

*This letter to the Swedish 'Justitiekansler' (Chancellor of Justice) Göran Lambertz was written by two of Prof. Christopher Gillberg's colleagues who were not part of Gillberg's research group. The letter requests legal review of this complex case which has already been heard in two Swedish lower courts and which is currently the subject of an appeal to the Supreme Court. The Chancellor of Justice is a parliamentary commissioner and in this specific case his role would be to receive complaints directed towards the State and act as the Government's ombudsman (commissioner) in the supervision of the authorities and the civil servants. He can take action in cases of abuse.*

Chancellor of Justice Göran Lambertz

We hereby request the Chancellor of Justice to examine the course of events leading to Professor Christopher Gillberg and Gothenburg University Principal Gunnar Svedberg being found guilty of breach of duty by the Tingsrätt (District Court) in Gothenburg because sensitive medical psychiatric research records were not released to outsiders; and which also led to three of Gillberg's co-workers being prosecuted. The matter is complex and has many facets - several of which we consider to lie within the Chancellor of Justice's jurisdiction. We interpret what has happened as a clear legal scandal which could lead to negative consequences for Swedish medical research.

This matter has had serious consequences for Gillberg. He was sentenced by the district court in Gothenburg to a severe fine and conditional sentence *in spite of the fact that:*

- he followed the current regulatory framework for research ethics in every respect,
- the judgement passed by the Kammarrätt (Administrative Court of Appeal) in Gothenburg, which implied that sensitive records from his project should be released, probably did not accord with Swedish law, and
- his decision not to co-operate with a violation of research participants' integrity was, from an ethical perspective, inevitable.

The legal process against Gillberg has in addition been exploited in the most wide-ranging slander campaign heard in current Swedish debate. This has meant that the public have been led to understand that Gillberg and co-workers have committed research fraud, *in spite of the fact*

- that there is no reason that they should have committed fraud, and
- that they were investigated and cleared of suspicion in accordance with current regulations.

There can be no doubt that the campaign being pursued against Gillberg, in part through the media, in part through direct contacts with various authorities, aims to make it difficult or impossible for him to be able to work as a researcher. The manner in which public officials contributed to the success of this campaign deserves analysis.

It is however not principally the injuries which Gillberg, his co-workers and the University's Principal have sustained which justify examination of this matter, but its fundamental implications and the fact that it demonstrates a systematic failure in the exercise of Swedish authority. That research participants should not have to doubt

whether promises of confidentiality made by public servants will be kept; that researchers should not risk being faced with the choice between being prosecuted and breaking a promise (made on the instructions of their employers) of confidentiality; and that the management of such serious matters as accusations of fraud should happen in a legally secure manner, are questions of significant interest to society.

There are four principal aspects which we consider would benefit from the Chancellor of Justice's analysis.

**First** we wish the Chancellor of Justice to examine the case's legal aspects. The Gothenburg Administrative Court of Appeal's judicial decision described above was legally doubtful in several respects. These judgements could not be appealed for procedural reasons, therefore the legal question in the case has only been tested once. Given the consequences of the court's decision for private individuals, given the anxiety it has caused amongst researchers, doctors and patients, and given the influence the sentences will exert over future medical research in Sweden, it is urgent that they should be subjected to the Chancellor of Justice's analysis. In addition we hope the Chancellor of Justice will consider whether it is legally acceptable that neither the researchers who have personal responsibility for this type of project being carried out in an ethically acceptable way, nor participants in the project, are seen as parties to the case when the question of release of sensitive information becomes the subject of judicial examination.

**Second** we wish the Chancellor of Justice to consider the rationality of Gillberg being ordered by a state power to promise confidentiality to participants in the study, while later he was confronted with the choice between breaking that promise and being prosecuted by the same state power. We find it especially disheartening that currently none of the authorities which must be considered to bear responsibility for implementing the ethical regulations Gillberg has followed (which imply among other things that participants in these types of studies are promised confidentiality) seem to want to acknowledge these regulations. A consequence of these authorities' timid actions is that Gillberg could be falsely portrayed in the media as a presumptive fraudulent researcher, in spite of the fact that there is no reason to believe that he has committed fraud.

**Third** we wish the Chancellor of Justice to examine whether the manner in which representatives of the authorities handled and commented upon the accusation of fraud against Gillberg and co-workers is consistent with the important principle, in a society ruled by law, that those who have been investigated for an accusation, and subsequently cleared of suspicion, have the right to be viewed and described as innocent.

**Fourth** we wish the Chancellor of Justice to consider whether the longstanding media campaign to which Gillberg has been exposed could be seen in any way as slander in the legal sense. We consider that this decision can be the responsibility of the Chancellor of Justice because of the fact that it is in his capacity as a state-employed researcher, in other words as a public official, that Gillberg has been attacked. We think, however, that the fact that private individuals could perhaps be considered to have slandered Gillberg and co-workers is less important in a legal sense than the fact that the campaign against him has largely been made possible through clumsy actions by representatives of the authorities.

Appended below is a list of 19 concrete questions on which we wish the Chancellor of Justice to take a position. Following this is a comprehensive account and analysis of the matter, in which the background to the questions are described.

Only a few supplementary items are appended to this document. We can submit, on request, written documentation concerning all the cited items occurring in the report and concerning all the remaining facts. Most of the cited newspaper articles can be retrieved from the databases 'Mediearkivet' or 'PressText'.

Finally it can be added that certain of the legal aspects of this matter are currently the subject of a trial in the Court of Appeal in Gothenburg. We believe however that the Chief Justice's analysis is urgent, regardless of the outcome of this process.

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*Annexes:*

- 1) Letter from CG Gottfries to Gunnar Svedberg
- 2) Debate article by CG Gottfries
- 3) Correspondence between EE and the regional ethics examination board
- 4) Essay by Elisabeth Rynning
- 5) Certificate issued by Thomas Brante
- 6) Petition signed by 300 specialist doctors
- 7) Email from Science Council's archives (Strandvik to Leijonhufvud)
- 8) Correspondence between EE and National Agency for Higher Education
- 9) Correspondence between EE and the central ethics examination board

## **CONCRETE QUESTIONS**

We hope that the Office of the Chancellor of Justice will be able to justify the analysis of the questions below. The background to the respective questions is given in the enclosed review and analysis of this case.

### **QUESTION 1:**

Is it an expression of a reasonable exercise of authority, and compatible with current principles of justice, that Christopher Gillberg was compelled by the State:

- to personally assure confidentiality to the participants in his study, through the university ethical committee,
- later to break this promise, through the administrative Court of Appeal,
- and that he was subsequently indicted and sentenced, through the Parliamentary Ombudsman of Justice and district court, because he, for ethical reasons, did not consider himself able to participate in the breach of that promise?

In other words: has the State the right to put a researcher in the moral predicament that Christopher Gillberg has been placed in?

### **QUESTION 2:**

Is it a reasonable exercise of State authority that participants in Gillberg's study, represented by Gillberg and co-workers, were promised confidentiality, and that their voluntary participation was based on the premise that this promise would be kept, but that, at a later stage, a court decides that the promise will be broken? And is the uncertainty which this decision has caused acceptable to people taking part in other studies, who believe that the researcher will keep his promise, but now have reason to fear that sensitive information about them can be released?

### **QUESTION 3:**

Is it compatible with justice that a researcher:

- is compelled to issue promises by an ethical committee and
- is compelled to confirm that with his signature, then
- in discussions with the research participants, he states in good faith that these promises will be held, but
- he is still not considered a party in the case when the judicial system makes decisions about whether the promises will be broken?

### **QUESTION 4:**

Is it compatible with justice that childrens' parents are not considered sufficiently concerned to have the right to speak when the judicial system has to take a position about what will happen when they have been given a guarantee by representatives of the Swedish State that that confidential information voluntarily given about their children will not be disseminated further?

### **QUESTION 5:**

Are those decisions announced by the Administrative Court of Appeal in Gothenburg on the 6/2 2003 in accordance with Swedish law, or is there any valid reason for the criticism aimed at them, for example by Elisabeth Rynning, Professor of Medical Law?

**QUESTION 6:**

Is it acceptable that researchers who intended to start clinical research projects in Gothenburg during 2004 were called upon by the regional ethics examination board to give the same promises of confidentiality to the participants that the Administrative Court of Appeal had called upon another researcher to break the year before?

We do *not* mean that those promises that the board has sanctioned are too far-reaching; on the contrary, we consider that this type of promise is necessary for people to be able to carry out clinical medical research. But we have difficulty seeing the reason for this type of promise to be sanctioned by the same senior legal authority – head of division of the Administrative Court of Appeal Gunnar Dyhre – who shortly earlier, in his role of judge in the Administrative Court of Appeal, had forced Gillberg to break comparable promises, and who then eagerly defended his decisions in the media.

It is difficult to draw any other conclusion than that Gunnar Dyhre considers it relatively unproblematic that one could issue undertakings of confidentiality that can be broken later. We hope that the Office of the Chancellor of Justice will consider the potential for damage to the general public's trust in medical research when the manager of an authority that ensures that research is carried out in an ethically acceptable way appears to look lightly on the importance of keeping promises.

**QUESTION 7:**

Are there reasons to aim criticism at Professor Thomas Brante because he formulated a testimonial that was interpreted by the Administrative Court of Appeal as meaning that a research project in which the sociologist Eva Kärffve wished to examine documents in Gillberg's archives **was** within the framework of Science Council funding. This question is justified *in part* because Brante had not applied for the required Science Council ethical examination of this part of his research project, and *in part* because he has denied that Kärffve's review constituted part of the project in other contexts.

**QUESTION 8:**

Are there reasons to blame Eva Kärffve because she, in her capacity as a government employee, during 2003 requested to get a number of confidential documents from Gillberg's archives, despite the fact that it must have been apparent to her that she had no reason to take these documents provided she did not intend to break one of the restrictions issued by Gothenburg's university and validated by the Administrative Court of Appeal, or alternatively intended to break the Science Council's regulations concerning ethical review of research?

**QUESTION 9:**

Are there reasons to blame Eva Kärffve because in May 2004 she requested access to confidential documents from Gillberg's archives, despite this being in breach of the research ethics regulation that had come into force on 1/1 2004, and consequently was also against the European Convention on Human Rights?

**QUESTION 10:**

Was it right that a Director at Gothenburg University in May 2004 issued an order indicating that Gillberg should immediately release confidential documents, despite the fact that this would have meant breaching research ethics regulation which came into force on 1/1 2004, and consequently also the European Convention on Human Rights?

**QUESTION 11:**

Was it right that - on the instruction of the Parliamentary Ombudsman of Justice – a prosecution was raised against Gillberg, and the district court sentenced him, despite the fact that he was not formally responsible for the documents in question being released, and despite the fact that the preliminary investigation had already shown that it was not his refusal to move the documents from one place to another that led to the documents not being released during the autumn of 2003?

**QUESTION 12:**

Is it reasonable that both prosecutors and Gothenburg's district court considered that the following circumstances *entirely lack relevance*, and therefore *should not be taken into consideration*, when taking a position on Christopher Gillberg's and Principal Gunnar Svedberg's unwillingness to take part in the release of the documents in question:

- A) that the judgement in the Administrative Court of Appeal that gave Eva Kärffve and the paediatrician Leif Elinder the right to gain access to the documents was a consequence of the court being wrongly informed about facts relevant to the case.
- B) that these decisions probably contravened Swedish law in several respects.
- C) that release of the documents would probably constitute a breach of the European Convention on Human Rights.
- D) that a release of the documents would also mean that an undertaking of confidentiality made by a representative of the State to individual citizens would be broken.
- E) that the participants in the study requested that the documents should not be released, i.e. that the undertaking of confidentiality issued to them by representatives for the Swedish State should not be broken.
- F) that neither Gillberg nor Svedberg could be secure in the knowledge that a release would not lead to damage for the participants.
- G) that there were good reasons to believe that a release would lead to violations of the law in the form of infringement of restrictions, a supposition confirmed by the interrogation of one plaintiff (Kärffve) in the District Court.

We understand that the position that neither private individuals nor authorities can avoid being corrected after judgements are announced, even if these are incorrect. Such is the power of law. Nevertheless, we ask ourselves whether it is reasonable that neither prosecutors nor the District Court considered that any of the above factors constituted *extenuating circumstances*, particularly in light of the fact that it was a third party that would be damaged if Gillberg and Svedberg had taken part in a release of the documents. We think what has taken place is a worrying indication that legal authorities care too little about the question of individual citizens' rights to an acceptable protection of integrity.

**QUESTION 13:**

Science Council representatives Björn Thomasson and Göran Hermerén have - during the ongoing legal process - seen reason to aim criticism at Christopher Gillberg because he issued promises of confidentiality to the participants in his study which were too comprehensive, despite these promises being made entirely in line with normal practise, and despite the fact that the Science Council - and in particular Hermerén himself - has had a crucial responsibility for the implementation of this practise. Is it reasonable for researchers to be criticised publicly in this way by representatives of an authority because they followed instructions developed by this authority?

**QUESTION 14:**

The lack of clarity of advice concerning the question about the ownership of documents has been established in connection with publicly funded research. The National Archive asserts that this type of document is owned by the authority, but practise and current law concerning researcher's right to their own data (the so called 'Exemption for University Teachers') means that researchers in general take this type of document with them when they change workplace. Does this uncertainty constitute a risk to the rule of law?

**QUESTION 15:**

Is it an expression of judicious exercise of authority that four Science Council employees, in their capacity as public officials, have publicly expressed regret that the question of whether Gillberg and employees have been fraudulent has been investigated with insufficient precision, *despite the fact that* there is no reason to believe that the researchers in question have cheated, and *despite the fact that* they have been exonerated from the accusations after an investigation conducted wholly in accordance with current regulation?

**QUESTION 16:**

Is the current wording recommended by the Central Research Ethics Committee, the National Agency for Higher Education and the Science Council when prospective participants in research projects are informed about confidentiality ethically acceptable? It states that no "unauthorized person" should be able to take part of the collected information. The question should be seen in light of the fact that:

- a) this wording is as meaningless as the wording "only those who may read the records will be allowed to read the records",
- b) the ethical regulation is clear that information provided to participants must be "understandable and genuine", and
- c) that there are reasons to believe that many participants do not realise that the word "authorised" can be taken to mean anyone who can convince the Administrative Court of Appeal of the fact that s/he would find it interesting in his/her spare time to gain access to the research data. This is a consequence of judgements in the Gothenburg Administrative Court of Appeal.

**QUESTION 17:**

In our capacity as medical researchers at Gothenburg University we have posed the question to concerned authorities (Gothenburg University , National Agency for Higher Education, Science Council, and central research ethics committee) about how we now ought to formulate the *verbal* information which complements the written information to prospective participants, in case they ask us what is meant by “unauthorized”. We have also asked how great is the risk that courts will decide in the future that this type of data will be released to private individuals. In addition we have posed the question about how a researcher should in practice handle that fact that sensitive information is stored about thousands of participants who have taken part in ongoing or completed studies. If the judgements in the Administrative Court of Appeal are correct, these people had the wool pulled over their eyes *de facto* when they were offered participation. Is it a risk to justice for researchers and research participants that the concerned authorities have neither succeeded, nor seen reason, to clarify these questions?

**QUESTION 18:**

Should the duties that publicly employed representatives of authorities enter into include carrying out critical, investigative, public opinion-creating journalism, of the type that has been carried out by Gothenburg University Magazine with respect to the current case? If so how should protection of communication be handled in relation to the requirement that letters coming in to authorities will be considered public documents?

**QUESTION 19:**

A) Does the Office of the Chancellor of Justice share our perspective that the State should require the Office of the Press Ombudsman to pay regard to normal rules of challenge in its activities? The activities of the Office of the Press Ombudsman and the Press Opinion Panel are officially sanctioned by letting senior publicly employed legal advisors constitute the Press Opinion Panel’s directorate, and through letting the Parliamentary Ombudsman of Justice take part in nominations to the board.

B) Does the Office of the Chancellor of Justice share our perspective - again in light of the fact that the Office of the Press Ombudsman’s activity is legitimated by the Swedish State - that it is urgent that the Press Ombudsman makes it clear when he comments on individual cases as the Press Ombudsman, after prior consideration, compared to when he expresses himself spontaneously without prior consideration, and when those concerned are unable to appeal against his position?

## **1. Introduction**

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*B. The importance of the Gothenburg survey*

### **3. Promises about confidentiality within clinical medical research**

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### **11. Is what Gillberg has been put through an expression of temporary or systematic error in the exercise of authority?**

## **1. Introduction**

The matter of this notification is complicated, and is multi-faceted. The review enclosed below is of necessity extensive. Those concrete aspects we ask the Office of the Chancellor of Justice to investigate are specified in the 19 questions above.

## **2. Background: The research project**

### *A. The Gothenburg survey*

For several decades a research project was carried out in Gothenburg - the so-called Gothenburg survey - in which a number of individuals with so-called attention disorder (ADHD /DAMP), were followed up. When the project started, the participants were children. A comparison group of children without this type of problem was also investigated.

The project was initiated in 1974 by researchers and doctors at the child clinic in Gothenburg. Since the middle of the 80's the current Professor of Child Psychiatry at Gothenburg University, Christopher Gillberg, has been principally responsible. Among other researchers involved we should mention the senior lecturers Peder Rasmussen, Carina Gillberg and Lars Hellgren.

Within the framework of the project, Gillberg and employees have collected detailed information about the studied children and their relations concerning matters such as domestic relationships, school performance, psychiatric disease, substance misuse, crime and sexual habits. Large parts of the material were collected when Christopher Gillberg and later Carina Gillberg were doctoral students at Uppsala University. The study's raw data were kept in premises in Gothenburg, a total of approximately 50,000 sheets including copies of medical records that had been requisitioned from the medical service. The documents showed the participants' names and social security numbers.

### *B. The importance of the Gothenburg survey*

The Gothenburg survey elucidates several aspects of attention disorder in a longitudinal perspective. The group of researchers who implemented the study is internationally renowned, partly as a result of this study, but also because of a large number of publications in other related areas, for example autism and eating disorders.

Although the Gothenburg survey is of scientific interest there are reasons to correct the highly exaggerated picture of its importance that the Swedish media, in polemic style, has attributed to the study. Thus it has often been stated - in for example Eva Kärffve's book 'The Brain Ghost' and in many contributions to the debate from Leif Elinder - that this single study is of crucial importance for how one should treat children with attention disorder within school, child health care and child psychiatry today.

This assertion is far from the truth. Medical practise is not based on individual studies, but on an assessment of the available literature. Furthermore, the results of the Gothenburg survey do not contradict concurrent or later studies performed by others in any important respects. Even if we disregard the Gothenburg survey's results management of children with this type of problem would not be significantly different.

In the intensive media debate pursued in recent years Christopher Gillberg has often been criticised for asserting that the disorder depends on biological factors rather than on

social relations. This was the theme of a lengthy review on SVT, Swedish Television (7/6 2005). Viewers of the programme must have believed *in part* that Gillberg's view was controversial, and *in part* that he relied on his own results from the Gothenburg study in support of his view. This statement, often repeated by others, should however be considered to be misinformation.

Most researchers within the field consider that attention disorder is largely hereditary, and that shared environmental factors among siblings play a secondary role in the condition's origin, because of a large number of so-called twin studies which unambiguously point in this direction. These survey results have sometimes been quoted by Gillberg, as well as by other researchers, but he himself has not performed any of these studies. In the Gothenburg study the question of the origins of attention disorder causation was not addressed at all.

Another major feature in the attacks aimed against Gillberg consists of his asserted willingness to treat children with attention disorder with central stimulant drugs, and that he also refers to the results of the Gothenburg study in support of this opinion.

As we will discuss, this criticism also is essentially misleading - Gillberg is more conservative when it comes to pharmacological treatment of this condition. Moreover it is important to stress that this question was also not addressed in the Gothenburg survey. Not one of the children examined within the framework of this study became subject to stimulant medication treatment.

In an attempt to prove Gillberg's research to be controversial, his antagonists made a point that in his studies of attention disorder he used the Swedish diagnostic term DAMP instead of the internationally accepted term ADHD. It is not however a demonstration of scientific controversy that these conditions, which are in principle the same, had various names in Sweden and in other countries. It is instead the result of different traditions, and of the fact there was no internationally established and accepted name for the condition when the Swedish term DAMP was established. Today DAMP is considered a subgroup of ADHD.

The assertions put forward in the debate, implying that the results of the Gothenburg survey are highly controversial, and that this one supposed controversial study forms the foundations for how one should treat children with attention disorder in Sweden, is thus false. The study in question was well conducted and of a pioneering nature, but the results are entirely in line with other similar studies. Furthermore it intended neither to examine the condition's causation, nor the question about how it should be treated.

As will be discussed below Leif Elinder has stated that the current study is of such importance in the treatment of children with these problems in Sweden that he felt compelled to gain access to the project's data in order to be able work part time as a teacher at a school for handicapped children - a type of school which does not deal with ADHD/DAMP. It is not only in light of what we have stated above that this assertion is extraordinary.

### **3. Promises about confidentiality within clinical medical research**

#### *A. The issue of promises of confidentiality in the Gothenburg study*

Central to this dispute is that the Gothenburg Administrative Court of Appeal compelled Gothenburg University to release research documents from the above mentioned study to uninvolved individuals, despite the fact that the participants had been assured that this would not happen. A comprehensive investigation of the matter is required because it must be determined why this type of undertaking of confidentiality had been issued, and whether Swedish authorities consider that such promises can be broken.

The parents of the children with ADHD/DAMP who participated in Gillberg's group's study contributed voluntarily, just like the parents of the children who constituted the control group. Their participation meant no advantage to them, but may be interpreted as an expression of a will to contribute to the development of knowledge within this area.

When faced with the question about whether to participate, the parents were assured that the sensitive information given about themselves and their children would not be passed on to anyone outside the current group of researchers. This assurance was given in writing and was signed by the researchers who ran the study, among them Christopher Gillberg.

The situation can thus be described as an agreement between two parties: the university/researchers on the one hand and the informants on the other. The meaning of this agreement was that each of the participants agreed to share highly sensitive information about themselves and their children. This information was collected, on condition that it would not be available to anyone outside the group of researchers. It must be assumed that the participants in the study, when agreeing to participate, believed that this agreement would not unilaterally be broken by the other party.

For those actually conducting clinical medical research dealing with sensitive records, it is not surprising that this type of promise was issued within the framework of Gillberg's study. This kind of assurance of confidentiality to participants constitutes the basis of what we refer to as research ethics, and it has constituted practise within clinically oriented medical research for decades.

The authorities charged with ensuring that these type of undertakings of confidentiality re issued are called ethical committees. We admit that ethical review of research was not regulated in law until 1/1 2004, but there can nevertheless be no doubt about the state's intention that researchers should let ethical committees review medical projects before their commencement, and that researchers should follow the committees' recommendations.

This relationship is demonstrated among other things by the fact that medical researchers have been obliged for decades to get projects reviewed and validated by ethical committees in order to receive research funding from the State financing authority, the Science Council (previously the Medical Research Council). The state's commitment to the ethical committees' work is also illustrated by the fact that the committees are often tied to universities.

That the ethical committees' activities have been considered an expression of exercise of authority is supported in the introduction to the new research ethics law:

“In practise the medical research ethics committees' work has long had the nature of exercise of authority”

We have obtained a large number of so-called participant information leaflets that have been approved by ethical committees around the country in recent decades. This review shows with all desirable clarity that undertakings of confidentiality of the same type that were issued in Gillberg's study are commonplace. There are probably thousands of studies based on this kind of promise. For practical reasons we do not enclose this extensive documentation as a whole: for some illustrative examples (from the year 2004) see however p. 19-20 in this letter.

