parts of the research and thus created a different agenda. This affected the researchers in Sweden who were working with XTP, and as this is a small research nation, the teams depended on cooperation with other international research groups. Sweden did not have the resources to develop their own transgenic pigs.

At the same time, there was an idea that XTP was a technology that could give Sweden an economic advantage in the future. Industries and some of the researchers had thought of this, and politicians also talked about it. Bertil Persson, former member of the Swedish Parliament, provides some insight on how XTP was discussed:

Bertil Persson: “There were two discussions. One was that exciting things were actually happening, particularly in Huddinge. Carl-Gustav Groth is a recognised figure of a kind not often found in Sweden. He produced publications on XTP. Then there also was an interest in finding new niches. Sweden had discovered that it was not sustainable to bend metal for cars in the long run. You have to have more advanced technology and find niches where we can be strong. Develop something that can be sold to an

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<sup>1</sup> See: Larsson, 2001 and Mirza, 2004.

astonished world. One does not build prosperity on unchanging technology; prosperity is built on products that no one has seen. XTP was a possibility.”

XTP was a biotechnology that was seen as a source of new capital, “*an economy of hope*”, something that in the future could build prosperity (Brown, 2005). This could be seen as a highly developed approach to biotechnology, and the Swedish culture is frequently characterised as being on the cutting edge of new technologies. This approach demands both eminent scientists and visionary politicians. Carl-Gustav Groth and Bo Samuelsson were two such scientists who pushed this field further in the 1990s.

With this short background we want to highlight how XTP research emerged in Sweden in the 1980s and 1990s. In chapter 3 we will discuss in more detail how this research developed in the 1990s.

## 2.2 XTP in the Swedish media

Swedish media reports on XTP research can be divided into three different phases.<sup>2</sup> The first phase, which lasted until 1995, is where the media reports were noncritical of the clinical XTP trials and they painted a picture of this technology as soon to be available as a treatment. The next phase, which started around 1995 and ended around 2000, saw media reports about the risks of XTP and about the committee that the government established to investigate the possibilities of continuing with XTP clinical trials. In the last phase, the media reported on XTP as an economic possibility for Sweden, but also as problematic from an ethical and a safety perspective. This phase is more or less still ongoing. Using this subdivision in this chapter, we shall discuss what it is that is discussed in the media as a policy problem with XTP.

In the first phase, the researchers told the reporters about their XTP research. Mostly it was the journalists who sought out the researchers because XTP was a new and interesting science to convey to the readers. The article that was written at this time was fairly traditional science journalism. Also, the relationship between the journalists and the researchers was traditional, in that the journalists attempted to communicate what XTP was in an educational way, not to critically examine the research bases. Professor Bo Samuelsson points out this relationship to the journalists in the interview: “*We had a very positive relationship with the media, the specialist reporters at both Dagens Nyheter and Göteborgs-Posten*<sup>3</sup>. *One of the journalists joined us for a month and was at the lab and the clinic so he could get a feeling for what this was about*”. In this way some of the larger newspapers in Sweden conveyed information about XTP research and what it was all about. Professor Bo Samuelsson remembers one of these articles and how he worked with the journalist.

<sup>2</sup> The material for “XTP in the Swedish media” is based on interviews and a previous report (Hansson, 2003).

<sup>3</sup> Dagens Nyheter is a Stockholm based newspaper and the biggest newspaper in Sweden. Göteborgs-Posten is produced in Gothenburg.

Bo Samuelsson: “The specialist reporters at Dagens Nyheter and Göteborgs-Posten called and asked if we had any news, had anything happened and how was the research coming along, and could they come out and ask us questions. Dagens Nyheter had a giant, two-page article in the Sunday Annex. Our fine pictures of molecular models and kidneys were published. Such a fantastic article! We worked along with them, we arranged the pictures and we went through their text. We worked together to convey the knowledge we had in an understandable manner.”

Thus the media provided the opportunity for the researchers to accurately share their XTP research knowledge. The researchers took their time to explain XTP to the journalists so the research was accurately presented to the public.

The big news in 1995 was the clinical trial at Sahlgrenska Hospital connecting a pig kidney to a patient; both *Dagens Nyheter* and *Göteborgs-Posten* reported about this on 4 February 1995 (c.f. Hansson, 2003). The newspaper’s journalists had been at a press conference at Sahlgrenska Hospital, where the researchers presented their successful trial made on 2 February 1995. The conference itself was the hospital’s invention, not the researchers’. Professor Bo Samuelsson remembers: “*That press conference was not our invention; it was the hospital’s own information officer who felt that this was great news for the hospital*”. At the press conference, the researchers were enthusiastic about their clinical trial done the same day. Samuelsson recounts what he felt that day when we asked him why the quotes in the articles are so positive.

Bo Samuelsson: “I had no other intention than to explain what we had done. There were several of us researchers attending the press conference; me Mattias Aurell, Lennart Rydberg and Michael Breimer. Mattias was most enthusiastic and positive, he also had his own press conference. Then we started our press conference and you get all fired up by the journalists’ questions. I was elated over the successful experiment and maybe it was a bit inflated. But I think the intention was that I should be objective.”

This enthusiasm is clear in the articles and highlights the feelings the researchers had for XTP at this time.

In the articles, XTP was framed in two different ways. The first was that this technology could solve the organ shortage, something we discussed in the beginning of this chapter. The other was that primates were unsuitable donors, and pigs would be better. The first framing was a part of the researchers’ enthusiasm, while at the same time Professor Samuelsson indicated that the research took time. To *Dagens Nyheter* he said,

“We had about 15 years of targeted research behind us before this experiment. Today we believe we have the solutions to the problems we’re aware of, but I think the reality is more complex and new problems will emerge. The situation is hopeful in many ways, and there are many suggestions on how to proceed,’ says Bo Samuelsson, professor of transfusion medicine (Dagens Nyheter, 04-02-1995).”

Thus XTP was framed as both a new and interesting technology that society should support, but that would take time to develop. XTP research was framed as an economic policy problem and if the community gave resources to this research, it would soon be usable in the clinics.

The second framing was that primates were too human-like to be used and for this reason pigs were better suited. The journalists wrote in their articles that there were few ethical problems with using pigs, as they were already part of an industrial process. The media did not deal with the animal rights issues.

Early in the latter half of the 1990s, the media increasingly reported on the risks that XTP could spread animal viruses to humans. In the Swedish tabloid *Expressen*, writer Tommy Hammarström published an editorial article on 18 June 1996 calling for a debate about XTP: “... before 2000, it is important that we have a proper debate about the new technology. First, there’s the risk of transferring diseases from animals to humans. Mad cow disease has shown that deadly diseases may well cross species barriers ...” (*Expressen*, 18-06-1996). Now XTP was not just a technology that could solve difficult medical problems, but also a risky technology. The framing of XTP research started to change and the Swedish media began generating more articles about this technology that were not solely positive. Instead, the articles became a mixture of reporting about both the risks and the hopes.

Professor Bo Samuelsson remembers that now a different type of journalists were coming to him.

Bo Samuelsson: “When it became a bit more critical, other kinds of journalists began seeking me out. I have been through this several times. There are those who are a bit more like torpedoes. They want to dig up scandals and stuff like that. Then there will be a different type of journalism.”

As we shall see in chapter 3, this more aggressive type of journalist had a role in the researchers’ decision to introduce a moratorium on clinical XTP trials in Sweden. In a way, the media influenced the policy process, but it is hard to say how. It was not only the more aggressive journalists who now began appearing in the media; politicians and scientists from the humanities and social sciences were also interviewed or wrote their own newspaper articles.

When the government decided to appoint a committee to investigate XTP, the media increased their coverage. Television news started to produce news segments, feature stories and debates. On 28 April 1998, the public-service television station SVT1's news programme *Aktuellt* aired a debate between politician Bertil Persson, from the Moderate Party and chairman of the XTP committee, and politician Gudrun Lindvall of the Green Party. The debate shows that at this time there were different views on XTP and that it were not only the researchers' positive images of XTP that existed.

Bertil Persson: "Within five or ten years I think we can, internationally, transplant cells and eventually basic organs. The heart is basically a pump, the kidney a filter, they can operate quite well I think. But it needs to be regulated, and we must move forward slowly and carefully."

TV host: "Gudrun Lindvall from the Green Party, you are currently against transplants of animal organs. You have presented a motion in the parliament, what is your main objection?"

Gudrun Lindvall: "The most important thing is that there is a number of new diseases emerging. For example, BSE, which leads to Creutzfeld-Jacobs disease; Ebola; and HIV. These are all examples of an animal virus producing a new type of human disease. This is an obvious risk with transplantation of pig organs and we can say that, as Bertil says here, we do not know what is happening and the terrible thing is that we cannot do experiments on something other than humans. So every person who gets such an organ becomes a guinea pig, and it can take a long time before we see these disease outbreaks (*Aktuellt* 20-04-1998, 21.00-21.30)."

The two politicians in the television studio represented two sides of the debate, a common way for the media to create news (c.f. Nord, 1997). The audience saw a polarised picture of how one could view XTP. It was not a new picture of XTP, but something that often appeared in the newspaper at this time (c.f. Hansson, 2003; Ideland, 2002a). What was unusual was that the Green Party got the chance to debate XTP research. This party, along with animal rights organisations, is more or less invisible in our media materials, thus one can also say that the critical voices were not heard as often in the media as the researchers. One reason for this may be that many of the Swedish researchers were nuanced and pointing to both opportunities and risks of XTP when they were interviewed. Also, there was no big debate about XTP in Sweden and, maybe, the media could not see the polarised image in the XTP research that they needed for creating "good" news (c.f. Nord, 1997).

In the TV debate Gudrun Lindvall also pointed out one framing of the XTP research that no one else in Sweden did at this time, and it was about what research funds should be spent on.

Gudrun Lindvall: “There is never an unlimited amount of research funding and science has already looked at this. There are other research tasks that do not get money and I am very doubtful if this is what we should be doing research on, or if we should improve people’s health in other ways (Aktuellt 28-04-1998, 21.00-21.30).”

This was a key issue, but not something that was discussed in the Swedish debate. The XTP committee (see below) had the mission of looking at other treatments that could resolve the same medical problems, but the issue was not explicitly addressed. In chapter 6 we will get back to this framing of XTP research.

What was widely reported in the media was the poll conducted by the XTP committee. Public-service television station SVT2’s announcer proclaimed that the study showed that: “Swedes are positive” about XTP, and he also said: “There was strong support for continued research” (*Rapport*, 20-11-1998). In the Swedish daily *Svenska Dagbladet*, the journalist was more cautious: “There seems to be no massive resistance in the Swedish population against the idea of using animal organs for transplantation” (*Svenska Dagbladet* 21-11-1998).

When the Swedish Government Official Report “From one species to another. Transplantation from animal to human” (SOU 1999:120) was released, the media reported that the committee proposed allowing clinical trials, but only to a limited extent and under careful control. Professor Annika Hallberg-Tibell (today Annika Tibell), an expert on the committee, was interviewed in the TV news and she nuanced the report’s conclusions: “We are not ready for clinical trials. We must first go further with our experimental animal models and get better results, so that we really believe we can help patients when we go to clinical trials” (Aktuellt 30-11-1999). Once the investigation was made public, the media also changed their coverage. In the 2000s most articles on XTP talked of international progress and setbacks in the field.

In comparison with the stem cell debate in the early 2000s, the media reported little about XTP (c.f. Ideland, 2002b). There was never any real debate discussing XTP and venting important questions. Perhaps the technology was too difficult to understand, or it was simply not a media-friendly topic.

### 2.3 XTP and the public

The public was more or less invisible in the media in the 1990s. The few times members of the public got to explain their perspectives on XTP it was, so to speak, affected. But this does not mean that the researchers or the authorities were not interested in the public’s views; it was rather the opposite. A smaller number of quantitative studies and some qualitative interview studies were undertaken. Here we present them to provide a background for how the public in Sweden related to XTP. What is central to this background

is that support for XTP in Sweden has gone from low (see the EU barometer from 1996) to much higher (Lundin and Idvall, 2003).

The first quantitative study that was done in Sweden was by psychologist Margareta Sanner, who conducted a survey to study how people generally felt towards transplants from related human donors, diseased human donors and animal donors (Sanner, 1998). Least accepted of these three donor types was the animal donor. In the abstract we get the following summary:

“A random sample of 1,500 inhabitants, 18 to 70 years old, in the county of Uppsala, Sweden, were sent a questionnaire asking about their opinion on transplantation and transfusion issues. The response rate was 71%. Ninety-five percent accepted receiving a blood transfusion, 89% bone-marrow transplantation and 85% transplantation of a solid organ. Organs from living donors were preferred (77%), then organs from deceased donors (69%), then artificial organs (63%), and last animal organs (40%). More than half of those accepting transplants made exceptions for some types of organs. The youngest and those with higher education were more positive towards receiving all types of organs than the older ones and those with lower education. Women were less prepared than men to accept animal organs. Those who accepted organs from animals usually also accepted all other types of organs, and were willing to donate organs and tissue more often than those who did not accept receiving animal organs (Sanner, 1998).”

As we can see, animals were least preferred as donors; also, women did not accept animal organs to the same extent as men. Margareta Sanner later became an expert on the XTP committee.

Medical scientist and transplant nurse Marie Omnell-Persson, a member of the XTP committee, did a survey study that was presented in the Swedish Government Official Report “From one species to another. Transplantation from animal to human” (SOU 1999:120). Besides being a part of the committee work, it also became a part of Omnell-Persson’s thesis (Omnell-Persson, 2003). As we pointed out above, in 1998 the study got media attention. The material was divided into two parts: 1,000 anonymous individuals representing the Swedish public and 596 individuals on the waiting list for kidney transplantation were asked the same questions. The abstract gives the following summary from the XTP study:

“The attitude towards XTP was surveyed among a random sample of the general public (596/1000) and all patients between the ages of 18 and 75 who were awaiting kidney transplantation (398/460). The majority of the respondents would accept an animal graft provided that the outcome was

the same as with a human graft. A life-threatening situation marginally increased the positive proportions. The overall impression is that the attitude towards XTP seems to be most influenced by whether the xenotransplant would involve whole organs or cells, and whether there would be uncertainty regarding the outcome (Omnell-Persson, 2003).”

60 % of the general public were positive towards XTP, and the patients from the waiting list were even more positive.

In 2000 ethnologists Susanne Lundin and Markus Idvall conducted a study to investigate XTP in relation to marginal donors and diseased human donors (Lundin and Idvall, 2003). What they point out is the increasing acceptance of XTP in Sweden. They write:

“Our survey confirms the picture of increased acceptance of xenotransplants. A majority – two out of three – of the respondents thought xenotransplants were morally acceptable. The tendency towards increased acceptance among the Swedish general public was strongest in men. Women were more doubtful about xenotransplantation. From the point of view of age, there is least acceptance among people aged between 30 and 49. This is particularly clear for men between 30 and 49, who are negative to xenotransplantation to a much greater extent than men of other ages. Opposition to xenotransplantation also seems to be more prevalent in the countryside than in the cities, and among socialist rather than non-socialist voters (Lundin and Idvall, 2003: 191).”

As in the study done by Sanner, Lundin and Idvall, this study also finds a greater acceptance of XTP among men.

Qualitative interview studies were also done in Sweden. These will be discussed in chapter 4. Ethnologist Susanne Lundin conducted interviews in the mid-1990s with those patients who had been part of the first XTP trials at Huddinge Hospital in the early 1990s (Lundin, 1999). She followed up this study by interviewing patients with Parkinson’s disease (they had not been transplanted with XTP) about how they related to being transplanted with cells from pig fetuses (Lundin and Widner, 2000). What was briefly pointed out in these articles was that patients’ positive attitudes towards XTP were more complex and would be understood in their individual situations.

In cooperation with Susanne Lundin, ethnologist Markus Idvall conducted interviews with individuals who might be affected by XTP development if it started. Twenty-eight individuals were interviewed including type 1 diabetics with renal failure, relatives of these diabetics, and medical staff working in either transplant clinics or diabetic care (Idvall and Tibell, 2003;

Idvall 2006). They were positive towards the development of XTP, although there were different attitudes within the interviewed group.

As we can see from these studies, there has not been a massive resistance towards XTP in Sweden. Rather it seems that the public has become more and more positive to this technology. What is also interesting, not only from a methodological point of view, is that the results from the quantitative and qualitative studies are quite similar. When the public and patients are asked, they exhibit a fairly positive attitude towards XTP.

## **2.4 Summary**

The XTP research in Sweden started in the latter half of the 1980s and was just basic research. As such, it was not discussed much in the rest of society, but this changed when the research teams took the experiments to the clinical stage. In the early and mid-1990s, media reports about XTP research were mostly positive; it was highlighted as a science that could help many sick people. When the risk for PERV viruses arose in the beginning of the second half of the 1990s, the media reported it and the positive picture gained a more negative side. At this time, quantitative studies and the qualitative studies done by scientists from the humanities and social sciences were done and they pointed out that there was no massive resistance to XTP among the public in Sweden. This picture has changed and studies that were done in the late 1990s and early 2000s show that the public has become more positive towards XTP. What is important to point out here is that XTP never became a big public topic in Sweden and there was never a big debate. Our own experience is that many do not know what XTP is. It was, and still is, a complicated question that was handled on the researchers' and the politicians' tables.

### 3 Policymaking as a will formation

In the late 1980s and early 1990s, medical scientists discussed research team formation policy. With researchers from many different disciplines, they also addressed other non-medical XTP questions. Thus, XTP was not only framed as a policy problem by the medical researchers, but other disciplines were able to make their voices heard. One example was Professor Bo Samuelsson, who led the EU-funded XTP project at Sahlgrenska University Hospital in the 1990s, and began collaboration with Professor Stellan Welin, a philosopher specialising in research ethics.

Bo Samuelsson: “When I wrote the application for the project it seemed relevant and important to have an ethical perspective. I contacted Stellan and he was very enthusiastic. Then one of our French colleagues suggested that we should have some kind of film documentary about the whole thing. We contacted a documentary filmmaker and it turned out that he had an historical interest in the development of XTP. I came to get a more holistic view of knowledge. You can’t just focus on molecules or technology, you have to seek a more comprehensive attack.”

What Samuelsson points out is that the researchers invited these other scientists in because he thought it was important for the development of XTP. The documentary filmmaker, too, was seen from what Samuelsson calls a holistic perspective. In the early 1990s this network of scientists, which included transplant surgeons, molecular biologists, biochemists, philosophers and others, began a policymaking process to develop different perspectives on XTP (c.f. Hajer and Wagenaar, 2003). In chapter 4 we will learn how these early policy discussions influenced Stellan Welin and other scientists from the humanities and social sciences. In this chapter we study the scientists’ routine practices of policymaking from a medical perspective.

This new type of network was not obvious to all the medical researchers in the early 1990s, as we see in this interview with Bo Samuelsson where he points out some of the problems.

Bo Samuelsson: “Stellan had written a paper and he was reading it, but it did not take long before X [name of medical researcher removed] said: ‘Listen Stellan, can you copy those papers so we can read them on the flight home instead. We have more important things to discuss’. But I got him to continue to read and there was a discussion about the paper afterwards. After the meeting X came to me and said: ‘We can’t keep having these meetings. I do not understand Stellan or the molecular biologist. There is no reason why I should come here and waste time on this’.”

The network did not immediately work as planned, with many different disciplines working together to overcome the obstacles to XTP. Samuelsson continued to work on how the meetings should be organised and the research presented. After a while it worked better and Samuelsson points out that: “*Suddenly we realised that this was important stuff*”. In this way the multidisciplinary environment became a central part of how the XTP research progressed, and also a central part of how the routine practice of policymaking formed, to borrow a term from Professor John V. Pickstone in the history of science field, *technoscientific complexes* (Pickstone, 2000). What we are interested in is the interaction and social relationship among the universities, governance and, to some extent, industry (c.f. Latour, 1987a; Latour, 1987b). This was also an international network of researchers; the EU-funded research programme, for example, consisted of researchers from Sweden, France, Switzerland, Germany, Belgium and a researcher from Russia working in Germany.

### 3.1 Framing an almost new field

Gathering facts in science is a collective process that depends on the conclusions of previous research (Latour, 1987b). But facts also define what a scientist sees as reality and while that statement does not mean that we should move away from empiricism in the natural sciences, we see facts as important evidence of how policy processes develop (c.f. Hacking, 1999; Latour, 2004). The scientific use of facts is important when we try to understand how XTP researchers framed their field in the late 1980s and early 1990s. Equally crucial is understanding, what facts the researchers did not have at this time and how this lack of knowledge affected the framing.

In reviewing our interview material, we found that XTP was framed in two different ways among researchers in Sweden before the PERV virus scare. First, the researchers addressed the question of animal models – that is, the need to use suitable animals – and second, XTP was framed as a risk to patients in clinical testing. This led to very different framings based on facts from laboratory research and medical ethics. We will first discuss the animal model and how the researchers framed this question.

Different animals have been used in XTP research; some examples are lambs, chimpanzees and calves (Deschamps *et al.*, 2005). In the late 1980s and early 1990s the discussion centred on whether nonhuman primates should be used, which was common in earlier experiments in the US. For reasons we will discuss here, nonhuman primates were never an option in Sweden, and instead pigs came to be the animal that the researchers chose for transplantation. Bo Samuelsson reflects on the discussion that went on at the beginning of the 1990s:

Bo Samuelsson: “Considering the number of pigs that we ate, it wasn’t so strange to use that animal. However, we felt very strongly that it was impossible to use nonhuman primates. Even though it was likely that it would

be easier to use a kidney from a nonhuman primate than from a pig, though I have no evidence of that. We just felt that it was not ethically acceptable. There were several in our group who felt this way. It is difficult when you have human-like structures, so to speak.”

Kristofer Hansson: “You talked about this in the beginning of the project?”

Bo Samuelsson: “Yes, we did. We talked about all sorts of animals. We read a lot about different kinds of animals and concluded that we would work with pigs. We realised that it was important to have constant strains; this was before transgenic pigs. There were inbred pig strains of different kinds and it seemed reasonable to use this preparatory work. Then transgenic pigs came along and that clinched it.”