The ethical committee at Gothenburg University has in recent years, until it was dissolved and replaced by an ethics examination board, laid out instructions to researchers on their homepage concerning the formulation of a participant information leaflets. These instructions stated among other things how researchers should inform participants about who would gain access to the collected data.

That it actually has been the ethical committees' policy to call upon medical researchers to issue far-reaching undertakings of confidentiality is also demonstrated by the enclosed letter (to Gothenburg University Principal - annex 1) and debate article (annex 2), written by emeritus Professor Carl-Gerhard Gottfries. He was chairman of the research ethical committee in Umeå for several years, and then had a corresponding position in Gothenburg for several years. Gottfries was, for example, chairman of the same ethical committee that dictated and/or validated participant information in the Gothenburg survey.

It is clear both that undertakings of confidentiality of the type Gillberg issued have been commonplace in clinical medical research, and that researchers have been called upon to issue them by concerned authorities. Nevertheless, the picture in debate and in the media has been the opposite. The impression the general public has been given is that the promises Gillberg issued were unique to his study, and that he should be blamed for having issued them.

When the journalist Maria Louise Samuelsson in the paper "Today's Research" (11/2003) described Gillberg's actions, the headline on the newspaper's front page was:

"Researchers defraud parents"

Retired military doctor Michael G Koch has described the issue thus in "Today's Medicine" (26/5 2004):

"... that the principle of openness (that regulates the state's activity, to which the university research belongs, should be scrutinized) bears more weight than individual - incompetent researchers' inadmissible promises. Being informed about which laws govern his activity should be included within a researcher's competence."

And the sociologist Eva Kärfve has stated in a debate article in "Today's Medicine" (15/10 2003):

"This promise was signed by Christopher Gillberg and Lars Hellgren, the latter now a medical expert on the National Board of Health and Welfare, but previously Gillberg's doctoral student. Nothing, least of all any ethical committee, forced the researchers to give such a promise. Neither was it in accordance with the law of confidentiality."

Kärfve's statement should be read side by side with the article of Gottfries. Her assertion that ethical committees do not require this kind of promise is untrue.

It is unfortunate that individual debaters, in aiming to damage Gillberg, choose to disregard the fact that Gillberg and employees, when they issued the promises in question, followed the authorities' existing practise. But what is far worse is that those public officials most closely responsible for ensuring the implementation of this type of promise have not maintained this state of affairs, but instead have agreed with the misleading criticism of Gillberg. We shall return to this below (point 3D).

*B. May undertakings of confidentiality be broken?*

We have made it clear above that criticism aimed against Gillberg for having *issued* the undertaking of confidentiality is misdirected. In this section we will discuss whether the criticism associated with whether he *should have broken* this promise is more justified.

Ethical investigation was not regulated in law until 1/1 2004, but in reality it was still mandatory for two categories of researchers: all those who work with clinical medical research, and for all researchers, irrespective of discipline, whose projects are financed by the Science Council. After 1/1 2004, ethical examination was statutory.

It is central to all research ethics regulations that individuals who voluntarily accept participation in a research project not will be subject to anything to which they have not agreed beforehand, unless they later accept that changes will occur. This applies to regulations which forms the basis for ethical committees' work, as well as for the new ethics examination law,

If Gillberg and Gothenburg University had submitted the documents to unauthorized individuals, contravening the promises they had made, they would undoubtedly have broken current medical research ethical rules. Gillberg would moreover have broken the ethical rules that apply to doctors undertaking research, the so-called Declaration of Helsinki, which the Swedish State, in various contexts, advises medical researchers to follow.

The document "Guidelines for Ethical Evaluation of Medical Human Research" published by the state authority Medical Research Council (now Science Council) 1996, revised in 2003, discusses the importance of the information study participants receive before their decision to participate - informed consent - and the ethical committees' central role in this context. This summary is prepared by Professor Göran Hermerén and Paul Hjelmdahl, and revised by Professor Giesela Dahlquist.

Quotations from this document:

"The information to patients and research participants has to be so easily understandable and adequate that they themselves can decide whether they choose to participate or not."(p. 13) (from the Helsinki Declaration)

"It is the doctor's obligation to set the research participants' health and wellbeing before the interests of the research."(p. 13) (from the Helsinki Declaration)

"The information is to be 'matter-of-fact' and above all easy to understand for the receiver."(p. 18)

“Incorrect, incomplete or misleading information breaks the fundamental ethical principle of personal integrity!”(p. 28)

“The condition for an individual to take a position independently about their participation in a research project is that s/he has been informed about what this participation means and that s/he has understood this information. This is the reason for the strong emphasis on the requirement that the information will be understandable for the ordinary person. In the USA for example it is required that the information is easily understandable for an averagely gifted sixth grader.”(p. 28)

“... it is the researcher's responsibility to assure that the information has been understood in the correct way.”(p. 29)

“The central principle is that the information should contain whatever reasonably can be intended to influence the research participant’s position.”(p. 30)

“The participant shall himself/herself be able to form a concrete view about possible discomforts and risks.”(p. 30)

“It is important that the information is checked carefully by the ethics committee that takes a position on the project.”(p. 31)

“The condition for the consent to be valid is that the participant has correctly understood the information, ie what the participant agreed to....” (p. 34)

“New consent must of course be received - and new information given if changes take place in the project's arrangements and aims of such a kind that it can be expected to influence the research participants’ willingness to continue to take part.”(p. 36)

“The ethics committee must approve the change, before it applies in the project.”(p. 36)

“The research participants have through agreeing given their approval to use the information for just that purpose which was described when the consent was acquired. If the purpose is changed a new approval is required.”(p. 37)

“Confidentiality in this context requires professional secrecy and document confidentiality, but usually implies more than legal protection (the information is protected by confidentiality although the requirement cannot be related to any specific section in the law).”(p. 40)

“With each application [to the ethical committee; our words] the information one intends to give to research participants and/or patients will be enclosed. ... particularly important is the fact that the information is understandable and genuine.”(p. 71)

With respect to confidentiality it is also clearly expressed in this text that researchers “may not promise more than the researcher can maintain” (p. 40).

One of the authors of this text - Professor Göran Hermerén – has, in his capacity as Science Council expert, played an important coordinating and policymaking role within the area of research ethics for many years. He can therefore reasonably be expected to know that the type of undertaking that Gillberg (among others) gave has been a normal occurrence within medical research for decades. From the wording that “one may not promise more than one can maintain” we must therefore conclude that, at least until very

recently, the Science Council's view was that that the type of promise Gillberg made should not to be regarded as promising more than he could maintain.

That the physician/researcher - in the current case Gillberg and co-workers - have a *personal* ethical/moral responsibility to protect the integrity of the participants in research projects is stressed also in the Medical Research Council's document. Among other things, it quotes the following passages from the Declaration of Helsinki, aimed directly at the individual physician/researcher, and regulates what must be aspired to:

"The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject."(p. 41)

In the Declaration of Helsinki the following is also stressed:

"In medical research on human subjects, considerations related to the wellbeing of human subjects should take the precedence over the interests of science and society."

"It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject."

"Research investigators should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements. *No national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this declaration.*" (Our italics.)

Also if we search the Science Council's homepage, and find the page dealing with research ethics (<http://www.codex.vr.se>), we find that the state sees reasons to emphasise the individual researcher's responsibilities:

"A researcher's work is regulated by more or less constraining rules and regulations. One could nevertheless say that the researcher's own ethical responsibility in a sense constitutes the basis for all research ethics. *The researcher has himself the ultimate responsibility for ensuring that the research is of good quality and morally acceptable.*" (Our italics.)

From the above we can see that representatives of the Swedish Medical Research Council/Science Council consider it important that the ethical regulations for medical research are followed. Among other things this means that promises issued to participants should not be broken, and that the protocol of a project may not be changed without the participants' agreement. This was regarded as important at least until the media debate around Gillberg's study made it inopportune to defend this position in public.

It is clear to us that an undertaking of confidentiality cannot eliminate a legally grounded release of documents in a strictly legal sense. But we consider that we have shown through the arguments given above that a researcher, ordered to break an undertaking of confidentiality, is actually obliged to defy such a request for ethical and moral reasons if he considers that he will damage the participants by breaking the promise. This position is validated by passages quoted from the Helsinki Declaration's:

*"No national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this declaration".*

As will clearly be shown below we within the medical community are not alone in expressing this opinion.

To sum up, we have shown above that the authorities that formulated and implemented the rules applying to the conduct of clinical medical research:

- a) called upon researchers to issue the type of undertaking of confidentiality that Gillberg issued,
- b) clarified the importance of promises not being broken, and
- c) saw reasons to emphasise the individual researcher's personal responsibilities in order for the ethical rules to be followed.

If we assume that the regulations for clinical medical research applied in Sweden for the past 30 years has been an expression of the state's and regulatory office's intentions, Gillberg and employees thus acted ethically and were legally correct when they stated that they could not participate in releasing the current documents.

*C. How did the central ethics examination board in Gothenburg view the confidentiality questions in spring 2004?*

The judgement in the Administrative Court of Appeal dictating that Gillberg's group's records should be released, despite the participants having been assured that no outsider would gain access to them, led, as shown above, to Gillberg and co-workers being blamed in the media for having issued these promises, and being accused of unacceptable legal ignorance.

We have demonstrated that this criticism is unfair, in so far as Gillberg's group's promise was entirely in accordance with undertakings issued by other researchers, and was entirely in line with the demands of ethical committees. The criticism aroused by Gillberg's supposed ignorance of legal matters made us question how legally competent people think we should inform participants in research projects, while avoiding the risk of them being misled if an Administrative Court of Appeal judgement again determines that sensitive information should be released to unauthorized people.

On January 1 2004 a possible way to find out emerged. On this date the new research ethics legislation was enacted. This, among other things, meant that the former ethical committees were replaced by judicially led ethics examination boards. Through taking a sample of a number of participant information sheets approved by these judicially led boards we hoped to find guidance on how legal experts consider an undertaking of confidentiality should be formulated in order to be compatible with Swedish law.

We therefore obtained a handful of participant information sheets sanctioned by the ethics examination boards in Gothenburg in early 2004. The outcome of this study was amazing. It showed that the ethics examination boards - as late as spring 2004 - had approved several participant information forms indicating undertakings of confidentiality of same type that had been issued of Gillberg more than 20 years earlier:

"Only researchers in direct connection with the study will read the collected texts" (dnr 074-04)

“Self-evidently only treating personnel and no one else will have access to your questions and replies.”(dnr 008-04)

“No one except treating personnel will have access to your record.”(dnr 097-04)

Especially notable is a decision, signed by the ethics examination board's manager, stating that a certain researcher might implement a certain project only on the condition that he – for reasons of confidentiality - must destroy the collected information directly after completing the project:

“Decision: Approved on the condition that the material is destroyed after survey completed” (dnr 073-04)

Shortly after Gothenburg University was instructed by the Administrative Court of Appeal to release highly sensitive documents, more than 10 years old, breaking promises that had been made, a judicially led ethics examination board required that another researcher promptly destroy less sensitive information in order to avoid offending the integrity of participants.

This inconsistency in exercise of authority could possibly have been explicable if the ethics examination board considered the judgements in the Administrative Court of Appeal to be incorrect. Against this supposition is the fact that that judge who announced the current judgements in the Administrative Court of Appeal, and who vigorously defended them in the media, is Gunnar Dyhre, and that that the ethics examination board's manager, who among other things signed the decision that meant that a researcher must destroy collected data directly after the collection, is the same Gunnar Dyhre.

In letters to the regional ethics examination board (annex 3) we pointed out that the participant information sheets it had sanctioned were inconsistent with the judgement announced by the board's own manager in his capacity as administrative Court of Appeal spokesman. Probably as a result of this the board developed a model for participant information forms which researchers henceforth were instructed to follow. According to this form, researchers were to assure participants that “no unauthorized person” will come to gain access to the documents. The thought behind this wording is presumably that a person allowed by the Administrative Court of Appeal to access the documents thereby becomes “authorised”, even if he – as in this case - is a private individual who wants to read the documents in his spare time. There is reason to return to the appropriateness of this wording (see section 10C).

Unfortunately it is clear, however – from the same model developed by the ethics examination board - that one should assure participants that only “the principal investigator” would have access to any possible code list, in the event that results are encoded. If the judgement by the Administrative Court of Appeal - that sensitive, non-coded records should be released - is correct, one can of course not ensure that in the future only principal investigators will have access to code lists. Possible code lists are of course as much public documents as other documents, and could surely be requested in the event that someone sees himself compelled to investigate whether research fraud has occurred. If Dyhre’s judgement in the Administrative Court of Appeal is correct, no one can anticipate whether any court in the future will allow unauthorized people to access

code lists. To assure participants that only the principal investigator will have access to the code list is therefore to give false assurance.

After first having taken part of a sample of participant information forms from the regional ethics examination board (see above) we later requested all validated participant information from 2004. Despite these being public documents the judge on the board to which we produced our application requested that we withdraw our request, partly because handing out the documents would mean additional work for the board's secretariat, and partly because she disapproved of the aim of our request:

“Your request to receive all patient information about examined cases for 2004 is not aimed towards progress, but is interpreted rather as a wish to find wrongdoings and to attack the spokespeople of the board. Your request will also mean a huge additional workload, especially for our overworked secretariat which will harm the work with ongoing cases. I therefore hope you will withdraw this request.”

After we pointed out to this judge that she did not have the right to question our reasons, or to persuade us to withdraw our request, we finally received the documents. The documents showed that after we had pointed out that earlier promises were not in accordance with judge Dyhre's decisions in the Administrative Court of Appeal, hundreds of researchers, at the request of the ethics examination board's had assured participants in research projects that only “principal investigators” would have “access” to possible code lists during 2004. If the day should come when the Administrative Court of Appeal announces that some of these code lists will be released to unauthorized people, the principal investigator in question - through the agency of the ethics examination board - will be put into the same ethical predicament as Gillberg has been, as discussed in this document.

We have difficulty seeing the administrative Court of Appeal judge Dyhre's actions in the Administrative Court of Appeal and in the ethics examination board as anything other than a legal failure. However it will be said that his and the board's incapacity to formulate a satisfactory proposal on how future undertakings of confidentiality should be formulated - assuming that Dyhre's own decisions should be considered correct - is an incapacity he seems to share with all other so-called experts on research ethics and research confidentiality (see section 10C).

On the fact that Dyhre instructed a researcher to destroy collected data immediately after the study's completion he chose to comment thus (Today's Medicine 16/3 2005):

“The case lacks general interest and can definitely not be taken as a justification for some general right to destroy research material.”

We certainly share Dyhre's view that his decisions cannot be taken as justification for some general right to destroy research material, but we do not share his opinion that the case lacks general interest. On the contrary it is of great general interest that the same judge who showed so little understanding for Gillberg's failure to release records, in another context found the defence of individual confidentiality so pressing that he required newly collected data to be destroyed immediately after the study's completion.

As a concluding comment, we do *not* consider that the promises issued by the board are too far-reaching. On the other hand it is clear that one cannot defend these promises, and

at the same time maintain that the judgements announced by Dyhre in the Administrative Court of Appeal are correct.

D. *The unwillingness of representatives of authority to acknowledge their own regulations*

The authority most likely to be considered to be responsible, if undertakings of confidentiality issued within Swedish medical research during the last decades actually have been too far-reaching, is as far as we can assess, the Medical Research Council/Science Council. It has not, admittedly, functioned as the monitoring authority for the ethical committees, but a central ethical board existed at both the Medical Research Council and latter the Science Council. This board has had an important policymaking role with respect to the Medical Research Council and latter Science Council's work.

The above mentioned document published by the Medical Research Council - "guidelines for ethical evaluation of medical human research" - illustrates this relationship, as in the following quotation from this book:

"The board's [within the Medical Research Council] purpose is to coordinate the working of research ethics in the country, and to discuss and make assessments in principle of individual cases remitted to the board as well as initiate courses and policy discussions. ... Questions of co-ordination are important, so that similar projects will get similar treatment in the all the country's committees. ... An example of a coordination question is... *formulation of information to research participants and patients*" (p. 56) (our italics)

There would have been a huge advantage to Gillberg if the representatives of the Science Council had admitted that the type of promise he had issued was in no way exceptional, and that the promise was entirely in accordance with implemented practise by the Medical Research Council/Science Council. The attempt at character assassination in the media, implying that he had illegitimate motives for assuring confidentiality, and/or for not breaking these promises, would have disappeared. Unfortunately the representatives of the Science Council have, however, not only omitted to present these actual facts relevant to the case, but they have made unjustified and misleading statements that must be interpreted as dissociating themselves from Gillberg's actions.

The Chairman of the Science Council's ethical group is currently Professor Göran Hermerén. His importance in the implementation of the ethical regulations which led to Gillberg and other researchers assuring confidentiality to participants in studies is illustrated by the fact that he is one of the authors of the above-mentioned document.

When Gillberg was sentenced by the Administrative Court because he had not taken part in handing out the records in question, Hermerén did not in any way express any kind of self-criticism on behalf of himself or the Science Council. Instead, in a large number of newspapers (for example the Gothenburg Post 28/6 2005) he gave the following picture of how he viewed the issue:

"One consequence of the judgement is that the researcher must learn which rules apply in the future and will need to abstain from making promises s/he cannot keep."

Hermerén has also commented on this in Swedish Broadcasts, for example in “Studio 1” on 27/6 2005. The reporter asks the two guests in the studio, Hermerén and Professor Martin Ingvar, the question whether they, in Gillberg's situation, would have submitted the documents. “Never in my life” replies Martin Ingvar. “I believe, unlike Martin here, that the researchers possibly promised more than they should”, replies Hermerén.

In November 2005 the Science Council arranged a hearing about problems handling sensitive research material. The summary of this meeting on Science Council’s homepage begins thus:

“In November the Swedish Research Council's ethics committee arranged a hearing about problems handling sensitive research material. The question has been raised again after the so called Gothenburg Affair, when unauthorized people were given the right to get access to sensitive research material collected at Gothenburg University concerning ADHD/DAMP, after two decisions in the Administrative Court of Appeal. Professor Göran Hermerén, chairman of the Swedish Research Council's ethics committee, clarified a basic rule already at the introduction to the hearing: “one can never give an assurance that no individual, outside the group of researchers, can ever gain access to sensitive material”, said Göran Hermerén.”

There is no doubt that Hermerén is addressing Gillberg. Instead of admitting that Gillberg's promises were entirely in line with the practises for which Hermerén alone carries a significant responsibility, this representative for Science Council, instead associated himself with those who criticise Gillberg for legal ignorance.

The two questions that should be asked of Hermerén, in the light of his statements, are

- 1) why he, as leader in the area of research ethics for many years, never intervened against the fact that that type of promises Gillberg had issued became standard practise, and
- 2) how one instead should formulate that section about participant information that deals with confidentiality.

We shall return to the latter question (10C).

It is important to bear in mind that Hermerén’s statements on this matter, if they actually reflect the Science Council’s views on these questions, indicate a drastic change of course, in so far as that the authority that makes policy within the area of research ethics in Sweden no longer considers that Swedish researchers/doctors should follow the Declaration of Helsinki as reflected in the quotations on p. 16-17. If this view by Hermerén has force it will hardly be possible from now to carry out clinical medical research in Sweden in a manner acceptable to the international community.

Another important person in the ethics work within the Science Council is its expert, Björn Thomasson. Thomasson has also not found reason to defend Gillberg when he was faced with the requirement to break the undertakings of confidentiality. In an interview in Gothenburg University ' newspaper (Gothenburg University Magazine, 15/6 2004) he was quoted thus:

“When it comes to the Administrative Court of Appeal's decisions in The Gillberg case Björn Thomasson sees nothing strange. The laws concerning confidentiality and openness have existed for many years.”

“So there is nothing wrong with the laws, according to Björn Thomasson.”

“The problem is that Gillberg has given assurances that he evidently had no right to give. One cannot promise that the material will not be scrutinized by someone outside the research group. He has simply gone too far.”

This statement by Thomasson has, as one could predict, been used by Gillberg's critics, for example in an article in the Gothenburg Post (19/1 2005), by the journalist Lars Nicklason:

“Björn Thomasson, the Swedish Research Council's ethics expert says for example: “The problem is that Gillberg has given assurances that he actually had no right to give. One cannot promise that the material should not be scrutinized by someone outside the research group. He has simply gone too far.”

We find the situation that has emerged Kafka-esque. The Science Council requires that one must acquire ethical approval from the ethical committee in order to receive a grant from the authority. And the ethical committee requires that one should issue the type of undertaking of confidentiality which Gillberg has offered (which has been attested by CG Gottfries, see annexes 1, 2). But when Gillberg, suffering in a slander campaign, is attacked by the media for having issued this type of promise, the representatives of the Science Council agree with the criticism.

Thomasson's statement can only be interpreted as meaning that Gillberg's promises diverged from the standard ones, which is demonstrably not true. It is also notable that Thomasson's opinion that there is “nothing wrong” with the current judgements in the Administrative Court of Appeal is not shared by prominent legal advisors who have assessed them. Thomasson is not a legal advisor.

In another issue of the same newspaper another ethical expert attached to the Science Council is interviewed: a member of the workgroup on dishonesty in research, emeritus Professor Birgitta Strandvik. In connection with the requirement for release of records from Gillberg's archives Strandvik gives advice about how one should proceed as researchers when wishing to release confidential documents to others than those first agreed to with the participant/patient:

“She considers that one has great power as a doctor/ researcher. If one is subjected to review of confidential material I believe that one can to speak to the participants: “you can rest assured, those who look at the documents will not take this further. They are bound to secrecy.”

The statement is of interest so far as it illustrates that one can possess a central position in an ethical body within Science Council without being familiar with the most basic research ethical principles. One must never try to persuade participants in studies to accept something they have not accepted before a project has started, and one may definitely not use one's “influence” as a doctor and researcher. These are the most central of the ethical rules concerning medical research.

The Science Council, as far as we can tell, has not collectively made a formal statement on this matter. On the other hand, those statements which have been made by individual representatives of the Science Council have given a uniform picture, signifying that they consider Gillberg should be blamed for having issued undertakings of confidentiality which were too extensive, and/or that he should have broken his promise.

The ignorance about important ethical principles within the Science Council, paradoxically enough, seems to apply to those individuals within the authority that are considered ethical experts. Concurrently with the ethics expert Thomasson announcing in the media that he found “nothing wrong” with the judgement in the Administrative Court of Appeal which was later questioned by several legal experts, the Principal of Gothenburg University was called upon by the chief secretary of the medical unit within the Science Council (now Principal of the Karolinska Institute) and the former assistant secretary for the medical unit (now the Science Council’s chief secretary). These two representatives of the Science Council expressed to the Principal their great concern for Swedish medical research if the University should submit this type of documents to a private individual, which of course was what the judgement in the Administrative Court of Appeal intended. The fact that Thomasson publicly put forward the view that the judgments in question are entirely unproblematic, at the same time that the highest representatives of medical research within the Science Council expressed an entirely different view in deliberations with Gothenburg University’s Principal, is distressing.

Freedom of speech probably gives the right for ethics experts at the Science Council to express their opinions freely to the media. In our opinion it is, however, urgent that there should be people in authority who with knowledge, consistency and integrity monitor the protection of research participants’ legitimate interests, even when such a position is inopportune. Against this background, we find it discouraging and worrying that none of the representatives of the Science Council who have special expertise within the area of research ethics have been able to publicly state what for most medical researchers is all too self-evident - i e that it is ethically impossible to break an undertaking of confidentiality.

#### **4. The legal process**

##### *A. The requirement to release (the research records)*

The current case began substantively during 2002. The sociologist Eva Kärfve and the paediatrician Leif Elinder had been launching strong attacks on Gillberg for some time in the media in connection with their disapproval of his supposed opinions on attention disorder, and in particular his supposed opinions on the condition's causes and treatment. It was, however, not until 2002 that they first both realised they could also accuse him of research fraud.

No convincing argument that Gillberg and his employees have committed fraud has ever been presented, and this will be discussed in detail below. This is also the conclusion that Gothenburg University came to, having investigated the accusation in accordance with current regulations. Gillberg is thus exonerated from the stated accusations.

In parallel with Elinder and Kärffve requesting that Gothenburg University should investigate the accusations of fraud made by them - which then came about - the two requested that they should personally get access to the confidential records.

As shown above (p. 17-18) current ethical regulations for medical research indicate that showing records to outsiders, if participants had not been informed in advance it would happen, must be preceded by them giving their permission, and it should be approved in a specific order by an ethical committee. Elinder and Kärffve, however, opposed the participants being consulted, and also opposed their application to read the records being passed for assessment to the ethical committee.

After Gothenburg University rejected Elinder's and Kärffve's application for reasons of confidentiality, the case ended up at the Administrative Court of Appeal in Gothenburg.

### *B. The Administrative Court of Appeal's first decisions*

On the 6/2 2003 the Administrative Court of Appeal in Gothenburg announced the two above-mentioned decisions that meant that both Kärffve and Elinder could get to gain access to the records. Gothenburg University applied to the Supreme Administrative Court for legal review, but this application was rejected on the grounds that an authority can not appeal against an Administrative Court of Appeal judgement. Christopher Gillberg also applied for legal review, but this application was rejected with the justification that he was not a party to the case, and therefore did not have the formal right to appeal. Some of the study research participants also applied for legal review, but this also was rejected, with the same justification.

Whether a release of the documents to Kärffve and Elinder is compatible with current law was thus only examined once, by the same Gunnar Dyhre who - in his capacity as chairman of the ethics examination board - shortly afterwards instructed another researcher, for reasons of secrecy, to destroy the information collected immediately after the study's completion (see above).

### *C. Was the Administrative Court of Appeal's decision on the case correct?*

As has been expressed by one of us (EE) in debate articles (the Gothenburg Post 10/7 2003, the Express 14/7 2004, Today's Medicine 23/2 2005, Today's Medicine 27/4 2005) there are several reasons to assume that the judgement in the Administrative Court of Appeal that the records should be released to Kärffve and Elinder was wrong. The responses written by the man who pronounced the judgement, Gunnar Dyhre (Today's Medicine 16/3, Today's Medicine 13/4 2005), strengthen our view that the above mentioned decision was not based on a sufficiently careful analysis of the legal situation.

Professor of Medical Law, Elisabeth Rynning, is probably Sweden's leading expert on the current legislation. Her analysis of this case, which is appended, constitutes strong support for the position that the decisions are incompatible with Swedish law (annex 4).

Reasons to question the judgements in the Administrative Court of Appeal include the following:

#### *1) Referring to the wrong paragraph*

As pointed out by Rynning, advice on this type of data confidentiality accords with Secrecy Law 9:4. The only situation when there would still be any question of releasing this type of information is when it will be used for “research purposes”.

That the Administrative Court of Appeal actually assumed that both Elinder and Kärffve are *researchers* is supported by the fact that Gunnar Dyhre commented on TV (debate 16/9 2003) that the Administrative Court of Appeal judgement, when he announced it, assumed that both Kärffve and Elinder are researchers.

On the other hand, Section 9:4 is not mentioned in the judgements in the Administrative Court of Appeal. Elisabeth Rynning discusses in her analysis possible explanations for this lapse (p. 477).

Dyhre's assertion that both Kärffve and Elinder are researchers is not correct. Elinder is not a researcher, and has never presented himself as a researcher. That Elinder was a researcher is thus something which Administrative Court of Appeal judge Dyhre incorrectly assumed, without having any reason for this assumption.

When this latter faux pas was disclosed Dyhre, in public debate, changed tack, and stated that it made no difference whether Elinder intended to use the information for research or not (Today's Medicine 27/4 2005). As far as we can assess, there is however no support for this view in law.

### *2) The Administrative Court of Appeal was wrongly informed concerning the aim of Kärffve's review*

As regards Kärffve the decision is based on the Administrative Court of Appeal being given the impression that she wished to check the documents within the framework of a research project at Lund University with Professor Thomas Brante as the responsible authority. As is discussed below the Administrative Court of Appeal appears, however, in this regard, to have been misled by a misleading certificate signed by Thomas Brante (annex 5). According to what later emerged Kärffve's activity did not form part of the Brante project. Also, the judgement concerning Kärffve was based in this way on the fact that the court had misunderstood the motive for her review.

The Administrative Court of Appeal cannot be blamed because it was presented with a misleading certificate. If it had had knowledge about the regulations governing clinical medical research however, some of the parties, or the court, should have reacted to the fact that Kärffve claimed that her activity constituted part of a of Science Council-financed research project, but that it still had not been subject to ethical review. The Science Council requires that researchers financed by the authority should subject their projects to this process.

### *3) Conditions for the representation of an authority had not been established for Kärffve*

In a debate article Dyhre underscored the importance of the fact that Kärffve was considered a representative of Lund University by the court:

“Eva Kärffve (OAK) is senior lecturer at Lund University. She wrote her application on University headed paper and stated in her application that the institution's managers supported her research programme. She stated further that the current research was

judged so urgent that it received a grant from the Swedish Research Council.” (Today's Medicine 16/3 2005)

Despite this the court instructed Gothenburg University to formulate which conditions would apply to a release of documents. Later certain of these conditions were approved by the Administrative Court of Appeal (see below).

As pointed out by Rynning (p. 482) however, conditions can not be issued about the act of transfer of information from one authority to another. This faux pas also indicates that the Administrative Court of Appeal did not have sufficient competence to process the case, with unacceptable consequences for individuals as a result.

#### *4) Reverse indemnity was not met*

“Reverse indemnity” applies to the type of information collected about the participants in Gillberg's study, according to confidentiality law, i e this type of information may be released only if it:

“is clear that the information can be disclosed without the person whom the information concerns, or someone close to him, suffering damage or injury” (which also means discomfort or aversion; our remark).

There are, however, five reasons why, in the current case, it can not have been possible for it to have “been clear” for the court:

A) The information contained in the records was of a very sensitive nature and did not concern only the informant but also their children. B) The participants had submitted the information on the premise that it would not be distributed further. C) The people who had requested to gain access to the information had not explained how they intended to proceed with it. D) The people who asked to gain access to the information had not allowed their proposed investigation to undergo ethical examination. E) The people who had asked to gain access to the information, following their earlier roles in the debate, were considered suspect by many people suffering from the disabilities in question and their relatives, as illustrated among other things by statements made by the interest group “Riksförbundet Attention”. F) As evidence – in retrospect - that it cannot have “been clear” to the court that no harm would arise if the documents were released it can also be stated that a large number of the participants approached Gillberg instructing him not to release them; some, moreover, had requested legal review or injunctions in the supreme administrative court and the EC Court of Justice. In so far as Gunnar Dyhre endeavoured at all to try to assess whether there existed a risk that the participants would feel negative about a release of documents, his assessment was incorrect. As has been pointed out by Rynning (annex 4) the Administrative Court of Appeal chose, moreover, to disregard the fact that new unambiguous information in this respect had been forthcoming when it later announced new decisions concerning conditions.

It can finally be stated that the decisions – if they are correct - mean that all those countless researchers, legal advisors, officials and ethics experts that for decades have contributed to current policy for formulating participant information (see above) can never have reflected on whether these are in accordance with Swedish principles of access to public records or not. Alternatively they have, in this regard, jointly made themselves guilty of a gigantic legal misjudgement.

If we take the secrecy law's reverse indemnity seriously it should mean - according to our understanding - that release of records with less than that the participant's expressed permission can almost never be permitted, especially when the collected information is as sensitive as that in the current case. And this is *de facto* what ethical committees imposed on practise in medical research: no assessment is implemented, beyond what participants gave consent to, without the participants being asked again.

That this is a reasonable way to interpret reverse indemnity shows, albeit from a somewhat different context, of the introduction to the research ethics legislation which came into force on the 1/1 2004:

"... In secrecy law 7 chapter 1§ it is decreed that confidentiality applies within health and disability services to information about individual health conditions or other personal circumstances, if it is not clear that the information can be disclosed without the individual or someone close to him suffering injury. This is a so-called reverse indemnity, which means that one must often question patients about whether one wants to use information in records for research."

Our assessment of judgements in the Administrative Court of Appeal is, in summary, that they were incorrect, and in conflict with the intentions of legislators. We consider that the enclosed article by the professor of medical law, Elisabeth Rynning, gives convincing support to this position (annex 4).

As well as Rynning, other prominent lawyers have questioned the judgements but we know of no jurist in the debate concerning this case who has asserted that they are correct - apart from Gunnar Dyhre who pronounced them. On the other hand, many players, for example Gillberg's antagonists, the Press Ombudsman and representatives of the Science Council, have seen reason to stress in the media that the decisions were an entirely natural consequence of current regulations.

#### *D. Consequences of the Administrative Court of Appeal's decisions*

If judgements in the Administrative Court of Appeal are compatible with Swedish law the implication is that not only the participants in Gillberg's study had the wool pulled over their eyes when they were consulted about participation, but also several thousand other research participants in other studies have been similarly misled. When we asked the chairman of the ethics examination board in Gothenburg, Gunnar Dyhre, if he saw this situation as worrying, his reply was the following (annex 3):

"The circle of people - in addition to participating researchers - that can get to gain access to confidential information is so small that there is no reason to make any obvious changes to the advice that has been accepted until now."

What Dyhre means by "obvious changes" is unclear. At a guess he means that the advice will not be changed at all, and that the participants, in the main, will not be informed that they have had the wool pulled over their eyes.

There are reasons to speculate about why Dyhre considers that the risk is small that new decisions similar to those announced in Administrative Court of Appeal will arise. The question that should be analysed here is whether in this particular case there were such *specific circumstances* concerning the documents in Gillberg's archives that there are

reasons to believe that others who demand this type of documentation will be less successful than Kärffve and Elinder, and if so what these special circumstances are.

1) Can we, for example, imagine that Dyhre considered that the information this current case concerned was not of a particularly sensitive nature, and that therefore a release was acceptable, despite the fact that the participants were not consulted? No, it is impossible to assert this. The current information was without doubt of an exceptionally sensitive nature.

2) Can we instead imagine that Dyhre considered that in this specific case there were particularly strong reasons for the documents to be released, despite this being a violation of the participants' integrity? No, this also appears improbable, given that Dyhre seems to have had a very diffuse picture of why Kärffve and Elinder wanted to gain access to the documents. As a matter of fact he had never understood that the background to their application was that they alleged fraud, according to what he emphasised afterwards (SVT debate 16/9 2003) and in newspaper articles. And even if he had actually understood this he ought - hopefully - to have realised that few people were less suitable to investigate an accusation of fraud than those who put forward the accusation. As regards Elinder's expressed reason to wish to read these research records - i.e. that he wanted improve himself in his occupation - it must be impossible to consider that this has particularly heavy weighting. If that were sufficient reason to get to gain access to sensitive, confidential research records hardly any health service employee could be denied access to this type of material.

3) Can we instead imagine that Dyhre considered that this case was special, in so far as those who requested the documents were specifically qualified to handle this type of information, and particularly competent to gain access to it, and that one therefore could assume that the participants should not have anything to object to? No, this theory is also improbable. Kärffve has, as far as we know, never devoted herself before to research involving the handling of sensitive personal data, which is among other things illustrated by her ignorance about current ethical regulations. As regards Elinder, he is admittedly a physician, but in this matter he acted as a private person. Those discussions that took place in connection with health service staff illegally taking part of Swedish minister Leif Blomberg's and Anna Lindh's health service records, and the legal aftermath to these events, illustrate the fact that if one normally handles confidential sensitive materials in one's work it does not mean that one is authorised to gain access to such information when it is not required in order to conduct one's health service duties.

4) Can we finally imagine that Dyhre considered that just Kärffve and Elinder were so extraordinarily confidence-inspiring, as people, that they could be entrusted with this sensitive information without the participants being consulted first? This is also improbable. Thus, the negotiations in the Administrative Court of Appeal appear not to have concerned Kärffve's and Elinder's personal characteristics at all.

5) A last possible explanation is that Dyhre considers that the circle of people who can get to gain access to sensitive information is so small that it does not matter that participants in thousands of studies have been misled, perhaps because he does not believe that it will be particularly often that this type of data is requested. But this explanation is also improbable. Dyhre has, in a debate article in the Gothenburg Post (3/7

2003), stressed that he sees it as quite natural that researchers should get access to raw data from each other's studies:

“It may according to my personal view be considered clear that researchers at other places of learning or active in other places than where certain research been carried out should be able to gain access to material that forms the basis for theories that have been proposed.”

(It should be noted that this was written after Dyhre had announced the verdicts, but, it appears, before he had realised that the Leif Elinder that he judged to have the right to gain access to the documents was not a researcher).

To summarise, it can be established - if judgements in the Administrative Court of Appeal are considered to constitute a correct interpretation of the law – that the University's conclusion should be that it henceforth should not deny the release of sensitive research documents to anyone who produces a request to the institution to gain access to such documents, and who promises to not to distribute the acquired information any further. It is amazing that Dyhre, against this background, does not see it as worrying that participants in thousands of studies have actually been assured that this type of information will not be released to any outsider.

#### *E. Why the Office of the Chancellor of Justice should analyse the judgements in the Administrative Court of Appeal*

In summary, we can identify several reasons why it is urgent that the Administrative Court of Appeal verdicts that Kärfve and Elinder should gain access to the documents in Gillberg's archives should become subject to the Office of the Chancellor of Justice's analysis:

1. The verdicts have far-reaching and serious consequences for individual people. As regards Gillberg have they not only meant that he has been indicted and sentenced, but he has also been identified in the media as a supposed research fraud.
2. The verdicts have created anxiety among those elements of the public who have submitted sensitive information in connection with research projects. Furthermore the view has arisen from the media attention around this case that those undertakings of confidentiality issued by public officials in connection with them being consulted about whether they wanted to participate will perhaps not be tenable.
3. The verdicts seem - to judge by statements made by representatives of the Science Council and National Agency for Higher Education - to be able to influence the authorities' views on how much confidentiality one can and should promise in connection with clinical research.
4. Trust in that authority which announced these decisions must be considered to have been shaken by that fact that that the judge who signed the verdicts shortly later, in his capacity as chairman of an ethics examination board, took a decision that another researcher could implement their project only on the condition that the data be destroyed immediately after collection.
5. Several leading lawyers have stated that they consider the verdicts incorrect or problematic, and extensive arguments for this position has been presented.

6. Several hundred researchers, of whom the majority probably share the fundamental view that normal judgement should be followed, have expressed their support for Gillberg's refusal to take part in the release of documents in both petitions and letters.

*F. The question of conditions (for release of the documents)*

Additional legal turmoil would follow the verdicts in the Administrative Court of Appeal on 6/2 2003. These decisions, as we have shown, meant that Gothenburg University was obliged to ensure that Kärffve and Elinder would gain access to the documents in question. Before then, however, the University had to establish which conditions would be applied so that the interests of individuals would be protected.

Among those conditions that the University established with respect to Kärffve's review were a) that a release must be preceded by the participants giving their consent, b) that information in the released documents might only be used for the research purpose that Kärffve had described in her application, i e a Science Council-funded project that she conducted along with Professor Thomas Brante at Lund University, and c) that her inspection of the documents would be preceded by the approval of a research ethical committee.

Kärffve appealed against these, and certain other, of the conditions that Gothenburg University had established. In a judgement dated 11/8 2003 the Administrative Court of Appeal removed the condition that meant that Kärffve's inspection of the documents would be preceded by the participants giving their approval to it, as well as the condition requiring research ethical review. On the other hand, it approved that condition that meant that Kärffve might only use the information in question within the framework of her Science Council-supported projects.

In relation to Elinder, Gothenburg University had also established a condition that the participants would give their approval - which was not accepted by the Administrative Court of Appeal. On the other hand, no conditions were established meaning that his inspection would be preceded by research ethical review, for the simple reason that Elinder is not a researcher. Nevertheless, Gothenburg University's management at this time took the view that Elinder intended to check the documents within the framework of his service as a doctor in Uppsala municipality.

Shortly after the Administrative Court of Appeal verdict concerning the conditions the situation became more complicated. The Court had, as we have stated, validated the condition based on Kärffve providing the information to the court that she would carry out her review within a Science Council-financed research project. The reason that the court had this view was that Kärffve had produced a certificate from the project's responsible authority, Professor Thomas Brante, with the following wording (annex 5):

“Senior Lecturer Eva Kärffve is participating in a project entitled “The Neurogenetic Paradigm: The Establishment of a Grand Theory in Sweden”, financed by the Swedish Research Council. It would be of great importance for the project that she could gain access to the research material from the longitudinal survey of DAMP/ADHD that is kept at the institution for women's and children's health, the Sahlgrenska University Hospital, Gothenburg.”

How the court had perceived this certificate, and what importance it had had for the verdict, is clear from the following quotation from the later administrative Court of Appeal judgement that referred to the reservations. What the discussion in the following paragraph concerns is therefore the question about whether the condition that meant that Kärffve might only use the acquired information within the framework of Brante's Science Council-financed projects would be approved:

“From the documents in that case [the first Administrative Court of Appeal judgement, our remark] it is evident that Eva Kärffve initially stated the aim of her application in more general terms on the basis of her research at the sociological institution, Lund University. Later, however, during the court case, she specifically stated the importance the material had for the research project “the Neurogenetic Paradigm” and then cited documents designated “detailed information” and “research programme” together with comments from Professor Thomas Brante. Against the background of the content of these documents we can assume that the Administrative Court of Appeal in its verdict on whether the requested documents could be released to Eva Kärffve assumed that the aim of her request was to use the documents in this research project. Later statements and what emerged regarding her aim does not lead to any other view. Given the circumstances, the current condition seems to be justifiable and will not therefore be changed.”

Later, Judge Gunnar Dyhre also confirmed that the Administrative Court of Appeal had attached great significance to the assumption that Kärffve would gain access to the documents within the framework of a Science Council-financed project:

“Such clear misunderstandings have arisen when it comes to the Administrative Court of Appeal's decisions in the matters of secrecy concerning Professor Christopher Gillberg's research ... that I can justify giving some further clarification. Eva Kärffve is active as a researcher at Lund University's Sociological Institution. She stated in the Administrative Court of Appeal that she desired to gain access to the material in question since she, along with the manager of the institution, Professor Thomas Brante, was conducting a research project within the field that was assessed to be sufficiently urgent for funding to be granted by the State Swedish Science Council.”(Gothenburg Post 3/7 2003)

“Eva Kärffve (EK) is a senior lecturer at Lund University. She wrote her application on the University's headed paper and stated in the application that the institution's managers supported her research programme. She stated further that the research in question was assessed sufficiently urgent that it received funding from Swedish Science Council.”(Today's Medicine 16/3 2005)”

The information that Kärffve intended to handle the confidential personal files within the framework of Brante's Science Council project reached the Science Council. An inquiry was therefore issued to Brante concerning why he had not requested research ethical review of this part of the project. Science Council grantholders are obliged to do this when their research involves the handling of sensitive, personal information.

Brante stated herewith that his certificates issued to the Administrative Court of Appeal had been misinterpreted. According to Brante, Kärffve's perusal of the records in question would not take place within the framework of their common VR-project. Brante's view

was that Kärffve would be reading the records as a private person. And ethical committee approval is not required for private individuals.

Brante has expressed this position in letters to the Science Council and in an article in *Dagens Nyheter* (4/3 2003). In the latter, he writes:

“I can guarantee that no individual data will be handled in the project.” The chairman of the Swedish Research Council's data preparation group, Björn Halleröd, in the internet edition of *Dagens Nyheter Debate* on 24/1 stated the same thing: “It is clear that the project does not aim to evaluate the results of psychiatric research in general, or more specifically Gillberg's research.” So it is. How many times does this need to be said?”

And in a letter to one of us he stated the following:

“My certificate states that EK's enquiry is of “great importance” for the project, i.e. the results can illuminate our understanding of elements of the impact of biological explanations. Observe that it does not state that the review “is a part of” or “is included” the project. If that had been the case it would have said so. That it does not do that means that it is not so. No individual data exist in the project. The letter to the Science Council is valid; it is still available to read, willingly complemented by what Bengt Hansson, Chief Secretary for Humanities and Social Science at the Science Council, writes in his memorandum on the case. Eva Kärffve describes herself as a private person in her dealings with the Administrative Court of Appeal. This is a legal term that shows that she does not act as a representative for the University or any other institution. It does not mean that investigation is her hobby. She is a private person with research competence, about which she informed the Administrative Court of Appeal.”

On the one hand, the Administrative Court of Appeal had in this way validated that condition which meant had that Kärffve could use the information she intended to acquire from the records only *within the framework* of her Science Council project. On the other hand, she did not have the right to use information in this way within the framework of the Science Council project, since her review was not validated by the ethics committee. And moreover the project's responsible authority had then clarified that her review would *not* take place within the framework of the current project. The Administrative Court of Appeal had therefore, demonstrably, pronounced the verdict concerning Kärffve on an incorrect basis.

Also the then Director General at the Science Council, Madeleine Leijonhufvud, Professor of Criminal Law, expressed the view in a debate article, and in deliberations with Gothenburg University's management that Kärffve, given the conditions validated by Administrative Court of Appeal, did not have the right to gain access to the documents.

The picture was complicated even in relation to Elinder. The Administrative Court of Appeal judgement announced on 6/2 2003 can be interpreted as saying that that the court had required that Elinder would carry out his inspection of Gillberg's records within the framework of his duties in Uppsala municipality. During the autumn of 2003 however Gothenburg University became aware that Elinder's employers did not consider that his review of Gillberg's records fell within the framework of his duties. Thus it became apparent that Elinder intended to read the records in his spare time, as a private person.

When informed about this, Gothenburg University decided to establish a new condition for Elinder, whose meaning was that he - in order to get to gain access to the documents - must be able to show that he acted within the framework of his duties. Thus, during the autumn of 2003, neither Kärffve nor Elinder gained access to the records, with reference to the circumstances presented above.

Two legal questions of a technical nature arise at this point. The first is whether one has the right to use conditions to prevent a person gaining access to certain documents, or if conditions may only be used to regulate how the acquired information is used. The second is whether one has the right to impose new conditions after earlier conditions have been laid down.

As regards these questions various legal advisors have had differing views. The former President of the Administrative Court of Appeal in Gothenburg, Nils O Wentz, who moreover contributed to the formulation of the Secrecy Law, has - in his capacity as counsellor to Gothenburg's University's Principal - expressed the view that the University had the right to establish a new condition with respect to Elinder, and - with reference to conditions - to deny both Kärffve and Elinder the right to gain access to the documents.

The thought might have been that the fact that the Administrative Court of Appeal gave Kärffve and Elinder the right to gain access to the documents respectively in their role as researcher within a Science Council-supported project and doctor in Uppsala municipality did not automatically give them the right to gain access to the same documents as private citizens. And that the fact that one would not be able to use acquired information without breaking imposed conditions means that neither should one get to gain access to it.

We consider it self-evident that Gothenburg University should not release these extremely sensitive documents without the question about the implications of the conditions first being examined legally. It is amazing that the Justice Ombudsman, and prosecutors appointed by the Justice Ombudsman, consider that this position is worthy of prosecution.

#### *G. Professor Thomas Brante's actions*

In our view the certificate from Professor Thomas Brante (see above; annex 5) exhibited in the Administrative Court of Appeal can not be interpreted in any other way than that Kärffve's examination would in fact be carried out within the framework of the Science Council-financed project he was conducting with her as a co-worker.