Early discussions about which animal to use for XTP also framed the research. There were some basic assumptions about how to reason regarding the animal model. As Samuelsson pointed out: (1) we already eat pigs, (2) nonhuman primates have more human-like structures than pigs and (3) there were constant pig strains to use. These points made it possible to argue for a more medically and ethically acceptable position for the use of pigs. There was also another reason that Samuelsson doesn't mention in the interview. Professor Stig Steen points out that a pig's growth was crucial: *“Pigs grow from birth to adult in a relatively short time. Chimpanzees take 20 years to grow to adult size; it would not work quantitatively”*. This is an argument that has many similarities with point three: pigs' biology was easier to work with. The researchers' arguments were based on a mechanical worldview in which certain anatomical parts from animals were better suited to humans than other animal organs, cells and tissues (Merchant, 1989).

Thus the researchers built up a set of facts that supported the use of pigs. The data were based on medical facts, biological knowledge, ethical facts and so on. But it was also a choice that was based on the interaction between the university and industry (c.f. Pickstone, 2000). When transgenic pigs came from the company Imutran Ltd. in Cambridge (UK), researchers decided to work exclusively with this animal, although there were no clinical trials with transgenic pigs in Sweden.

The second framing is how the researchers relate to the risk to the patient in clinical experiments. The experiments conducted in Sweden should be viewed from the perspective of the ethical framework that the researchers already worked with, for example the Nuremberg Code and the Declaration of Helsinki. But there is also the story of how the transplantation of human organs emerged in the 20<sup>th</sup> century, which the researchers related to in different ways. The early history of transplantation is a tale of surgeons who had little or no success in their endeavours. There are many similarities with how XTP developed in the 1980s; however, these were not clinical trials. We must be aware of this background in order

to understand how the Swedish researchers carried out their XTP research in the early 1990s. Professor Samuelsson points out why he thought it was wrong to use patients who were very sick.

Bo Samuelsson: “There is an ethical principle that I do not really agree with – that if the patient is sick enough, you have much freer hands. There are two things that bother me about this reasoning. First, the patient should not have to suffer more, regardless of how sick he or she is. Second, it is scientifically worthless when you transplant a pig organ into a severely ill patient.”

Kristofer Hansson: “Was this the reason why the patients in your clinical experiment were relatively healthy?”

Bo Samuelsson: “Yes, they had kidney disease but were otherwise very healthy. In one of the two clinical cases, it was actually a strain on the individual in question. If there had been a patient who was a bit sicker, we do not know what would have happened.”

Here Professor Samuelsson is critical of how earlier XTP research was conducted, using severely ill patients. This constitutes another framing of XTP research and how it should be done, one that may have had an impact on how research is related to XTP and patients. Instead of doing heroic transplantations with pig organs on severely ill patients, the researchers now approached this field in other ways. Professor Samuelsson also points out his own experience with previous XTP experiments. When one of the two clinical trials of an in-vivo link between a porcine kidney and a human did not progress as planned, the patient was exposed to a strain that could, as Bo Samuelsson says, have ended badly.

A framework that emphasizes the importance of not exposing the patient to unnecessary risk also affected the clinical experiments in several ways. Who is responsible for the risks that must be taken? How can the researchers minimize the patient’s risk exposure? Professor Bo Samuelsson dwells on these questions.

Bo Samuelsson: “I had the overall responsibility for the project. I think Mattias Aurell, who was the Chief of Nephrology, also felt that he had an overall responsibility. But when it came to the clinical experiment the responsibility was on a person who had no personal stake in the experiment, preferably someone from anaesthesiology with great experience, whose word was law. He said, “Now we start”, or “now we do this”, and there was no discussion of what he said. We had gone through this very carefully. It is awfully easy for researchers to follow their own agenda, but the leader of the clinical experiment looks only to the patient’s best.”

One discussion among the researchers at Sahlgrenska University Hospital (who framed those policy problems) was particularly important for XTP research in the early 1990s. This discussion can be seen as a routine practice of policy-making, where some experts had the privilege of framing the issues in this specific biotechnology (c.f. Clark and Murdoch, 1997; Pellizzoni and Ylönen, 2008; Pellizzoni, 2001a). It was an inside affair for researchers in this field (Wright, 1996). Initially the XTP researchers had this discussion on their own, but in the mid-1990s they began to collaborate more with scientists from the humanities and social sciences, who were seen as experts in the more ethical, human aspects. This was when questions came up about whether clinical trials with XTP were possible at all, considering the Declaration of Helsinki and imperative to ensure patients the best care available, which would be transplantation with human organs (c.f. Persson and Welin, 2008).

### 3.2 A new phase in XTP research

If the first phase of policymaking in XTP research started in the 1980s and early 1990s in Sweden, it took a new direction in 1995 when the problems of PERV became increasingly apparent. A moratorium on XTP research was introduced in Sweden, and the researchers were not able to continue the policy process by themselves; now politicians got involved in the process. Thus, the technoscientific complex expanded with actors from politics, state officials and scientists from the humanities and social sciences (Pickstone, 2000). As we will discuss later, this can be seen as a formation of a political will, where the researchers expanded their networks to involve new actors in the policy process (Hajer et al., 2003).

From Professor Samuelsson's point of view, a specific situation occurred when those involved began to question the facts that XTP research was based on. This in turn started to change how the XTP researchers saw their research (c.f. Latour, 1987b). These events took place at a symposium at the Physicians Meeting in Stockholm.

Bo Samuelsson: "I remember it very clearly; we had a symposium about xenotransplantation at the Physicians Meeting in Stockholm. I had arranged the symposium. In the question-and-answer session afterwards, one of the great virologists from Stockholm asked us if we had thought about retroviruses. It was a pretty sharp criticism against the project. I had heard of retroviruses, but I had not imagined what could happen more concretely."

The PERV virus was not unknown to the research groups in Sweden, but at the time there was no evidence that dormant pig viruses could transfer to the human body. Perhaps it had not been one of the specific facts in what Bruno Latour calls the "*black box*", the established facts of a science that get people to believe in that science (Latour, 1987b). The PERV virus was something over which the XTP researchers had no control. This new knowledge was the weakest link, and it began to transform how the researchers related to XTP research.

This new knowledge also came to affect how XTP research was framed as a policy problem in Sweden. The previous framings, the animal model and the relation to the patient, became less central and the main framing became instead what risks XTP could pose to the general public. The focus shifted from individual and patient risk, to a risk to society (c.f. Beck, 1992). Professor Bo Samuelsson continues to describe what happened in the Physicians Meeting in Stockholm.

Bo Samuelsson: “I was moderator and the symposium had a broad mix of experts: Carl-Gustav Groth, Erna Möller, Michael Bremer and Annika Tibell. Then the virologists asked this question. I am not a virologist, so I couldn’t answer. I turned to the others, but none of them wanted to answer. It was a bit embarrassing. A great presentation but it fell flat. We sat down afterwards and talked about this.”

Kristofer Hansson: “How did you proceed after this?”

Bo Samuelsson: “It led to a moratorium. It took a while, because there was not much evidence, but then more and more people joined the criticism against us. Then the media got hold of it and it got to a point where we were forced to make a decision.”

The moratorium did not come immediately after the Physicians Meeting, but was discussed in the research group for some time. A new framing emerged from these new facts, and one can only wonder how the research groups related to it initially. There were no clinical trials under way in Sweden at the time, which probably meant that the issue was not immediately forthcoming. At the same time, criticism was growing, which probably made it more difficult to decide how to proceed with the research.

But eventually the media more or less forced Professor Samuelsson to make a decision. It was when the Swedish TV4 News interviewed him about the PERV virus.

Bo Samuelsson: “If I remember correctly, we talked about the PERV virus [in the research group]. But the decision to put a hold on this research in Gothenburg was made in the laboratory when TV4 interviewed me. I had not conferred with many others at the time. Right after that, I communicated with Carl-Gustav Groth and the others in Stockholm and we agreed on it.”

As pointed out in one of our earlier articles, the moratorium in Sweden was introduced before more research was published showing that the PERV virus could transfer to the human body and form a new virus (Hansson, 2003). From this perspective we want to point out that Professor Bo Samuelsson’s decision was not solely based on scientific discussion with other researchers, but was also influenced by how the media works. Journalists are always looking

for scoops that both reveal a hidden “truth” and confront different perspectives (Allan, 2002). The PERV virus fit this media logic: it was unknown to most people and presented unknown risks. Trying to argue for further clinical trials at this time would probably have made the journalists even more suspicious.

This event can be seen as a point of no return, where the researchers could no longer justify why they should continue with the clinical trials. At the same time, there were no clinical trials in Sweden at that time, and introducing a moratorium would probably not jeopardise the research at that moment. Professor Carl-Gustav Groth and his research team in Stockholm could accept this and still continue with the basic research. What the researchers did not know was that the moratorium would last for a long time. Thus, the moratorium in Sweden was a decision made more or less by one Swedish XTP researcher, but it developed into an agreement among all researchers in the field.

It is difficult to analyse Professor Samuelsson’s decision on the basis that new facts about the PERV virus challenged the established facts of XTP at this time (c.f. Latour, 1987b). But even if the decision was more influenced by the media than by research, new facts were revealed that challenged the black box of XTP. An international discussion about the PERV virus in the latter half of the 1990s largely cemented the Swedish moratorium. Annika Tibell remembers how the discussion developed:

Annika Tibell: “What actually started the discussion was Fritz Bach’s article in *Science*. I was at an American meeting, regulation xenotransplantation, the morning *Science* was published. The magazine cover showed a big pig running wild, with a little man struggling to remain on its neck. It was about the risks of PERV viruses. What also affected the discussion about xenotransplantation was the hype about the possibilities of solving things with stem cells.”

The discussion that followed the moratorium was influenced by factors other than just the risk of PERV viruses. In this new phase, many different factors were added to the criticism of XTP – factors that the researchers had never thought about before. The very promising stem cell research was one factor; another was that other viruses of animal origin began appearing at this time.

Håkan Widner: “Then came the discussion of cloning and foot-and-mouth disease. And some other viruses came during that period, like the Nipa Virus in Malaysia. Then came the pig viruses in human cells. So there were three or four things that made us more cautious.”

What the quotes from these interviews indicate is that the narrative of how XTP went from a future story to a scare story is based on different narratives that combined to become “fact”.

This accumulation of narratives about the risks and problems of XTP made the researchers feel that they could not handle future XTP research on their own; they went from unawareness to what Ulrich Beck called “awareness of our unawareness” (Beck, 1999: 123). Now, the researchers felt compelled to push the government to take up the issue. The researchers could not continue alone, they needed a broader approach to the risks linked to XTP. Now the policymaking process changed into one in which the researchers asked the government to come up with what Maarten Hajer and Henrik Wagenaar call a political will formation. In other words, *“Whereas in the past we used to think of policymaking as the consequence of political will formation (‘We should rebuild the inner cities!’), it is now often the policymaking process that leads to political will formation”* (Hajer and Wagenaar, 2003: 13). Professor Samuelsson describes contacting the Ministry of Health and Social Affairs to get them started on an investigation of how XTP researchers could continue with clinical trials.

Bo Samuelsson: “I had active contact with Lena Jonsson (Deputy Director at Ministry of Health and Social Affairs). Both Carl-Gustav Groth and I contacted the Ministry several times to get this inquiry started. It is a very slow process. We were in contact with them fairly often, to get this started.”

There was also one politician, Bertil Persson from the Moderate Party, who pointed out early on that XTP would develop and result in a complicated debate in the coming years (parliamentary record 1996/97:77). Bertil Persson is a doctor and there may have been contacts between him and the researchers, but neither he nor the researchers remember that today.

One year (1997) after the politician Bertil Persson talked about XTP, a committee report recommended that the government appoint a committee on XTP, which the researchers welcomed. In an article submitted to the debate page of Swedish daily newspaper *DN*, they presented their hopes for what this report could mean for the future of XTP research in Sweden. The title of the debate article was: *“Pig organs offer hope. In a few years we will be ready to give people organs from pigs”* (Dagens Nyheter, 08-04-1997).

*“Transplantation of organs and tissues from pigs to humans offers hope to thousands of patients with life-threatening conditions. In Sweden, patients have already had their bloodstreams linked to pig kidneys. At the same time, there are risks of viral infections. However, we are confident that this problem will be solved. We must not be deterred. In a few years we should be ready to take the step and transplant organs from pigs to humans. Five professors and experts in transplant medicine write about this.*

*Over a year ago, researchers in the UK announced that there was now hope for the many patients who are waiting for a new heart or a kidney. They would soon be able to get pig organs.*

*The reports brought interest and surprise. Was it really possible to transplant organs from pigs to humans? Won't pig organs cause an immediate rejection?*

*The British researchers announced that genetic engineering had solved the rejection problem. Hearts and kidneys from transgenic pigs were not affected by immediate rejection, as experiments on nonhuman primates had already shown. They were planning to make the first transplantation from pig to man in the next few months.*

*At about the same time warnings from other researchers came: There was a risk that pig viruses could be transmitted to the patient and cause infections. Not only could the transplant patient be affected, but the virus could also spread and lead to serious epidemics.*

*They pointed to the similarity with AIDS; the HIV virus was probably transferred from an animal (green monkeys) to man. Was it worth the risk? Was transplantation from pig to human a future hope or a danger to mankind?*

*The first transgenic pig was born five years ago in the UK. Today there is a colony of about 500 pigs containing a human gene.*

*After several years of laboratory work, the scientists felt they were ready to transplant from pigs to humans. But in January 1997, the worldwide media reported that British authorities had banned transplants from animals to humans.*

*A commission led by Ian Kennedy, professor of medical law and ethics, examined the issue in detail. The commission felt that transplanting genetically modified pigs could be accepted from an ethical point of view. The risk of infection by bacteria and fungi, and in other contexts prions, was so low that transplantation was acceptable. So the commission was positive.*

*But the commission cited inadequate knowledge of the immunological problems, and moreover, the risk of transferring viruses from pigs to humans needed to be carefully investigated. When additional expertise in these areas becomes available, the commission will re-evaluate.*

*If the risk is found to be 'acceptable', transplantation from pig to human being may be tested. They did not issue a ban, but they wanted to await more knowledge.*

*The proposal to defer has already proven to be wise. In February a research team in London reported that viruses from pig cells can be transmitted to human cells when the cells are mixed in test tubes. The question that must now be investigated is whether pig viruses can be transmitted to human cells inside the body and then cause disease, exposing the patient to a risk.*

*A number of attempts at using porcine tissue or organs have already been made. In the early 90s, 10 diabetes patients received insulin-producing cells from pig foetuses at Huddinge Hospital.*

*Two years ago at Sahlgrenska Hospital in Gothenburg, pig kidneys were linked to the bloodstreams of two patients suffering from renal failure. The experiment lasted several hours.*

*Blood samples from these patients were recently sent to laboratories in the US, which had special methods for detecting pig viruses. None of the Swedish patients had any symptoms that would indicate that they are infected with pig viruses.*

*In the United States there are currently similar tests approved by the Food and Drug Administration and Centers for Disease Control. Some 20 patients with Parkinson's disease and other severe neurological disorders have received pig cells transplanted in their brains. In addition, a number of patients with severe liver failure had a pig liver connected to their bloodstreams for a few days.*

*Xenotransplantation – that is, transplantation from animals to humans – currently faces an ethical dilemma: on the one hand, a new treatment offers hope for thousands of patients with life-threatening conditions; on the other hand, it may cause immunological problems and risks for viral infections.*

*We scientists who have engaged in xenotransplantation in Sweden, at Huddinge and Sahlgrenska Hospitals, are convinced that these problems will be solved by future research.*

*We must invest more time and resources, and not be deterred. In a few years we should be ready to take the step of transplanting from pig to man.*

*The Swedish government has recently decided to appoint a committee on xenotransplantation. We welcome this initiative. We intend to continuously consult on the investigation of issues within this medically important future area. Carl-Gustav Groth (Professor, Chief Physician in transplant surgery, Huddinge Hospital), Mattias Aurell (Professor, Sahlgrenska Hospital, Gothenburg), Claes Hellerström (Professor, Biomedicum, Uppsala), Erna Möller (Professor in Transplantation Immunology, Huddinge Hospital), Bo Samuelsson (Professor, Sahlgrenska Hospital, Gothenburg)” (Dagens Nyheter, 08-04-1997).*

When the government decided to appoint a committee, the researchers pointed out that this was an important decision that they intended to support. Professor Bo Samuelsson was also appointed to serve on the committee as an expert. Here, he describes why he and the other researchers wrote the article about continuing XTP research.

Bo Samuelsson: “It was the fear that this would somehow fall between the cracks. We had been in the spotlight, and all of a sudden we risked falling into the shadows. We thought the expertise in Sweden was pretty good. Hellström in Uppsala was conducting world-leading experiments with islet cells. Then there were Groth and Möller, and us in Gothenburg. You can’t ask for better. We just wanted to clarify that we had voluntarily taken this position, to impose a moratorium. We wanted this inquiry. We wanted it to, so to speak, produce a result so that we could continue safely.”

Scientists, politicians and industry representatives dominate Sweden’s opinion pages; they have what Lars Gustafsson calls the privilege of problem formulation (Gustafsson, 1989; c.f. Nord, 1997). Going back to the debate article, we can see that the professors have the opportunity to define the problems and what solutions there were while XTP was in this specific situation. At the same time, this critical approach must be nuanced and we can also see that the article was a way for the researchers to inform the public about the problems of XTP and where the researchers stood on the issue. The problem is perhaps not so much the scientists’ article, but rather that the news media did not invite other voices to be heard.

When the committee started its inquiry, it also took over the XTP policy process. We will get back to the policy work in the committee in the chapter “The parliamentary committee”, but first we are going to discuss what happened to the researchers and their research projects when there was no framework to work within and clinical trials could not be done because of the moratorium.

### **3.3 After the committee**

Two researchers, professor Bo Samuelsson and Annika Tibell, came to be a part of the committee, which gave the research teams in Gothenburg and Stockholm some influence over the routine practices of policy-making regarding XTP. We will get back to this in the

chapter “The parliamentary committee”, but first we are going to look closer at what happened to the research when the moratorium came and later, when the committee started its work. Was there any XTP research going on? What impact did the researchers have on policy-making regarding XTP?

Sweden was not the only country that imposed a moratorium on XTP during the 1990s; internationally most clinical trials stopped. This was during a period when stem cell research was on the rise, making it difficult to get research funding for XTP. Professor Bo Samuelsson became aware of this.

Bo Samuelsson: “Our first project worked out very well. I think we recorded 70 original works, three monographs and three or four documentary films. We were praised by EU officials. Then we submitted another application. It was the best application I had written in my life. And we got turned down because stem cells were on the agenda instead. You see how different currents in science suddenly stop something that probably could have been quite good. Then it takes 10, 15 years before it gets started again.”

There were no opportunities to obtain substantial research funding for XTP in the latter half of the 1990s. The research teams had difficulties retaining researchers, who moved on to other research. Professor Bo Samuelsson became Vice-Chancellor of the University of Gothenburg in 1997, a post he held until 2003. But individual researchers and smaller research teams continued the XTP research in the laboratory. Professor Annika Tibell continued to have some form of XTP research in Stockholm.

Annika Tibell: “Less funding means that I work more in the clinic. But my research has taken some other avenues. I carried out some xeno research some years later. But it was obvious that the large projects vanished with this discussion. The major funding and support for xeno research disappeared. We had received financial support and access to pig cells from Imutran, and that support disappeared, of course, when Imutran disappeared. The opportunities were affected. It was impossible to find greater funding for xeno research for a while. Maybe it was seen as controversial, but it was also viewed as unnecessary because stem cells would solve the problems. It just so happens that there are trends in research, what is in fashion at the time.”

Professor Bo Samuelsson paints a similar picture of the research field. The major research foundations were not interested in supporting this research, and at the same time the XTP companies, such as Imutran, could not stay in business when no one requested their products. Consequently, the promising technoscientific complexes of big research teams at the universities and their relationships to other international researchers and companies

disappeared or diminished (c.f. Pickstone, 2000). XTP research became more basic national research, far from clinical trials. A similar picture of the research comes from Professor Erna Möller: “*We followed this group for quite some time [patients who received transplants]. We thought it was interesting because the problem was not as easy as we originally thought*”. At Lund University, XTP research continued into 2000s.

Håkan Widner: “I had two graduate students who earned their PhDs in 2001 and 2004. We started out with EU funding in 1997 to 2001, then we had some extra grants here. So we studied the feasibility of doing this to patients and trying to understand the mechanisms, rejection, also to understand the biology, so that the nerve cells fit.” [...]

Kristofer Hansson: “Your graduate students did the continued work in this field after they earned their PhDs?”

Håkan Widner: “Not really. We still do some XTP work, but it is about how the immune system works in the brain. Lena [one of two PhDs] is interested in inflammatory mechanisms in the brain and other diseases, for example depression. That is a direct spin-off effect, she learned, immunology and inflammation. It probably has quite a large role in many other diseases. Xenotransplantation has become a very good model for acute inflammatory response in the brain. If you learn to understand how it works, you can understand how inflammation is controlled and regulated in other diseases. Lena would probably not be doing what she’s doing now if she had not done this. So, even if we do not have transplantation of pig nerve cells on the research agenda, the research on inflammation has benefited a lot.”

Kristofer Hansson: “So it is a spin-off from what happened in the 1990s?”

Håkan Widner: “Yes, and the other researcher is now a neurosurgeon and is currently working in London. He has an eye for neuroinflammation in, for example, the surgeries he does now. He has done some research on controlling the inflammation in the brain. The XTP research has by no means been wasted. We have learned very much about how the biology works.”

The XTP research generated knowledge that is currently used in other areas. The quote also points out that the research continued after the moratorium on clinical XTP trials. But this kind of research was not framed as a policy problem; it was simply basic research about human biology. However, it was research that was still influenced by the discussion about XTP. There were, for example, no plans to take the XTP research to clinical tests.

The researchers' framing of XTP as a policy problem continued in the late 1990s and 2000s, but in other arenas. For Professor Annika Tibell, that meant that the policy process around XTP became an international issue.