From the discussion above about the conditions, it is clear that the Administrative Court of Appeal considered the certificate in the same way, and that this certificate was a crucial explanation for why Kärffve was given the right to gain access to the documents. In our view there can be no doubt that it was actually Brante's intention that the certificate would be interpreted as it was, and that it would influence the court's decision in the direction it did.

That Brante's certificate additionally influenced the court's position in relation to Elinder also appears likely. If his application to gain access to the documents in order to improve himself in his profession had not coincided with the corresponding application from a

supposed Science Council-sponsored researcher, the decision concerning him would probably have been otherwise.

It is possible that Brante, whose experience of research dealing with access to confidential information is perhaps limited, did not actually know that - according to the Science Council's regulations - it is obligatory to seek ethical approval for this type of activity. When the Science Council advised him of this requirement a natural reaction would have been to submit an application to the ethical committee, and to call upon one's co-workers that, pending the matter being dealt with, they should refrain from expressing renewed requests to gain access to the documents.

As we have stated, Brante nevertheless chose an alternative way, in so far as he asserted instead that his certificate had been wrongly interpreted. His new line was thus that it was *not* within the framework of their common project that Kärfve would read the records, but rather as a private individual.

The scenario depicted by Brante - in which the researcher Kärfve interviews the private person Kärfve about what she found in Gillberg's records - expresses judicial gymnastics defying ridicule. But irrespective of whether Kärfve would check the documents within or outside the Science Council-project, Brante can not escape criticism.

If it is true that Kärfve's review would take place independently of Brante's Science Council-project the Administrative Court of Appeal were misled with a false certificate. If this was unintentional, when it became clear to him that the Administrative Court of Appeal had misinterpreted his certificate, Brante could have tried to correct what happened by advising Kärfve to delay her investigation, since the Administrative Court of Appeal judgement clearly represented a misunderstanding to which he himself had, to a large degree, contributed.

However, no such measure was taken by Brante: on the contrary, he appears to have been pleased with the fact that Kärfve would gain access to the documents on condition that she would only get to handle the information within the framework of their common Science Council-project. This is despite the fact that he was aware that she did not have a right to gain access to the documents within the framework of this project. It is reasonable to conclude that Brante was aware that he misled the Administrative Court of Appeal with a false certificate issued in his capacity as a public employee and representative of authority.

If, on the other hand, it is true that both Brante and Kärfve's intention actually was that her inquiry would take place within the framework of the Science Council project, no criticism can be aimed against his certificate to the Administrative Court of Appeal. Nevertheless Brante, in that case, would have broken the Science Council's regulations that this type of research must be ethically scrutinised. That he still declined to do this after he had been informed by the Science Council that he was forced to allow ethical examination of this project, but instead asserted that his certificate had been misinterpreted, cannot be excused on the grounds of ignorance. Moreover, this interpretation of the course of events means that Brante was dishonest with the Science Council and in the media.

It can be added that Kärffve, in connection with the court proceedings that led to Gillberg and Svedberg being sentenced for breach of duty, was questioned about how she would have used the information she had intended to acquire from Gillberg's records. Kärffve replied that she would primarily use it within the framework of her and Brante's Science Council-project, but that she might use it for other purposes, possibly an article, possibly a book. At least Kärffve thus at this time was of the view that she actually would use the documents in her and Brante's Science Council project, despite this being in breach of Science Council regulations, and despite the project's responsible authority having pledged to the Science Council that Kärffve's review would not take place within the framework of this project.

One of the most crucial circumstances in this whole case is that that the researcher, Eva Kärffve, who requested to gain access to sensitive individual data, insisted this would happen without prior ethical review. It is Kärffve and Brante that breached ethical regulations, while another researcher, Gillberg, was thereby placed in an ethical dilemma. It was of course Gillberg and co-workers - not Brante - that with their signatures, and in agreement with the participants, had guaranteed to them that the research would be carried out in accordance with current ethical rules.

Brante can be considered to be the one who - through issuing a false certificate - indirectly caused the documents in question later to be destroyed. His actions have had significant consequences for individuals in that they - in the long run - led to prosecutions and sentences for Christopher Gillberg and Gunnar Svedberg, and to prosecutions for the three of Gillberg's colleagues who considered themselves obliged to destroy the documents, in order to prevent an inadmissible violation of individual integrity.

That the same Brante has used the destruction of the documents, provoked by him alone, to besmirch Gillberg in the international scientific press does not make the picture of his actions any more attractive:

“Rutter's critique and other circumstances strongly indicate that the maxim referred to by Clifford G. Miller, BMJ, July 14, is applicable: ‘Omnia praesumptor contra spoliorem’ (Everything can be presumed against a despoiler of evidence). This is especially so since it would have been so easy for Gillberg to resolve the whole affair by simply de-identifying the data.”

(<http://bmj.bmjournals.com/cgi/eletters/329/7457/72#67809>):

It should be noted that Brante, who without doubt attempted to destroy Gillberg's reputation in the international scientific community, misinformed the journal's readers in this contribution. The reasons why the situation that emerged could not be resolved through anonymisation of data will be demonstrated in a later section of this document.

Brante is also eager in the Gothenburg University newspaper to exploit the publicity value of the fact that the documents were destroyed:

“Finally I want to give a general comment. In view of all circumstances and the course of events that led to Gillberg's group's raw data being destroyed there is, to my mind, only one reasonable interpretation. The destruction is a tacit confirmation that Rutter, Kärffve, Elinder etc. have been right all along; that major deficiencies exist in the material and the research that builds on it and therefore the material can not be held up to critical review.”

We can add to this comment that Rutter – a child psychiatric researcher in England – as far as we know, and after what developed in the Swedish debate, never asserted that Gillberg should have made himself guilty of any impropriety.

#### *H. The University management's order concerning movement of documents*

Gothenburg University's official position, as expressed in the form of decisions by the Principal and statements from the University's management board, were, until the last administrative Court of Appeal verdicts on 4/5 2004, that the documents *should not* be released, since the conditions, in the University's view, were not met.

After the other verdicts in the Administrative Court of Appeal, despite having no intention of releasing the documents – because of the conditions – the University Principal, on the instruction of the Director Bengt Wedel, issued an order on the 14/ 8 2003 to Gillberg's department that the current documents would be moved from the archive at Gillberg's department to other premises within the University, over which Gillberg did not have control. This order was not in accordance with the ethical regulations that mean that the doctor/researcher responsible for a study has a personal responsibility for - and will have supervision over - archived confidential records.

Gillberg believed consistently that the personal responsibility that rested upon him as a researcher and doctor to protect the participants' confidentiality made it impossible for him to take part in the movement of the records unless it was under his control. He refused therefore to follow the Principal's order about releasing the documents from his control. Nevertheless, in a letter to Gillberg, and when he was interrogated by the district court, the University Principal emphasised that the documents would not have been released to Kärffve and Elinder before the question of conditions had been examined, even if Gillberg had permitted a movement of them from one location to another.

Why this order was issued at all is unclear to us, since some decisions about whether the documents would be released had not yet been taken at this time. The question is not without interest, since Gillberg could not have been indicted if this order had not been issued. One possible explanation is that Svedberg at this stage was a newly installed Principal, and that the Director Bengt Wedel was therefore given a disproportionately large influence over the processing of the case.

Wedel is not a lawyer, nor does he have legal training, and his knowledge about the confidentiality that applies within the health service and medical research is, as far as we can assess, very meagre. That his attitude on this matter for a long time was that there was nothing problematic in Kärffve and Elinder being permitted to gain access to the documents, and that it should have happened earlier, has been apparent to those who discussed the question with him (including the signatories of this letter). That this was Wedel's view, and moreover that he holds a personally coloured aversion against Christopher Gillberg, is evident also from his witness statement before the district court, and from interviews he granted to the media (the Gothenburg Post 27/5 2005).

Why Wedel, who is not legally trained, unlike many qualified lawyers, considered the release of these documents an uncomplicated matter, is a mystery to us. But if Wedel had not had this very definite opinion, and had he not been the one within Gothenburg

University that had to process this case, the unjustified order that eventually meant that Gillberg was indicted and sentenced would probably never have been issued.

### *I. The destruction of the documents*

After the Administrative Court of Appeal determined on 4/5 2004, with reference to conditions, that the release of the documents could not be refused, Gothenburg University considered that it had reached the end of the road from the legal point of view. On 6/5 2004 - a Thursday - the Director Wedel thus submitted a new order to Gillberg's unit with the instruction that the documents would immediately be made available to Eva Kärfve.

Understanding that a release was probably immediately imminent, two of the researchers responsible for the study, Carina Gillberg and Peder Rasmussen, during the weekend 8-9/5, along with a co-worker, Kerstin Lamberg, destroyed the records in question. They have now been indicted for this. Our assessment was that this destruction was necessary in order to prevent an illegal violation of the participants' integrity. We would, in the researchers' place, have acted in a similar way.

Christopher Gillberg at this time was abroad, and was not informed about what happened until afterwards, probably because his colleagues desired to spare him from being also made responsible for this matter. Gillberg had already been notified of the accusation about a breach of duty in connection with his opposition to a movement of the documents.

### *J. Did the destruction prevent a breach of the new ethics examination law?*

Kärfve produced her last request to gain access to the documents in May 2004, and it was also then that Bengt Wedel at the Principal's office instructed the group of researchers to submit the keys to Gillberg's research record archives to her.

As from the 1/1 2004 the new ethics examination law applied however, which meant that that ethical regulations that earlier were imposed for example by the Science Council - but which Kärfve and Brante chose to disregard - was now in statute. This law decrees that handling of this type of sensitive information in research aim *must* be preceded by ethical review and approval.

Leif Pagrotsky (Secretary of State) expressed the matter in this way during a current debate in Parliament:

“It is prohibited to start research before a research project has been approved in an ethics examination. Those who break this proscription can be sentenced to a fine or imprisonment. “

As regards Kärfve, it must have been presumed that she would carry out her planned reading of the records in her capacity as a researcher, which she also herself often stressed. The review of Gillberg's records that she planned is in any case indubitably a research project of the type that could not be commenced without prior ethical examination since 1/1 2004, as described above.

Completely unprotected by the earlier verdict in the Administrative Court of Appeal, Kärfve would thus have broken Swedish law if she had gained access to the records at this stage. The Ethics Examination Law makes it clear that this applies to all activity that was not initiated before the 1/1 2004.

Had Gothenburg University's management at this stage, i.e. in spring 2004, played a part in Kärffve being able to read the records, it would thus, as far as we can tell, made itself guilty of complicity in an offence. What saved the University from this infringement of law was that Gillberg's colleagues chose to destroy the records in order to protect the participants' integrity.

Worthy of note is that Wedel's order of 6/5 2004, if it had been obeyed, would not only have meant an offence against the Ethics Examination law, but also an offence against the European Convention on Human Rights with which Sweden has aligned itself (see Rynning, 2005).

#### *K. Justice Ombudsman's prosecutions*

As we have described, Justice Ombudsman Kerstin André raised prosecutions against Gothenburg University's Principal Gunnar Svedberg, its board chairman Arne Wittlöv and Christopher Gillberg on 19/12 2004. The charge was that during autumn 2003 the documents were not released to Kärffve and Elinder. The plaintiffs at the legal action were Kärffve and Elinder. The Justice Ombudsman has stated in the media that she considers that the case is uncomplicated.

Svedberg and Wittlöv were indicted because they, according to the prosecutor, had the formal responsibility for the documents being released. Why Gillberg was indicted is less clear, since the prosecutor made clear that she does not consider that he had any formal responsibility for the release of the records. The prosecution against Gillberg is probably based on the position that it was his refusal to follow the order that led to the decision being defied. This is however peculiar, since the preliminary investigation, if we take it that Svedberg's information is correct, shows that it was not Gillberg's refusal of the order that led to the decision being defied.

We consider that the Justice Ombudsman's decisions to raise prosecutions against Gillberg, Svedberg and Wittlöv were a mistake. Even if it is true that the judgements in the Administrative Court of Appeal have not been followed, the extenuating circumstances - for example that these decisions were not supported by Swedish law, that they were based on incorrect premises and that a release could have caused third parties irreparable damage - must be of such weight that prosecutions should never have been raised. And we find it notable that the Justice Ombudsman had as plaintiff in the legal action Eva Kärffve - who, to judge by her own witness statement (see above), would herself have committed an offence if she gained access to the documents. The Justice Ombudsman's strong commitment to Kärffve being given the opportunity to break the law on this occasion seems excessive to us.

#### *L. The District Court's decisions*

The District Court acquitted the Board's chairman, Arne Wittlöv. Gunnar Svedberg was sentenced to a salary-based fine. Notable in this context is that the court did not regard as illegal the fact that Svedberg did not release the documents, with reference to the conditions, from 10<sup>th</sup> October 2003. Even if the Administrative Court of Appeal gradually rejected this interpretation of the conditions, unlike the prosecutor (and the Justice Ombudsman?), the court accordingly considered it acceptable that the University made another assessment.

On the other hand, the District Court considered it illegal that Svedberg did not ensure that the documents were released during the weeks before the 10/10. Why it was acceptable to be reluctant to release the documents after the 10/10, but unacceptable to be reluctant to release them before the 10/10, is not clear from the text of the verdict.

Despite the fact that had become apparent during the legal action that Gillberg was not formally responsible for the documents' release, and that it was not his refusal to move the documents from one set of premises to another that led to the decision being defied, he was sentenced to the most severe penalty: a fine of 50 days salary and a conditional sentence.

It is notable that both the prosecutor and the District Court emphasised that the question of whether the judgements in the Administrative Court of Appeal were correct, and whether a release of the documents had meant an offence against the Secrecy Law, were entirely irrelevant factors that should not be weighed in the court's assessment of Gillberg's and Svedberg's actions. We find it amazing and worrying that both prosecutor and court consider that offending citizens' personal integrity, in contravention to Swedish law, is so unproblematic that it does not see Gillberg's and Svedberg's ethical dilemma as an extenuating circumstance.

## **5. Comments on the question of the release of the documents**

### *A. How should Gillberg have acted?*

Our opinion is that it is apparent that a researcher who has assured confidentiality to participants in a study cannot break this promise if he assesses that a release of information may mean a risk of damage to the participants. Despite the judgements in the Administrative Court of Appeal, we consider that Gillberg would have made an ethical and moral error if he had contributed to the release of the documents.

Common to most participants in the public debate who have attacked Gillberg for his attitude - for example Leif Elinder, Eva Kärfve, Thomas Brante, the Press Ombudsman Olle Stenholm, the Director Bengt Wedel, emeritus professor Ove Lundgren, Med. Dr. Michael G Koch, the editorial staff of Gothenburg's University's newspaper and the journalist Maria Louise Samuelsson - is that they lack experience of research dealing with sensitive records, and they probably also lack knowledge about the rules surrounding this activity.

As a consequence of a few protagonists' oft-repeated contributions in the media, the general public has probably gained the impression that Gillberg stands alone in his position that it is ethically impractical as a research physician to release this kind of information, after having ensured the participants that it will not happen. That this is an incorrect picture is however shown by the large number of researchers, doctors and psychologists, who wrote to Gothenburg University pleading that it should not obey the verdicts of the Administrative Court of Appeal. And furthermore 300 doctors, including a large number of professors and Sweden's latest Nobel Prize winner, Arvid Carlsson, expressed their support for Gillberg's attitude. (This petition was published in Today's Medicine 23/3 2005, see annex 6, but has since then collected more signatories).

Note also that the Prime Minister's distinguished advisor in research matters, the former Principal at the Karolinska Institute, professor Wigzell, along with the previous manager

of the Sahlgrenska Academy at Gothenburg University, Professor Göran Bondjers, expressed that the verdicts in the Administrative Court of Appeal constitute a threat against Swedish research in a debate article in the Stockholm newspaper Dagens Nyheter (4/3 2003):

“In a notable decision the Administrative Court of Appeal in Gothenburg has given access to patient information in a large clinical study to a Senior Lecturer in Sociology and a Paediatrician with no research training. This decision could lead to far-reaching consequences and breaks the ethical principles that surround medical research. It is urgent that the general public, and of course also government and parliament, realise what effects this decision may have on personal integrity.”

Unfortunately these unambiguous opinions from people with their own experience of clinical medical research have had a limited impact on the media. The picture that the general public has gained of the question, after more than five years of the media campaign, is that Gillberg lacked legitimate reasons to decline to submit the documents, and that his actions therefore must have ulterior motives. How representatives of the authorities – particularly the Science Council - have come to contribute to this incorrect attitude has been discussed above.

*B. How should Svedberg have acted?*

The Justice Ombudsman’s prosecutions, and her statement that the case is uncomplicated, must mean that she considers it self-evident that Svedberg should have rushed to break the locks of Gillberg's archive and remove their extremely sensitive documents in order to hand them over to Kärfve and Elinder early in the autumn of 2003.

These are the measures she believes that Svedberg should have taken

*despite* the participants having been assured that the documents would not be released by the representatives of the University of which he was the manager

*despite* the participants having pled that the promise they had received should not be broken

*despite* the fact that the researchers, who at the University's request had assured the participants that the documents would not be released, considered that a release would be a offence against medical and research ethics

*despite* a large number of researchers, particularly from the medical research community, having pled with him to not break the undertaking of confidentiality

*despite* the fact that he knew that the judgements giving Kärfve and Elinder the right to take part of the documents were probably made on an incorrect basis

*despite* the fact that he could not promise the participants that releasing the documents to Kärfve and Elinder would not cause them irreparable damage

*despite* the fact that he had reason to believe that releasing the documents to Eva Kärfve would lead to an act of violation of the law unless she did not intend to submit to the condition concerning the aim of her inquiry, and

*despite* the fact that a release would lead with absolute certainty to the participants in the study launching a prosecution against him, Gillberg and Gothenburg University.

We are convinced that, both for Swedish medical research and to Sweden as a constitutional state, it is good that we did not have to experience the scene in which representatives from the Principal's office – in front of patients and staff, television, demonstrating patient associations and pleading research participants - along with policemen and locksmiths break down the door to an archive full of extremely sensitive documents, including copies of medical research records, carry out these documents, and - in contravention with what the State assured the participants - hand them over to two people, one of whom wants to read them in his spare time, and one who will probably break the law as she receives the documents. That Svedberg did not allow this scene to be realised is an expression of good judgement, but it rendered him subject to prosecution.

*C. Was the ethical problem resolved through the requirement on confidentiality being transferred to the receivers of the information?*

It has been stated in the debate that Gillberg should have released the documents to Kärffve and Elinder, since there was no reason to believe that they would show the sensitive information to others. This is, for the following reasons, not a sustainable argument:

*1) The uncertainty about how Kärffve and Elinder would use the documents*

Kärffve had declared that she intended to spend a lot of time in the archives, and that she intended to use photocopying equipment. That she would have published the names and social security numbers of the participants in the study in the media is of course highly unlikely. But on the other hand it is not at all unlikely that she would have chosen to publish extracts from the records in her next book - perhaps sufficiently detailed that the individuals' identities could have been detected by people who knew them. The important thing is however not how Kärffve and Elinder would have handled the information, but that Gillberg could not guarantee to the participants that the information would be handled correctly.

If Kärffve and Elinder had broken established conditions they would admittedly have been made responsible, but that would not have repaired the damage caused to the participants in the study. It is also evident, through her media statements, that Kärffve seems not to be conscious of, or lacks interest in, how ethical legislation applies to the handling of this type of data. And as Kärffve's testimony in the District Court showed, she had in fact intended to disregard the conditions, in so far as she intended to use acquired information also for other aims than her Science Council project, for example books and articles. The misgivings that Gillberg and Gothenburg University management had about Kärffve's intentions to follow established conditions therefore seems justified.

It is not up to us here to assess Kärffve's and Elinder's judgement or morals. It is however true in our view and that of others that much of the information they chose to propound in the media has been highly misleading or untrue, and this of course does not increase our confidence in them.

As quoted above Professor Birgitta Strandvik stated that one - using the "power" one has as doctors/researchers - can persuade participants to agree that documents are shown to unauthorized people, with the argument: "you can rest assured, those who read this will not take it further. It is an act of confidentiality". A central question is how the

researcher should act if he is compelled to release documents to people for whom there are no reasons to guarantee that they will handle the information correctly.

### *2) The legislators' intentions*

In the introduction to the Secrecy Law it is emphasised that the fact that the recipient of sensitive information has to take confidentiality into consideration, does not eliminate the requirement that participants in the study should clearly have no objections to the fact that the information is handed out. In the current case, it is clear (see above) that many of the participants had strong objections to the information being released to Kärfve and Elinder. The fact that they were still given access to the information must have been against the intentions of the legislators.

### *3) The promise issued to participants*

Regardless of what assessment Gillberg himself had concerning the possible risks associated with releasing the documents, such a measure would mean breaking a promise. The fact that Kärfve and Elinder, through their previous actions in this question, are very well-known amongst people with attention disorders, and are considered as highly controversial individuals by several of them, makes it reasonable to assume that this breach of promise would not have been taken lightly by the participants.

#### *D. Could the case have been resolved through anonymisation?*

Gillberg has been criticised for not anonymising the documents - among others by Thomas Brante on the British Medical Journal website, quoted on p.37 above, and by Professor Ove Lundgren on Swedish Television on 7/6 2005. There are therefore reasons to analyse whether the current problem could have been solved by anonymising the documents.

Whenever possible in clinical research names and social security numbers are replaced with a code, in order to make it possible to show data to unauthorized individuals without violating the participants' integrity. In order to do this it is however necessary that only a small amount of information has been recorded about the individuals. When, as in Gillberg's project, participants have been followed up for decades and a large part of their life history has been recorded, anonymisation does not give secure anonymity since individuals who read the documents can possibly identify the participants from the collected information.

A definitive anonymisation is moreover for practical reasons not viable, if as in the current study, one returns to the participants on many occasions over a long period. Hermerén and Hjemdahl thus write in the above quoted Medical Research Council guidelines for medical research ethics:

“Certain types of surveys cannot be implemented with anonymised data. This applies for example in longitudinal studies. “

The documents from the Gillberg group's longitudinal study were, as stated, not anonymised, which accorded with the plan for the study checked and validated by the ethical committee. As we have shown, this is not anything for which Gillberg should be blamed; the handling of non-anonymised documents in this type of studies is nothing exceptional. When Leif Elinder, at a current hearing arranged by the Science Council and

with Hermerén as moderator, criticised Gillberg – who was not present – for not anonymising the data, Hermerén unfortunately found no reason to make it clear that Gillberg had acted in this matter entirely in accordance with the Medical Research Council/Science Council's guidelines, as formulated by Hermerén.

To review approximately 50,000 sheets in Gillberg's archives, erase names and social security numbers as well as other information that could have led to identification – because of Kärffve's and Elinder's request to access the documents – would probably have taken at least two years of full-time work. Nevertheless, the importance is not the cost or the difficulty of the work, but the fact that not even after doing this would it have been possible to release the documents without the risk of offending the participants' integrity.

It can therefore be established a) that the documents in fact were not anonymous, b) that an anonymisation was hardly possible within reasonable time, and c) that anonymisation would not have served the purpose, since it would nevertheless have been possible to identify the participants.

At this point the question arises about whether anonymisation is actually irrelevant. After the Administrative Court of Appeal had obtained a number of the documents from the study, they judged that anonymisation was not a feasible way to proceed. The verdict of the Administrative Court of Appeal which raised the debate, and which eventually led to Gillberg and Svedberg being indicted and sentenced, meant therefore that Kärffve and Elinder were permitted by the court to access non-anonymised documents.