Annika Tibell: "There have been no clinical trials in Sweden since the early 1990s. However, I am in the international xeno-organisation, on the board and the Ethics Committee. I have been involved in assessing the clinical studies being conducted now and helped to put out guidelines. Basic requirements, which we believe are necessary in order to move forward in clinical trials. I am active in terms of policy making and regulatory affairs. That has become my sphere along with ethics."

The problematic questions about XTP have become more international, and Professor Annika Tibell has been working more in this arena than nationally. The quotation can be interpreted as meaning that when XTP research in Sweden was no longer a reality, the international arena became more important. Policy questions continued to develop, and there were also opportunities for those researchers who did not want to abandon XTP research.

### **3.4 Researchers and the public**

The XTP researchers' relationship to the public and affected patients so far has not been widely discussed. In the next chapter we will discuss how the scientists from the humanities and social sciences began collaborating with the XTP researchers regarding the need to inform the public and patients about XTP, and also understanding how they related to XTP. But there is also a tradition among researchers to communicate their research to, mainly, the patients. Håkan Widner is one of the researchers who have been working hard on different ways to reach out.

Håkan Widner: "It is our duty to reach out to the public with research information. You can do it in many different ways. I work with patient-related research, and then it is primarily for patients. Specifically in Parkinson's disease, the patient associations are strong. They have a magazine, which reaches fifteen thousand people or something, and there are chat sites and websites. There are a lot of other websites where we provide information in various ways. We get a lot of questions, so there is a need for information, about future plans, and about information on coming studies. We ask an open question, if anyone wants to volunteer. Then you give more information. [...] We have meetings with the Parkinson's association here, usually once a year in the hospital auditorium, with three or four hundred people."

Here Håkan Widner is talking more generally about his research and not specifically about XTP. What is crucial is how he has built a relationship with the patients and patient organisations that are important to both the researchers and the affected. The patients and their families can keep abreast of the research and the researchers can build confidence in those who want to participate in the studies.

Annika Tibell also works with the patient relationship in various ways, and she sees the lectures about XTP as what the university world calls a ‘third task’. Asked about the aim of the lectures she answers: *“I had no particular aim; if I can, I do it. It is about spreading the information you have, but I have not had any particular policy”*. This is the approach that many of the researchers take with the media. They provide information about their research when approached by the media or patient organisations.

We do not see that the information the researchers provide to the public increases public participation. We define public participation by the definition that Gene Rowe and Lynn J. Frewer give when they write: *“Public participation may be defined at a general level as the practice of consulting and involving members of the public in the agenda-setting, decision-making, and policy-forming activities of organizations or institutions responsible for policy development”* (Rowe and Frewer, 2004: 512). We cannot see that there are any practices of consulting and involving patients in decisions that aim to influence the research agenda-setting, decision-making or policy-forming. This does not mean that no such effects exist, but it is not pronounced as a practice in our interviews with the researchers.

Another possibility is that the information the researchers provide can have a long-term effect in which the patients and their relatives later participate in agenda-setting, decision-making or policy-forming in various ways. This is difficult to investigate and is beyond the scope of this study. However, the central relationship is between the researchers and the patient organisations, something we will return to in the chapter “Stakeholders taking place”.

### 3.5 Summary

The researchers work with policy problems in many different ways. First, XTP has always been framed as a science that can give sick people new organs or a cure. This is a central framing for the entire XTP project. Other framings in the early 1990s were the question of which animals to use and how to ensure patient safety during clinical testing. Patient safety was a significant framing issue arising from the first clinical XTP attempts in the 1980s. These framings became less important with the criticism that the donor animal carried PERV viruses that could transfer to humans. XTP was then framed as a risk for both the individual and humanity, and something with which the researchers could not continue. The extension of this framing was a moratorium on XTP, which Swedish researchers embraced. This specific framing made it impossible to continue with clinical trials. Some researchers continued with their laboratory experiments, others tried to influence politicians to begin

investigating on what premises XTP research could continue. But this external impact did not give the results the researchers wanted. By the end of the 1990s, stem cell research took over, the XTP researchers were split up, and there was no policy for how their research could continue striving for clinical trials. Some researchers found other ways to work with XTP, in the laboratory or continuing with policymaking and regulatory affairs on a more international level.

## 4 A new research field

Through our interviews we learned that the medical field related to transplantation has more ethical dilemmas than other medical fields. First, this field involves not only the doctor–patient relationship, but also a relationship with the surrounding community as a supplier of organs. Transplant surgeon Nils H. Persson points this out when he discusses why he worked with researchers from the humanities when investigating ethical dilemmas in his practice:

Nils H Persson: “It is perhaps more relevant for someone who does kidney transplants than someone who operates on, say, colon cancer. The latter only involves the doctor and the individual – and, of course, resources from politicians. We tend to be more dependent on others and, sometimes we face ethical challenges.”

This closeness to ethical problems is interesting for our case because it highlights the XTP researchers’ experience with talking about difficult ethical issues and their relationships to professions working with these ethical questions. What did this infrastructure mean for the ethical problems of XTP that became increasingly visible in the mid-1990s? We will discuss this question in this chapter.

In the mid-1990s, Sweden’s XTP researchers began cooperating with scientists from the humanities and social sciences. The research team in Stockholm started collaborating with the ethnologist Susanne Lundin, while in Gothenburg, Professor Bo Samuelsson and his team began collaborating with Professor Stellan Welin in bioethics and Anders Persson from sociology. The research application that Bo Samuelsson and his team submitted in the 1990s also included an application for Stellan Welin’s and Anders Persson’s participation in the research. The formulation of the application provides insight into why the XTP researchers established this collaboration.

**“Workpackage 6: Evaluation of ethical issues/attitudes towards xenotransplantation**

*Xenotransplantation is a controversial subject from an ethical perspective. It is known that some countries harbors strong militant, “animal rights movements” opposing the use of animal organs for human transplantation. The situation in some other countries is so far positive. Xenotransplantation is widely covered by mass media in a positive way. There are also examples where the patient organisations for kidney diseases are strongly in favour for research on xenotransplantation. It is however not known what attitudes “normal healthy” citizens carry. It is expected that there are cultural differences, national differences and religious differences. A change from a positive to a negative attitude against xenotransplantation is easily initiated by misconducting the knowledge transfer to the public or by misconducting the relations with mass media. We feel the ethical question of such importance for the progress of the project that we have one workpackage included addressing the issue.*

*This workpackage addresses 2 topics:*

**6.1 Historical, cultural and ethical perspective**

*The work will result in a) a report; b) a 1.5 hours documentary film for distribution through european TV channels. The film is produced and financed by Les Film d’ici, but the research behind it is partly supported by expertise within the project. The report will contain all the material resulting from the research for the documentary film, is more comprehensive than the film and will be presented in the scientific format together with a popular science book edited and printed by Abbeville press. The production of the report will be financed by the project. Both a) and b) are expected to contribute to the knowledge transfer between the project and the public in an objective, informative way.*

**6.2 Attitudes from an ethical perspective**

*This work will result in an analysis relating the various ethical attitudes emerging in public and among animal welfare organisations, religious leaders to known ethical structures and norms. Data on ethical attitudes will be collected through interviews. The results will be published in the scientific format. The results will evidently sharpen the ethical questions, structure possible public debates, and increase our knowledge and awareness in these and related questions.*

*To have the workpackage included in the overall project is motivated by the accumulated competence, the natural need within the project to discuss ethical issues and the obvious need for integrating humanistic and social science perspectives in a truly natural science project.” (University of Gothenburg, Unpublished application)*

In chapter 3 we discussed this as Professor Samuelsson’s holistic perspective on XTP. The XTP researchers had reached a point where the ethical issues were apparent, and they felt that they needed experts in the field to respond to them. As we see in the application, they were also focused on informing the public.

In the 1990s, ethical questions concerning XTP had become so sensitive that the XTP researchers had to respond to them. It was no longer possible for medical teams to conduct research; instead it became crucial to obtain ethical expertise and to determine how society perceived the research. It was important that the research was accepted among the public –

both that the public was informed about the research and that the researchers proceeded in an ethical manner. Professor Håkan Widner points this out:

“If it was totally impossible to get this accepted, then we could not continue. This is more about intuition than dialogue, so to speak. No one is an absolute authority on these questions. You have to have intuition in some way”. Widner and Susanne Lundin began collaborating to learn more about this intuition (c.f. Lundin and Widner, 2000).

Kristofer Hansson: “The collaboration with Susanne Lundin, what has that meant to your research and your research group? How did you integrate it into the medical research?”

Håkan Widner: “I think it is been very rewarding that someone comes in and asks questions on a slightly different plane. What does it mean for patients and how are we affected? What is it we want to achieve to make it clear? It also allows us to formulate and justify our work. It has been rewarding in every way.”

Kristofer Hansson: “Is it affecting what you earlier called the team’s intuition in any way? On what route your continued research should take?”

Håkan Widner: “Yes or at least, it could have been able to do so. Had we received signals, a response that this is unethical, then we would have really taken that to heart.”

The XTP researchers began cooperating with the scientists from the humanities and social sciences before the moratorium; there was an idea that XTP research was risky and that it could develop into something controversial that patients and the public would oppose. It had become important for the XTP researchers to proceed with great sensitivity. For Professor Bo Samuelsson, it was about having a holistic perspective on XTP, while for Professor Håkan Widner it was about gaining a better understanding of the intuition regarding this technology. The fact that scientists from the humanities and social sciences were interested in XTP research encouraged collaboration.

#### **4.1 New relationships and new research issues**

Different researchers from the humanities and social sciences got into XTP research in different ways, and how they got into the field affected how they came to frame this specific research. Looking closer at three different researchers’ narratives on how they started their

XTP research, we see the possibility of discussing the issues that were important to them. We were particularly interested in studying how the collaboration with the XTP researchers created relationships that affected the development of different policies. The scientists from the humanities and social sciences were independent researchers in these specific collaborations with their own scientific agendas. But they also had tasks to fulfil that were defined by, for example, their research grants.

When Professor Bo Samuelsson needed to complement his EU application with an ethical perspective, he contacted his old colleague Professor Stellan Welin: *“I was contacted by Bo Samuelsson, who was setting up an EU project on xenotransplantation. They wanted something about ethics, so I wrote a short text. At the time I was a part of the Gothenburg group along with Anders Persson”*. This was when Bo Samuelsson prepared the EU applications seen in Work package 6 above. Stellan Welin and Anders Persson joined the research team after the first attempt at two clinical trials of an in-vivo link between a porcine kidney and a human. These experiments had been reviewed by ethics committees, but the XTP researchers now felt that they needed their own ethicists in the project.

Anders Persson had worked with Stellan Welin in different projects since 1995, and when Welin began to cooperate with the XTP researchers, Persson was also given this opportunity. Persson’s academic background gives a picture of the way scientists from the humanities and social sciences get involved in this type of project.

Anders Persson: “I am a 51-year-old sociologist and earned my PhD in 2002. In 1995 I was working with Stellan Welin doing a study on medical research priority for the government’s Research Advisory. We were contacted by the Rector of the University of Gothenburg [Bo Samuelsson] for this xenotransplantation project. The project included mainly medical people, transplant surgeons, but also people from basic research, clinical specialities, molecular biologists, biochemists and so on. Our task was to look at the ethical and social aspects of this technology. We had the last meeting in the spring of 2000, and by then there was not much xenotransplantation research going on.”

Both Welin and Persson were part of a bigger research team consisting of many different specialities. They were, in this sense, also a part of what Bruno Latour calls fact-builders (Latour, 1987b). Many different participants were involved in technoscientific complexes, with specific roles in building up a strong rhetoric for specific research; the scientists from the humanities and social sciences should be seen as part of this complex (c.f. Pickstone, 2000). Bruno Latour points this out when he describes how this works in practice: *“The picture of technoscience revealed by such a method is that of a weak rhetoric becoming stronger and stronger as time passes, as laboratories are equipped, articles published and new resources brought to bear on harder and harder controversies”* (Latour, 1987b: 103). From this

perspective, they can be seen as researchers who will, in practice, solve problems and publish articles in order to get the laboratory better equipped to handle the social, cultural and ethical questions (c.f. Wright, 1986). But as Anders Persson points out, by spring 2000 the problems with the PERV virus had become so big that the research teams had problems coping with the problem and built stronger rhetoric.

But the researchers from the humanities and social sciences were not only a part of the technoscientific complexes; they also had their own research logic and their own research agendas that differed from those of the natural scientists. This meant that the humanists and social scientists were sometimes assigned tasks by the XTP researchers and sometimes they sought these tasks out themselves. This indicates that this group had their own agendas. If we look closer at how the ethnologist Susanne Lundin approached the XTP field, we can see how she was an active part of building up relationships with the XTP researchers.

Susanne Lundin: "In 1996 or 1997, I think, I lived in Cambridge and was finishing a research project on reproductive technologies. Then I came in contact with a very different reproductive technology, how to create genetically modified pigs with human DNA. While seeking partners in this research field, I got to know the research group in Stockholm, Huddinge, linked to Karolinska Institute. They worked specifically with developing xenotransplantation. Their contact person in Cambridge was David White from the Novartis Company. He had the 'pig farm', as it was called, where they did these inseminations and breeding of genetically modified pigs. I came in contact with them and we began collaborating. When I got home to Sweden I was asked by one of the researchers in this Swedish xeno group to try to access how individuals think and feel about this. The research team in Sweden had done a study, the first in the world – an insulin study with xenotransplantation. I had the task of interviewing these patients."

After the project Susanne Lundin contacted Professor Håkan Widner, medical researcher at Lund University and a specialist in Parkinson's disease. They agreed to collaborate and one of their XTP research tasks focused on how patients with Parkinson's disease might possibly be transplanted with cells from a pig foetus (Lundin and Widner, 2000).

The relationship the researchers from the humanities and social sciences were part of created a collective process where specific facts were identified (c.f. Latour, 1987b). This collective process was related not only to the XTP researchers, but also to the humanities and social sciences. For this reason, it is also difficult to more precisely define how these scientists framed the XTP question, because it was framed in many different ways in the articles that were produced from these three scientists and their colleagues (see for example Hansson, 2003 & 2005; Ideland 2002a; Idvall 2003a, 2003b & 2006).

In the 1990s, Susanne Lundin began to focus on how patients were affected by XTP and how they related to it. A key focus of her articles is the cultural complexity of the patients' relationships to their bodies and to the new technology (c.f. Lundin, 1999; 2002a; 2002b; Lundin and Idvall, 2003). In the interview with Professor Stellan Welin he points out what came to be his task in the project: *"I came to look at clinical trials and when it was time to begin them. How should these trials be organised and how can they be offered? They wanted to get started on clinical trials"*. In the interview with Anders Persson he summarises their tasks:

Anders Persson: "Stellan was to look at when and under what conditions the clinical trials could start and what types of patients should be selected. Then there was one task that we actually chose not to do. It was about studying the growth of knowledge in this field. It would have required a more bibliometric study. I was more interested in looking at the conflicts regarding this, what groups are pushing this forward and what groups are against it. What types of arguments are used and, above all, what arguments are used to shut out their opponents."

Like Susanne Lundin, both Stellan Welin and Anders Persson published articles that presented their facts. These facts became part of the XTP project, but there was more to it than that. Persson's statement that he chose not to carry out some of the tasks from the application highlights the independence the scientists from humanities and social sciences tried to create for themselves in this project. Our hypothesis is that their framing of XTP research can be understood from what has been called the counter-cultural movement originating in the 1960s (Pickstone, 2000). This perspective questions the romantic view of natural science and has a more complex and questioning perspective of it (c.f. Foucault, 1972). The three scientists had this perspective when they began working with the XTP researchers. At the same time, it is important to point out that the scientists became an important part of this discourse on XTP research, and that, as we will see later, was related to a political practice (c.f. Foucault 1991). This was not necessarily a perspective that opposed the XTP researchers' work, but something that the XTP researchers, for various reasons, saw as necessary in their projects. Professor Stellan Welin points this out:

Stellan Welin: "I think he [Bo Samuelsson] partly had a genuine interest in getting the ethics right. [...] I do not know if he had received a tip that this would be good to have. I think the politicians had complained in earlier versions about the lack of ethical considerations – it was like that in Brussels. It turned out later in the evaluations that they received a lot of positive response that they had integrated this element." [See the application in the beginning of the chapter]

What we want to point out is that this collaboration was important for the humanities and social sciences to become a part of XTP research. It also gave the XTP researchers tools for talking about a holistic perspective, as Bo Samuelsson calls it, or intuition, as Håkan Widner says. At the same time as the scientists from the humanities and social sciences were invited to the projects, an equally important aspect was to convey facts to the XTP researchers.

## 4.2 Mediating knowledge

Besides writing scientific articles for international journals, the researchers from the humanities and social sciences worked at mediating their facts in two directions: to the XTP researchers and to the public. It is hard to describe the results of these different policy processes, but looking closer at how the researchers worked at conveying knowledge, we can say something about their role in the policy process. Professor Stellan Welin describes how he came to work with the XTP researchers:

Stellan Welin: “We were really a part of this project, so it was really fun. They were very suspicious at first; in the first meeting we had to declare whether we were for or against XTP. I said I was for everything that was good and against everything that was bad. Then it got better. Then we took on a consulting role, which also happened in the stem cell project. They called me and asked questions. We became a part of the inner circle.”

Kristofer Hansson: “Asked about what?”

Stellan Welin: “For advice, and to discuss what is wise, not just what was right or wrong.”

Stellan Welin’s and Anders Persson’s roles on the research team gradually became clearer in that they were to act according to their specific professions. Thus, they also had direct influence on how the XTP researchers reasoned and acted. This input could be to discuss difficult ethical questions with the researchers, or to present an argument when the research team met. So, the scientists from the humanities and social sciences mediated their facts, or, as Paul Ricoeur puts it, the facts that were presented can be seen as narratives that created a form of action (Ricoeur, 2008). This action might be to say no to a particular form of clinical trial or to discuss different forms of clinical trials. As Susanne Lundin points out that new technologies, like XTP, often “*challenge established values without giving new guidelines*” (Lundin, 2004: 107; see also Bauman 1993). The scientists from the humanities and social sciences were important actors who could present their perspectives so that the XTP researchers could manage ethical dilemmas. Anders Persson also reasoned about this in the interview.

Anders Persson: “There was a French researcher who was close to clinical trials. He wanted to replace a trachea on a small child and this trachea had been grown in a mouse stomach. But because of the risk of infection and the debate that followed, it was stopped. He really wanted to start. He even wanted to do this against the hospital’s wishes. This was his workday – to see these children die. Because there was nothing to do, this was a last resort.”

Kristofer Hansson: “But how were you and Stellan advice-givers?”

Anders Persson: “Above all it was our ethical competence that was requested. When can we start, when is it right to step in and do this? These types of questions, what would the ethicists say? It was pretty broad, you could say, many different issues. But most revolved around this: When can we get started, when is it ethically correct, which patients should we focus on and so forth.”

In summary, the ethical competence which developed during the course of the XTP project were valuable to the XTP researchers. We think this was crucial in a period where there were no obvious guidelines to follow; instead, XTP researchers were compelled to start a discussion to find new guidelines. This is also something that Susanne Lundin mentions in the interview.

Susanne Lundin: “I presented for the research groups and there was good collaboration with them in Stockholm and in Lund. An understanding from both sides, an understanding of this irrational opinion that the public can have, an understanding of me as a cultural researcher, an understanding that you sometimes have to distance yourself and just watch what happens in the lab and so on. It has been built on a lot since then, to take this interdisciplinary approach seriously, trying to understand each other.”

What the interviews reveal is how an understanding of the different perspectives grew among these researchers from different fields. This strengthened the ties between the natural sciences and the humanities and social sciences.

There were no more clinical trials in the 1990s and the PERV virus created an ethical dilemma that the scientists from the humanities and social sciences couldn’t handle, so a new policy process started in a parliamentary committee (which we will describe more specifically in the next chapter). For this reason, it is hard to pinpoint specific policy changes from the work that Stellan Welin, Anders Persson and Susanne Lundin did in their different projects. But the scientists from the humanities and social sciences had an impact on different levels in the 1990s, which becomes visible in the interview with Susanne Lundin.

Kristofer Hansson:” How do you think you influenced with your ethnological knowledge?”

Susanne Lundin: “Looking at the Swedish Gene Technology Advisory Board, or the Nordic Council of Ministers, where I have been a member, I think there has been an impact. Take for example the Swedish Gene Technology Advisory Board. When I started there, they only focused on ethics. If there was anything that was not hard data, it was ethics. This has been replaced, more and more, with a cultural studies perspective, and today they bring in anthropologists and social scientists in a completely different way.”

The researchers from the humanities and social sciences seem to have an impact on different levels of society, not only affecting specific medical research groups but also different committees. In the example that Susanne Lundin refers to, she has not only initiated a cultural competition, but she also demonstrates the importance of the academic fields of, for example, ethnology, anthropology and social science. Once again, it is hard to say more precisely what impact there has been on policy processes. What we can say is that there does not seem to be much impact on the XTP committee. The members of the committee were interested in the articles Stellan Welin, Anders Persson and Susanne Lundin had written, and the articles are referred to and discussed in the report. None of them were experts on the committee.

Going back to Bruno Latour once again, we want to emphasise that the scientists from the humanities and social sciences were, from their own profession, fact-builders (Latour, 1987b). In different contexts, they built their own facts on how to relate to XTP and XTP research. They were also a part of the XTP research teams and mediated these facts on different levels, which, we assume, had an impact on how the XTP researchers acted. Their involvement on different committees was significant, but this was not the only field where they mediated their knowledge; the media was also an important arena for these scientists.

As we pointed out in earlier articles, the scientists from the humanities and social sciences wrote their own articles for the newspapers (Hansson, 2003). Journalists also often contacted them for comments on XTP. In addition, this group saw that they had a task in the community informing the public about these technologies. Susanne Lundin says:

Susanne Lundin: “What happens when you have this mandate, which we cultural researchers have, is that there is always a demand from the media. So the media notices you and the media is a third party in this context. I became involved in the media via many discussions with doctors or politicians on the radio and TV.”