#### *E. Could the case have been resolved through external review?*

Within the framework of the media campaign against Gillberg it has often been stated that he could have avoided criticism and prosecution if he had accepted that external review of the documents in question, or if the case had been remitted to the Science Council for investigation of whether research misconduct had occurred. The fact that Gillberg, according to these critics, allowed himself to be indicted rather than submitting himself to external review, led to the hypothesis that he had something to hide. This is however, entirely misleading, for the following reasons.

##### *1) No connection between the verdict of the Administrative Court of Appeal and the accusation of fraud*

The reason for giving access to the documents was not because the Administrative Court of Appeal considered there was any reason to investigate whether Gillberg had committed research fraud. The reason Kärffve and Elinder were given the right to peruse the records is still unclear to us, but the reason *was not* that the court regarded it to be of urgent public interest to investigate whether Gillberg had been guilty of research misconduct or not.

##### *2) External review had not cleared away the consequences of the Administrative Court of Appeal's judgements*

Referring to judgements in the Administrative Court of Appeal, Kärffve emphasised in the media that she insisted on checking the documents in question on her own. She thus had not agreed to forgo her inspection of the records, although other reviewers had been called for. Discussion about whether Gillberg would have welcomed external reviewers

to visit the archive - in return for Kärffve and Elinder forgoing the right to visit the archive given them by the Administrative Court of Appeal – is therefore irrelevant.

### *3) Obvious reasons for reviewers not being called for*

There is an obvious reason that external reviewers were not called in to investigate Gillberg's records. The accusations of fraud expressed by Kärffve were investigated for eight months by the Ethical Council within the Sahlgrenska Academy. The council obtained views from Gillberg and his colleague, Peder Rasmussen, and gave Kärffve the possibility of responding, whereupon Gillberg and Rasmussen were allowed to respond to Kärffve's response. Moreover several doctors who had taken part in the study were interviewed, as well as the person who acted as the study coordinator. The investigation led to the conclusion that the Ethical Council had no reason to believe that misconduct had occurred. The council therefore recommended that Sahlgrenska Academy should consider the case closed.

After this statement there was no reason to call for external reviewers, or to remit the case to the Science Council for assessment. A reasonable legal principle must be that it is the investigating authority, rather than the one who has made an accusation, that decides which investigations are required. It can also not be the responsibility of the accused to prove that he is innocent, nor to initiate additional investigative measures after he has been absolved from the accusations.

The statements above show that there is no reason to criticise Gillberg because his research archive was not sent for external review. It was not implemented because the investigating authority did not consider this measure justified. This question will be discussed further in future sections.

As an aside, it should be noted however that the much repeated assertion in the media that Gillberg opposed all external scrutiny, for example expressed in a major article in *The Express* (22/5 2005), is untrue. The fact is that Gillberg and co-workers called upon the University Principal to request external reviewers to accelerate the painful process when the ethical council's investigation experienced delays and when they noticed media coverage of the accusation of fraud. The University however chose at this stage to oppose Gillberg's request, and not to call for external reviewers, but instead waited for the outcome of the Ethical Council's review.

After the Ethical Council had announced its decision that it had not found any reason to suspect fraud, and that additional measures should not be implemented, Gillberg withdrew the requirement for external scrutiny - which must be considered a natural response. Someone who has been put through an eight months long fraud investigation with exposure in the media, despite there never having been any rational reason to believe that fraud occurred, would not wish to prolong this process once the investigation has been closed. This cannot be considered surprising.

Our opinion is that it would have been entirely unwarranted to call for external review, irrespective of whether had been requested on the ethical council's, Principal's or Gillberg's own instructions. In each situation there must be a reasonable proportionality between the credibility of an accusation and the kind of investigation the accusation justifies. Since Kärffve's and Elinder's accusations lack credibility in all respects –

regardless of any examination of the archive – they have been the subject of far more attention than they deserve.

Nevertheless, one issue of major importance is what should be done in those cases when the authority concludes at an initial investigation that it *does* actually have reason to suspect fraud, and where inspection of sensitive, non-anonymised documents seems urgent in order to investigate these suspicions. Strictly interpreted, the promises that no one outside the group of researchers will gain access to collected information could of course also prevent the documents being shown to an external, competent reviewer appointed by the academic institution.

Against this position it can on the other hand be stated that, to quote the Secrecy Law, it is probably “clear” that this type of breach of promise will cause no harm to the participants. Moreover, most participants would probably permit these kinds of measures.

In the current case the question about external scrutiny of the documents would probably have been resolved in an ethically acceptable way in the event that there had been reason to implement it. In other words if the ethical council had found the accusation of fraud so convincing that it considered yet another investigation justified. In our opinion it is a reasonable attitude that Gillberg and co-workers found it impossible to show the documents to two self appointed outside investigators. At least one of these investigators acted as a private individual and Gillberg and co-workers had no idea about how they intended to proceed with the information. On the other hand they would not refuse to show the documents to a reviewer appointed by the research community.

Nonetheless it is desirable that ethical regulation of medical research is changed so that participants would be informed about the fact that documentation can occasionally be shown to representatives of a named authority, for example the National Board of Health and Welfare or the Science Council with a view to investigation. As we discuss further below, a similar principle already exists within the field of clinical drug trials. The participants give signed consent in advance stating that their records may be shown to representatives of the medicines agency.

#### *F. The researcher's and the participants' lack of legal rights*

The research physician's personal responsibility for research participants' welfare is, as mentioned above, often emphasised, for example in the Declaration of Helsinki and Medical Research Council/Science Council's ethical regulations.

The researcher's personal responsibility is illustrated by the fact that it is he or she that signs the participant information with their own hand, despite this information being produced in collaboration with other authorities (formerly the Ethical Committee, now the Ethics Examination Board). And it is also the researcher who explains the conditions applying to the study to the participants, particularly in relation to confidentiality.

But despite Gillberg being thus considered the moral guarantor of the promises in the participants' eyes, he was not considered a party to the case when the Administrative Court of Appeal examined it. And his application for legal review in the Administrative Court was dismissed because he and some of the research participants were not a party to the case. Not until he was indicted - for not having contributed to the documents being released - was he in any legal respect considered a party in a judicial sense.

Our opinion is that this constitutes a threat to the rule of law. If the researcher signs undertakings of confidentiality to research participants with his or her hand and is therefore the guarantor that these promises will not be broken, it is unreasonable that s/he is not considered a party when the question of whether the promises will be broken or not becomes subject to court proceedings.

It may also be added that it seems that Gillberg was probably disadvantaged by Gothenburg University handling the Administrative Court of Appeal case with apparent incompetence. It was not for example clearly demonstrated that there were reasons to question the motives presented to the court by Kärffve and Elinder, and also that the wrong section of the Secrecy Law seems to have been referred to in support of their expressed opinion (see Rynning: annex 4).

Within this context there is reason to discuss not only the researcher's but also the participants' lack of legal rights. Despite it being the participants who can be said to have entered an agreement with the University concerning the handling of collected information, and despite it being the participants whose integrity would be damaged if this agreement is broken, they are considered insufficiently concerned by the Administrative court to have the right of legal review. We have difficulty seeing the rationale for this order.

The Professor of Public Law, Wiweka Warnling-Nerep, discussed this case in an essay in the Legal Magazine (2003/04, 133-144), from (among other things) this point of view:

“It is a little discomfoting that L.L., i e the parent of one of the children who appeared in Gillberg's research, was not given any possibility of challenging the decision to hand over the documents. He was told – rather light-heartedly - to be happy about the efficiency of the principles of access to public records, and at the same time that he must hope his private life would not be “hung out” in an unfortunate way.”

The conclusion of her article is as follows:

“In the longer perspective there is a risk that research will be damaged by too broad an ideology about openness. Perhaps parents of children with DAMP and other dysfunctional disorders in the future will be a lot less open to letting their children enter research projects. In that case, Senior Lecturer Kärffve can be happy that the “Brain Ghosts” are left in peace, but the question is whether other and - in my opinion - far more important values will not be lost.”

Elisabeth Rynning also discussed the fact that interested parties lacked the right to speak in her analysis of the case, and the consequences this might have for the court's actions.

#### *G. Who owns the documents?*

The actual ownership of the documents in question is yet another question that representatives of authority have not succeeded in clarifying in discussions about the current case.

It is often claimed that all documents established within a research project carried out at a University, even before completion, should be considered public documents. The investigation by Alf Bohlin performed on behalf of the National Archives (“Openness

and confidentiality in the research activity of authorities”, NA report, 1997:2) is generally referred to in support of this position.

We have no reason to question this conclusion, but we note at the same time that this question still is surrounded by significant uncertainty, which can threaten the legal rights of researchers. For example it is normal practise that researchers who relocate from one place of work to another take their research documents with them. As far as we know it has never been clarified who is responsible for keeping the documents appropriately at the place to which the researcher has moved: the researcher, the responsible manager at the University where the documents were collected or the responsible manager at the University to which the documents have been moved.

This question is further complicated by the so-called “teacher’s exemption” according to which researchers own the right to their own discoveries and results in the event that they might lead to patents. It is difficult to see how this law can be compatible with the provision that all the documents collected in connection with research at a University are owned by the University. In the event that University-employed researchers choose to leave their service at the University in order to start a private business based on the discoveries made as University employees, it seems natural that they refer to the above mentioned “teacher’s exemption” and move the documents which form the basis for a patent application, for example, to their business. On the other hand, if Bohlin’s conclusion that all documents collected within the framework of research projects are owned by the University it is difficult to see how they could be transferred to a private entity.

The Administrative Court of Appeal instructed Gothenburg University to release the documents in question without even, as far as we know, asking the involved researchers who they considered owned the documents, or within which authority they had been collected. Note that both Christopher Gillberg and Carina Gillberg were doctoral students at *Uppsala* University when large parts of the information were collected. It may thus have been a mistake that *Gothenburg* University became the opposing party to Elinder and Kärffve in the current legal dispute. This is an aspect upon which the legal authorities do not seem to have reflected.

Our opinion is that the uncertainty concerning the right of possession of this type of documents is unsatisfactory from a legal point of view.

*H. Does Gillberg's and Gothenburg University's unwillingness to submit the documents constitute an offence against the principle that “all research can be scrutinized”?*

In the media debate the argument has often appeared that “all research can be scrutinized”, and that Gillberg, when he opposed the documents being released, broke this fundamental principle. It is Gillberg's antagonists who seem to have the intention of damaging his reputation who have principally promoted this point of view, but unfortunately they have been given “supporting fire” in the form of less well thought-out statements from various public officials.

In connection with the judgement against Gillberg in the Administrative Court the chairman of the ethics committee within the Science Council, Göran Hermerén, made the following statement (for example in the *Gothenburg Post* 28/6 2005):

“Concurrently with wanting to protect informants no one wants research that cannot be scrutinized.”

The statement must be interpreted as “no one wants to have” Gillberg's research, for example, since it is not open to everyone to read his patient records.

In Gothenburg University's newspaper, GU Journal (4/03), this emotional case was presented by interviewing Professor Sven-Axel Månsson, who made the following comment:

“Gillberg is an odd person who, surrounded by his guard dogs, refuses to stick to the rules of the game. Gillberg has the same responsibility as other researchers – to keep his research open to scrutiny.”

In the subsequent edition, the editorial office kept up this theme by letting the chairman of the Sahlgrenska Academy's ethical council, Emeritus Professor Ove Lundgren, in connection with same case, state that “all research must be able to be scrutinized”, clearly with the aim that one ought to be able to scrutinise raw data.

In Today's Research (3/3 2003) the same Ove Lundgren found reason to state the following:

“To oppose scrutiny only arouses suspicion. I work myself in animal experimentation; I know that total openness is what applies, even if one believes that it is difficult to be the object of suspicion.”

For the general public who read this type of contribution from researchers - combined with the barrage of similar contributions written by Gillberg's ideological antagonists – it must appear as a positive consideration that all research can be scrutinized and that there is something underhand in Gillberg's refusal to show his records. We consider however for the two reasons below, that this is an incorrect point of view.

1) *Firstly:*

Any review of a researcher's results in general consists of reading his or her publications, and one tries to replicate his/her results in independent studies. The kind of “review” in which researchers visit research archives and gain access to original documents, occurs, but in our experience is very unusual.

One important reason for this is that the question of whether a researcher has committed fraud or not often cannot be clarified through inspection of his or her own notes from the experiments that have been conducted. The above quoted Ove Lundgren is as stated an animal researcher. Not even from the most detailed survey of his notes can one clarify if he for example, as he himself may claim, administered the exact dose of a medicine to a group of rats. Even if researchers had technical forensic education, which they have not, surveys of a colleague's original documents are therefore a far poorer method of review than trying to replicate the results one has reason to doubt. They are therefore seldom used

Moreover, many researchers have the habit of destroying original data after 10 years. If inspections of this type of document had such a crucial importance, the practise of permitting the documents being destroyed after such a short time would have been unreasonable. It is thus true that many studies, still quoted and considered important,

cannot “be reviewed” since the original data are more than 10 years old and therefore destroyed.

Review of research is certainly important, but researchers carrying out a kind of non-professional forensic investigation into others’ archives to determine if their colleagues have committed fraud or not, cannot be of particularly high priority.

2) *Secondly*:

Swedish (and international) research is *de facto* organised in such a way that one presumes that certain research actually will not be scrutinised, if one means by “scrutinise” inspection of non anonymised, sensitive records.

Planning to show results from, for example, animal experimental studies to the public is understandable and desirable, as is showing results from studies on people where data have been anonymised securely. But the principle that “all research can be scrutinised” has never applied, and should not apply to the type of research that deals with sensitive individual data, if the word “scrutinise” means that people critical of the actual research will have access to the data.

In the quote above (p. 50) Lundgren sees reason to compare Gillberg's unwillingness to show up psychiatric records with his own exemplary “openness” with respect to his own rat experiments. The argument is difficult to understand, because the rules about confidentiality which made it impossible to get the records from Gillberg's archives entirely lack relevance if the object for the research is rats instead of people. As far as we understand there is no reason whatsoever to believe that Gillberg would show less openness than Lundgren concerning protected research data. If he had devoted himself to clinical research Lundgren would hopefully not have been any less anxious to protect his research participants’ integrity than Gillberg and the hundreds of clinical researchers who have expressed their sympathy for Gillberg's attitude.

Evidence that the legislators did not intend this type of document to be released for review to anyone who makes a request stems from the fact that they are protected in law by comprehensive secrecy. Neither can it have been the Science Council’s aim, as shown above, that this type of document should be released for review. This organisation, with Göran Hermerén as a leading expert, sanctioned the regulations that meant that researchers have for decades promised that collected information will not be transmitted further.

A type of research that often has immediate consequences for people's health is the so-called clinical drug trial, a study intending to establish the basis for registration of new medicines. For this type of research, separate control mechanisms have therefore been introduced, among other things in order to ensure that irregularities do not occur. Thus it must be made possible for representatives from the State authority, the Medical Products Agency, to scrutinise collected data including records, as described above, if one wants a drug trial to establish the basis for registration. In order to do this it is however necessary under current regulations that participants approve access by representatives of the Medical Products Agency to their records through signing a specific form before the study.

Had it been self evident that this type of data would be released in order to ensure that “all research can be scrutinised”, this rule would have been completely unjustified and possibly counterproductive. If there was a risk that sensitive records could be shown to people other than representatives of the Medical Products Agency, it would of course have been misleading the participants to ask them to approve in advance that representatives of the Medical Products Agency might gain access to the documents in question. When this rule was introduced the basis must thus have been that representatives for the Medical Products Agency, *but no others*, should be able to scrutinise the documents.

The National Board of Health and Welfare has for a long time provided researchers with sensitive information from registers concerning for example issues such as cancer incidence. In order to gain access to such data the researchers have however been obliged to first sign an assurance in which the following wording is included:

“When the project is completed i.e. when the survey results has been presented and scientifically reviewed, or at the latest the DD-MM-YYYY, the material must be made completely anonymous or be destroyed.”

By “scientifically reviewed” must be meant the process implemented by journals preceding publication. Had there been a general rule that “all research can be scrutinised” even long after publication, this request to researchers by the National Board of Health and Welfare to destroy data as soon as possible would of course have been highly inappropriate. Even though original data exist in the National Board of Health and Welfare's archives it is of course impossible to reconstruct a researcher's calculations and conclusions if s/he has destroyed the documents that formed the basis for the published analyses.

In conclusion, it is easily demonstrated that what in recent years has become a mantra - that “all research can be scrutinised” - has not served as a guiding principle in Swedish research policy, if by “scrutinised” one means that unauthorized individuals will be permitted to read confidential records.

A frequently restated assertion in the debate is that researchers must show sensitive, non-anonymised documents about patients to opponents in connection with dissertations and defence of theses and to reviewers for scientific journals. Our experience is that this assertion - pursued by Leif Elinder and Göran Hermerén - is untrue. We have thus – in more than 25 years as researchers - never heard any examples of an opponent or journal reviewer who required access to confidential documents.

As regards Professor Månsson, quoted above, who attacked Gillberg for not keeping his research open for review, we can state that in his own research he has interviewed, for example, HIV-infected homosexual people, prostitutes' clients and people who use the internet for sexual purposes, about their sexual lives in great detail. He has of course ensured them confidentiality. The double standards and hypocrisy in the public debate surrounding Gillberg's actions have been, to say the least, embarrassing.

## **6. The slander campaign against Gillberg**

Given Gillberg's strong position, his importance in Swedish and international child psychiatry, his clearly expressed opinions on questions that are considered controversial

by certain people, and the fact that at times he has chosen to participate in the debate, makes it self-evident that he must anticipate and accept being the subject of critical review and questioning.

It may therefore be considered as entirely legitimate that Gillberg's opinions, results and interpretations have been criticised in books and debate articles. And that his opinions, theories, the organisation of his research and the conclusions of his studies are forcefully and intensively attacked is also entirely in order.

Two circumstances, on the other hand, do motivate us to consider elements of the last years' activities aimed against Gillberg as a slander campaign rather than an exceptionally hostile scientific debate.

One is that the assertions surrounding Gillberg's person and actions essentially are untrue. He has thus been slandered in a number of respects, with a consistency and perseverance exceptional in this kind of journalistic debate. Many of the more hateful attacks, from for example Michael G Koch and Leif Elinder, have occurred in 'letters to the Editor' columns, and perhaps they have only caused minimal damage. But for example the four full cover pages in *The Express* (22/5 and 24/5 2005) was devoted to slandering Gillberg was evidently seriously damaging to him.

The other is that his antagonists time after time- for no reason - have singled him out as guilty of research fraud. One can attack a researcher for carrying out poor research, for erroneous interpretation of the results and for being unskilled in general without this being particularly objectionable. But when one accuses someone of deliberate dishonesty one has exceeded a clear boundary. To accuse someone of fraud is thus completely equivalent within the framework of an ideological debate to accusing your opponent of serious crimes such as extensive tax fraud, deceit, theft or abuse.

The last years' battle has sometimes been described as a war where two sides are attacking each other with roughly the same intensity. This is an incorrect image by a long way. There is no doubt that criticism has been targeted towards Kärfve and Elinder for *their ways* of attacking Gillberg, but as far as we can judge, this criticism has been essentially correct. As far as we can tell however, his antagonists have been entirely spared from the ongoing slander to which Gillberg has been subject.

There are only a handful of participants in the campaign against Gillberg who keep re-appearing: the sociologist Eva Kärfve, the paediatrician Leif Elinder, the retired military surgeon Michael G Koch, freelance-journalist Maria Louise Samuelsson, the Editor of the newspaper at Gothenburg University and the Swedish affiliate of the Church of Scientology. These debaters have on the other hand been highly active. Leif Elinder alone has written far more than 50 debate articles, with similar contents, of which the majority question Gillberg's honour.

The principal conclusions of the attacks on Gillberg have been the following:

1. The reason that Gillberg and his colleagues carry out research on ADHD/DAMP is that they want to segregate less valued individuals from society, in a way reminiscent of the Nazis' awful deeds during the 1930's (expressed by Eva Kärfve). *The truth is in fact that research on DAMP/ADHD has the purpose of counteracting segregation.*

2. Gillberg wishes to drug a huge part of all Swedish children with powerful narcotics (expressed by Eva Kärfve and The Church of Scientology). *The truth is that Gillberg always expressed conservative views on medicating the conditions in question.*

3. Gillberg and colleagues have, in order to achieve this segregation and mass medication, devoted themselves to research fraud. *The truth is that the investigation of the accusations found no grounds to believe that fraud had occurred.*

4. Gillberg has no convincing reason to oppose Kärfve and Elinder gaining access to the records in question, so his opposition only strengthens the suspicion of fraud. *The truth is that a large number of medical researchers have stated that Gillberg's position is self-evidently a consequence of current ethical rules for medical research.*

The question about drugging Swedish children deserves additional comment. In the Swedish morning paper Dagens Nyheter (5/1 2003) Kärfve writes about Gillberg:

“If one makes the assertion that 10 percent of all children suffer from a newly established neuropsychiatric, congenital, organic disturbance which damages future possibilities and makes treatment with heavy narcotics necessary, one must realise that sooner or later one has to show one’s evidence”

The message cannot be misinterpreted: Kärfve claims that Gillberg has “made the assertion” that 10% of all children should be treated with heavy narcotics. This assertion is - of course – untrue in every respect. Neither Gillberg nor any of his co-workers has ever stated anything which can be interpreted in this way. On the contrary, Gillberg adheres to a more restrictive policy when it comes to medical treatment, clearly shown for example in an article published some years before the current feud broke out (Dagens Nyheter 19/9 1997):

“Christopher Gillberg stresses that centrally stimulating drugs only will be used in a small minority of, and carefully selected, cases ... Medication can never be the only treatment; one will always primarily use educational and psychological measures”, he says.

The impact of the media campaigns is illustrated for example by the fact that in the Google database one obtains 323 hits when searching on the words “Gillberg” and “research fraud”. The newspaper The Express has, as mentioned, devoted four entire pages to the case, each filled with essentially untrue information, as an attempt to convince readers that Gillberg committed fraud. SVT (Swedish Television) devoted a section of the TV-show “Investigative Assignment” to giving a highly incorrect picture of the current research situation regarding attention disorders, and presented Gillberg's unwillingness to release the documents as a reason to question his honour.

The campaign against Gillberg is carried out with a high intensity also outside the media. Thus several of Gillberg's employers, in Sweden and abroad, have been regularly contacted with questions about whether the accusation of fraud and the judgement against him should not be reason to dismiss him. And similarly the Science Council and the Swedish General Inheritance Fund have for example been contacted with requests about withdrawing their financial support for Gillberg.

When Gillberg recently received a prestigious scientific award, representatives of the information department at Gothenburg University (also journalists at Gothenburg's

University's newspaper) – who are usually delighted about this kind of success for the University's researchers - chose to contact the donor to inform on Gillberg's supposed dishonesty.

In order also to discredit Gillberg internationally his antagonists have contacted the British Medical Journal, and given an incorrect picture to its editor of what has occurred in this matter, leading to international publicity regarding Gillberg's alleged fraud. It is quite clear that the goal of this campaign, at least for some of those who are conducting it, is to hamper or make it impossible for Gillberg to continue his work as a researcher.

The National Board of Health and Welfare's manager Kjell Asplund was also contacted by Leif Elinder in 2004, with an inquiry about whether Gillberg actually could remain as a scientific advisor at the National Board of Health and Welfare. Asplund did not contact Gillberg, but, as result of Elinder's initiative, made an official note that Gillberg until further notice would not be engaged in any assignments. Only in connection with a request from Today's Medicine to gain access to this public document was Gillberg informed. Since the indication that the National Board of Health and Welfare no longer has confidence in him was made public, it has of course been used in the campaign against him. Consequently Elinder's conversation with Asplund was not in vain.