For the humanists and social scientists, it was essential not only to produce facts for the XTP researchers, but also to inform the public about their findings. Thus, they became a link between XTP research and the public by being interviewed or writing their own articles. At the same time, and this is a criticism of the media, many times the humanists and social scientists were expected to tell funny anecdotes about how people related to XTP (c.f. Hansson 2003). For example, that people thought they would develop animal characteristics if they received animal cells or organs in their bodies. Journalists never asked XTP researchers such questions. There were also questions that resulted in other, perhaps more important, issues not being discussed in the media. For example, the journalists never asked about what role the animals would have in a future XTP society.

At the same time, there were arenas where the social scientists could present their own arguments. One was in their own articles in the media; other arenas included oral presentations to the public, sometimes in collaboration with the XTP researchers. Professor Stellan Welin contributed at the Science Festival that was held in Gothenburg and other contexts where the public were present. He says: *“Mostly we were at the Science Festival at Chalmers [University of Technology in Gothenburg], where they had Science Days each year for the students”*. This was how the researchers reached out to the public with their knowledge about XTP. What is crucial to note in this context is that none of the three scientists interviewed had any intention of creating public opinion about XTP; they simply saw it as their task to inform the public about their knowledge.

### 4.3 Summary

Researchers from the humanities and social sciences began collaborating with XTP researchers in the 1990s and soon had an independent role on the research teams. The initiative of this collaboration came from both sides. Along with producing their own research, they came to act as referees to whom the XTP researchers could turn with specific issues such as ethics. This became a clear influence on the XTP researchers' work. However, it is difficult to more precisely define what the input led to. What can be said is that much of the work that the scientists from the humanities and social sciences did was to mediate knowledge. This also became central in their relationship to the public. Journalists often contacted the scientists for interviews where they talked about XTP and XTP research. The researchers also wrote their own articles in the newspapers and in this way framed the question from their perspectives.

## 5 The parliamentary committee

When the Swedish Parliament created an inquiry to investigate XTP, the XTP policy process moved to a new group called the XTP committee. Hence, the XTP discussion now moved from the domain of the research teams and the media to a group of politicians and experts who now was specially appointed to investigate the issue. In this section, we will study how XTP research came to be framed, how the committee worked and what results the investigation produced.

The committee's work was defined by its Terms of Reference from the government, written in consultation between politicians and officials at the ministries, often with help from outside experts (c.f. Ahlbäck, 1997). The entire Terms of Reference are presented here as they provide an important background to how the politicians and experts argue in our interviews with them.

***“Transfer of organs and tissue from animals to humans***

***Terms of Reference:*** TOR 1997: 44

***Department:*** Ministry of Health and Social Affairs

***Date:*** 06-03-1997

***Dir*** 1997: 44

***Decision at the governmental meeting of 6 March 1997***

***Summary of the mission***

*A committee has been established to assess the ethical, medical, legal and animal welfare aspects of the transfer of organs, tissues or cells from animals to humans. Against the background of the potential risk of spreading infections from animals to humans, the committee shall consider and submit proposals for the conditions under which clinical trials must be conducted and which forum should determine this. The committee will also consider and submit proposals for a system for recording and monitoring patients who may be transplanted with organs or tissue from animals, and if required submit proposals regarding any infectious agent, such as viruses, that turns out to be transferred from animals to humans.*

*The committee shall also propose guidelines for ensuring the safety and quality of organs and tissue from animals that may be used for transplantation into humans. The committee shall also propose guidelines for determining who should receive human organs or tissues and who should receive organs or tissue from animals, if the use of animal donors becomes a reality.*

***Background***

***Research situation***

*Research and trials of so-called xenotransplantation, i.e. transfer of organs, tissues or cells from animal to human, are in progress in different parts of world. In the following, the term xenotransplantation refers not only to complete organs but also to tissues or cells from animal donors.*

*In various contexts, it is predicted that xenotransplantation will be common in 5-10 years. Such transplants could in principle solve the problem of organ shortages.*

*Today many people requiring transplants must wait a long time for a suitable donor.*

*If animal organs could be used, this would essentially eliminate the waiting list.*

*However, transfer of organs from animals to humans raises a number of issues, particularly of medical and ethical nature. These include the risk of disease transmission between species, consent issues, principles for allocating organs from animals and humans respectively, and animal welfare aspects.*

*In the model experiments that are under way, animals that are genetically modified*

*(transgenic animals) are being used to prevent acute rejection of the animal organ in the human body. Both the UK and the US have now developed transgenic pigs, which is a major step towards the transfer of organs from animals to humans. A research team in Cambridge, linked to a biotechnology company, has previously assumed that the first transplantation of a transgenic pig heart into a human would take place by 1997. In the United States, research is being conducted in which pig cells are being used as alternatives to human embryonic cells in patients with Parkinson's disease. A total of twelve patients with Parkinson's disease and six patients with Huntington's disease have been transplanted in the United States with embryonic porcine neural tissue.*

*Sweden is among the countries conducting the most research in the field. There are a total of 10–15 research groups in Sweden working with xenotransplantation. Several of these projects also involve collaborations with the British biotechnology company, including the project 'Xenotransplantation in Gothenburg before 2000'. An early milestone for the project was achieved in February 1995, when a porcine kidney was connected to a dialysis patient's circulation. Another Gothenburg group is conducting research aimed at using a pig liver as a temporary support while waiting for a human liver donor. Lund University is pursuing research into the possibility of transplanting pig neurons into patients with Parkinson's. The Karolinska Institute and Huddinge hospitals are conducting research on the transplantation of insulin-producing cells from pigs. Between 1990 and 1993, 10 diabetic patients received insulin-producing cells obtained from pig fetuses.*

#### *Society's attitudes*

*The issue of transplantation of organs and tissues from animals and how society should relate to this has been raised in reports from Britain and the United States in the past year. One report from the British Ministry of Health, dated January 1997, notes that the British Government is currently not prepared to approve human trials because of, among many other things, the risk of contamination. Several international organisations are also discussing the issue.*

*Sweden has no regulatory framework for xenotransplantation. The Transplant Act (1995:831) does not cover organs transplanted from animals to humans. However, the Animal Welfare Act (1988:534) has special rules and regulations with regard to taking organs or other materials from animals, there are special rules for particular surgical procedures, as well as the use of animals for scientific purposes and so on.*

#### *Transmission of infections*

*It is currently not known whether animal organs or tissues may transfer certain types of viruses or other agents to humans. Such cases have come to light in recent years, such as BSE ('mad cow' disease), HIV, the Ebola virus and other similar diseases, some of which present clear evidence of having been transferred from animal to human, others of which are somewhat less certain.*

*Animals can carry disease-causing organisms, such as viruses, which do not cause disease in the animal but which could lead to severe consequences in humans. A virus that is harmless in a pig could behave quite differently in humans.*

#### *Consent*

*The transfer of organs or tissues from animals to humans gives rise to new, potentially severe risks to the patient, especially for those transplanted in the initial experimental stage. It is therefore essential that conditions are established that allow truly informed consent.*

#### *Animal welfare*

*Animal experimentation is constantly debated. Animal welfare aspects must always be kept in mind. There is also an ambition to limit the use of animal experimentation.*

#### *Distribution of organs*

*During the experimental phase, as well as at such time as transplantation of animal organs might be an established treatment method, the task of deciding which patients will receive a human organ and which receive an animal organ will be highly sensitive.*

**The mission**

*As previously mentioned, Sweden has no specific guidelines for xenotransplantation. However, the transfer of organs or tissues from animal to human gives rise to issues that are of great interest to society.*

**Clinical trials**

*In accordance with the regulations applying to research in Sweden, all research involving human trials must be assessed and approved by a research ethics committee. This committee is tasked with determining that the necessary conditions exist for the patient to give informed consent, and with assessing the project's scientific viability. However, there is a difference between clinical trials involving xenotransplantation and other clinical trials. The risk of spreading an infectious agent of some sort, while primarily a concern for the person subjected to the trial, also poses a potential risk to other individuals.*

*The question of the risk of infections passing from animals to humans is too broad to be assessed by a research ethics committee.*

*With regard to risk of contamination, there is a boundary between basic research, including animal studies, and actual human trials. For this reason, this inquiry shall consider and submit proposals regarding on what grounds clinical trials can be conducted and which forum should be allowed to approve such trials.*

*The inquiry shall also consider whether there is reason to establish a system for recording and monitoring patients who have received organs from animals and, if so, what action may be required if it should turn out that an infectious agent is transmitted from animals to humans. It is especially important, of course, to monitor patients in the experimental initial stage.*

*The inquiry shall also propose guidelines on how the safety and quality of animal organs used for transplantation into humans will be controlled. This also includes proposing guidelines for registration of the donor animals and archiving of tissue from them.*

**Other issues**

*Because xenotransplantation trials entail unknown and unpredictable risks, the formulation of consent forms is critical. The inquiry shall consider and propose specific actions required to ensure that informed consent can be obtained. One issue that needs discussion is whether it is possible to consent to a treatment trial that can not only lead to consequences for the patient, but perhaps also for other people. Another question is whether children should participate in xenotransplantation trials. It has also been discussed whether consent to transplantation of animal organs should be made before the patient is in serious condition.*

*The committee shall also propose guidelines for determining who should receive human organs and who should receive organs from animals, if the use of animal donors becomes a reality.*

*International reports indicate that many people are willing to accept organs from pigs but not from primates, such as monkeys. This does not, however, mean that issues can be raised about the transfer of organs from animals to humans. The inquiry shall therefore acquire knowledge of what attitudes people may have of transferring organs from animals to humans and how individuals with transplanted animal organs may react.*

*The inquiry should also examine animal welfare problems that may arise in connection with the use of animals for xenotransplantation. In particular, they shall investigate how such use can be reconciled with the Animal Welfare Act. On the whole, the question should be dealt with based on our approach to animals. This may include ethical issues such as if it is justifiable to keep animals as 'spare parts'. It can also apply to various practical aspects of breeding.*

*There is a need for international consensus on the risks associated with xenotransplantation. The committee shall therefore keep itself informed about the debate and the positions in other countries and in international organisations.*

*On the basis of the considerations and proposals presented by the inquiry, the*

*government recognises the possible need for constitutional amendments. The inquiry shall include consultation with the Swedish National Council on Medical Ethics, the Swedish National Board for Laboratory Animals and relevant research groups. The government's Terms of Reference to all committees (TOR 1994:23), to appoint an inquiry chair for review of public commitment, applies. The committee shall also report on gender equality policy implications (TOR 1994:124), regional policy implications (TOR 1992:50) and impact on crime and crime prevention (1996:49). The committee shall complete its work by 1 June 1998. (Ministry of Health and Social Affairs)"*

The commission's task was to investigate and propose a system for how clinical trials in Sweden could be carried out. This was clearly defined in the sentence: *'For this reason, this inquiry shall consider and submit proposals regarding on what grounds clinical trials can be conducted and which forum should be allowed to approve such trials'*. The inquiry was not to determine whether the moratorium on XTP should stay in place. This is a key framing of the commission's work, and must be affirmed when analysing the quotes from the politicians and experts who were involved in the commission. In other words, the inquiry was to present a system for how clinical trials could be approved.

Bertil Persson: "Six months before the commission started, we discussed in the Social Committee, if I remember correctly, that there is really no set of rules on how to do clinical trials. There was no proper obligatory inspection of this. There were ethics committees that one could tell what one was doing, but they had no power to prohibit and seriously stop research. This was something that we wanted to look at. It was not my idea to do the investigation, but I expressed that there was poor awareness of the ethical review of medical experiment. Basically you could do what you wanted and no one could stop you. It was good if you had ethical review and it was an advantage when it was published. But I thought it was too weak. So that was the kind of discussion that was behind everything. This was a good area to start with."

From this perspective, the investigation was not just about XTP research, but also about the larger issue of how medical trials would be controlled in Sweden. This major issue was not a specific question for the XTP commission, but it was developed in the investigation 'Ethical review of research involving humans' (Ds 2001:62) and in 2004 became a law in Sweden, 2003:460, the Act concerning the Ethical Review of Research Involving Humans. At the time, there was a need to look closer at the ethical control of research involving humans.

The investigation followed a traditional pattern for how these types of questions are investigated in Sweden. The government framed the Terms of Reference, and then appointed a committee or an investigator to look closer at the question. The XTP commission was parliamentary, consisting of three politicians of the parties that together had

a political majority in the parliament at that time. The committee consisted of politicians, experts and government officials. They started by gathering knowledge about XTP: articles, interviews, field studies and public opinion surveys. The committee had meetings where they discussed the policy problem and wrote the report. More about how this work was done is discussed in the coming chapters.

The report was submitted to the Swedish Minister of Health in October 1999 as a Swedish Government Official Report under the name: 'From one species to another. Transplantation from animal to human' (Government Official Report 1999:120). Later the official report was distributed for consultation to selected bodies and 97 answers were received. This later process will be presented in this chapter.

## 5.1 The organisation of the committee

The government Terms of Reference are central to how the committee will work because it frames the work. Luigi Pellizzoni points this out when he writes: *'It is very important how an issue is institutionally approached from the outset, and the place it finds within the broader policy context and institutional record'* (Pellizzoni, 2001b: 219). Thus, it is important to study how the committee is organised, the policy context, because this will have an impact on the outcome of the investigation. Who chairs the committee? Who are the members? How is the work carried out? These questions say something about why the outcome developed in a certain direction, but also about how the Terms of Reference were framed in that committee.

The head of the Ministry of Health and Social Affairs appointed Bertil Persson (born 1937) as chairman of the committee on 10 November 1997. He was a member of parliament and represented the Moderate Party in Sweden. He had discussed XTP concerns earlier, for example in the Swedish Parliament in 1996, when he pointed out to the parliament that the issue of XTP would develop into a complicated debate in the coming years (parliamentary record 1996/97:77). Bertil Persson has a background as a doctor of internal medicine and was formerly the assistant chief of the medical clinic in Malmö. He also has a PhD. As a politician he had worked with many different political issues and had extensive experience of health policy. When he was asked to chair the committee, he began to build support for the coming work in his own party and in the other parties represented in the parliament.

Bertil Persson: "When I got the offer to head the committee, I raised and discussed the XTP questions in my party's ethics committee, and they gave the green light immediately. Then I talked to the people I wanted to have serve on the committee. They gave me free rein. I talked to the people I wanted involved in the inquiry and they also agreed. It consisted of Social Democrats and Centre Party members. I talked to the other parties as well, but I particularly wanted to have those two parties in the committee. People thought it was interesting, in particular the idea of curing diabetes by

injecting beta cells from pigs. If it was possible to manage the risks, they would give the go-ahead.”

Before the committee defined its task, Bertil Persson had set up the framework of what was politically possible in the investigation. He did this by building support for the XTP question in his own party and the other parties represented in the parliament. By including representatives of the Social Democrats and Centre Party in the committee, he also established broad support for the committee’s work in the parliament. As Bertil Persson says in the quotation, he met no resistance to XTP among the other parties, if the technology could develop with out taking excessive risks. This reflects the public view of XTP at this time in Sweden. Only one party was openly critical to XTP at the time, the Green Party. We will get back to them in chapter 6.

Bertil Persson was also given fairly free hands to choose who he wanted in the committee, and the appointed members as of 10 November 1997 were: Members of Parliament Ingrid Andersson and Karin Israelsson, as well as experts Professor Emeritus Sven-Erik Bergentz, Chief Physician Annika Tibell from Huddinge Hospital, Professor Göran Hermerén from the University of Lund, Deputy Director Lena Jonsson of the Ministry of Health and Social Affairs, Director-General Erik Nordenfelt of the Swedish Institute for Infectious Disease Control, Professor Kerstin Olsson from the Swedish University of Agricultural Sciences, Professor Bo Samuelsson from the University of Gothenburg, Associate Professor Margareta Sanner from the University of Uppsala and former Judge Carl-Edvard Sturkell. On 1 January 1998, two people were appointed secretaries in the committee: Associate Judge of Appeal Stefan Reimer and transplant coordinator Marie Omnell Persson. At the same time, Chief Physician Nils H. Persson was appointed to assist the committee and the Secretariat. Here, Bertil Persson talks about how he chose the politicians and experts for the committee.

Bertil Persson: “Ingrid Andersson, Social Democrat, is an extremely intelligent person, one of those really warm, compassionate, wise people. Karin Israelsson, Centre Party, is a reasonable person. Then we had Sven-Erik Bergentz, an extremely important surgeon from Malmö. I got everyone I wanted. I didn’t invite Groth into the committee because he’s so overbearing. I brought in one of his colleagues instead, Annika Tibell, who also is incredibly talented. She did these diabetes tests with him. Then we had Göran Hermerén. And Lena Jonsson, who deals with these types of questions in the Ministry of Health and Social Affairs. And we had Erik Nordenfelt, who was head of the Swedish Institute for Infectious Disease Control.

The big problem here is, looking at it from a purely technical standpoint, the latent viral nuclei in the pigs. How much consideration does this require and

how much risk are we willing take? Then we had Erik Nordenfelt, a virologist, and Kerstin Olsson, a physiologist, so we had experts about the animals. Bo Samuelsson, who is a geneticist and physician at the University of Gothenburg, was our expert on chromosomes. Then we had Carl-Edvard Sturkell, a lawyer for the Swedish National Council on Medical Ethics, in which Göran and I were members. So we had ties to the Council on Medical Ethics. I have been a member there almost since it started. I have also been a member of the Swedish Gene Technology Advisory Board, although I left both groups when I left the parliament in 2002. We had a strong group.”

Appointing the politicians in these committees is a delicate task, with the goal of creating a committee that represents the majority in parliament. The committee has to be able to negotiate on difficult questions, instead of going for a vote, and also to avoid having reservations in the official report (c.f. Lewin, 1996). In this way, the appointments of the politicians are political. Karin Israelsson, a former member of the parliament, explains.

Karin Israelsson: “There was an allocation; there were three parliamentarians, and the chairman was also a parliamentarian. Ingrid Andersson and I have been involved in other inquiries together, so we know each other. Then the parties themselves settle how the allocation is done. Probably it is done on a government level when you appoint people for this kind of investigation. Then each party appoints one member who has an interest in the field. That is probably why I got appointed.”

Kristofer Hansson: “Your party chose you because you had worked with these questions before?”

Karin Israelsson: “Yes.”

The government appoints the inquiry and determines which parties are represented in the committee. When this is decided, the party is officially asked if they have a political representative who will represent the party in the committee. In other words, the parliamentarians who are appointed also represent the people who elected them. Karin Israelsson continues about the selection process.

Karin Israelsson: “I’ve never been very involved in the appointment process. You can be made a member of an inquiry if you are able to be a part of the committee. I was appointed to around twenty inquiries over the years that I was a Member of Parliament. The leadership in the parliamentary group picks out suitable candidates. I do not really know how this is done in other parties. But they find the people who have a background in those areas, then it is up to you if you want to be appointed or not. It is very exciting.”

Looking at the appointments for the committee and the quotes, one can say two things. First, the committee had very competent members in their fields. The three politicians had extensive experience of committee work and had worked with similar questions regarding biotechnology. Some of the experts in the committee were the most prominent experts in their fields in Sweden. Second, since Sweden is a relatively small country, many of the members knew each other and had worked together in other areas. Both Bertil Persson and Karin Israelsson mention this. Nils H. Persson expands on this in the following quotation.

Nils H Persson: “Bertil Persson was chairman of the committee and a Member of Parliament, and we had worked together as fellows here at the hospital. When we started at this hospital, we were both asked to organise the emergency intake. However, I was not contacted directly by him, but by Sven-Erik Bergentz. He was a professor here and one of Sweden’s pioneers in transplantation and vascular surgery. Sven-Erik was asked to join the committee and asked if it could have its headquarters in Malmö.

I got a request to serve as secretary in the committee. But I couldn’t give it as much time as needed because of my call schedule and management assignments. Instead, Marie Omnell Persson was asked, and she had worked as a transplant coordinator and was interested in research. She had collaborated with the Department of Medical Ethics [at the University of Lund, where Göran Hermerén was professor]. Göran Hermerén was also a member of the committee. We decided that she could be the secretary in the committee and that I would support her with 20 per cent of my working hours.”

Some of the committee’s members were included in an already established network. Bertil Persson, Nils H Persson, Sven-Erik Bergentz, Marie Omnell Persson and Göran Hermerén had all worked together working in various networks, mostly in Malmö and Lund, where they got to know each other. How this affected the investigation is difficult to say, beyond the fact that the five people represented a medical perspective. But it was not obvious that everyone in this network would be on the committee. Chief Physician Nils H Persson remembers that they had to argue for Marie Omnell Persson’s involvement. *‘I know that I talked to Carl-Gustav Groth, who is a big name in transplantations in Sweden, you’ve probably already come across his name. He was interested in xenotransplantation. He was a little hesitant to have a nurse in that position’*. But the group convinced him that Marie Omnell Persson, with support from Nils H Persson, would be a good combination.

What also is interesting in Nils H Persson’s statement is that Carl-Gustav Groth had the opportunity to influence the appointment of the committee secretary. This shows how close the collaboration is between politicians, officials and experts in Sweden. We were unable to interview Carl-Gustav Groth about his ability to influence the Terms of Reference and the

appointments. But he was one of Sweden's leading researchers on XTP, and also one of the most active researchers, so he probably had a finger in the process.

From Marie Omnell Persson's perspective it looked like this.

Marie Omnell Persson: "Because the medical issues were so prominent in this collaboration, not just the enactment of laws, it was appropriate that the lawyer, who would be chief secretary, had a medical professional to assist him. So I was a part of the daily work at the secretariat and Nils H Persson was an additional medical support to the secretariat. I got a call at home from Sven-Erik Bergentz, who has always supported me. He wanted me to consider this."

The lawyer who was appointed to the secretariat was Associate Judge of Appeal Stefan Reimer. Looking at the Terms of Reference from the government, we can see that one part of the investigation was to propose a law that would regulate XTP research and the other part was to investigate XTP as a medical technology.

## 5.2 The committee's work

Understanding how the committee worked is key to understanding how the Terms of Reference from government were processed. How did the committee members approach the issues assigned to them? Different methods will give different outcomes. The committee was to be guided by the Terms of Reference, while the investigation would be influenced by, for example, what type of survey was done, what questions were asked, who the committee did and did not choose to interview and so on. The chairman was responsible for how the committee went about collecting material, while at the same time the secretariat did a lot of the work, and therefore the secretaries would affect the outcome in different ways. The parliamentarians and the experts were central in reading and discussing many of suggestions that the secretariat presented. However, starting with Chairman Bertil Persson and his thinking about the committee's work will give use a picture of how the committee progressed from the Terms of Reference to the final Official Report. Our initial question to Bertil Persson was what he thought about the leadership in the committee.

Bertil Persson: "It is very individual, of course. I am always very keen to do my homework first. To ensure that we are properly informed, that we have received plenty of material. That we get proper interviews with people. I can't speak for everyone else, but I always make sure we do our homework first, so we understand all aspects of the question. We do not take a position without doing our homework. Then when we have done our homework, we have a feeling of where we are, where we agree, and then we start writing. We do a rough sketch of how the chapters will be. We have always one

person who writes, in this case a very good lawyer. I had a connection with the Court of Appeal in Malmö and they helped me. I wanted someone who was near Malmö. He is very clever and has very good language skills. Then he sat down and wrote this and presented the text at the next meeting.

At the meeting, we went through the text and discussed the next chapter, where we thought we had reached a consensus. I do not like to submit a report with a lot of reservations, so I usually try to piece together the inquiry and see where the limits are, as long as I do not have the feeling that it is completely wrong. But if you can come to a sensible agreement with reasoning, then I think it is better to come up with something that everybody in the committee can accept. It is often possible to do this, unless you're discussing when human life begins. But otherwise we usually arrive at a common decision. We write our chapters and eventually you're finished.

Then when it was finished, we reviewed the text again and examined the chapters and made sure they included all our thoughts. Then we went out on study trips and came home with materials, which also led us to rework our texts. When we had reached a consensus, we wrote, and then we got new input and we looked it over again. We also attended one or two gatherings, which I like. We went to 'Almarstället'. Gatherings should be held far from Stockholm, so people can't go home in the evening. You're forced to sit and chat there all day. It is a lot of work, of course, but the atmosphere is cosy. In the evening, you can talk through what you discussed in the morning, with new input. I think it is good if you have gatherings where everyone is forced to be, not in some place with a lot of distractions, but like on a farm in the middle of nowhere."

Based on the Terms of Reference, the committee started to gather information to make it possible to answer the questions that were raised. This is what Bertil Persson calls "homework". Only when there is enough information to "understand all aspects of the question" can the discussion start in earnest, and the participants in the committee can agree on the different issues and agree on a similar argumentation (c.f. Pellizzoni, 2001a). From this first agreement, the secretariat starts to write the texts that will eventually turn into the report, after being read, commented and revised multiple times in the group. This process has many similarities to the way science is done with methods like collection, analysis and presentation. What distinguishes the inquiry from scientific work is that the committee takes a political position in valuating issues. This is what Bertil Persson calls "reaching a consensus". In science, the theory and how it is used shape the result; in a governmental report it is the parliamentary committee and its politicians that define what will be in the final text.

This political perspective explains Bertil Persson's unwillingness to have reservations in the report. Having reservations in the finished report shows that the committee failed to agree. Bertil Persson thinks that it is better to try to come to a reasonable agreement that everybody can accept, or in other words to reach a consensus (c.f. Lewin, 1996). However, getting back to the discussion about the organisation of the committee, we may wonder if the ability to reach a consensus in a parliamentary committee is a process that actually starts with the selection of parliamentarians. With the right collaboration partners, it is easier to agree on a common argument. It is also easier for the committee to change its own premises and, as Bertil Persson says, "come up with something that everybody in the committee can accept".

What was it the committee members had to agree on? The work was not first and foremost to investigate what the Swedish people thought about XTP, but to construct a legal framework that the researchers could work within. Bertil Persson highlights this: "*However, I cannot say that there was a debate that motivated this investigation. And politicians need to be in the forefront and present options for people to choose from. We are not a survey institute*". The committee did, as we wrote in chapter 2, conduct a survey, but it was used only to investigate if there was massive opposition to XTP in Sweden. When it was found that there was no strong opposition, the committee was able to focus on its primary task: to present a solution for how XTP research could continue.

Our interviews with the other members of the committee showed that all were in agreement on that point.

Karin Israelsson: "I think we were probably pretty cooperative in the investigation of risk assessment and the possibilities of XTP. We had research expertise, both in terms of retention and transplant surgery. The ethical aspects of this made it extra important for the committee to agree. It felt as there was no politics, absolutely no politics in this, it was more of a humane approach to the whole area."

Kristofer Hansson: "Cooperative?"

Karin Israelsson: "Yes, that's how I see it, although it was a long time ago, I do not remember everything, but I have no recollection of any real arguments; we were all looking to find a good solution on this, so there were no problems."

The investigation was framed more as a technical problem that could be solved, than as a political standpoint for or against XTP. This more technical framework made it easier to find common ground. Nils H Persson also remembers this approach: "*I can't recall any question where different factions of the committee were completely at odds; we were all working in good faith*".

Karin Israelsson further explains her thoughts on the committee's cooperation, pointing out that this was not only the way this committee worked, but also how she as a politician worked.

Karin Israelsson: "We have a party committee in the parliamentary group, where we report from all the various investigations we're involved in. When we get to a point where we feel we need advice from some parliamentary colleagues, we turn to this group. In this case, I ended my work in the parliament in the autumn of 1998 and was therefore outside the parliament, but I had contact with my parliamentary colleagues when we had to make crucial decisions in the committee. It was not something that was, how shall I say it, politically controversial, but I think everyone's perception was that we had to resolve this in the best way we could. It is different when you're on a committee that can be very controversial. It could have been controversial here if the committee had been unanimous and some thought that it was okay to ignore all warning signals. But we all thought that we needed to be extra careful. This committee worked in a way that was supported by the observations that the committee members made. We were all quite comfortable with the members' backgrounds, and we brought in lecturers from elsewhere."

Kristofer Hansson: "So, when you had to make more concrete decisions, you discussed them with your party colleagues?"

Karin Israelsson: "Yes, they knew what was coming."

In addition to coming to a consensus among the members of the XTP committee, the parliamentarians also discussed the issues with their party colleagues and found a common party position with them. The parliamentary group in the parliament was central for Karin Israelsson's work in the committee; this was where they discussed the perspective that the party would take. In this way, the parliamentarians represented their parties, but at the same time the work in the committee meant finding new ways to relate to the issues that the Terms of Reference had set up. In this specific case, this seems to have been a more technical issue than a political one. In this perspective, the committee's task was to gather information and see how other countries had solved similar problems and, of course, how Sweden could solve these problems.

Bertil Persson: "Political work is of course very much about keeping up to date, keeping track of what other people think and how they act. It is not wrong to steal ideas from others. We travelled a lot and watched what others did, how they reasoned, or we reasoned with them. Then you look beyond that. You can learn much from the US, or from Germany. They are often

quite smart. In some areas the French are brilliant; they were good at this field.”

With this working attitude, the committee members collected a large amount of material. The Official Report details the work that was done and gives a good picture of how the committee gathered its material. Here it is set in bulleted form, from the start of the committee’s work in January 1998:

- *“Took note of literature, articles, studies and reports from the field.*
- *Conducted the survey ‘Transplants from animals to man – in general, and in severe renal disease patients’.*
- *Noted attitudes towards XTP in national and international surveys.*
- *Held a hearing with research groups from Huddinge, Uppsala, Lund, Gothenburg and representatives from the Karolinska Institute.*
- *Held an internal seminar on infectious risks of XTP with Professor David Onions and national experts.*
- *Attended a lecture about risk and risk rating by Professor Nils Eric Sahlin.*
- *Participated in six different international meetings and conferences.*
- *Study visit to the companies Diacrin and Genzyme in Boston.*
- *Study trip to the UK to visit the European Agency for the Evaluation of Medicinal Products (EMEA), the United Kingdom Xenotransplantation Interim Regulatory Authority (UKXIRA) and the company Imutran.*
- *Participated in two national meetings and seminars.*
- *Met and consulted with the National Board of Health and Welfare, the Medical Products Agency, the Board of Agriculture, the Swedish National Board for Laboratory Animals, the National Veterinary Institute, the Zoonosis Centre, the Swedish National Council on Medical Ethics and the Swedish Medical Research Council’s Research Ethics Committee.*
- *Consulted with the Committee on Research Ethics.*
- *Obtained input from the Swedish Diabetes Association, the Swedish Heart and Lung Association, the Heart and Lung Club Viking, Life as a Gift, the Swedish Association of Persons with Neurological Disabilities reference group for Parkinson’s disease, the Swedish Kidney Association, the Swedish Parkinson’s Association, Younger Parkinson and Transplant Sweden.*
- *Obtained input from the Swedish Animal Rights Association and Animal Welfare Sweden.*
- *Co-organised the conference Xenotransplantation – Hope and Risks.*

This list gives a good idea of the input to the committee, as well as of what Bertil Persson calls *“doing our homework”*. By making field visits and consulting with people who are specialists in certain fields, the committee expanded their own knowledge in this area. Karin Israelsson believes that: *“As a parliamentarian in a committee, the task is to absorb all the knowledge that is available in this area and the knowledge of the experts on the committee”*, so that one can make an informed decision. With this attitude to the committee’s work, it is clear that there will be a lot of work for the parliamentarians who are not experts in the field.

At the same time, it is important to point out that the committee, and especially the politicians, saw this input as a way to learn more so that they could make a balanced decision. When asked about the significance the group attached to a group such as the animal rights association, Bertil Persson answers:

Bertil Persson: “They are stakeholders and they represent a small group in society, and that’s why we do not want them in this committee. They represent special interests and should be listened to, because they can have objective views that can be good to take advantage of. But the balance of the input must primarily come from people who have, so to speak, a familiarity with ethics, law and specialist knowledge. When we eventually get to the stage where our work becomes a proposal, then it becomes political. But I think that in the investigation stage, they should not have more influence than what the investigators believe that their opinion warrants.”

Kristofer Hansson: “They are also part of this homework?”

Bertil Persson: “They are homework.”

In chapter 7, we will get back to the stakeholders and their perspectives on this matter.

After collecting information in the field, another process began: reworking the input into a possible outcome, in this case the Government Official Report. We have already discussed the role of consensus in the political outcome, but we want to conclude this section by taking a closer look at the more practical work of creating the policy. Marie Omnell Persson gives a good overview of how it proceeds.

Marie Omnell Persson: “There are three parts: first you collect knowledge, then you make considerations, and then you write down your conclusions. It is important to collect a wide range of knowledge. Of course, the secretariat can influence that to some degree. I feel that we were active in the secretariat and pushed the work forward. We prepared the meetings, sending out information and bringing up various issues. They were discussed and we wrote memos. After this we thought, all right, how do we move on with this? Then we started to write the background, and much later we wrote the sections with the considerations. For that section, we communicated with the committee the entire time.”

When the committee is ready to start writing what will be the inquiry’s outcome, the secretariat becomes crucial. They write most of the texts that will become the final report, and this gives them the opportunity to shape the content. How the secretariat shapes the

content goes beyond this study, but it is vital to note that they are a key part of the policy work that is done in the committee. Nils H Persson also points this out.

Nils H Persson: “The secretariat played an important role in presenting suggestions and summarising what had been said at the meetings. As a lawyer, Stefan Reimer had an important role in learning and expressing this field. And everything that was written was sent out to all committee members and all had the opportunity to be heard. It was discussed just like when you write an article. You know how it is, you have co-authors and in this case the whole committee were co-authors in a way.”

In pointing out the similarities between writing the report and writing a scientific article, Nils H Persson gives us an insight into how the work was done. Although the secretariat had the privilege of formulating the text, the rest of the committee had to comment on and approve it. In other words, the committee’s final report was a team effort.

We will end this chapter with a quote from Karin Israelsson that further reveals the work process.

Karin Israelsson: “Chapter by chapter is examined to see if you have got it right. It is very much paperwork. The final document is the result of numerous reviews”.

Kristofer Hansson: “How are decisions made in the committee?”

Karin Israelsson: “You read the text and make sure everyone agrees that it is right.”

Kristofer Hansson: “So you read and then you meet?”

Karin Israelsson: “And you recognise that we should write more in this chapter, and in this chapter it is enough if you write like this. Or you remove text. It’s a combination of proofreading and substantive reading, to explain what you want to present.”

This is another example of consensus, a key element of the Swedish parliamentary system (Lewin, 1996). What is important is that even the parties that do not have the elected power must be represented in policy formulation. This tradition has a long history in Sweden, but it also has a more concrete and everyday expression in political work. Sometimes it is called the politics of compromise (Rustow, 1955). In this report, we call it the politics of consensus, and we can see it as a practical activity in the committee in which the members discuss with each other what should be the main point in the text. It is a culture where the

parliamentarians advocate their party's line, but at the same time have a great understanding for the other parties' views and the experts' views. The result is that when a parliamentary committee presents its official report, the outcome of the committee, it is established among a majority of the political parties in the parliament.

### 5.3 Survey

As we wrote in chapter 2, the committee did its own survey with the aim: *“to look at the general attitude towards the transfer of living biological material from animals to humans, and to examine if there is any difference in attitude between the general public and patients with severe kidney disease”* (Government official report 1999:120: 267). The questionnaire was answered by 596 anonymous individuals representing the Swedish public and 398 individuals on the waiting list for kidney transplantation. The results showed that 60 percent of the general public was positive to XTP, and the patients from the waiting list were even more positive (Omnell-Persson, 2003; Government official report 1999:120). In this section, we focus on why the committee conducted the survey and how the results influenced the inquiry.

Marie Omnell Persson explains the simple reason for the survey: *“The ambition of conducting our own survey was to determine, in an unscientific perspective, if there was massive opposition or is this a possible way to go?”* Of course there were more specific scientific reasons for this survey, especially considering that it also was a part of Omnell Persson's thesis. But first and foremost, the intention was to try to understand the public's perspectives on this specific biotechnology (c.f. Pellizzoni, and Ylönen, 2008). For this reason, the survey was designed to answer a complicated question about the public's relationship to XTP.

Marie Omnell Persson: “The idea was that it would be good to take note of the [attitudes of the] healthy public and a group of sick people who actually could, potentially, be targets for this kind of treatment. The idea was that a healthy person has a bit more difficulty imagining this scenario, but it was important to have the healthy population in this survey. This let us compare the two groups and ask them questions regarding different degrees of illness and different degrees of risk. That was the basic foundation, and we felt it was important to listen, in a wide sense, to the public about their perspectives, so that there would not be massive opposition. Because there was clearly concern about this technology, and we talked a lot, back and forth, about how to best learn about this.”

By focusing on two groups, the committee could compare the public's attitude to XTP from a risk perspective and from an illness perspective. How was the risk evaluated by the public, and was this different if the respondents had a severe illness that might be cured by a future

XTP treatment? The latter perspective was a key element of early discussions, and Marie Omnell Persson and Nils H Persson suspected that severe illness would affect attitudes towards XTP.

Nils H Persson: “Marie and I discussed this a lot, how we could capture this. We chose to ask both the general public and individuals who would be directly affected. We thought that there would be a quite big difference between a public that is not directly involved in this and those who are in a vulnerable position, but as I recall, it was not a big difference.”

Kristofer Hansson: “No, it was not, a slight difference but not remarkable.”

Nils H Persson: “Perhaps it was statistically significant, but it was not as impressive as we thought it would be. This was because the public was quite positive. But many of the patients were positive and that says something about their desperate situation.”

Kristofer Hansson: “Yes, of course. You thought these two groups would be interesting to compare?”

Nils H Persson: “Yes.”

Kristofer Hansson: “In order to?”

Nils H Persson: “To show that you cannot ask people in general how important something is if they do not have the need. It is much easier to say yes to something when one is in a life-threatening situation, than to say yes to something that someone else might find useful, especially if there is a risk with it. We tried to cover both the opportunities and the risk adequately, which is not so easy to do in a survey.”

The committee suspected that the perspectives on XTP of the general public and of those directly affected would vary more than it did. The primary hypothesis was that the relation between opportunity and risk would be different between the two groups, and that this difference was vital to explore. What the committee found was that there was no great difference and that the public was positive to further research to develop XTP. But it is interesting to see how the “*public interest*” is transformed in a society with biotechnologies that are risky, turning into something that must relate to the “*affected interests*”. Jürgen Habermas states that modern society focuses on how to translate the “public interest” into general laws, equal for all (Habermas, 2009). Surveys have always been a way of determining the “public interest” where the citizens are not a part of the decision-making process, but instead a mass whose views can be examined and valued. Our hypothesis is

that this relationship between the state and the public changes when the relationship between opportunities and risk in biotechnologies become more tangible. We feel that this is what Nils H Persson is saying when he comments that affected parties have a vested interest that is different from the “public interest”.

At the same time, the committee’s task was not to investigate the public’s view in this question in more depth, but to present a solution as to how the researchers could continue with XTP research. A more informed political discussion, in which the public would hopefully be more integrated, would come later in the process.

Bertil Persson: “I did not perceive that our task was to identify in detail the public’s perception of this matter, but to develop, from as many angles as possible, a factual basis for a political decision. If this had come through as a bill, then we would have had a debate, and then the political parties would have had to respond to the public debate that had cropped up because of the bill.”

If the committee’s proposal had led to a political decision, there would, and rightly so, be more discussions and maybe the public would also have become a part of these discussions.

From this perspective, the results of the survey confirmed to the committee that it could, under certain circumstances, be okay to continue with XTP research and clinical trials. The survey was a litmus test for the committee that let them know it was meaningful to continue the investigation in the direction they had begun. What the committee found is summarised below:

- There was no massive resistance to XTP.
- Those who were waiting organs for transplantation were more positive than the general public.
- The attitude towards transplantation from animals was affected only to a small extent by a life-threatening situation.
- Greater uncertainty about XTP breeds insecurity and negative attitude.
- There was a high acceptance for the use of animal cells, tissues and research.

These results were presented in chapter 14 of the Swedish Government Official Report, followed by discussions of psychological, social and cultural aspects in chapter 15, using the studies of Margareta Sanner and Susanne Lundin (see chapter 2). Chapter 13 of the report presented international studies on the public’s relationship to XTP. These three chapters of the report covered public opinion, but the committee members also dealt with public opinion on other occasions that were not included in the report. For example, some people phoned Marie Omnell Persson after receiving the survey and talked with her about XTP, and the

politicians in the committee met people in a range of contexts. One of these occasions was the XTP conference that was arranged by the Swedish Gene Technology Advisory Board in 1998 in collaboration with the committee and twelve other organisations.

#### 5.4 The XTP conference

In November 1998, the Swedish Gene Technology Advisory Board arranged a Swedish conference about XTP – “Xenotransplantation – Hope and Risks”. Around 250 participants attended the conference, which aimed to start a Swedish discussion of the possibilities and risks associated with XTP, or as stated in a summary report from the conference: “*The conference aimed to highlight and facilitate a comprehensive discussion of the technologies, possibilities and risks*” (Spri report, 1999:4). This report was written by science journalist Monika Starendal and released by the Swedish Health Care Development Institute (which closed down in 1999). The report describes the conference as a kick-off for a Swedish discussion on XTP, but unfortunately the debate never got going. In addition, the XTP committee was a co-organiser of the conference, which was held at the end of the committee’s work. There seems to be no discussion from the conference that later become an input to the committee work, although the committee lists it as one of their key activities.

Many of the committee’s experts presented their work at the conference. Göran Hermerén emphasised that the social and ethical values related to XTP needed to be discussed in the debate, Annika Tibell talked about her XTP research, Marie Omnell-Persson presented her survey, Kerstin Olsson talked about how the law protected animal rights and Bertil Persson presented the committee work. The three scientists from the humanities and social sciences, Susanne Lundin, Anders Persson and Stellan Welin, introduced in chapter 4, presented their work. Britta Wahren, professor in clinical virology, discussed the risk of the PERV virus. In addition, XTP was presented from a health-economic perspective. Thus, all presentations at the conference featured experts from a wide range of fields.

Although the aim of the conference was to facilitate a comprehensive discussion about XTP, it did not stimulate a public debate, not immediately afterwards or later on. Now the conference was not organised so that the public voice could be heard; it focused only on the experts’ presentations. In this way, it was very much in line with the educational ideal that has been so central in the modernisation of Sweden from the 1940s on (c.f. Frykman and Löfgren, 1987; Waltersson, 2005). The core premise is that citizens must be educated in order to be able to take responsibility for their individual and collective development – education creates democratic citizens.

This ideal becomes clear when we note that representatives from the animal rights movement were not invited to present their views at the conference. The reason was a concern that the debate would not be factual if this group were allowed to participate. The educational ideal embraces objectivity above all; only knowledge that is defined as objective

should be presented to the citizens, in what Pellizzoni calls a “best argument” (Pellizzoni, 2001a). It seems that this has changed in Sweden today; when interviewing Staffan Persson, who represents Animal Rights Sweden, he points out that he was given the opportunity to be more active in other conferences: “I wasn’t invited or anything. I listened to the speakers, but I do not think I was a part of any discussions. But then there was another conference on cloning, and that time I was invited as a special guest to present comments’. It is likely there has been a change, but in the 1990s, representatives from the animal rights movement were not accepted in these forums – they had a language and a knowledge that was defined as ‘not objective’”(c.f. Pellizzoni, 2001a). We will get back to Animal Rights Sweden in chapter 7.

## 5.5 The committee’s outcome

The headings in the report’s summary provide a good outline of the committee’s outcome. We have made a bulleted list of the headings to give a brief insight into the report’s findings, before we get back to the interviews and what politicians and experts put forward as the inquiry’s outcome.