In many respects, this campaign is strongly reminiscent of corresponding campaigns abroad staged against international researchers within Gillberg's research area. The Church of Scientology's role should not be underestimated: the initiation of legal processes against what one considers as ideological antagonists has been an important strategy for the Church of Scientology for a long time. It is stated on the homepage ([www.kmr.nu/23\\_5.2a.htm](http://www.kmr.nu/23_5.2a.htm)) of the KMR, Committee for Human Rights, with close links to the scientologists:

“Gillberg has moreover accused KMR in the press of having pursued a “well directed campaign” against him for a long time. Something we do not deny.”

## **7. The accusation of fraud**

### *A. Background*

Cases of genuine research fraud are usually revealed either because a colleague - or ex-colleague - discloses that s/he has witnessed irregularities, or because the researcher's results cannot be confirmed by others. Neither of these circumstances applies in relation to Gillberg's research.

Furthermore, the Gothenburg survey was conducted by a large number of researchers; and the fraud hypothesis thus requires that a bizarre conspiracy took place involving many more than Christopher Gillberg and Peder Rasmussen. This is a highly implausible scenario.

Moreover, studies in which fraud actually has occurred most often occur where the researcher has had a strong incentive for a particular, sensational outcome, for example that a certain medicine is effective for a certain disease. To commit fraud in descriptive research such as the Gothenburg study is by contrast completely pointless. Furthermore it is apparent that the results of the study are not at all controversial, but entirely in line with other surveys.

The reason most often expressed by Kärffve and Elinder in asserting that Gillberg and co-workers committed fraud is that they have had a relatively low attrition of participants. The Gillberg group – their opponents assert – must therefore have included fabricated participants. This argument would have been more convincing if the attrition actually had been remarkably low compared with that in corresponding studies, but this is not the case.

To refer to low attrition in a study as a reason for accusing the researchers in question of fraud, when the loss is not low, is tantamount to a false accusation. It can be added that a far more common reason for criticism of clinical studies is that the loss is too high; the opposite of what the Gillberg group has been accused of. It is thus a major strength of their study for which Gillberg and co-workers have been criticised.

In order to carry out scientific activity researchers must generate funding from State and private donors. The generosity of these funders is largely influenced by scientific reputation, so rumours about fraud, even if unfounded, evidently hamper continued activity or even make it impossible. If an individual, for ideological reasons, wants to obstruct research which displeases them it can be effective to accuse the researcher of dishonesty.

There can be no doubt that Kärffve really wanted to influence public opinion with her accusation. Her criticism of Gillberg had been pursued for several years - but based on other accusations - before she and Elinder realised that they could intensify their attacks, and maintain media interest, through an accusation of fraud.

It is notable that they were extraordinarily swift in announcing to the general public through the media that they had submitted their accusation. There was no wish from the accusers that the allegations ought to be investigated with a certain discretion, as is customary in serious fraud accusations.

In an interview in the newspaper SIF (6/2 2003) Eva Kärffve stated for example:

“I’m becoming increasingly certain. It is most probable that Gillberg has committed fraud.”

In terms of slander this would probably be equivalent to claiming that one is almost sure that someone else is a tax fraud, or is guilty of theft, despite any grounds for the suspicion, and despite the accused having been investigated and cleared of the allegations.

One can never prevent private individuals from accusing researchers of fraud in public. But it is on the other hand a priority that the authorities handling such cases act with the same professionalism, impartiality and judgement as if the accusation had concerned any ordinary crime. Unfortunately, the way the accusations against Gillberg were handled constitutes a template for how this type of case should not be processed.

A fundamental circumstance that should be taken into consideration in this context is that it can more or less never be proven – as discussed above – that a researcher has *not* committed fraud. Thus, an extremely extensive investigation – including for example a review of the 50,000 sheets of paper in Gillberg's archive – could never prove that his study had been carried out correctly in all its parts. The information in the now destroyed documents was largely recorded by the researchers; to establish that this agreed with the

information in the authors' articles would not constitute evidence that fraud had not occurred. In order to prove that Gillberg had not cheated one would be forced to seek out the participants and ask them to remember what they had stated to the researchers in the various surveys they had undergone over a period of several decades. This would of course have been impossible.

An investigation of the accusations of fraud against Gillberg can thus not aspire to prove that fraud has not occurred, in the same way that it is never the task of a court to prove that a culprit is innocent. Instead, what a fraud investigation should focus on is the analysis of whether the accusations that have been put forward give reason to believe that fraud has occurred, and, if so, to try to prove it. To state in the media that one cannot eliminate the occurrence of fraud after a completed fraud investigation which has exonerated the accused is therefore both pointless and misleading. As we shall show, those who investigated the accusations against Gillberg unfortunately chose to make statements of this kind.

There are regulations governing the implementation of fraud investigations, developed by the Swedish Universities and Higher Education Association (SUHF). It appears that the government is aware of the existence of these regulations through preliminary work on a current law within the higher education environment, and considers that most universities follow it. It has therefore seen no reason to enact the regulations in law. SUHF's regulations can consequently be considered to be sanctioned by the state. If a person had been investigated in accordance with these regulations and no reason to suspect fraud was found, one should thus have the right to be considered free from the accusations.

From the regulations it appears that the responsibility for investigating allegations lies with the university where the researcher is active. This is what happened in this case, as in all previous cases of alleged fraud in Sweden. Thus the University's Principal delegated the issue to the manager of the Sahlgrenska Academy, who in turn assigned the investigation of the accusation to the Academy's ethical council.

Although the ethical council's investigation did not include a review of the actual documents in Gillberg's archive, it did take other measures, for example interviewing researchers and employees. The investigation took eight months to conduct, and concluded that no reason could be found to suspect that fraud had occurred (25/2 2003). During the investigation the ethical council discussed whether the data should be reviewed but concluded that this was not required.

The ethical council thus recommended that the Sahlgrenska Academy's manager should take no further action on the case, which it also stated in a letter dated 26/2 2003 to the University Principal. On March 3 2003 the Principal of Gothenburg University announced this in an official decision to this effect. With this, Gillberg was intended to be exonerated, and thus he should also have the right to be regarded as exonerated. He is, to quote SUHF's regulations, entitled to "the redress indicated by an acquittal".

The redress has not however meant very much for Gillberg. Instead, his antagonists have continued to accuse him of fraud in the media.

*B. The ethical council's comments concerning the accusation of fraud*

The reason that Gillberg's antagonists can continue to question his honour in the media, even after the acquittal, is largely because of the statements made by representatives of the authority which investigated the accusation, i.e. the ethical council at the Sahlgrenska Academy.

There can be no doubt that the ethical council's statement was actually a recommendation for acquittal. In letters to the accused, Christopher Gillberg and Peder Rasmussen, and to one of the accusers, Leif Elinder, the ethical council's chairman Ove Lundgren, described the result of the ethical council's investigation as an "acquittal".

On the other hand, Lundgren felt compelled to assert in the media that the researchers had *not* been exonerated. In an interview in the newspaper "Psykologtidningen" (11/2 2004) he is quoted thus:

"A misunderstanding has been spread that the ethical council had acquitted the researchers from the accusations of research fraud. We did not do this."

And in the magazine "Today's Medicine" he writes on 13/4 2005 (along with other members of the ethical council):

"The truth is that the council never exonerated Gillberg from the accusations."

The degree of stringency and integrity in the ethical council's way of referring in the media to what had occurred is perhaps most clearly illustrated by this statement made by one of the members of this council, who, shortly after the other statement above, made the following contradictory statement (Today's Medicine, 2/6 2005):

"We did not find anything [any factors making it reasonable to suspect fraud, our remark] and consequently we recommended that the accusation should not be considered further, and this also became the University's decision. *This means that the Gillberg group is acquitted of these two accusations. We have emphasised this.*" [Our italics.]

The ethical council's proposal to the university's management thus meant that the two researchers should be acquitted, and this was also the implication of the decision that was taken by the University Principal. And the word "acquittal" was also used by the ethical council's chairman when he described the findings of the investigation in letters to the accused. But he forcefully stressed in the media that the accused were *not* acquitted, while at the same time the same ethical council stated that the accused actually were acquitted.

The ethical council's work is well summarised in a debate article in "Today's Medicine" signed by Professor Ola Stenquist (15/6 2005), and through comments by the newspaper's editor-in-chief PG Holmgren (6/4 2005, 13/4 2005). This question will not be addressed any further here, since we have been told that this is the subject of a separate notification to the Chancellor of Justice.

We will however in a later section analyse what the reason might have been for the ethical council's seemingly irrational behaviour. A crucial factor seems to be that the ethical council's chairman sometimes means by the term acquittal '*there are no reasons to believe that fraud has occurred*', and sometimes that '*there is evidence that no fraud has occurred*'. Nevertheless, as we will discuss below, other factors have probably also been significant in relation to what has occurred.

### *C. Swedish Science Council's comments concerning the accusation of fraud*

As described above, the Science Council founded a group a number of years ago, on its own initiative, to deal with questions of dishonesty. Membership of this group included, among others, the same Birgitta Strandvik who participated as a member of the Sahlgrenska Academy's ethical council in the investigation of the accusations against Gillberg.

From the regulations of the Science Council's group it appears that the only people who might remit cases to the group were University Principals, and that Principals could remit cases to the Science Council only if in their own assessment there was reason to suspect fraud.

The Science Council's group is not mentioned in the SUHF's regulations. At this particular time, the universities seem to have remitted very few of this type of case to the Science Council. Very few, if any, cases had thus been processed by the current group. It was thus normal that accusations of fraud were handled at university level, in accordance with SUHF guidelines sanctioned by the government.

An argument often expressed is that this type of question should be handled by a central authority, for example within the Science Council rather than by an authority at the university, since those who work at the institution could be considered as 'open to challenge'. It is apparent that the members of the ethical council at the Sahlgrenska Academy did not consider themselves too 'open to challenge' to handle this kind of case since over the years they have processed several accusations of fraud concerning researchers from Gothenburg. Even council member Birgitta Strandvik did not see herself as barred from participation in the processing of the accusations against Gillberg, despite the fact that she both works at, and is a manager in, the same institution as the accused.

Whether it is preferable that accusations of fraud are investigated at the same university or at a central unit is however irrelevant for this case, since the rule that applied, and still applies, is that the primary investigation should be made locally. During the time in question Madeleine Leijonhufvud was manager of the Science Council, and responsible for the council's processing of this case. In early 2004, i.e. long after the eight month-long investigation of the accusations against Gillberg was completed and Gillberg had been exonerated, Leijonhufvud as the Director-General of the Science Council chose to make the following statement in Gothenburg University Journal (1/04):

"Why does Gothenburg University not let the Swedish Science Council review this? It is important, for everyone's sake, that we do this."

And in the Science Council's own newspaper 'Research & Medicine' (4/03) we read:

"Madeleine Leijonhufvud regrets that the Swedish Research Council was not given the possibility to assist in the current case."

There was no reason for Leijonhufvud to regret that the Science Council had not reviewed whether Gillberg was a fraud. As a legally trained person, she should know that an accusation should only be investigated on the basis of its merit, regardless of how many times and with what intensity it has been expressed in the media. And from this point of view the accusation against Gillberg had already been investigated in far more detail than it deserved.

As a legally trained person Leijonhufvud should also know that someone who has been investigated and acquitted in accordance with current regulations also has the right to be considered and described as innocent. That she, as a public official, publicly regrets that an acquitted researcher has not been further investigated, is unacceptable.

And as a representative of the Science Council Leijonhufvud should moreover know that the regulations which applied to the Science Council's research misconduct group meant that there was no possibility of remitting cases to the Science Council unless there were reasons to suspect fraud: "it is thus the responsibility of the Principal to ensure that matters reported to him which, in his assessment, lack justification do not become subject to further investigation."

When the accusation against Gillberg had been investigated for eight months, and after the investigators had established that there was no reason to suspect fraud, the University Principal thus had no right to remit the case to the Science Council.

The Science Council has a unique position and prestige among researchers in Sweden. That a representative of the Science Council should proclaim in the media that it is regrettable that the authority has not investigated whether a named researcher has committed fraud will probably cause significant damage to that person, for example by hampering his chances of receiving grants from other organisations. For those whose objective is to scandalise Gillberg, Leijonhufvud's entirely unjustified statements meant a significant success.

It is difficult to understand why Leijonhufvud chose to make these statements. We have posed the question to her, but without receiving a satisfactory reply. As we discuss below, it is possible that her error depended on the fact that she had incorrect or insufficient information concerning the case and the outcome of the fraud investigation that had been done in Gothenburg.

We had reasons earlier to scrutinise Göran Hermerén statement in connection with the judgement against Gillberg that Gillberg had issued undertakings of confidentiality which were too extensive, and that "no one wants to have" research that cannot "be scrutinised". In the same context he found reasons to update his accusations of fraud against Gillberg (Gothenburg Post 28/6 2005):

"If there are any suspicions about scientific dishonesty they must be able to be reviewed, he says. The Science Council is already preparing guidelines on how researchers should handle the conflict of interest between confidentiality and control of research results."

In connection with the sentence against Gillberg by the district court, Hermerén chose, clearly addressing Gillberg, to state that suspicions of dishonesty must be verifiable.

The reader is thus given the impression that there are suspicions about whether Gillberg actually has carried out an act of dishonesty in research, and that it is because of his unwillingness to let these suspicions be investigated that he has now been sentenced by the District Court. But the truth is – as discussed above – that the Administrative Court of Appeal had not even understood that Gillberg had been accused of fraud when it gave Kärfve and Elinder the right to access the documents. Whether it was right or wrong that the court gave them the right to access these documents, and whether it was right or wrong of Gillberg to oppose them being released, therefore has nothing to do with the

question of how dishonesty in research should be investigated. And hopefully Hermerén shares our view that accusations of fraud should not be investigated by those who put forward the accusations. His comment is therefore difficult to understand.

Also internationally the representatives of the Science Council have seen reason to spread the message about the need to review Gillberg. On the homepage of the Norwegian ethics committees ([www.etikkom.no/Nyheter/2005/270505](http://www.etikkom.no/Nyheter/2005/270505)) the above mentioned Thomasson states:

“The issues concerning Gillberg's research have become far-reaching. It is a pity that the core question; whether or not Gillberg's research is scientifically viable or not, has been put in the background, he says.”

Among people who, unlike Thomasson, are well acquainted with the field of research—and who are not filled with an ideological or personal aversion against Gillberg – Gillberg's results are not at all controversial. And that the Science Council's own scientific assessors do not see any reason to question his research is shown by the fact that he was highly rated, and was allocated a large grant, when an application from him was dealt with recently. Against this background it is both surprising and unfortunate that an official at the Science Council finds reason publicly to state that it is a pity that the “core question” of whether Gillberg's research is “viable” is “put in the background”.

A fourth expert linked to the Science Council in ethical questions is the previously mentioned Birgitta Strandvik, a member of the group dealing with questions of dishonesty. Shortly after a majority of the ethical council had established that they found no reason to suspect that Gillberg had been guilty of misconduct, and that it therefore advised the Principal not to take any further measures, and shortly after the Principal had made a decision exonerating Gillberg from the suspicion about fraud, Strandvik chose to come forward in Gothenburg University Journal:

“If the Science Council could have scrutinised Gillberg's research he would have been cleared and the whole thing would have been over. This would also have been good for the general public's confidence in medical research, says Birgitta Strandvik.”

If one became subject to an investigation that led to the finding that there is no reason to suspect fraud, one has, according to SUHF's regulations, the right to redress. That a representative of the Science Council – who moreover happens to be a member of the local ethical council – discusses in the media what should have been done in order for the researcher in question to be “cleared”, and in order that “the whole thing would had been over”, is not committed to promoting this redress.

In the next issue of the University journal Strandvik returns to the matter, this time with an article written personally by her. She begins – quite groundlessly - by stating:

“Gillberg and his many supporters assert that accusations of fraud are slander and therefore should be disregarded.”

And she continues by regretting that the Principal at Gothenburg University has not remitted the case to the Science Council for further review:

“I still regret that the Principal has not done this so that we could end this morbid and damaging polemic – for all involved and for the scientific community as a whole.”

There would have been no problem if Strandvik had chosen to mention in her article that Gillberg actually had been investigated for eight months, in accordance with current regulations, and acquitted. But she does not mention this. And neither does it appear anywhere in the article that she had participated in this investigation, as a member of the ethical council.

The assertion that Gillberg's "supporters" consider that the accusation of fraud should be disregarded is completely plucked from the air. What Gillberg's defenders had pointed out was that he actually was both investigated and acquitted.

It would also have been helpful if Strandvik had informed the newspaper's readers that the Science Council's own regulations stated that cases can not be remitted unless a primary investigation at the University had led to the conclusion that there were reasons to suspect fraud. Strandvik does not mention this, and neither the fact that she also is a member of Science Council's ethical group, and thus one of those to whom she considered that the question should have been remitted.

Four representatives of the Science Council - Strandvik, Thomasson, Hermerén and Leijonhufvud – in various contexts, after Gillberg was investigated and acquitted, made statements that can be interpreted as meaning that the matter should have been sent for further review. These actions – not based on any assessment of the essential credibility of the accusations – are inappropriate, partly because it is not up to them as representatives of the Science Council to express any opinion on this matter, and partly because there is no reason to believe that Gillberg has committed fraud. The damage caused by their initiative becomes so much greater since it took place concurrently with an extensive slander campaign in the media targeted against Gillberg, alleging that he has committed fraud, and that he has not been sufficiently investigated.

The impression that the ethicists within the Science Council have taken a position *against* Gillberg on this matter is enhanced after a hearing was arranged about investigations of dishonesty. Leif Elinder, who is not a researcher, and whose only qualification in this context was probably that he reported Gillberg for research fraud, and who probably intended to cause damage, was invited to this meeting. On the other hand, Gillberg himself was not invited.

The same impression is enhanced by the fact that the Science Council's ethics expert Björn Thomasson in "Today's Medicine" illustrates the importance of the ability of the Science Council to take disciplinary measures, for example discontinuation of grants, against unethical researchers, by referring to the Gillberg case (24/11 2004). It should be mentioned however that Thomasson regretted the formulation of this article in a later issue of the newspaper.

From a legal point of view the four representatives of the Science Council should probably have the right to express their opinion on various questions in the media, however thoughtless these opinions may be. On the other hand these events should possibly lead to an overhaul of the Science Council's engagement in research ethical questions, and of which form this should take.

*D. The ethics expert's dual roles.*

There may be reasons to speculate on why representatives of both the ethical council in Gothenburg and the Science Council made the damaging (to Gillberg) statements mentioned above. The media pressure on all those who engaged in the matter may of course have played a part. The premature actions of the management of Uppsala University in the current Eva Lundgren case mentioned below illustrate the difficulty of public servants remaining level-headed during this kind of media attention. Nevertheless, the attitude and actions of Birgitta Strandvik are probably factors of greater importance.

When, after eight months' investigation, the ethical council at Gothenburg University, took its decision to recommend that the President and Principal should close the case, Strandvik registered a reservation. Note that this reservation, according to her clear statements, was not because she thought that the investigation had yielded any reason to suspect fraud, but because the case had received extensive media coverage. Strandvik thus chose to relinquish the self-evident principle taken from other contexts that an accusation will only be assessed on the basis of its own qualities, and that irrelevant factors may not be permitted to influence the process.

Our firm impression is that Birgitta Strandvik – after the ethical council submitted the case – was not satisfied with the fact that she had made a reservation in the council's minutes. Instead, she has continued – with a certain frenzy – to state her view through various channels that the case should be remitted to the Science Council for continued investigation. Our supposition is supported among other things by an interview she granted Gothenburg University Journal, and by a debate article she wrote for the same newspaper (see above).

We have moreover gained access to an e-mail correspondence between ethical council members approximately 10 months after the council had submitted the case and recommended the acquittal of Gillberg to the President and Principal. The question that the council's chairman, Ove Lundgren, wished to review with the council's other members – after having contact with Strandvik – is whether they thought at this stage that the ethical council should contact the University Principal and suggest to him the referral of the fraud accusation to the Science Council. The proposal seems to have been rejected by the council's other members, since no formal question to the Principal was raised. However, the correspondence between Lundgren and Strandvik still illustrates how they felt free to act on this matter – as members of the ethical council – long after the question had been dealt with by the ethical council, and therefore no longer concerned its members, and long after the official decision which stated that Gillberg was acquitted.

Birgitta Strandvik was – as mentioned – not only a member of Sahlgrenska Academy's ethical council, but also member of a corresponding group within the Science Council, i.e. the group to which she wanted the accusation against Gillberg to be remitted. It is possible that her eagerness that the case should be remitted to the group was simply because she was disappointed that universities in general had shown very little enthusiasm in referring cases to this newly formed group, and that it was therefore essentially still non-functional. And it is possible that she, despite being a member of the group, actually had not acquainted herself with its own regulations showing that cases could not be remitted to the Science Council unless there was reason to suspect fraud.

It may be that the unfortunate statements made by various representatives of the Science Council might have been influenced by the fact that the information they received about the process of the case in Gothenburg mainly came from someone who was displeased with this process, i.e. Strandvik. That contacts on this matter between representatives of the ethical council and the Science Council occurred after the ethical council submitted the case and no longer had formal reason to concern itself with it, is clearly shown in an e-mail from Strandvik to Leijonhufvud archived at the Science Council and appended in this notification (annex 7). Note that Strandvik finds reason in this letter to describe the ethical council's eight month long investigation as "preliminary", despite it leading to an official decision indicating that the case was signed off. The situation is additionally complicated by the fact that Strandvik works at the same institution as Gillberg, and as head of department should be considered as one of his managers. Our specific opinion is that she should not have participated in the process of this case because of this conflict of opinion. It is out of the question that her position in connection with the ethical council's processing, and her continued actions when the ethical council closed the case, should have been influenced by a major disagreement between her and Gillberg a number of years ago. On the other hand, this disagreement constitutes yet another reason why she should have reported conflict of interest at an early stage.

We believe that those who participate in the investigation or judgement of this kind of process should limit their discussion of the question in the media and other contexts. *Either* one accepts a commission to act as a reviewer, but abstains from debating the different aspects of the question in the press, *or* one can choose to discuss the question publicly - but then one should decline a formal investigative role. Both to participate in the formal processing and publicly debate different aspects of the case, seems inappropriate to us.

#### *E. The visit to the archive*

Yet another aspect of the investigation of the accusation of fraud should be touched upon; not because it has any specific relevance to the formal processing of the case, but because to a great extent it has moulded the image provided by the media of whether Gillberg and employees have been exonerated or not.

After the investigation of Gillberg's and Rasmussen's supposed fraud was completed, and the ethical council had come to the conclusion that they found no reason to suspect fraud, the ethical council's chairman Ove Lundgren was interviewed in the Gothenburg Post (26/2 2003) and elsewhere.

It would have been most appropriate if he had declined the interview and instead referred to the ethical council's written statement, or to someone who had to take the formal decisions in the case, i.e. Sahlgrenska Academy's President or Gothenburg University's then Principal. We must bear in mind that the ethical council is only an investigatory and advisory authority, and thus can only issue a recommendation on the question of a possible acquittal. But Lundgren unfortunately was willing to comment on the case.

From the interview with him the following emerges:

"There are no reasons to believe that there has been any dishonesty in their research."

But later in the article this passage follows:

“The Principal passed the question on to the ethical council which in total has collected four official letters from the parties. Ove Lundgren has also been in personal contact with three of the four child psychiatrists who, at Gillberg's request, performed the actual survey and also interviewed the co-ordinator who kept the lists with the different groups of participants, a person who “gave a very solid impression”. But she of course got the list from Rasmussen and Gillberg and does not know how they were actually compiled. If we want to find out whether outsiders were incorporated into the groups we must investigate the original material, and we have not had access to this.”