- **The mission and general points of departure**
- *Survey of people’s attitudes towards xenotransplantation*
- **Factors influencing the position taken**
- *Basic principles*
- *A balance between requisite knowledge and the precautionary principle*
- *The animals must be given a good life*
- *Needs and opportunities*
- *The shortage means that patients’ needs cannot be met*
- *Alternative ways to meet the patients’ needs*
- *Problems and risks*
- *Infection transmission – an entirely likely scenario*
- *Immunological and physiological problems can be overcome*
- *People’s attitudes towards receiving animal organs vary*
- *Unacceptable to use primates as animal donors*
- *Healthy animal life requires special measures and safeguards*
- *Risk factors and knowledge gaps require an individual risk-benefit assessment*
- *People’s perception of risk is due to impact and controllability*
- **Routing and position**
- *Clinical trials should be permitted only to a limited extent*
- **Implications and suggestions**
- *Separate legislation based on the precautionary principle*
- *A central decision-making body established*
- *A special register and a special biobank for xenotransplantation*
- *The situation of the patient requires special efforts and considerations*
- *Framework for monitoring and control is determined by the xenotransplantation board*
- *Measures in case of transmission of infection*
- *Evaluation and renewal of commitment to treatment phase*
- *No clinical trials before the parliament has taken a position*
- *Other issues*

- Costs
- Date of entrance

The headings give an insight into what the committee came up with. The committee closely studied four different areas: the virus risk of XTP, ethical questions, animal protection and legal questions. These four areas related to each other in different ways, and also came to have different significance. Marie Omnell Persson describes how the different areas were valued.

*Marie Omnell Persson: “The medical risks, ethics, animal protection and legal considerations were all important, but the discussion of risks took the most space. But I wouldn’t say that we downplayed the other fields. There was a lot of focus on the animals. We went to Cambridge to look at the pigs they had there. We conducted interviews with several animal rights organisations. Kerstin Andersson, professor at the Swedish University of Agricultural Sciences, was a member of the committee. So we had representatives and discussions on all four areas, so to speak.”*

The committee’s task was to propose a change of the law, in the field called legal questions. This field includes the other three; the proposal would create a policy that dealt with risk, ethical and animal welfare questions. As Marie Omnell Persson points out, and as the report makes clear, the risks became the big question. This chapter focuses on how risk was perceived, leaving ethical and animal welfare questions aside. Animal welfare will be discussed in chapter 7.

The heading “*Clinical trials should be permitted only to a limited extent*” contains a summary that provides a brief but detailed procedure regarding clinical XTP trials.

“Based on current knowledge, we do not believe that the risks of xenotransplantation are such that a permanent or temporary ban needs to be implemented. The uncertainty about existing risks requires specific measures based on the precautionary principle. Therefore, only a limited amount of well-controlled clinical trials in which the risks are considered manageable are approved. In our view, today’s regulatory system is inadequate to address these issues. Therefore we propose the addition of a special regulatory framework for xenotransplantation. The regulatory framework must include specific decision processes that require an examination of applications for clinical trials, a special xenoregister and a special xenobiobank.

Before providing a permit for any project, the state requires careful consideration during the decision process. Proceedings will be conducted in a central decision-making body, in a research ethics committee and in an animal experimentation ethics board.

We believe that the choices we have made can be reconciled with the principle of good animal life, if the fundamentals behind this principle are satisfied in each case (Government official report 1999:120).”

This summary, and the interviews we conducted, reveal a strong consensus on what the committee’s outcome was: the precautionary principle and how to relate to the risks involved in clinical trials with XTP. At the same time, we can see in the bulleted list above that there were a lot of other outcomes. These other outcomes were also important, but did not have as much impact on how XTP was perceived after the committee had finished its work. In other words, XTP was and still is perceived as a risky technology. This is the interesting aspect of the committee’s outcome, an acceptance that this was a risky technology and that it probably would transfer animal viruses to humans if clinical trials started. The risk was defined as real and the question was how to still continue with clinical trials. Bo Samuelsson states:

Bo Samuelsson: “Göran Hermerén had this thesis that we must consider retroviral epidemic as a plausible result. So we had to try to find ways of preventing or minimize this. I think I also got into that line of reasoning very early. I can’t remember who came up with the idea first, but it just isn’t possible that the risk is so small that it is nonexistent. I learned a lot from Göran. I felt a little resistance from those who had a surgical background.

[...]

Bo Samuelsson: Some surgeons thought we were a little too cautious. If I contributed anything, this was it.”

To assume that infections were unavoidable had a critical effect on the committee’s thinking. On this basis, the work focused on how to best manage risks and what to do when someone became infected. Under the heading “*Infection transmission – an entirely likely scenario*” in the summary, the committee wrote: “*Transmission leading to infection must thus be considered a conceivable scenario*”. This was the formulation the committee agreed on, which also affects the whole approach to XTP.

What is also interesting in Bo Samuelsson’s quote is that he is saying that the experts with a surgical background did not accept this approach to begin with. This shows that there were different ways to approach this field, and that this idea could be perceived, more or less, as controversial. If the point was that infection transmission is a likely scenario, then it would also likely become harder to promote the development of this technique. The public could also perceive it as a dangerous technology. An alternative argument could be that there would be no clinical trials before the researchers could control retroviruses. But the fact that

there would always be a risk, even if it was a small one, made the committee reason this way.

Bo Samuelsson: “It doesn’t matter how small the risk is, even if there is only a theoretical possibility. We also did a calculation of how many transplantations might be done in the world. I do not remember the figures anymore, but it might be something like 10,000. And if the risk is 1 in 100,000, which is a very small risk, much like the risk of getting HIV from a blood transfusion, which is less than 1 in 100,000, but you reach those numbers quite quickly. We had many interesting discussions that taught me a lot. I think Göran was amazing, a remarkable guy.”

Thinking about risk in terms of probabilities changed Bo Samuelsson’s relationship to XTP; he developed a new perception. With this reasoning, it was impossible to ignore even the slightest risk. And so the committee framed XTP in a very special way, which also had implications for its outcomes. This was a very scientific way of reasoning about risk, with a specific language and knowledge style (c.f. Hacking, 1992; Pellizzoni, 2001a). At the same time there, was also a more practical approach to the risks, which emerged in the interviews.

Bo Samuelsson: “Hermerén played an important role. He got us to reflect on what a little risk and a minimal risk is compared with the volume of transplants. He also asked if it matters if it takes one or five years before the disaster occurs. That made us realise that you can’t conjure away the risk, so it is better to turn it around and say that we take it for granted that this will happen sooner or later. Therefore, we want to create a system that allows us to minimise the risks.”

The starting point of this reasoning was very simple; the committee assumed that if we started to use XTP, an infection transmission would occur sooner or later. Agreeing on this approach also means that we must consider the meaning of the concept of risk, which they discussed in their chapter “*Risk – a general background*”. In the introduction to this chapter the committee writes:

“This section focuses on how to more generally look at, evaluate and manage risk in the community in relation to different policy decisions. The emphasis is on factors known to affect human perception and concern about risks and dangers, and how to manage risks when there are gaps in the knowledge base that forms the basis of risk determination (Government official report 1999:120).”

One important outcome from the committee was this perception that risk was something that politicians and policy makers needed to respond to when creating policies for XTP.

Therefore, XTP was framed as a policy problem interconnected with a specific approach to risk, risks that policy makers must make visible. In other words, policy decisions had to include a form of managing risk assessment. Nils H Persson gives a good description of what this means in practice.

Nils H Persson: “It was largely about managing risk assessment. It is very easy to say that this is a risk, and so we will not do it. But in society we have quite a lot of risks but we still proceed with the actions. This is a discussion I have with living kidney donors – they are exposing themselves to a risk when they help someone else. How great is that risk? This is a new risk, but just driving to the clinic is also exposing oneself to a risk. To help an individual, the community exposes other people to risks. An ambulance drives fast and exposes others on the road to risks. To save one person, other people are exposed to risks. How great is the risk of XTP? Getting sick? The real threat was if it caused a pandemic of diseases that was difficult to treat and that we previously had not been exposed to. How big is the risk? Then you see that lots of people have been in close contact with animals and nothing has happened to them. There are quite a few patients who have received a transplant and a virus with it. Did they get immune-suppression therapy? Maybe the risk increases when you give immune suppression. Or perhaps if you’re sick like this, you are simply more susceptible. Perhaps once you’ve been infected, the virus will mutate and infect healthy people. It was easy to invent a risk scenario. At the same time we had to consider values, briefings of information from tests that were conducted. In Russia, there were quite a lot of examples where they had mixed various diseases with transplants of pig spleens and things like that. So there were cells that were transferred from pigs to humans.”

Based on this reasoning, one can say that the outcome was that society must accept that some risks must be taken. Nils H Persson argues that society takes risks in many other situations in order to save people’s lives, so why shouldn’t society be able to take the risk and develop XTP. Taking this risk was, in this perspective, about creating opportunities – for example, new treatments. But it was also an argument that required a specific framework.

Marie Omnell Persson: “We started with what opportunities we have to control the risks. This committee adopted a precautionary principle and declared that a special xenotransplantation board should be established to conduct reviews. The precautionary principle gives you an idea of what we were thinking. It was the eye of a needle, and those who made it through the eye of the needle would really be safe, as safe as you can be. We had a very interesting presentation by Nils Eric Sahlin about risks and risk assessments. Stefan has also written a chapter about risk. Sometimes you

have to make a decision to proceed even with unknown variables. The precautionary principle and this board would carry out reviews, which would serve as a kind of guarantee, if you can call it a guarantee, so that no more risks were taken than what was acceptable.”

This reasoning is reflected in paragraph 6, point 3 of the law proposal.

“Paragraph 6

When considering a trial for authorisation, the board shall examine the trial from the medical, ethical, animal welfare and legal perspectives. In doing so, the board shall consider:

1. the value of the knowledge, based on science and proven experience, that the study can be expected to give,
2. the experiment’s potential to cure or alleviate the patients’ diseases,
3. the risk of harm or discomfort to patients’, volunteers’ or other people’s physical or mental health caused by the trial and the security measures or other precautions that may be appropriate, and
4. how the experiment can be expected to affect animal welfare and health (Government official report 1999:120).”

What is interesting in this proposal is the formulation that emphasises other people’s physical or mental health. From the risk perspective the committee had adopted, it was a logical extension to also create a law that protected third parties. This perspective was an important outcome from the committee.

On 30 November 1999, the committee submitted its report to Minister of Social Affairs Lars Engqvist. After this, the report was sent to selected reviewing bodies in Sweden, discussed in next section. That was as far as the report got, because around the millennium shift, the political and media focus had shifted to stem cells. In addition, the moratorium had been in place for so long by the time the committee finished its report that most of the bigger research groups in Stockholm and Gothenburg had already split. Many of the researchers had moved on to other research fields or other tasks. The report remained with the Ministry of Health and Social Affairs and was not submitted to the Parliament as a bill. Or as professor Annika Tibell said in the interview: *“The issue was dead; the investigation in Sweden was put in a box at the department”*.

## 5.6 The consultation system in Sweden

Sweden has a special system for obtaining comments on government official reports. When the report is finished the government sends it out to government agencies, organisations and

communities for comments. The government then writes a bill based on the report and the comments, and this is sent to the parliament, who comments on the bill in the form of motions. The parliament then submits the bill to fifteen committees that continue to work with it. The committee members discuss the bill and the issues it addresses with their own party group in the parliament. Then each committee submits its proposal and the parliament as a whole begins to debate and decide on the new law. After the decision, the parliament sends a parliamentary letter to the government about its decision, and the government puts the law into effect with help of the ministries and state authorities. An important aspect of Swedish government is that state authorities are independent and not controlled by the prime minister. This is rather unique for Sweden, with a long tradition that goes back to King Gustav III (1771–1792). But the Official Report about XTP never got that far, so the discussion here will focus on what agencies, organisations and communities commented on the report.

Anyone can respond to a consultation exercise in Sweden, even everyday citizens. However, most commonly only those who have been selected to comment write a response. Ninety-seven comments were submitted to the Official Report, *“From one species to another. Transplantation from animal to human”* (Government official report 1999:120), all of them came from agencies, organisations or communities. Most were positive to the continuation of XTP research under the restrictions suggested by the XTP committee, although many commented in a more technical manner on how the proposed law could be developed. Some comments also pointed out areas that needed further discussion in society.

Some examples of agencies, organisations and communities that submitted extensive comments include: the Court of Appeal for Western Sweden, the Svea Court of Appeal in Stockholm, the Swedish Gene Technology Advisory Board, the National Board of Health and Welfare, the Medical Products Agency, Uppsala University, the Swedish Board of Agriculture, the Stockholm County Council, the Uppsala County Council, Region Skåne, the Swedish Society of Medicine, the Swedish Association of Health Professionals, the Christian Council of Sweden, the Archbishop of Uppsala, the Swedish Kidney Association and the Heart and Lung Club Viking. All are major government agencies, organisations and communities in Swedish society.

Four of the commenters felt that Sweden should introduce a moratorium for XTP: the Green Party, Animal Rights Sweden, the Swedish Animal Welfare Association and the Friends of the Animals. In chapter 6, we will analyse the Green Party and their criticism of XTP, and in chapter 7 we will take a closer look at Animal Rights Sweden. The criticism from the two other associations was that XTP would increase the suffering of animals and for this reason should be forbidden.

Based on the comments, there seems to be a generally positive attitude to continuing XTP research in Sweden at this time among agencies, organisations and communities. Nothing happened with the comments and the official report was not discussed any further.

## 5.7 Summary

When the committee stated its inquiry, the XTP policy process in Sweden was transferred to the parliamentary XTP committee. Now a group of politicians and experts specifically commissioned to investigate the issue took over the routine practices of policy-making. The core of the committee's work was the Terms of Reference from the government, which stated that the committee would investigate and give a proposal as to how clinical trials in XTP research could continue on safe grounds and what body would approve these trials. The terms were written in collaboration between politicians, officials at the Ministry of Health and Social Affairs and external experts in this area. Our study has not been able to clarify who had the opportunity to influence the issues in the Terms of Reference. What we can say is that even at this early stage, there was a close relationship between elected politicians and experts, who in this case were XTP researchers.

This relationship was further enhanced in the committee group, where some of the members had worked together previously. Sweden is a small country in which politicians and experts build this type of relations all the time. Our empirical data shows that the group had a way of reasoning that strengthened their relationships, making it difficult for outsiders to influence the process. The group's membership is crucial; with another composition of the group, the results would probably have been different. But also, and this is typical for Sweden, the parliamentarians in the group played a very specific role by ensuring that the committee's conclusions are rooted in both their own party and among all parties represented in parliament. This political process depends on the politicians, even those who are opponents, reaching consensus on crucial questions. This ensures the support of the elected politicians, even if it says nothing about the public's ability to influence the policy process.

The committee framed XTP research as a technical problem that could be solved. The Official Government Report, *"From one species to another. Transplantation from animal to human"* (Government official report 1999:120), submitted to the Swedish Minister of Health in October 1999, introduced a statutory framework of how XTP research could proceed with clinical trials. An important outcome from the committee was that the risks of XTP were acceptable and that the committee presented a framework on how to control them.

## 6 A green framing of XTP

The only party that criticised XTP research in the 1990s was the Green Party of Sweden.<sup>4</sup> They were elected to the parliament in 1988, but lost their seats in the 1991 election. Then they came back in the 1994 election and have been represented in the parliament ever since. During the term between 1994 and 2002, Gudrun Lindvall – born 1948 – was a member of the parliament for the Green Party and responsible for matters related to biotechnology. As a former biology teacher, she found this field interesting. In our interview with her, she commented that a background in natural science is unusual among Swedish politicians. Gudrun Lindvall was also a member of the Swedish Gene Technology Advisory Board and the genetic engineering investigation.

In chapter 2, we reproduced part of the 1998 television debate between Gudrun Lindvall and Bertil Persson. That debate showed that there were politicians who had other perspectives on XTP and XTP research. Gudrun Lindvall's main point in the debate was that XTP was too risky, as it could create new viruses and that XTP research was not a technology in which society should invest. She was asked to participate in the debate after she wrote a motion against XTP in 1997, which we will return to in this chapter. She felt that although the discussion of XTP started in Sweden, it had grown tremendously.

Gudrun Lindvall: “When I started to write the first motion, I hoped to kick off a discussion. What year was that?”

Kristofer Hansson: “The motion came in 1997 or 1998.”

Gudrun Lindvall: “Yes, I remember I was on a TV program together with someone from the Moderate Party who was a doctor.”

Kristofer Hansson: “Yes, Bertil Persson.”

Gudrun Lindvall: “Then the discussion had started, but it was never a terribly hot issue.”

Kristofer Hansson: “No, it was not.”

Gudrun Lindvall: “But there were a few people discussing it. It is complicated and difficult for people to be well informed about, and for other politicians to

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<sup>4</sup> The Christian Democrats submitted a motion in 2003 expressing the importance of a debate on XTP. The party wrote that it is: “[...] *not acceptable that animals are bred solely to serve as spare parts for human beings if it undermines the animals' opportunities to enjoy their natural behaviour or if the result of the foreign organ is reduced well-being*” (Motion 2003/04:MJ367 Animal Welfare). The motion was rejected and there were no follow-up discussions on XTP (2003/04:MJU14).

feel that they dare take a position. Also, as we discussed, many of the politicians do not have this background [natural science]. We had it, this Moderate and I, but we had different opinions.”

Guðrun Lindvall’s premise is that those who did not have a background in natural science or take the time to understand the question found XTP a difficult issue. This may explain why few people in Sweden discussed XTP. As a politician in charge of biotechnology issues, it was obvious that she should take responsibility for these questions. Apart from the televised debate, she discussed XTP mainly in the political arena. As we will see later in this chapter, there was little time for a parliamentary politician to prepare the public in this specific debate. But in the 1990s, biotechnology became a political issue on which the Green Party could focus. Lotta Hedström, spokesperson for the Green Party from 1999 to 2002 and born in 1955, highlights this as important to the party.

Lotta Hedström: “Guðrun Lindvall was very good at articulating our line. I think she is the one who really put words to what we stand for. In motions and debates, on the Swedish Gene Technology Advisory Board and in investigations, she gave voice to an unarticulated view that the party had.”

[...]

Kristofer Hansson: “So you trace the discussion back to her? The discussion within the Green Party began with her?”

Lotta Hedström: “Yes, I think so. That’s how I perceived it.”

Kristofer Hansson: “So you took over from her?”

Lotta Hedström: “Yes, I picked up from there. What was important in the debate was to point out that the Green Party does not have a hostile or anti-scientific perspective. We have a positive view of knowledge accumulation.”

The Green Party has sometimes been defined in the debate as being against technological development. But as Lotta Hedström says, this is not the party’s line.

Lotta Hedström: “There is always a need for basic research, and the Green Party has a positive attitude towards this. Basic medical research and genetic and biological research are good; there is no doubt about that. But if there are greater demands for commercialisation and application, then the basic research becomes biased, and the interests of the consumers, the patients, may become secondary. There has been a fundamental approach to raise a warning finger.”

The Green Party took an interest in these issues and saw their task as representing a different approach than the Moderates and Social Democrats. The central point here is that the party is not against biomedical development in general, but critical of how some types of technologies might be used. They are also critical of the commercialisation of technologies. This is the central perspective of the Green Party's framing of XTP in the 1990s.

## 6.1 Framing from another perspective

The first time the Green Party criticised XTP was when Gudrun Lindvall and Eva Goës (Green Party) submitted their motion to the parliament on 6 October 1997. The motion should be seen as a response to the Terms of Reference "*Transfer of organs and tissue from animals to humans*" for which a committee was appointed to investigate XTP research on 3 March 1997.

### **"Motion 1997/98:So319 Xenotransplantations**

*Motion to parliament*

*1997/98:So319*

*by Gudrun Lindvall and Eva Goës (mp)*

#### **Xenotransplantations**

##### **1. Introduction**

*There is a shortage of organs for transplantation. Therefore, medical science, in collaboration with the pharmaceutical industry, has begun to transplant animal organs into humans. This is known as xenotransplantation, and it involves taking organs from a genetically modified animal and transplanting them into a human.*

*There have been tests on transferring organs from nonhuman primates to pigs. Early experiments with chimpanzees and baboons have been abandoned because of the risks of eradication and contamination, and many people react emotionally to the use of nonhuman primates.*

*To most people, a pig feels sufficiently foreign so that it is emotionally acceptable to take organs from them. The pigs, which are in large supply, should be genetically engineered so that they have proteins that are similar to those in humans in order to reduce the risk of rejection.*

*Along with the surgeons' determination to help save human lives, there are very strong commercial interests behind xenotransplantation. In 1995 it was anticipated that pig organs could sell for about \$6 billion per year and immunosuppressants for about \$10 billion per year.*

##### **2. Heed the warnings**

*There have been some very serious warnings about the high risks associated with xenotransplantation. They state that the risks to organ recipients are obvious and cannot be overcome through experimentation.*

*Today we know that DNA is composed of 2% to 4% endogenous retroviruses in both animals and humans. There it lies dormant, in a quiet, trouble-free slumber. But what happens if they are introduced into a stressful environment where the normal immune system is suppressed to prevent rejection? What happens when endogenous retroviruses from two different species merge, forming a so-called recombinant virus, which is facilitated by genetic manipulation? There are tests for exogenous retroviruses, but not for endogenous ones.*

*Doctors and Lawyers for Responsible Medicine (DLRM) warn about xenotransplantation and believe that we must learn from history. Virologists and immunologists also warn about the risks. As examples they name AIDS, hepatitis B, influenza, Ebola and BSE (mad cow disease), all of which with certainty were*

*transferred from animals to humans through combined vaccines, drinking water and meat. They all have different life cycles; some may be latent for 20 years. Some people may have immune systems that suppress virus attacks and let them take over. Xenotransplantation could be a new, sophisticated way of spreading new potent viruses to humans. The natural barriers that are built up between different species during evolution which stop most animal diseases, are now broken. In connection with mad cow disease, a committee was appointed in the UK (Nuffield Council on Bioethics), to investigate xenotransplantation. It was composed of medical experts (who were not directly linked to the field) as well as ethical and philosophical experts. It all culminated in a ban against xenotransplantation on humans. In Sweden there was no prohibition.*

*Given the serious public health problems, which are foreseeable as a result of xenotransplantation in humans, should all activities in this area be prohibited? All work with inter-species transplants must be regulated by specific national guidelines. Community intervention should instead focus on preventing problems that may require transplantation. Preventive health care and education about the importance of a healthy lifestyle must be expanded.*

*The human benefits of such work are enormous and involve no health risks.*

### **3. Requests**

*With reference to the above, we request that the parliament, in its referral, ask the government to:*

- *prohibit xenotransplantation on humans as defined in this motion,*
- *adopt national guidelines for research on organ transfer between species as defined in this motion,*
- *enhance disease prevention work in health care to reduce the need for transplantations, as defined in this motion,*
- *enhance public knowledge about the importance of lifestyles for good health, as defined in this motion.*

*Stockholm 5 October 1997*

*Gudrun Lindvall (Green Party) Eva Goës (Green Party)”*

All four points were rejected by the parliament on 10 October 1997. This is when the XTP committee was beginning to take shape, and the other parties in the parliament were awaiting the outcome of their work. Also, the XTP committee was a parliamentary deal in which the other parties had agreed to go further with the investigation. The Green Party had a different perspective, being a new party in the parliament with few networks and therefore few opportunities to influence the political discussion. Thus, the motion can be seen not only as a statement from the Green Party, but also as a way for the party to find its political identity in the parliament.

This motion demonstrates a whole different way of reasoning about XTP than the media or the established parties had pursued. The discussion about risk and XTP was debated in other arenas at this time, but the focus on priorities in research funding was new. Instead of investing resources in XTP research, Gudrun Lindvall and Eva Goës propose that the resources should go to changing people's lifestyles for better health. Gudrun Lindvall also mentioned this in the 1998 televised debate – discussed in chapter 2 – when she said, “There are other research tasks that do not get funding, and I am very doubtful that this is what we should do research on, or if we can get people healthy in other ways” (Aktuellt 28-04-1998, 21.00–21.30). Even though this was a different angle on the XTP issue than

researchers and politicians had taken previously, the point was still a criticism that XTP was too risky to continue.

Gudrun Lindvall: “I have never believed in it. If we do research on this, then there are other things we cannot do research on. I think there are many more possibilities in other areas of genetic engineering, if that is what we want to do research on. I have never believed in xenotransplantation, it is a dead end. It is too difficult and there are so many risks. I’m sure many better and safer discoveries will come along in genetic engineering, so I believe this field would disappear even if we invested a lot of money in it. I have been confident about this all along; this was not the way to go.”

The criticism from the Green Party was not against genetic engineering itself, but a political argument for some technologies and against others. XTP was too risky and too complicated to make it worthwhile to invest resources in it. What is interesting in Gudrun Lindvall’s argument is that it is political: we have different paths to choose from and the XTP path was not one of them. She was not just critical of XTP, but she formulated a policy dealing with genetic engineering in the 1990s. The motion should be seen from this perspective. It was a first step towards defining the Green Party’s politics.

Some parts of Gudrun Lindvall’s reasoning can be related to “the green ideology”, which the Green Party of Sweden sees as an important part of their political identity and background. The green ideology has its origins in Norwegian philosopher Arne Næss’ philosophy from the 1970s (c.f. Næss, 1981). What the Green Party embraced from this philosophy is, for example, solidarity with animals and nature and criticism of capitalism. At the same time, Gudrun Lindvall’s reasoning is not completely in line with this ideology, and there were other politicians in the Green Party who advocated this ideology to a greater extent.

Gudrun Lindvall: “It was all about retroviruses, and for many in the party it was also about putting human genes in pigs, manipulating pigs genetically to become something else. But to me, it was almost exclusively about the risk of retroviruses, and also that I saw it as a dead end. I never saw it as a future possibility; I always saw it as a side track before we found better opportunities to use gene technology in other ways.”

The Green Party was also critical of genetic manipulation of animals, which is clearly related to the green ideology and its solidarity with animals and nature. Gudrun Lindvall did not develop this approach to XTP in her first motion, but we find it very much articulated in Lotta Hedström’s political perspective on gene technology. When she became the spokesperson for the Green Party, she felt that this perspective was missing in the Swedish debate.

Lotta Hedström: “I think the reason biotechnology issues were so important to me as soon as I became a spokesperson is that there was something missing in the political debate. Biotechnology was on the scientific agenda, but it had not had any public impact. Our green ideology involved having a critical approach to the system, and that made it very rewarding to focus on these questions.”

Lotta Hedström became a spokesperson in 1999 and did not act politically on the issue of XTP. Biotechnology became central for shaping her political identity. The green ideology allowed her to take Gudrun Lindvall’s earlier work in this field and continue to develop it into a clear policy for the Green Party.

Lotta Hedström: “I didn’t feel that the public debate included any voices defending life affirmation and the intrinsic value of all life forms. There were hints of it among the Christian Democrats, but we also needed it in a non-religious form. I felt that it was the Green Party’s task to articulate this ideology. We are green, and that means we’re all about living things and life science. If you make it too technical and reductionist, then you miss essential elements of the human relationship to the biosphere; it has implications for health and environment.”

This perspective on biotechnology is not included in the first motion that Gudrun Lindvall wrote. What we want to point out is that these perspectives were growing in the Green Party and are related to the biotechnology debate in Swedish society in the late 1990s and early 2000s. It was a debate in which many parties in Sweden were struggling to find a possible approach to these questions, to create a policy for the future (c.f. Hedlund, 2007).

Gudrun Lindvall: “There were no obvious truths in the debate; we guessed what was coming and we speculated on the future in a way.”

Kristofer Hansson: “That is how it felt?”

Gudrun Lindvall: “Yes that was how it felt. And we had different views on what hazards there were.”

This report will not look closer at the different political debates that took place at the millennium shift concerning these questions, but only points out that the Green Party developed its own policy in this period (c.f. Eklöf, 2007; Hedlund, 2007). On 5 October 2000, Gudrun Lindvall submitted a new motion on XTP. This time it criticised the XTP committee’s proposal for continuing XTP research in Sweden. This was the second attempt by the Green Party to get XTP research prohibited in Sweden. We present the entire motion here, as it

gives a good picture of the political development in the Green Party from the first motion in 1997. The green ideology appears clearer in the motion from 2000.

**“Motion 2000/01:So533 Xenotransplantations**

*Motion to parliament*

*2000/01:So533*

*by Lindvall, Gudrun (Green Party)*

*Xenotransplantations*

*Proposal for a parliamentary decision*

- 1. The parliament announces to the government its vision of a campaign to get more people to take a stand for organ donation, as defined in this motion*
- 2. The parliament announces to the government its perspective on clinical trials for transferring organs from one species to another, so-called xenotransplantation, as defined in this motion.*

**Introduction**

*This winter the Xenotransplantation Inquiry presented its report (Government Official Report 1999:120). Xenotransplantation is controversial and has been seen as an opportunity for many who do not see much hope in the waiting list for a transplant with a shortage of organs.*

**Report good, but surprising findings**

*The report describes in detail the present xenotransplantation research both internationally and in Sweden. Ethical issues relating to both animal behaviour and animal testing that is inevitable if xenotransplantation is to progress, are described in a good way. It also provides a rich account of the lack of knowledge about potential contamination risks. It is therefore surprising that the committee, after this review, concludes that clinical trials may be allowed. The precautions that the committee advocates are only organisational and will not protect the animals and people as intended.*

**Animal rights**

*From an ethical point of view, the Green Party considers the modifications required of both the animals’ genome and their environment, to be unacceptable. The preclinical part, that is, the research in which organs are transferred between different animal species, is not consistent with the beautiful words that the inquiry used about ensuring a good life for the animals. Animal husbandry for clinical trials will require microbiologically controlled environments; that is not compatible with natural behaviour.*

*A recently published work stated that the baboons used at Huntingdon’s research laboratory in the UK suffered greatly. In the animals that lived the longest, the pig heart had grown enormously and it is beyond dispute that the animal suffered. Other baboons exhibited many symptoms of stress, pain, abnormal behaviour and suffering. From all indications, it appears that these facts were suppressed and distorted.*

**Infection prevention**

*One of the strongest objections to these activities, however, is the risk of so-called endogenous viruses from pigs being transmitted to humans along with the organs. Endogenous viruses exist in the cell nuclei of all animals, including humans, and are inactive virus residues that are transferred from generation to generation. These viruses are not pathogenic in their native hosts, but what is worrisome is the risk that they might be brought to life if they enter an alien species, thereby giving rise to new diseases. This concern is now being fuelled by a new research report published in an issue of the journal Nature.*

*Under the supervision of Daniel Salomon in La Jolla, California, an international team of researchers examined the risk of endogenous viruses from pigs crossing the species barrier and spreading to human cells in connection with a transplant. They found two disturbing signs that the risk is not as low as they hoped. The researchers*

studied the insulin-producing cells from a porcine pancreas. These cells are of interest to medicine because it has been shown that transplanting pancreatic cells from healthy humans to a diabetic can cure diabetes, and the hope is that these transplants will eventually be possible from pigs to humans. Trials have been done in Sweden.

When Daniel Salomon and his colleagues cultured pig cells together with human cells, it was shown that endogenous pig viruses were transmitted to the human cells. Other research groups have previously found similar results. Salomon's group further examined what happened if pig cells were transplanted into living mice and found that endogenous pig viruses spread to the mouse's own cells in areas adjacent to the pig cells. However, the mice in the experiment had an inherent lack in their immune systems, which may explain the results.

None of these experiments imply that a virus from a transplanted pig organ could spread to cells in a living person's body, because our immune system may be able to prevent it. But the risk seems obvious.

#### **The precautionary principle**

The inquiry recommends that the contamination risk be managed within the framework of the precautionary principle. This sounds good, but there is hardly any precautionary principle to approve further trials in an area where knowledge is minimal and the consequences of continued trials can be fatal. Creating safe systems for tracking infections is hardly any help if the damage is already done. We do not know which infectious agents might be distributed, or if the spread can be limited. New infectious agents such as prions, which were completely unknown until recently, are continuously being identified.

The following quote from the inquiry may illustrate the current state of knowledge:

*'It is obvious that xenotransplantation implies a risk that infectious agents can be transferred, leading to serious infection. This infection may possibly infect not only the transplant, but also spread to surrounding organs. There is insufficient knowledge and we cannot yet predict the outcome. Infectious substances in xenotransplantation may be previously unknown pathogens and/or be xenotropic, i.e. not pathogenic to the animal host, but can cause disease in humans. 'New' infectious agents can cause an unknown clinical syndrome of unknown latency, and diagnostic tests may not exist for such agents. Therefore, there is a risk that xenotransplantation may lead to significant infectious medical problems. That is why the epidemiological aspects must be an important part in considering and handling the problems surrounding this issue.'*

#### **Alternative use of available research resources**

Xenotransplantation research will require very substantial resources. The report is very clear that these should come from a priority ranking of existing research budgets. Therefore, one must consider what priority will be given if we continue with xenotransplantation. Unfortunately, the inquiry devotes only about four pages to 'Alternatives to the development of xenotransplantation'.

The Roslin Institute in Edinburgh, famous for the cloned sheep Dolly, ceased its work on producing pigs as organ donors. The institute's director said in a comment on the BBC that the decision was not due to fear of viruses, but because they do not consider the field to be commercially interesting. It would be too expensive.

The progress and hopes that are now linked to stem cell research will hopefully do that. Then xenotransplantation research will be a track that does not need to be developed. The organ shortage is a problem, and it is regrettable that so many people choose not to donate at their death. This suggests that the government should take the initiative to develop a new campaign and take an active position to encourage more people to donate. This should be announced to the government. Certainly there is a lot to be sceptical about with xenotransplantation, both the risk of retroviruses and the animal welfare issues, as well as the financial requirements of the research. Clinical trials of xenotransplantation should not be allowed in Sweden. This should be announced to the government.

*Stockholm, 4 October 2000*  
*Guðrun Lindvall (Green Party)*  
*Gunnar Goude (Green Party)*  
*Thomas Julin (Green Party)*”

The Green Party tried to implement a ban on clinical trials of XTP in the early 2000s, but the motion was rejected on both points on 11 October 2000. Its main criticism was the same as in the first motion from 1997 – the risk of endogenous viruses and an exhortation for society to sort out its research funding priorities. What was new in this motion was that it also spotlighted animal welfare. Our hypothesis is that there was a development in the Green Party in which the latter motion is closer to the green ideology. This discourse is evident in how Guðrun Lindvall criticised the treatment of animals in XTP. But still, Guðrun Lindvall sees the risks as the main reason for banning XTP.

Guðrun Lindvall: “It was retroviruses. We really didn’t know if we could handle them, when there’s no way to know what risks there were. I thought that was very uncomfortable. I think this was so serious that it should directly lead to stopping the research. We had no idea what could trigger the biological processes.”

From these different perspectives, we believe that the Green Party encompassed several different ways to frame XTP, but they all came to the same conclusion: that XTP should be banned.

## **6.2 Creating other policies**

As we wrote in the introduction to this chapter, the Green Party got into parliament in 1988 as the first new party to enter the Swedish parliament since 1932. In the 1991 elections, the party received no seats in parliament, but it returned in 1994, receiving 5.02 percent of the votes. The leader of the Swedish Social Democratic Party, Ingvar Carlsson, formed a one-party government and came to govern with support from the Left Party. In the 1998 election, the Green Party won 4.49 percent of the votes. The leader of the Social Democratic Party, at this time Göran Persson, formed a minority government with support from the Left Party and the Green Party, which would cooperate on the economy, employment, equitable distribution, gender equality and environment. Therefore, it is clear that the Green Party was able to influence policy in the 1990s when the Social Democratic Party needed support. It was important for the Green Party to act as a supporting party because it gave them the opportunity to negotiate their own policy (c.f. Lewin, 1996; see also chapter 5 in this report).

In the 1994–1998 term, the Green Party had little opportunity to influence policy alongside the major parties. They had no influence, for example over how the Terms of Reference to investigate XTP research were formulated. This was partly because the Social Democrats

had a one-party government, but also because the Green Party was a newcomer with little experience in the workings of parliament and few political networks.

Gudrun Lindvall: “We got into the parliament in 1994. Most parties have some experienced people who can take over, but we were all new in the parliament. In those first years it is a lot of work just keeping your head above water. It is so totally new – there is no work that can be compared with parliamentary work. It takes time before you start to structure your efforts. It takes a while. The Green Party has a rule that no one should have more than three terms. And that’s good. But you spend most of the first term learning, and we really had no time to learn, we just had to get to work, and that took all of our time. In the second term, we started to negotiate more with the government. Then we began to see how the government worked. Looking back, I probably should have tried to negotiate at an earlier stage. The Green Party does that now. But it takes a while before you learn how it works. By the second term, people from the ministries started contacting us and asking what we thought about various issues. We started developing somewhat more established partnerships and began to have an effect on certain issues.”

As a new politician in a new party in parliament, you do not have many senior party colleagues to turn to for advice. Gudrun Lindvall believes that she had no knowledge of how to influence the politics at an early stage. The Green Party missed that critical privilege of formulating problems in many political issues in that first term. For example, it seems that the Green Party had no opportunity to influence the officials who wrote the Terms of Reference “*Transfer of organs and tissue from animals to humans*” in the beginning of 1997 (c.f. Ahlbäck, 1997). They also had no political representative on the committee. When the Terms of Reference were written, the other parties had already agreed on how they would handle the XTP issue. The Green Party was left to comment on the terms afterwards, and their first motion had no direct political influence other than pointing out their position in the issue.

In the 1998 election, the Social Democratic Party dropped to 36.39 per cent of the vote, while the Left Party had one of their best elections ever, winning 11.99 per cent of the votes. This election result opened the door for the Green Party, which was now invited to cooperate with the Social Democrats. According to Gudrun Lindvall, this meant that the party started to negotiate more with the government, which in this term was a minority government, and consequently they also learned more about how the political process in the government worked. Although the Green Party had a poorer election outcome in 1998 than 1994, it was now possible to influence policy. But they appear to have only a minor effect on the XTP issue. In the beginning of the term, the policy process regarding XTP was centred in the XTP committee, and once the investigation was finished in 1999, no other party wanted to proceed further with the investigation. So, our hypothesis is that the motion from 4 October

2000 can be seen more as a statement from the Green Party than a serious political effort to push through a ban on XTP research. It can be seen as a political comment on the official report 'From one species to another. Transplantation from animal to human' (Government Official Report 1999:120).

As a parliamentary politician, Gudrun Lindvall feels that there was not much time left for discussing this question in arenas other than the parliament. It is not always the parliamentarians' job to spend their time discussing a matter with the public. Their task is to represent the public and be an opinion leader (c.f. Widfeldt, 1997). For Gudrun Lindvall, the XTP issue became a political question that was more or less only discussed with her party colleagues, and if it had become a public question, it was the aegis of the Green Party's spokespeople.

Gudrun Lindvall: "Parliamentary work is so terribly demanding. Unfortunately, you could say, you do not have the resources that you'd like. You work 60 hours a week anyway, so, unfortunately, I cannot say that I did any more outreach than what you have seen."

Kristofer Hansson: "So you concentrated on influencing the politicians, from within?"

Gudrun Lindvall: "Yes, and you just have to hope that the spokespeople will highlight these issues if it becomes necessary, that they are informed and well-informed if the question expands into a wider context. It is quite hard work being a member of parliament; I was talking about genetic engineering internally within the party."

Only in the 1998 televised debate did Gudrun Lindvall talk about XTP in the media; the rest of her work was concentrated in the parliament and to other Green Party politicians. Thus, it was possible for parties to create other policies, but at the same time, there were structures that made it difficult for individual politicians to work as actively as they maybe wished.

### 6.3 Summary

The first time the Green Party presented their XTP-policies was in a motion to the parliament on 6 October 1997. The motion should be seen as a response to the Terms of Reference "*Transfer of organs and tissue from animals to humans*" for which a committee was appointed to investigate the XTP issue on 3 March 1997. The requests were rejected on all four points in the parliament on 10 October 1997. The motion showed another way of looking at XTP than the media or the established parties had previously done. The discussions about risk and XTP were debated in other arenas at this time, but the discussion about priorities of research funds was new. The Green Party's framing of this question can be

understood from their relationship to “the green ideology”, which emphasises solidarity with animals and nature, and a criticism of capitalism. In the beginning of 2000, the Green Party presented a new motion to parliament, trying to ban XTP clinical trials. The motion was rejected.

The Green Party had little influence on XTP policy in the mid-1990s. They were a small party with few relations to other parties or the government. Also, with little experience of the workings of parliament, it was difficult for them to influence the Terms of Reference “*Transfer of organs and tissue from animals to humans*”. After the election in 1998, the Green Party had more opportunities to influence the government, but at this time it seems that the XTP issue was no longer on the political agenda in Sweden.

## 7 Stakeholders making their voices heard

Various stakeholders were interested in influencing the development of XTP research. The stakeholders that were interviewed by the committee were split into two groups (see chapter 5): Those anxious to see XTP evolving into an available medical technology and those who believed that the research should not continue. The first group includes patient associations like the Swedish Diabetes Association, the Swedish Heart and Lung Association and the Swedish Kidney Association. There may have been others, such as representatives of the medical professions or the pharmaceutical industry, but we didn't find them in our material. The stakeholders who believed that the research should not continue were primarily animal rights organisations, which felt that XTP subjects animals to unnecessary suffering.

The patient associations were able to act as stakeholders in the early stages because the XTP researchers often had a relationship with patients and informed them about their research at various meetings (see chapter 3). They were able to express their opinions on XTP and stress the importance of developing the technology so more human lives could be saved. In our study we did not interview representatives of patient associations, but the researchers did. Here, Professor Håkan Widner reflects on his contact with patients outside the clinics.

Håkan Widner: "For many years, we held lectures for patients or had a lot of contact with patients outside the clinic. At least twice a year we hold lectures where we inform them about new treatments, treatment protocols and what is going on in our research. Earlier we presented transplantation with pig cells and how it works biologically. I have asked younger people with Parkinson's, 'would you consider having a pig cell transplant?' Many said: 'Yes, if you investigate the safety of the technology'. They had a very pragmatic attitude. I can't recall anyone saying that this is something we should not do."

Informing patients about new treatments and the progress of research is a part of research work. These occasions can also give the researchers insight into the patients' attitudes towards XTP. There are also examples in our material where the patient associations more actively influenced the researchers' work.

Kristofer Hansson: "How did the patient associations relate to XTP? Was it something positive?"

Bo Samuelsson: "Yes, very positive. The kidney patients' association was very positive. There is a foundation, the Gelin Foundation [Professor Lars-Erik Gelin Memorial Foundation for Transplant Research], which is run by

the kidney patients' association. Over the years they have been extremely positive about this research, and my PhD students received a lot of funding from them.”

Over time, a give-and-take relationship developed between researchers and patient associations. The patient associations did not have any influence on the relationship between researchers and politicians that arose with the commission, but they had their own relationships with the researchers. This allowed them to support the research on a small scale with funding and of course the use of their own bodies for trials. Some of the associations also commented on the committee work when the report was circulated. What is important is that patient associations have a relatively small influence on the government's allocation of research funds. This is pointed out in Anders Persson's thesis about cancer research funding organisations in Sweden and the United States:

“In the past decade, the perspectives of cancer patients have been more apparent especially in the USA, with patient movements successfully lobbying for their priorities in cancer research. As for the question of why the cancer funding structures in USA and Sweden seem paradoxical, it is argued that in the USA the political culture of lobbying has permitted actors outside the social contract between the government and the scientific community to penetrate it and have their own priorities put on the agenda. Through lobbying, such actors forced the federal government to assume the main responsibility for cancer research. This has not been the case in Sweden, where the corporatist political culture has been dominant and has prevented attempts from outside actors to establish cancer as a major social and political problem (Persson, 2002: Abstract).”

When it comes to XTP, the relationship between patient associations and the government seems similar. The corporatist political culture in Sweden has strengthened the relationship between the state and the researchers and prevented outside actors from influencing the development of XTP research.

Animal rights organisations were seldomly discussed in the interviews with the researchers, which is not surprising since they were opposed to the XTP research. For this reason, it has been important to interview them separately to study how they acted as stakeholders. This allows us both to study their ability to influence the policy process and to consider the committee work from a different perspective.