This comment by Lundgren was – for Rasmussen and Gillberg – quite devastating, since it effectively cleared away the redress they were entitled to. Lundgren should have understood that Gillberg's antagonists would continue to build on the suspicions of him with reference to this statement, as if the accusation had never been investigated. Through his statement, Lundgren made the eight month long investigation that Gillberg and Rasmussen endured completely ineffective.

Imagine that a police commissioner receives a completely groundless notification from a private individual indicating that his neighbour – with whom he has an ongoing bitter conflict – is a large-scale thief. Assume furthermore that this policeman, after a certain period of investigation, establishes that there are no reasons to believe that the accusation is justified, and therefore chooses to close the investigation. And imagine finally that he is interviewed about the case in the media after the investigation is closed. The accused is a well-known person and here he states that after all he cannot of course exclude the possibility that this person is a large-scale thief because the police never saw fit to search all the many places in the town where he might possibly have hidden his allegedly stolen goods if he had after all been a large scale thief.

Or assume that a judge after having announced an acquittal in a murder case holds a press conference at which he announces to the press that the court has indeed acquitted the accused since they found no grounds to believe that he is guilty. But one still cannot be entirely certain that the acquitted person actually did not commit murder, since one could not, or did not try, to prove that he is innocent.

Lundgren's statements about the investigation of Gillberg's supposed fraud seem to us equally well thought through.

Moreover, Lundgren's comment was unfortunate in that it gives the reader the impression that the ethical council did not have the possibility of checking whether the list in question was correct or not. But this was not so. Lundgren had at an earlier stage made an agreement with the Gillberg group about an inspection of the archive. He could have checked the lists at this time, to see if – as Kärfve and Elinder asserted – any participants had been added to the study afterwards, and if the list seemed correct. Note that this control could have been carried out without Lundgren gaining access to any sensitive information about the examined individuals. Lundgren however cancelled this meeting at the last minute, since the ethical council did not consider this on-site inspection necessary in order to announce the recommendation that the case should be closed.

As a result of Ove Lundgren's entirely unjustified statement in the Gothenburg Post the managements of Sahlgrenska Academy and Gothenburg University were put in a quandary. They had put Gillberg and Rasmussen through the discomfort and damage

caused by being subject to a highly publicised fraud investigation for eight months. On the other hand they could not ensure – despite the acquittal – that the accused were given the redress they were entitled to, since the ethical council’s chairman had disavowed the investigation that resulted in the acquittal in the media.

At this stage, the thought arose to ask Lundgren – who had established in the interview that he had no possibility of examining whether the list that he may have gained access to was correct – should subsequently undertake this further inspection. If he agreed to this commission, and if the outcome of this inspection gave no reason to suspect fraud, maybe that result would neutralise his comment. After having discussed this possibility with the Academy's manager, Göran Bondjers, and – in the Principal's absence – with the Director Bengt Wedel, who both supported this measure, Lundgren accepted this assignment.

We again wish to stress that Lundgren himself, along with the majority of the ethical council's members, had recently established that an inspection of the documents was unjustified, since there was no reason to believe that any participants had been included afterwards. It was thus *not* because there were considered to be any real reasons for Lundgren to check the documents. But as a consequence of Lundgren's statements in the media this seemed to be both a necessary and acceptable solution.

It should also be stressed that Lundgren’s visit to the archive could not in any respect contribute to the decision on whether Gillberg and Rasmussen would be exonerated or not, since there was already a formal official decision that Gillberg and Rasmussen were exonerated on the basis of the ethical council's earlier investigation. His own statements in the Gothenburg Post therefore constituted the only reason that Lundgren was asked to visit the archive in question. Had he not made these statements he would never have been requested to visit the archive.

Lundgren spent as much time in the archive as he considered he could allocate, and then reported what he had observed to President Göran Bondjers. Lundgren did not gain access to any sensitive information about the participants at the inspection.

We know nothing about what was expressed during the deliberation between Lundgren and Bondjers, but in discussions with the two of us Lundgren later said that his inspection give him no reason to assume that the groups had been manipulated in any inadmissible way. Clearly this is also what he expressed to the reporter of the Swedish Television show “Investigative Assignment” since in this programme, where Lundgren was interviewed, they stated the following:

“Ove Lundgren saw that the researchers had not added any new participants to the material, which they have been accused of.”

Also Lundgren seems to have expressed the same thing to Bondjers. The immediate result of Lundgren’s review was thus that Bondjers decided to make a press release, whose only aim was to repair the damage caused to Gillberg and Rasmussen by Lundgren's earlier statement in the Gothenburg Post. However this could of course not act as a new “acquittal”, since Rasmussen and Gillberg had already been acquitted.

On the basis of Lundgren's report and his own assessment of the case, the Academy's President Göran Bondjers decided to make a press release. The main theme of this press release was a repetition of what had already established - that Gillberg and Rasmussen

were exonerated. Lundgren was thus *not* requested to make his *own* new assessment of the case, and neither was he conducting his inspection on behalf of the ethical council.

At this point this case could have been closed, if Lundgren – probably after he had been contacted by the members of the ethical council – had not once again found reason to present himself to the media. This time his message to the general public was that his four hour long investigation was *on the one hand* too brief to lead to an exoneration of Gillberg and Rasmussen, *and on the other hand* that he should not have undertaken this review since he was active in the same institution as Gillberg and Rasmussen, and was thus open to challenge. Lundgren's summary of what occurred has been in repeated statements that he felt “used”.

The following can be stated about Lundgren's arguments:

1) He had already suggested to the Academy's manager to exonerate Gillberg and Rasmussen *before* he carried out his inspection of the documents, and an acquittal had also been issued. His visit to the archive thus did *not* form a basis for the acquittal of the two researchers.

2) Lundgren could understandably not *guarantee* that the researchers had *not* cheated, even if he had spent 10 years in the archive, and even if assisted by a staff of forensic scientists. To issue a final exoneration, if by “exoneration” we mean it being proved that not even one irregularity had occurred in the mass of material, is entirely impossible in this type of study, as well as in almost all other research projects. But this can on the other hand never be the task of a fraud investigator, just like it is not a policeman's job to prove that someone is innocent of a crime. There is thus no one who has considered, or asserted, that Lundgren – after his limited inspection – could vouch that the project whose archives included approximately 100,000 pages had been implemented correctly in all respects.

3) It is peculiar that because he is an employee at same university as Gillberg and Rasmussen, Lundgren considers himself too ‘open to challenge’ to carry out this limited review, but had not considered himself open to challenge when he investigated the accusation of fraud for eight months. And it is also peculiar that earlier, within the framework of the ethical council's activity, he considered himself, along with colleagues at the same university, able to make decisions in several cases without considering whether being open to challenge would be problematic.

4) It would of course have been better if he had declined the offer if he had felt doubt before the assignment in question. If he considered himself so much open to challenge, and if he did not consider that he could draw any conclusions from a visit to the archive, it was of course entirely pointless that he carried out this assignment at all.

One explanation for this remarkable event could be that the ethical council incorrectly considered – or chose to consider – that Lundgren visited the archive in his capacity as the council's chairman, and criticised him for taking this measure without first consulting with them. And that this criticism made such an impression on him that he felt himself compelled forcefully to dissociate himself from what had taken place. Since Strandvik acted in parallel with this with some frenzy in order to get the case remitted to Science Council it is easy to imagine that she did not approve of Lundgren's actions.

Lundgren's visit to the archive was later the cause of another conflict about who initiated the inspection in question. In a letter to the University Principal that must also have been sent to Leif Elinder since he quoted it in one of his published debate articles (*Today's Medicine* 9/3 2005) before it was registered at the University, Lundgren accused Gillberg of "a pure lie", since – in a letter to the previous Principal – he claimed that the inspection was made at Lundgren's own initiative. This criticism by Lundgren of Gillberg is based on an unfortunate misunderstanding, since Gillberg does not claim anywhere in the letter that it was on Lundgren's own initiative he visited the archive. Lundgren's statement that Gillberg was lying was thus inaccurate. But it is true that Lundgren's inspection was not made on his own initiative, which no one has in fact claimed, but must be regarded as an assignment from president Göran Bondjers and – in the absence of the Principal – Director Bengt Wedel. One of us (EE) was directly, but informally, involved in the discussions that preceded Lundgren's visit to the archive, and therefore has first hand information about the background to this event, and the other one of us (KH) later discussed the question with Lundgren. From our perspective there is no doubt that a) Lundgren did not implement the inspection on his own initiative, b) the factor that initiated this measure was his own unfortunate statements in the *Gothenburg Post*, and c) prior to the visit to the archive he had direct contact with Bondjers and Wedel, who both supported the inspection.

To Gillberg's antagonists, Ove Lundgren's actions have been very useful, since the public have been given the impression through his statements in the media that the fraud suspicion was never investigated, and that no acquittal ever occurred. Here are a few examples:

*News article by Maria Louise Samuelsson, "Today's Medicine", 3/3 2003:*

*Headline: "GU's "acquittal" of Gillberg built on superficial review"*

*Our commentary:* The acquittal was not built on the "superficial review" referred to, i.e. Lundgren's visit to the archive. Gillberg had already been exonerated when Lundgren implemented his inspection.

*Article by Michael Koch, "Today's Medicine", 26/1 2005:*

"The ethical council's chairman wrote that he had made it entirely clear to the current research group and to the University President (manager) that he considered that his four-hour long investigation was not sufficiently extensive and that a thorough review... should be carried out by an outside reviewer. (7/5 2003, Ove Lundgren, Emeritus Professor, Sahlgrenska Academy)."

*Our commentary:* The ethical council's actual recommendation to the Academy's President and the University Principal was in fact that a "thorough review" was *not* justified, but that the case should be closed.

*Article by journalist Lars Nicklason, Gothenburg Post, 19/1 2005:*

"That Gillberg was acquitted by Gothenburg University's ethical council is incorrect. No proof of research fraud has been found for certain, but the ethical council's chairman Ove Lundgren has pointed out in a letter that the four hour long investigation was insufficiently extensive and that a more extensive review should be carried out by an outside expert group."

*Our commentary:* Gillberg was exonerated, and this acquittal was *not* based on Lundgren's four hour long investigation that was carried out after the exoneration was already a fact, but after an eight month long investigation. Niklason's assertion that Gillberg is not acquitted should be read side by side with the above quoted statement from "Today's Medicine" 2/6 2005, in which a member of the ethical council establishes: "This means that the Gillberg group is acquitted from these two accusations. We have emphasised this." And Niklason's assertion that Ove Lundgren suggested a more extensive review should be read side by side with the ethical council's decisions to recommend that the President and Principal should not take any further measures.

*Article by Leif Elinder, "Today's Medicine", 9/3 2005:*

"Elias Eriksson pledges that the Gillberg group has been acquitted. This is wrong. In a letter to the University Principal the ethical council's chairman writes the following: It was clear before that four hour long review of the material (N.B. 22 metres of shelving, 100 000 pages of research material), that I made it entirely clear to Gillberg and Rasmussen that I could never certify on the basis of the survey that dishonesty in the research had not occurred. Finally, I have never in my professional life felt as used as I have in this affair (February 21, 2005, Ove Lundgren, Emeritus Professor of physiology, member of the Academy of Science)."

*Our commentary:* Gillberg was, as stated, already acquitted in accordance with current regulations before that four hour long inspection took place.

The message that Lundgren's inspection was too limited to make an acquittal was also provided in the earlier mentioned articles in "The Express" and in the TV-show "Investigative Assignment" in which Lundgren was interviewed. Nowhere in the programme is it mentioned that Gillberg and Rasmussen actually are exonerated, and that this had already happened before Ove Lundgren visited Gillberg's archives. And neither does it say that Ove Lundgren, who was annoyed in the programme that a more extensive survey was never implemented, is the same person who – in his capacity as chairman of the ethical council – made the decision to advise the President and Principal not to engage any external reviewers. It is not known to us whether Lundgren expressed to the editorial board at "Investigative Assignment" after the programme that a strongly misleading image of his own role on this matter had been presented.

In direct discussions with Lundgren one of us (KH) brought to his attention that he had been misquoted, and this had been used by those running a media campaign implying that Gillberg has not been exonerated from the accusation of fraud. A public clarification from Lundgren would, in our opinion, have been a reasonable measure.

#### *F. Comments from Gothenburg University management about the accusation of fraud*

The management of Gothenburg University (the previous Principal Bo Samuelsson and the current Principal Gunnar Svedberg) and the Sahlgrenska Academy (the previous president Göran Bondjers) have tried to perform what should be their duty, i.e. to give the accused researchers the redress an acquittal should mean. That they failed to do this, after the eight month long fraud investigation ending in acquittal, results from unfortunate statements from other public servants: the employees who constitute the editorial board at

Gothenburg University Journal (see below), and the members of the ethical council at the Sahlgrenska Academy.

In retrospect we can see that it was a mistake to entrust the ethical council with the sensitive assignment of investigating this accusation, since the council proved itself insufficiently competent. The management of the University and the Academy could not however have anticipated this, and can therefore not be blamed. On the other hand, the previous management of the medical faculty should have issued clear regulations to the council, which seems never to have taken place.

A more obvious mistake was that long after the that the fraud investigation was completed, and long after an official decision was taken indicating that Gillberg and Rasmussen were exonerated, a meeting of the University Board in December 2004 took up the question of whether there were after all grounds to remit the accusation of fraud to the Science Council.

One reason for this unjustified measure was probably that the Board nourished a hope that by engaging further investigators it could resolve the predicament the University had been placed in by the judgements in the Administrative Court of Appeal. As discussed above (p. 45) there was however no connection between the accusation of fraud and the judgements in the Administrative Court of Appeal which could possibly have justified any kind of bargaining between the University and Kärffe/Elinder.

The mistake of raising this question at all at a board meeting is however compensated by the memorandum that Principal Gunnar Svedberg laid before the board at this meeting, and which they unanimously supported, in which it was stated refreshingly clearly that there were no reasons to resume the fraud investigation.

To illustrate the fact that the University management, despite good efforts, failed to give the researchers the redress they were entitled to, is shown by the following example. The Express, as mentioned above, devoted four entire pages to this case, in which the readers are provided with the impression that there is something dubious about Gillberg's research, and that he has not been exonerated from the allegations of fraud. When in a notification to the Press Ombudsman (Olle Stenholm) Gillberg points out that he actually had been investigated and acquitted according to current regulations, the Press Ombudsman's comment is this:

“The complainant considers that the newspaper has given an incorrect picture by not taking into consideration that Gothenburg University had rejected all suspicions against him for dishonesty in his research. No press ethical reprimand can be aimed against The Express for not making the same evaluation as the complainant about the review that the University performed.”

Irrespective of what one thinks about the Press Ombudsman's statement it shows that no reparation of Gillberg's honour was made, even though he had been investigated for eight months and even though no reasons to believe that he committed fraud were found during this investigation, and even though the investigation led to an official decision that the case was closed.

Stenholm's wording that the University has made “its own review” is an echo of what Elinder (for example) usually states, namely that the acquittal of Gillberg is inadequate

because the University reviewed its own case. This argument should be seen in the light of the current, government-supported, regulations which clearly state that it is the researcher's own university that should process this kind of case. And it should also be seen in light of the fact that all previous cases concerning potential research fraud in Sweden have been processed according to these regulations, except when the acquittals (or judgements) that these investigations led to have been questioned.

Finally, it should again be emphasised that what we describe at length above regarding the fraud investigation appears even more bizarre in light of the fact that those accusations of fraud on which the case was based are entirely without substance, and should, in our view, have been laid to rest immediately. This position is strengthened because before it investigated the accusations from Kärffve, the ethical council had processed a similar application from Leif Elinder with essentially the same accusations, and then – unanimously – had decided to reject this notification without any investigation at all. That fact that it could reject Elinder's notification directly, but considered it needed eight months to reject Kärffve's accusations, give us reason to assume that unimportant aspects – for example the media attention – unfortunately influenced the council's work. It can be added can that SUHF's regulations stipulate that this type of investigation, with respect to the accused, should not last longer than two months.

The ethical council's actions are as we have said subject to a separate notification to the Chancellor of Justice, and thus we are not asking the Chancellor of Justice to investigate this matter.

#### *G. Why Gillberg continues to be an object of suspicion*

Despite the lack of reasons to believe that Gillberg has committed fraud, and despite him having been investigated and acquitted entirely in accordance with current regulations, many writers still feel able to identify him as a potential fraud. In summary, we can identify four reasons as to why Gillberg has not received the public redress he is entitled to, and which has been given to all other innocent researchers in Sweden accused of fraud after they have been investigated and exonerated.

**1.** Many accusation of fraud – both justified and unjustified – have their basis in bitter disagreements between the reporting party and the reported. But this is still, as far as we know, the first time that those who accuse someone of research fraud concurrently raise their accusations in the media, and moreover, repeat them with increased intensity after the accused has been investigated and acquitted. Although this of course is the single most important factor in the survival of the accusations, it is however not a sufficient explanation. If public officials had handled the question correctly, Gillberg's antagonists' questioning of the acquittal would have had limited success.

**2.** A crucial factor in the development of the case was probably that the Science Council, some years before Gillberg became accused, had created its own group to pursue investigations of possible dishonesty. Unfortunately this group was not incorporated into the current regulations for fraud investigations, i e those developed by SUHF. The fact that the universities, in accordance with SUHF's regulations, long went without remitting dishonesty cases to the Science Council's group, and instead continued to investigate these kind of cases within the respective universities, appears to have led to disappointment within the Science Council. That Birgitta Strandvik, in her capacity as

member of the Sahlgrenska Academy's ethical council, acted so forcefully to get the accusation against Gillberg to be remitted to Science Council, is probably connected to the fact that she was also a member of the Science Council's corresponding group, and of the view that this authority was more suited to handling this type of question than the university. Had Strandvik succeeded in achieving a referral of the accusation made against Gillberg to the Science Council's group it would probably have meant some kind of a breakthrough for this authority, for which Strandvik was probably striving.

3. Yet another important factor would probably have been the ethical council chairman's unfortunate tendency to comment on the case in the media. In this type of question, for reasons of justice, all the investigating authority has to state should be clearly shown in a written statement; a good rule is that one should not make *any* additional statements, and in particular no statements that can lead to a decision about acquittal being questioned. Lundgren's many statements in the media have undoubtedly been of great value for those who run a campaign against Gillberg. Criticism can in this respect be aimed against the Sahlgrenska Academy because they had established an ethical council seemingly without giving the members any basic instructions about what should be expected of them as members of this council.

4. The probably incorrect judgements in the Administrative Court of Appeal, and the fact that Gillberg considered himself for ethical reasons unable to take part in obeyed them, has self-evidently also lent itself to being used as a reason to suspect him. This negative consequence could have been weakened if public servants had made clear that Gillberg was right when he stated that it is a breach of current ethical regulations to break promises. But instead the Science Council seemed keen to publicly dissociate itself from Gillberg's actions despite these being entirely in line with the regulation the authority has implemented. The officials at Gothenburg University's information department, i.e. the editorial board of the Gothenburg University Journal, also came to play a crucial part, in so far as they carried out what can be considered as a journalistic campaign against Gillberg due to the fact that he acted in accordance with ethical regulations.

#### *H. A general view on fraud investigations*

A false accusation about research fraud can have consequences for the individual as serious as a false accusation about having committed any crime. In the event that authorities should devote themselves at all to investigating and to making judgements on questions of alleged research fraud, it is important that it is carried out with a high requirement for justice.

Although the processing of this actual case has been handled unusually unprofessionally, the difficulties of handling this type of question correctly – and the risk that fraud investigations do not end in anything conclusive – can be illustrated also by another current case, namely the case of Professor Eva Lundgren at Uppsala University. For our own part we are highly sceptical about the theories and results that Lundgren has put forward, but we share her and others' criticism aimed at the way Uppsala University initiated and investigated her alleged fraud. There are reasons to agree with the comment below from one of the two researchers who investigated the accusations against her, Professor Jörgen Hermansson:

“I cannot, in conclusion, abstain from providing a more general reflection around this case. How should one reflect on how research becomes reviewed in this kind of quasi-judicial review? My view is most decidedly that this is a most unfortunate solution. To begin to speak about dishonesty and fraud, when one considers certain researchers’ results as odd or controversial, only risks destroying one of the most fundamental things – both within science and in the public debate – namely, in essence, that we try to refute and to criticise each other.”

Cases of gross research fraud occur; just recently a case in Norway and a case in Korea aroused justified attention. Some kind of system for investigating this type of suspicion, conducted in a public way, should probably exist. But concurrently one should clearly understand that it is hardly ever possible – as discussed earlier – to prove that a researcher has *not* been dishonest: the original documents that the investigators have to review are in general established by the suspect alone, and the level of truth in the information that exists is often impossible to establish afterwards. And one should also take into consideration that those researchers who in general are assigned to investigate this type of question does not have that forensic competence that would often be needed in order to get to the bottom of an accusation.

In cases when fraud has actually taken place, and is easy to disclose, there are often no problems. But the difficulties mentioned above mean that there is a significant risk that fraud investigations noticed in the media seldom lead to the complete redress to which an innocent accused researcher is entitled, but instead leave a distrust towards the accused, which can become seriously damaging for him/her. The case discussed in this letter is an unusually clear example of this.

If society should take part at all in this matter, outside the regular administration of justice, the requirements of professionalism and justice must be set very high. The authorities’ handling of the accusations against Gillberg and Rasmussen must, in our view, be considered a scandal that must never be repeated.

A proposal has recently been launched for the establishment of a central judicial authority where researchers can be judged guilty of fraud without the right to appeal. There are reasons to feel a certain scepticism about this proposal. A better way is probably clearly to make research fraud – when it is carried out with public resources – a criminal offence, and let this type of case be processed by the general court system, with researchers as consultants and expert witnesses.

## **8. Campaigning journalism as an exercise of authority**

Leading the slander campaign against Gillberg in the media has been Gothenburg University’s own staff newspaper, GU Journal. The newspaper’s attacks on Gillberg have been so slanted and untrue that on three separate occasions within a short period it was forced publicly to apologise to him - probably some kind of record in Swedish press history. These reverses appear however to have immediately spurred the editor to intensify his attacks against Gillberg.

The trigger for GU-journal’s critical coverage of Gillberg was their attitude to the question about the release of the documents in question, but over time the newspaper’s attacks also came to deal with other, entirely irrelevant questions. When Gillberg was

awarded a scientific prize it tried for example to insinuate that the prize committee's chairman had close personal contacts with Gillberg, in other words - by implication - that the award was an expression of nepotism. The news item was wrong about the matter, and a correction was later published.

In the very latest edition yet another in the list of powerful attacks against Gillberg was published, this time in the form of a letter to the editor, written by Michael G Koch, containing a series of untrue assertions. In a contribution in the same issue the newspaper's editor-in-chief defends Koch, and establishes, in connection with the ongoing court process: "and now justice has its time." The wording cannot be interpreted in any other way than that the editor, who is also a civil servant and public officer, is pleased with the verdict of the district court, and considers hereby that justice hereby has been done.

Our intention is not that Office of the Chancellor of Justice should check the published articles from the point of view of press ethics. On the other hand, we think that there are reasons to raise the question about whether, on the whole, civil servants should be carrying out campaigning or investigative journalism. It is admittedly true that the State carries out such activity through SVT and the Swedish Broadcasting Corporation, but it deals then with an activity which is strictly regulated with respect to, for example, requirements for fairness, and which is conducted within an independent company.