We interviewed Staffan Persson, who represents Animal Rights Sweden. He is responsible for animal issues and has been employed by the organisation since 1989. He became an animal rights activist at the end of the 1970s. The group's website describes its organisation as follows.

*“Djurens Rätt (Animal Rights Sweden) is the largest animal rights organisation in Scandinavia, with a membership of about 35,000 (as compared to Sweden’s entire population of 9 million). Animal Rights Sweden was formed in 1882 with the mission of ending painful animal experiments. Since the 1970s, the organisation has dealt with issues other than animal experiments, particularly involving farm animals and fur production.*

*Animal Rights Sweden is an animal rights organisation opposed to all experiments, procedures, production methods and other uses of animals that cause them pain, suffering and distress. Animals are sentient beings that deserve to be treated with respect, and humans have no morally acceptable reasons to subject animals to suffering.*

*The organisation has a staff of about 27, most of them in the main office in Älvsjö, south of central Stockholm. Animal Rights Sweden has local branches and contacts in about 100 of Sweden’s 288 municipalities.*

*The organisation is led by a board consisting of nine members and three deputies, elected by representatives from the local branches at annual general meetings. The current president is Camilla Björkbom.*

*Animal Rights Sweden is a member of Eurogroup for Animals, the European Coalition to End Animal Experiments, the European Coalition for Farm Animals, the World Society for the Protection of Animals, IAAPEA, the Fur Free Alliance and the recently formed Baltic-Nordic animal rights network.”*

Animal Rights Sweden works to influence society’s attitudes and change legislation. Staffan Persson describes what this means in real terms: *“We propose amendments, but we also try to obtain changes. We have been involved in several investigations, both in the peer group and as experts in the investigation”*. They are also a reviewing body for the Swedish Government Official Reports.

## **7.1 From the margins**

XTP was a focus of Animal Rights Sweden long before it became a hot topic in the mid-1990s. Staffan Persson says, *“We saw that the issue was debated and we saw it in the councils that approve animal testing”*. For them it was not the risk of viruses that grabbed their attention; it was XTP as a technology that would expand the use of animals in experiments and eventually in the clinic.

Staffan Persson: *“One aspect is that xenotransplantation is an extension of the use of animals, and it is a completely wrong development in comparison with developments in the animal welfare field in general. When Sweden introduced animal ethics committees, a bill was formulated in 1979 stating that animal testing should be limited and controlled. There were several*

similar proposals after this. That is the direction Sweden has been going in, but xenotransplantation would mean an expansion of animal testing and animal use. So it is important to decide if we should really continue on that path that we once decided to take.”

With the basic premise that the use of animals for scientific purposes should be reduced, Animal Rights Sweden also came to frame XTP research as something that should be stopped. The association itself was working for this framing, but Staffan Persson also relates the argument to a larger context in society. From his perspective, society had already made a decision, which was evidenced in many different documents, that animal use in scientific experiment should be reduced.

At the same time, new biotechnologies were creating new needs for using animals. This created new issues for the Animal Rights group.

Staffan Persson: “Xenotransplantation is related to other biotechnologies. Gene technology offers a potential for creating transgenic animals and cloning. The researchers talk about genetically modified animals to reduce the rejection problem. Internationally there have been attempts to clone transgenic pigs to be used for xenotransplantation. Then you have all three techniques, and each is potentially problematic for the animals. You do not suddenly have an animal that you can clone and that works well and is happy and healthy.”

This perspective, that the new biotechnologies will increase the use of animals, is not found in any of our other materials from interviews, media and governmental documents. Our hypothesis is that this is connected to the difficulties that the Animal Rights group has reaching out with their perspectives in public debate.

Staffan Persson: “Spontaneously, I remember we had a protest campaign to act against the establishment of xenotransplantation. It was addressed to the minister, but that does not mean that we reached out to the media with that question. [...] So what is reflected in the media is not always the real debate. I do not really remember how we handled this, but it may well have been that we didn't have much media contact.”

Although Animal Rights Sweden is an established organisation in Sweden, the media does not see it as a group that must be consulted on animal welfare matters. This is probably one of the reasons that we do not find them in our media materials (c.f. Hansson, 2003). There also appears to have been a resistance from the media when this organisation tried to inject itself into debates with articles.

Staffan Persson: “I wrote several debate articles that we never got published. It is very hard to get debate articles on this subject published, even if we related them to a current debate. There were occasions when we wanted to respond on a debate, but we were stopped. It has happened many times. It is very hard for us to get our views out.”

Thus, Animal Rights Sweden had difficulties communicating their message through the media, as they didn't have the privilege of determining what problems the media should be discussing (c.f. Gustafsson, 1989). XTP was never discussed from an animal rights perspective in the Swedish media. But as Staffan Persson says, *“the real debate is not always in the media, but in other arenas.”*

## 7.2 With minor influence over the committee

Previously we showed that the committee worked very independently. It is difficult to say what consequences this had, but it is clear that most of the stakeholders had only one occasion to present their views for the committee members. This also applies to Animal Rights Sweden, which had one meeting with the committee. Another organisation, Animal Welfare Sweden, was also represented at this meeting. As a reviewing body for the Swedish Government Official Reports, Animal Rights Sweden also commented on *“From one species to another. Transplantation from animal to human”* (Government Official Report 1999:120).

As a representative of Animal Rights Sweden, Staffan Persson describes his recollection of the meeting with the committee: *“We were invited to a meeting and we had some time to present our perspective on the subject. But we were not a part of the investigation and that is something we criticised”*. The criticism should be seen in relation to the influence Animal Rights Sweden had in other investigations, especially in the 2000s. Staffan Persson compares how he has worked in other investigations.

Staffan Persson: “We were not a part of the investigation, we had no insight into what was going on. We were invited on one occasion, but we had no idea how the investigation worked. I compare this with other investigations of which we were a part. The best example is the animal ethics investigation where, through the reference group, we were told how the investigator would work with the investigation. She informed us how she would invite other people and she explained the different groupings. We got involved in the work and we were informed how the work was conducted. That was not the case with the xenotransplantation investigation.”

How the chairman and the rest of the committee plan the work impacts how stakeholders can offer input into the committee. There are many different ways of collaborating with stakeholders. In the example above, Animal Rights Sweden had the opportunity to observe

the work from the beginning and therefore also comment on how it was planned. This specific investigation was a one-man inquiry consisting of department council Madeleine Emmervall and secretary Master of Laws Lisen Sjöling; it was not a parliamentary investigation. In the Official Report from this inquiry, XTP is discussed from an animal experiment perspective and the new challenges of the ethical examination through the genetic engineering and biotechnology of animals (Government Official Report 2003:107). With the XTP committee, Animal Rights Sweden did not have such insights and was only asked to submit comments on one occasion.

Staffan Persson: “It was a round table meeting. I have been to so many of these meetings in other contexts, so I have to think about it. If I remember correctly, we had little time to give our views on the xenotransplantation question. There was also a little discussion – a give and take session. It was only one occasion.

[...]

We were invited to the xenotransplantation investigation and we were asked to briefly state our views. Compared with other investigations we were allotted very little time.”

From the committee’s perspective, the argument was that they already had the expertise and knowledge to answer questions about animal welfare. Kerstin Olsson at Swedish University of Agricultural Sciences was the committee’s expert on these questions. The committee group also visited the Imutran company to get an idea of the pigs’ living conditions (Government Official Report 1999:120). But Animal Rights Sweden felt this was not enough. In particular, Staffan Persson states that, “*there was no representative for the animals in the investigation*”. It is important to note that he does not see Kerstin Olsson as a representative for the animals. He points this out when he says: “*She does research about animals, and the committee may have seen it as such, but we did not see that she was a spokesperson for the animals. She is a researcher and knowledgeable about animals from that perspective*”. The differences in how to frame this issue about animal welfare are that the committee had a lot of knowledge about animals, but there was no one representing the animals.

The way the committee framed this question depends in part on the composition of experts on the committee and on the Terms of Reference from the Ministry of Health and Social Affairs, as we pointed out in chapter 5. Staffan Persson’s statement clarifies this.

Staffan Persson: “I think that the Terms of Reference could have been clearer. But the committee did not take up these questions. The animal welfare issues were not adequately addressed. I think they discussed the animal origin concept, which animals that were going to be used, but they

did not tackle the preclinical phase, for example. This phase involves a lot of animal experiments related to the infection risk. Then there's the question of organ functions and rejection problems, of producing an animal that you can take organs from. Then there's the question of genetic manipulation and perhaps cloning of animals, another technology with complications for the animals. Just because you have genetically engineered an animal does not mean that you have a functional animal the first time. A lot of animals are injured, killed and/or deformed. The inquiry did not look into this. The issues of animal use are much larger and more comprehensive than what the investigation studied."

A closer look at Animal Rights Sweden's argument gives us a chance to consider the committee work and its framing of the policy problem from a different perspective. What Staffan Persson emphasises here is that the committee missed some important perspectives on the animal issue. Quite simply, the animal issue is more complex and involves more steps than the committee investigated.

An important perspective here is that Animal Rights Sweden and the committee were speaking two different languages when discussing XTP. Luigi Pellizzoni highlights this when he writes: "*The parties are unable to agree on an adequate language with which to handle the issue. Some of them may even deny that a problem exists or that something is actually happening, as is the case with climate change*" (Pellizzoni, 2001a: 70). There is a risk that a controversy may arise between the two parties because the parties have different facts, the facts are based on different principles or a combination of the two (Pellizzoni, 2001a). But there was no controversy, and our hypothesis is that Animal Rights Sweden was outmanoeuvred in the 1990s and had no opportunity to create an arena that it could participate in. For example, because the committee did not have this animal perspective, they could not argue that the Animal Rights group would have more input into the investigation or the conference. This may have changed in the 2000s, but we have no material on this.

### 7.3 Summary

There were two types of stakeholder groups in Sweden – the groups that were keen to see XTP evolve into an available medical technology and those who believed that the research should not continue. The first group, consisting of patient organisations, was already collaborating with researchers. They are not visible in our media material. It may be that they were happy with the relationship they had and they did not need to affect other groups in society concerning this question. It may also be that this group had no culture of exerting pressure on public funders.

The second group, the animal rights organisations, were not satisfied with how XTP developed. They primarily saw this technology as resulting in more suffering for the animals; this was how they framed XTP as a policy problem. We looked closer at Animal Rights Sweden, and they had another view of XTP technology that they tried to communicate to other groups in society. As shown in the interview, they had difficulty reaching out to the media. But they were able to have input in the committee because they were interviewed and they later commented on the Official Report. What impact their input actually had on the committee is hard to say, but the interview with Staffan Persson indicates that the input was rather minor.

## 8 Conclusions

In this case study we were interested in how experts and elites frame the issue of biotechnology – that it is controversial and risky – and thus create an allocation of responsibility where the public's voice is not heard (Pellizzoni, 2001a and 2001b; Pellizzoni and Ylönen, 2008). This case study shows how the XTP researchers (the experts) and the politicians (the elite) established a power relationship in the 1990s, through the XTP commission, where they could give various parties a legitimacy to speak about problems related to XTP research. They developed a language and arguments that stated how to talk about XTP. In addition, the asymmetries between the voice of the general public and experts/elite was not problematized to any greater extent. Instead the relation to the public was traditional in the sense that the public voice were heard through the studies carried through by the scientists from the humanities and social sciences alternatively directly through the survey.

This development had already started in the XTP research community, where the researchers framed the XTP policy problems. When this biotechnology began to be perceived as controversial and risky, the XTP researchers first began collaborating with researchers from the humanities and social sciences. These researchers had the task of studying the ethical questions linked to the XTP questions and also to come up with a solution on how XTP research could continue to a clinical phase. In this collaboration as well, there was a relationship established on who could speak and how they might speak, which meant that the public's voice was heard through the researchers' articles and presentations to the XTP researchers.

When the risk of the PERV virus became apparent, XTP scientists and researchers from the humanities and social sciences could not solve the ethical problems on their own, so a new collaboration was started with the politicians. This collaboration took place in the parliamentary commission that was assigned to investigate how XTP could move from basic research to clinical trials. It was not a primary task for this commission to consistently hear the public's voice. As a parliamentary commission, it was rather a representative of the public. They had the privilege of formulating problems that would be discussed at a later stage, though this later stage did not occur in Sweden. The only time the public was heard was when the commission did a survey, in which the individual answers were translated to the public's interests.

Both the Green Party of Sweden and Animal Rights Sweden had views on XTP that did not agree with the commission. They had the opportunity to communicate their views to the commission and to the public. At the same time, it seems their perspective on XTP did not appear in this specific policy process. They were heard, but their language and knowledge styles were too different. Taking the perspective of Jean-François Lyotard, we hypothesise

that the Green Party and Animal Rights Sweden became “*the Other*”, someone with a life perspective that was not in line with the experts and elites at this time (Lyotard, 1983). Naming them “*the Other*” gave experts and elites the chance to frame the biotechnology issue and simultaneously determine who is entitled to have a say and who is not (c.f. Pellizzoni, 2001b).

Our hypothesis is that by defining “*the Other*” we can also discuss the policy-making processes from a gender perspective that focus more on the cultural structures and less on the representation of women and men in different expert bodies and policy-making. Central for Sweden is also that the representation in for example the XTP committee is equal from a gender perspective - seven women and eight men. In our material we can see that “*the Other*” is all people and groups that do not see the possibility of overcoming technology problems. As Carolyn Merchant indicates, there is a long history in the West where nature, like women, has been seen as something that could be chastened and controlled (Merchant, 1989). XTP technology fits into such a perspective, where nature and animals can and should be controlled by humans and for humans’ benefit. “*The Other’s*” perspective cares more about nature and animals – which throughout history have been defined as feminine. Our hypothesis is that the power relationship between the XTP researchers (the experts) and the politicians (the elite) can be understood from this perspective. It is not a question of gender equality, but that the system is based on a specific view of what is nature and what is culture. Thus, what is seen as controversial and risky has its origin in the cultural division between nature and culture. If we want to understand how the public’s voice can be heard, we need to understand how this division is constructed and what the power relationship is between the experts and the elites.

## 9 Annexes

### 9.1 Political System

**Cabinets:** Coalition governments with minority or majority governments, with cooperation between the parties. Much of the policy is based on agreement between the government and other parties, with little conflicts. In the 1991 election it was a majority government, consisting of a multi-party government with the Conservatives, the Liberal Party, the Centre Party and the Christian Democrats. In the 1994 election the Social Democratic Party formed a one-party government in minority, with a broad cooperation between the party blocks. In the 1998 election Social Democratic Party formed a one-party government in minority, with support from the Left Party and the Green Party.

**Legislature:** One chamber that is representing the citizens, called “Riksdagen”. Consists of 349 members and is headed by a speaker (“talman”). It takes at least four percent of the votes for a party to take place in the Parliament. The politicians in the Parliament get their information from own staff, federal ministries and interest groups/social partners. Consideration of proposals for new laws is done by propositions, which are written proposal by the government, and motions, which are proposals authored by the parliamentary politics.

**Executive-legislative relationship:** Consensual were the laws are steered through Parliament. Proposals and motions are addressed in specific committees in charge of the proposed topic. The decision from the committee is presented in a committee report. Much of the work the parliamentary politics do is done in the specific committees.

**Bureaucracy:** The Swedish Constitution Act distinguishes between two types of public bodies: the decision-making bodies and government agencies. All state and municipal agencies, with the exception of the decision-making assemblies as for example the Parliament, are government agencies. The government agencies are rather large in Sweden and operate at arms length from government; they are not governed by the politicians. They have the authority to execute the policy decisions from the Parliament.

**Judicial review:** The courts are less important for political decisions in Sweden.

**Party system:** Around 7 parties are represented in parliament. Social Democratic Party and Moderaterna are the two biggest parties in Sweden.

The election in 1991: the Conservatives, the Liberal Party, the Centre Party, the Christian Democrats, the Social Democratic Party, the Left Party and the New Democracy.

The election 1994: the Social Democratic Party, the Left Party, the Green Party, the

Conservatives, the Liberal Party, the Centre Party and the Christian Democrats.

The election 1998: the Social Democratic Party, the Left Party, the Green Party, the Conservatives, the Liberal Party, the Centre Party and the Christian Democrats.

**Interest group system:** Sweden has a corporatist system meaning that the politicians listen to what the interest group has to say.

**Direct democracy:** There were no instruments for direct democracy in Sweden concerning the XTP-case. To get the public and interest groups views on the question there were a survey done and the XTP-committee interviewed interest groups. There were also an XTP-conference where expert presented their views on XTP, but this did not lead to a broader discussion. When the XTP-committee was finished with their report, it went on referral to authorities and interest groups.

It is similar for other policy processes concerning biotechnology.

**Political culture:** Sweden has little tradition of participation in politics from the civil society. The decision-making is rather open but there is no tradition of participation in it. The attitude (or culture) in Sweden has been that politicians are representing the public in decisions concerning complicated technology. In this way there was no direct citizen involvement in the policy-making concerning XTP.

**Science-society relations:** Scientific experts play a big role in policy-making concerning XTP and other policy processes concerning biotechnology: it was the XTP-scientist who ran the issue and made it a policy issue. The scientist was also part of the XTP-committee and had considerable potential to influence the politicians and the XTP-committee.

Some of the scientist also tried to create relations to the society, for example through mass media.

It is similar for other policy processes concerning biotechnology.

**Constitutional division of territorial power:** Concerning XTP the state was central when it came to the policy-making process. But the country council (landsting) are independent when it comes to controlling the healthcare. They can decide how the healthcare shall prioritize between different expenditures. Under the last years the state has intervene more and more in healthcare policy questions.

**Electoral system:** The electoral system is disproportional, were also minority rights can be strong.

## 9.2 Policy Field

**Cabinets:** Cabinets had a central role in the policy-making process concerning the XTP case. When they started to investigate the XTP-question, it was also they who took control over the policy process. The politicians decided how it would be a part of the XTP-committee and how it would not. At the same time, they had a close collaboration with the researcher in XTP.

It is similar for other policy processes concerning biotechnology.

**Legislature:** The government presents proposals for new laws that the Parliament is authorized.

**Executive-legislative relationship:** There were no Executive-legislative relationships in this case.

**Bureaucracy:** Ministry of Health and Social Affairs dealt with the policy problems concerning the policy-making process of XTP. It seems, as they were the first party to start-up the policy process after contacts with the XTP-researchers. They also had contact with the different parties in the beginning and had one person in the XTP-commission.

It is similar for other policy processes concerning biotechnology, where a Ministry takes responsibility for a policy field.

**Judicial review:** The tradition is a Roman law where the courts have little input in the policy-process concerning biotechnology. Concerning the policy-making process of XTP, the only influence they had was when they got the possibility to comment the XTP-committee investigation when it went on referral.

**Party system:** The parties in the Parliament have been positive about biotechnology. The Green Party and the Christian Democrats have in some questions been critical. The Green Party was the only party in the 1990s that were negative to the XTP-investigation.

**Interest group system:** We have not found that interest groups were involved in the policy field, but experts that represented interest groups were invited to the XTP-commission to be interviewed and present their view on XTP. Also, interest groups got the possibility to comment the XTP-committee investigation when it went on referral. It is similar for other policy processes concerning biotechnology.

**Political culture:** Civil society has not been involved in the policy field.

**Science-society relations:** Scientific experts played a central role in the policy-process

concerning biotechnology.

**Direct democracy:** There are no examples of direct democracy in Sweden concerning biotechnology.

**Constitutional division of territorial power:** There were no regions that were active. Some regions comment XTP-committee investigation when it went on referral. It is similar for other policy processes concerning biotechnology.

**Demand for XTP:** There was an interest for XTP in Sweden in the 90s. Almost all parties were positive about the installation of the XTP-committee and if it could develop to be a save technology it had the support from most parties. Patient organizations were also positive to develop XTP.

The XTP-researchers saw XTP as a great opportunity to help patient and be in the fore front on a international scientific race.

There was also a survey done and it showed that there was no strong resistance to using biological material from animals for transplantation, provided that the results and the risks were similar to transplantation in humans, among the public.

**State-EU policy relationship:** In the XTP-commissions investigation there were no relationships done to EU policy. After the investigation some experts in Sweden work with XTP policy-processes in EU and international. In those cases where EU have a policy for biotechnology Sweden apply this.

## 9.3 List of interviewees

### 9.3.1 Swedish Committee on xenotransplantation

Bertil Persson, chairman and politician, former member of the Swedish Parliament.

Karin Israelsson, fellow and politician, former member of the Swedish Parliament.

Annika Tibell, chief physician and expert, Karolinska Institutet.

Bo Samuelsson, professor and expert, Professor in transfusion medicine, Sahlgrenska Academy in Gothenburg.

Marie Omnell-Persson, secretary and transplant coordinator, Coordinator of transplantations, Malmö University Hospital (UMAS).

Nils H Persson, chief physician and expert, Chief physician, Malmö University Hospital (UMAS).

### **9.3.2 Politicians**

Gudrun Lindvall – Green Party, former member of the Swedish Parliament.

Lotta Hedström – Green Party, former member of the Swedish Parliament.

### **9.3.3 Physicians and medical scientists**

Stig Steen, Professor in Thoracic Surgery, Lund University.

Håkan Widner, Professor in Neurology, Lund University.

### **9.3.4 Clinical immunologists**

Erna Möller, Professor in Clinical Immunology, Karolinska Institutet.

### **9.3.5 Humanities and social sciences**

Susanne Lundin – ethnology, Professor in Ethnology, Lund University.

Anders Persson – sociologist, Associate Professor in Sociology, Trollhättan College.

Stellan Welin - research ethics, Professor of Biotechnology, Culture, and Technology at the University of Linköping.

### **9.3.6 Associations**

Staffan Persson - Animal Rights in Sweden, member representing Animals Rights association.

## **9.4 Material**

### **9.4.1 Media**

Aktuellt 28-04-1998, 21.00-21.30

Aktuellt 30-11-1999

Dagens Nyheter, 04-02-1995

Dagens Nyheter, 08-04-1997

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#### **9.4.3 Unpublished material**

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