Campaigning journalism as a form of exercise of authority, about which there are questions in relation to the GU Journal, seems to us essentially more problematic. Apart from the international and historical experience of State-driven journalism being unattractive, there are also practical problems if government officials act as investigative journalists. An example of this is if the person who turns with confidential information to GU-journal's editor-in-chief, in the faith that he is protected by confidentiality, and can expect his anonymity, has in fact written a letter to a government official, a letter that thereby becomes public.

This relation is illustrated by the following event: one of the signatories of this document (EE) contacted journalists at GU-Journal, in order to provide information to them about facts relevant to the case that he though would be relevant to their continued journalistic monitoring of the case in question. He emphasised, when he contacted the newspaper for the first time, that he saw himself as an anonymous source – a constitutional right – which the journalists accepted. That this anonymity was nevertheless never taken into consideration became clear at a later stage, partly in so far as that those contacts which occurred between EE and the newspaper's editor were reviewed in another newspaper (The Journalist 17/11 2003), and partly in so far as it emerged that Eva Kärffve had been informed about those letters that EE had sent to the editor. When EE asked the managing editor why an outsider (Kärffve) had been informed about the email he had sent to the newspaper's journalist - and to which he had requested that confidentiality should apply – the reply was: "we do not really understand your anxiety. The principle is that all documents that are submitted to an authority are public, irrespective of the means of distribution."

The episode is in itself of no significance, and has not had any negative consequences for those involved. But it still makes clear that the roles of investigative journalist and public officer can be difficult to reconcile, and perhaps should not be reconciled.

There are also other reasons to ask if it is appropriate that journalists – who are subject to and dependent on University management - see as their responsibility the critical investigation of activity carried out within the same University, and in doing this do not hesitate to launch attacks against individual employees. We do not believe that this is usually a staff role within private companies, nor within other public authorities. If one critically investigates an activity one ought not to be in position of dependence on the management of the activity in question. It is for example difficult to imagine that journalists at the Express in an editorial role would carry out investigative journalism targeted towards the newspaper's editor-in-chief or at other journalists at the same newspaper.

The situation that has emerged has also been strange in that it was the University's information that ensured that Gillberg obtained the redress denoted by an acquittal from the accusation of fraud. But while the Academy's President and the University's Principal acted to realise this redress, officials at the information department that makes up the editorial staff of the GU Journal have taken up the cudgels for a continued accusation of Gillberg.

Long after the Sahlgrenska Academy's ethical council recommended the President and Principal not to take further measures (eg external review), and long after the Academy's manager and the University's Principal had announced management decisions stating that Gillberg and Rasmussen were acquitted, GU Journal (1/04) published for example an article in the news section with the headline:

“Most people want to have an independent review”

The article does not show how GU Journal could draw the conclusion that “most people”, i.e. a majority, thought that Gillberg should be investigated further, despite it never presenting convincing explanations for him to have been dishonest, and despite him being acquitted, and entitled to the redress denoted by an acquittal. The article did show however that GU Journal could identify in total three who stated this as their view: Leif Elinder, Eva Kärfve and Madeleine Leijonhufvud. On the other hand was there only one of those interviewed who did not consider that this measure was justified: the University's Principal. So of the four interviewed it was undeniably “most” (3-1) advocates of continued review of Gillberg's alleged fraud, in contravention of current regulations, and in contravention of the law stating that a favourable official decision for a citizen does not get to be overturned.

We consider it a peculiar form of exercise of authority that one and the same authority on the one hand investigates and exonerates a researcher accused of fraud, while on the other hand, via its information department, it publicly questions this acquittal. And it is also peculiar that an authority, via its ethical committee, calls upon its employee to follow a certain ethical regulation, and that same authority, via their information department, publicly accuses a researcher of having done precisely this.

Self-evidently the University and its employees should be prepared for intensive and critical media review, but this will, in our view, be carried out in general by the independent media, rather than by civil servants employed at the University's own information department.

### **9. The Press Ombudsman's actions**

At the same time as highly qualified jurists in the field, such as Elisabeth Rynning and Nils O Wentz, described as highly problematic the judgement in the Administrative Court of Appeal ordering records from Gillberg's archives to be released, Press Ombudsman Olle Stenholm already at an early stage, in a debate article, considered himself able to assert that the case was uncontroversial, and that the University should obviously have released the documents in question immediately (Today's Research March 3-4, 2003). In the same article, he also found reason to assert that the person to be considered as unfairly attacked in the current dispute was Kärffve, rather than Gillberg.

With respect to the conflict between openness and confidentiality Stenholm writes:

“The [debaters in an earlier contribution, our remark] assert that a practise needs to be taken forward that permits confidential storage of information about individuals in order that the patients' confidence in the research should not be damaged. This practise exists! The verdict of the administrative Court of Appeal is an expression of it.”

That Stenholm is incorrect here is clear, and follows from what has been stated above. The generally applied practise concerning undertakings of confidentiality is demonstrably not in harmony with the Administrative Court of Appeal's verdicts. And that these verdicts would be a natural consequence of principles of access to public records and of Secrecy Law has been questioned by a series of jurists whose knowledge of the field would probably be more extensive than Stenholm's.

Stenholm states in his contribution also that only poor researchers have anything to “fear from the principles of access to public records”. He clearly considers it out of the question that respect for the participants' integrity would actually constitute a reason not to want to release sensitive records.

Some time later the GU Journal published its first big attack on Gillberg. After having noticed that the article was highly one-sided and misleading the newspaper's publisher chose, to the editor's displeasure, to offer Gillberg an apology in the subsequent issue.

Following this the publisher, Siv Bondenäs-Brink, was contacted, according to her own information, by Press Ombudsman Olle Stenholm. Exactly what was said at this deliberation we do not know, but it has been asserted in other newspapers (see below) that the Press Ombudsman reprimanded the responsible publisher because she had offered Gillberg an apology. Given the Press Ombudsman's position and authority it naturally meant a significant success for Gillberg's antagonists that the Press Ombudsman hereby seemed to have assessed and validated an article representing Gillberg as dishonest. Without the case having been treated formally, and without Gillberg being able to comment or appeal, Gillberg's antagonists could refer to the Press Ombudsman in this way to support the view that an article which portrayed Gillberg in an extraordinarily poor light did not constitute reason to offer an apology.

Normally the Press Ombudsman's position is formalised in questions of press ethics, in so far as the Press Ombudsman does not generally express criticism unless a notification exists, and in so far as appeals against his decisions can be made to the Press Opinion Panel. We found it amazing therefore that the Office of the Press Ombudsman chose in this case to establish direct contact with a publisher, in order to criticise her for her written apology since it was produced in the media.

We tried therefore to obtain elucidation from the Press Ombudsman about whether he had acted in his capacity as Press Ombudsman or as a private individual in this matter. No answer on this point was forthcoming. Admittedly, the Press Ombudsman has denied to us that he would have issued any reprimand, but he has not wished to respond regarding whether any deliberation that could be considered a reprimand in any way has occurred.

That uncertainty exists on this point is illustrated by the following quotations:

“Moreover the publisher got a reprimand from the Press Ombudsman that meant that there was no reason to offer an apology for the article.” (Lars Nicklason, former journalist at GU Journal, Gothenburg Post 12/2 2005)

“I do not know of any reprimand of the type mentioned.”( Press Ombudsman in e-mail to EE 21/2 2005)

“In order that you will not need to see things that never happened I can tell you that the Press Ombudsman has no authority to issue “reprimands” against newspapers, that it never submitted any notification against GU Journal and that no such case thus has been treated neither by the Press Ombudsman nor the Press Opinion Panel.” (Press Ombudsman in email to EE 24/2 2005)

It has been noticed that the Press Ombudsman has appeared in the media as if he acted in his capacity as Press Ombudsman on this matter, but he has not seen reason to correct this misunderstanding. The result is that the Press Ombudsman wrongly came to serve as a weapon in the campaign against Gillberg. The conversation with Bondenäs-Brink has been referred to not only in Gothenburg Post but also in a gossip column in the newspaper The Journalist, in which it is stated that the Press Ombudsman expressed to Bondenäs-Brink that it was “deplorable” that she gave in to pressure.

The Press Ombudsman's very clear attitude to the question of the case itself recently came to be expressed in connection with hearing arranged by the Science Council, to which he - according to his own information - had been invited by a friend from the military service, the previously mentioned Science Council employee Björn Thomasson. Here he portrayed it as an “incredible scandal” that the confidential records had not been released to Kärffe and Elinder.

In line with what he stated earlier in his debate article, and in line with what Thomasson has stated in other contexts (see above), the Press Ombudsman regretted also that the *questions of the case* had been discussed insufficiently, by which we must understand the alleged deficiencies in Gillberg's research. However, what these alleged deficiencies are, and what Stenholm and Thomasson - old friends from military service - think should have been further discussed, has not become apparent. Perhaps it refers to Gillberg's alleged desire to drug 10% of all Swedish children with narcotics. Or perhaps at the

hidden aim of his research, which according to the critics is to separate inferior individuals from the society. Or is it about the assertion that Gillberg and his many colleagues, entirely without reason, would have invented non-existent research participants, within the framework of their descriptive research? The accusations against Gillberg have been so many, and so bizarre, that it would have been desirable that the Press Ombudsman and the Science Council's ethics expert had specified which questions should primarily be regarded as requiring urgent further discussion, especially since one has expressed himself in his capacity as Press Ombudsman, and the other in his capacity as public official.

In summer 2005 Gillberg reported two articles in the Express to the Press Ombudsman. From the Press Ombudsman's earlier debate articles, and from his contact with GU Journal, it had - as mentioned above - been apparent that he, like the author of the article, was highly critical of Gillberg's and Gothenburg University's actions. Moreover it had been shown from earlier letters from Gillberg's co-workers to the Press Ombudsman that they on their side were critical of the Ombudsman's unconventional method of criticising GU-journal's publisher because she had offered Gillberg an apology. There can be no doubt about the fact that there existed a disagreement between Gillberg and Stenholm, and that the latter had invested significant prestige in his attitude to this question.

Had the Press Ombudsman been a State institution Stenholm would have been prevented from processing Gillberg's complaint about the Express, as a result of administrative law provisions about challenge. And even many private companies and institutions have ethical regulations that mean that those who for some reason can be expected to be biased with respect to a certain case will not participate in the processing of this case.

In his complaint, Gillberg suggests that the case should not be processed by Stenholm personally, because of the above mentioned situation. Stenholm rejected this request, with the wording: "Special treatment is out of the question".

From this one can draw the conclusion that the Press Ombudsman *never* follows the quite reasonable principle that one should not treat cases for which there is a risk that one as a reviewer takes into account irrelevant considerations; to take challenge into consideration would, according to Stenholm, be synonymous with "special treatment". We believe that this is an unfortunate attitude. Even though those who are displeased with the Press Ombudsman's position can appeal to another authority, the Press Opinion Panel, it can never be appropriate that a case - at any stage - is prepared by a person that can be considered as liable to challenge by others.

Given the importance of the Press Ombudsman's assessments we think it is amazing that his activity is not encompassed by an ethical regulatory framework. We believe for example that one should be able to require of the Press Ombudsman that he makes clear when he comments in his capacity as Press Ombudsman, and when he comments as a private individual. Thus, in the future the kind of uncertainty about the advice concerning Stenholm's deliberations with the publisher of the GU Journal can be avoided. And we believe further that experience has shown that this regulation should mean that the Press Ombudsman should not process questions for which he can be considered as liable to challenge.

The Press Ombudsman, like the Press Opinion Panel, are not of course however State authorities, but organs financed by the newspaper publishers. It does not fall on the Office of the Chancellor of Justice to express any opinion about Stenholm's actions on this matter. On the other hand, the Press Ombudsman and Press Opinion Panel win a significant legitimacy through that fact that members of the Press Opinion Panel are appointed by the Justice Ombudsman, and that senior jurists constitute the Press Opinion Panel's governing board. We think that there are reasons to consider whether it is reasonable that the State in this way to some extent legitimates an activity to which elementary rules of challenge do not apply.

#### **10. How can cases like this be avoided in the future?**

##### *A. What measures should this case have given rise to?*

If the judgements in the Administrative Court of Appeal are correct, it means that many thousands of people have been misled by representatives of the universities, i.e. the Swedish State, when they were offered participation in state-financed research projects. Even if in the future participants are not given assurances of confidentiality this does not alter the fact that a large number of studies which are currently being undertaken, or which have been completed, are based on incorrect promises.

We think that anyone who takes research ethics at all seriously should be concerned, and consider what the results of this will be. Will those studies that are based on this type of promise and which have recently been started, and to which participants are still being recruited, be aborted? And will those participants in completed studies, whose sensitive information is still archived, be informed that those promises of confidentiality that were issued when they agreed to participate may not be honoured? And how should one calm the anxiety that the current case has caused within the research community? There are clearly many researchers who agree with Gillberg's attitude, and can as a result risk prosecution if new judgements are announced with decisions similar to those of the Administrative Court of Appeal in Gothenburg.

This case highlights the question of how participants should now be informed in studies concerning the handling of confidential information. If Gillberg's promise actually was too far-reaching, how should it be formulated instead?

Moreover the written information that participants are given should be verbally clarified. The MRC/Science Council's ethical regulations state:

"It is the researcher's responsibility to assure him/herself that the information has been correctly understood."

It also states:

"The written information should therefore always be completed with a wording of the type: 'if you have any additional questions you are always welcome to dial XX...'" (p. 30)

It is therefore important that a researcher gets to know what s/he should say to a prospective participant who asks how large the risk is that a court might decide that the confidential information that the participant has given will be released to a private

individual who wants to read it in his/her spare time in order to develop in his/her profession.

As researchers we find that we have a legitimate interest in getting guidance on these questions. For this reason, we have repeatedly asked the management of Gothenburg University if there is any risk that the University will require us to participate in releasing sensitive records to private individuals as in Gillberg's case. And we have also asked whether recently started studies that are based on the same undertakings of confidentiality as were issued by Gillberg may be completed. We have not had any replies to these questions, but on the other hand Gothenburg University - fortunately – recommended that the National Agency for Higher Education should investigate whether laws and regulations within this area should be reviewed.

We have moreover posed the same question to the National Agency for Higher Education, and the regional ethics examination board (annex 3, 8, 9). How the respective authorities responded to these questions is shown in the enclosed correspondence. Our conclusion is that none of the concerned authorities can give any worthwhile guidance in any of the current questions. We believe that this constitutes reason enough to review the current regulations. As is shown by the following sections, this point of view is however not shared by Science Council and National Agency for Higher Education.

*B. The rejection of the requirement for an investigation*

Gothenburg University has requested that - in connection with the case reviewed in this letter - the National Agency for Higher Education should analyse whether those ethical regulations that are applied in clinical research are compatible with current law, and whether the various laws are inconsistent in this respect. From the National Agency for Higher Education's replies it appears that "there is no reason to initiate additional investigations or to suggest changes in the regulations". The only measure the National Agency for Higher Education regarded as necessary was to further train researchers on "how personally sensitive material should be handled".

In what respects the Agency considers that there are currently deficiencies in researchers' ways of handling personally sensitive material, and how these deficiencies relate to the current case, is not made clear in the letter. In the worst case the intention is that researchers will learn how to release confidential documents to unauthorised individuals, despite having given assurances that this will not take place. In the best case the intention is that data will when possible be anonymised, which - as shown above - is a correct but trivial, and in this context, irrelevant statement.

The National Agency for Higher Education established what information study participants should receive about how data will be handled in a memorandum following a recent decision of the Central Ethical Council (on a specific case) that the following wording should be used:

"Your responses and your results will be treated so that no unauthorized person can gain access to them".

We can take from this that "the question Gothenburg University has taken up has thus been solved and there is no further reason for investigation".

We find the National Agency for Higher Education's replies unsatisfactory. The fact that Swedish researchers have been called upon for decades to issue possibly incorrect undertakings of confidentiality, and risk prosecution for malfeasance if they find it unethical to break them, ought to have compelled the authorities to take some kind of action.

The agency's reference to the Science Council's recommendation concerning how participant information should now be formulated is inadequate, since it does not solve the problem that a large number of both completed and ongoing studies are actually based on other kinds of promises. Moreover, as we discuss in the following section, there are reasons to question whether the Science Council's proposals are actually ethically acceptable.

Note that the National Agency for Higher Education has replied to Gothenburg University after consultations with the Science Council. Unfortunately, these consultations are not documented. Given the obvious active role the Science Council played to persuade researchers to issue the type of undertakings of confidentiality that were issued in Gillberg's study, the Science Council's lack of interest in resolving the question is confusing. Moreover this position contrasts with how representatives of the Science Council in deliberations with the Principal of Gothenburg University emphasised the negative consequences for Swedish medical research if the administrative Court of Appeal judgement that records should be released to a private person were obeyed.

We have corresponded with the National Agency for Higher Education on this matter; this correspondence is enclosed (annex 8). It is apparent that the agency does not have an opinion on the nature of the concept "unauthorised". Regarding the question of how a researcher should now inform prospective participants about how collected data will be protected, the agency is content with establishing that the information should be correct and in accordance with the law. On the question of how the new ethics examination law will influence how researchers inform participants about these issues, the agency refers to the Central Ethics Council. On whether and how the judgements in the Administrative Court of Appeal should be considered as a legal precedent, and whether researchers should - as a consequence of these decisions - now directly release sensitive documents to someone who, for example, wants to read them in his/her spare time, the agency replies that researchers should handle this type of case in accordance with the provisions of the Freedom of the Press Acts and Secrecy Law. On the question of whether there might be a risk of lying to participants in drug trials if, in accordance with current regulations, they are asked to give signed permission that information may be shown to representatives of the Medicines Agency (which probably make the participants believe there is no risk that the documents will be shown to others), the agency states that the information the researcher issues should be correct. On the question how researchers should deal with the fact that many studies actually seem to have been implemented on the basis of incorrect undertakings of confidentiality the agency replies that researchers should not give over-comprehensive undertakings of confidentiality. On the question of what responsibilities the Science Council has in the event that incorrect promises have been issued it appears that the National Agency for Higher Education do not have the right to monitor the Science Council. And in response to the question of whether it might be a problem that many researchers risk being indicted if they consider it ethically

impossible to break undertakings of confidentiality the authority expresses what must be considered as contentment with Gillberg's sentence: "Hopefully the judgement against Professor Gillberg means that researchers in Sweden will follow court decisions."

To sum up it is apparent that no clear answers were to be found in National Agency for Higher Education's replies on how researchers should act in order to meet both ethical regulations and current law.

We are not alone in having wondered about the National Agency for Higher Education's lack of commitment to this question. Professor of Medical Law, Elisabeth Rynning, who is probably very familiar with the regulations within this area, has written thus in "Dagens Nyheter" (14/5 2005):

"The question about a review of the rules has been treated in Parliament's constitution committee and at the National Agency for Higher Education. There however it is considered that the regulations are not problematic, but it is only the researchers' inadequate knowledge about the regulations. These deficiencies will be dealt with through education and local guidelines.

The question however is what one should say if the current regulations actually become so complicated that not only researchers and Gothenburg University have difficulty in applying them. What risks for justice arises if a court makes dubious interpretations or even applies the wrong regulations, when one cannot appeal against it? Is it possible that we could have a regulation over which Parliament's constitution committee does not have control, but which can lead to violations of personal integrity or indirectly to liability to malfeasance for concerned public servants?

Will regulations that legal experts clearly have difficulty mastering achieve an impact among researchers with no legal training? Is it reasonable to relate the problems in implementation only to the research community's inadequate awareness of the regulations?

One undeniably gets the impression that even the National Agency for Higher Education and Parliament's constitution committee have insufficient knowledge about the content and complexity of the regulations, and therefore have not seen the deficiencies in the Administrative Court of Appeal's decisions. It is difficult to find any other explanation for their incomplete answers about research confidentiality and their negative attitude towards a review of the regulations.

Through our connection to the European Convention on the Protection of Human Rights Sweden has undertaken to prevent inadmissible violations of individual private lives. When other important exceptions of interest must be given precedence this should be clearly shown in law ... in order to serve the interests in a satisfactory way of both research and those individuals entitled to it, we require a different and more accessible regulation than what we have today."

And in her scientific essay about the same matter (annex 4) Rynning states:

"To sum up one can hardly say that the Swedish confidentiality regulations in the research context are satisfactory. The uncertainties must be considered to be a disadvantage for the concerned individual as well as the scientific community. A contributing reason to the area's complexity is undeniably the interplay between the

confidentiality rules and the regulations on treatment of records, but this is not a reason to abstain from a review of the regulation, rather the opposite. Why can we not admit that the current regulations are actually so difficult that even legal experts have difficulty interpreting them?”

We think that Rynning’s comment in the same essay summarises the whole case clearly:

“Of all those who have had reason to judge, or otherwise comment on the Gillberg case, is there actually anyone who has succeeded in describing research confidentiality in a satisfactory way?”

### *C. How should future undertakings of confidentiality be formulated?*

Many competent people have lately been eager to stress that the type of promise Gillberg issued is not acceptable. Björn Thomasson has stated in the media that Gillberg promised too much. And at the Science Council hearing Göran Hermerén presented it as a central rule that one cannot promise the all-embracing confidentiality that Gillberg did. The question must then be how one instead should formulate promises about confidentiality?

According to what Hermerén stated at the Science Council’s hearing one can assure the participants that their information will be anonymised, so that names and social security numbers are not shown. And in line with this Science Council now seems to see as their main task to inform researchers about how one ‘de-identify’ data.

Unfortunately Hermerén does not seem to have thought through this question with sufficient care. If the judgements in the Administrative Court of Appeal were correct we can definitely not assure participants in research projects that their information will be anonymised or become de-identified in a secure way.

1) First; the judgements meant that the documents would not be released in an anonymised manner.

2) Second; the code key that is established in connection with the anonymisation is as much a public document as the actual records. We are thus prohibited from destroying it, even though ethical committees recommended precisely this measure for a long time. We can never guarantee that it will not be released. We can of course imagine that a future reviewer, following Hermerén’s much trumpeted principle that all research should be capable of scrutiny, will want to have the code list, in order to establish that the participants are not fabricated.

3) Thirdly; there are many studies where such detailed information about the participants has been collected that a secure anonymisation is impossible to implement - this applied for example to Gillberg's group's study.

We do not object to the Science Council informing researchers about how data should be de-identified, but in order to solve the important problems of principle which this case has raised, this measure is entirely irrelevant.

As shown above the National Agency for Higher Education considers that the current problems would be solved through the use of the Central Ethics Council recommended wording that no “unauthorised person” has rights to access the documents. As we will show in the following section this is unfortunately a delusion. First however we should mention that the Central Ethical Council, through its chairman, Justice of the Supreme

Court Johan Munck, is the only authority that has responded to our letter in a way that gives us grounds to believe that it realises that the current questions are urgent and problematic (exchange of correspondence: annex 9)

A central starting point for all regulations that apply to research ethics, national and international, is that the information the participants receive before the study will be complete, unambiguous and easy to understand. Before the participant decides whether to participate or not, s/he must have received detailed information about which risks this may imply. Many quotations reproduced above (p. 16-17) from the Medical Research Council/Science Council's instructions illustrate this situation, for example:

“The information must be matter-of-fact and complete, and must above all be understood by the person it is intended for.”(p. 18)

“Incorrect, incomplete or misleading information breaks the fundamental ethical principle of personal integrity!”(p. 28)

This was also recently discussed in a debate in Parliament. Minister Leif Pagrotsky stated the following:

“The central point here is which conditions people are offered when they are offered the choice to participate in research projects. The rules have been tightened up considerably since the research in question was carried out and the agreements between the researcher and the participants were met. The mistakes that may have happened here could not have taken place if that research had been carried out today. Today's rules are different in that the agreement between the researcher and the participant needs to be a lot clearer, and to offer much clearer choices for the participants. Moreover it should be able to be scrutinised by independent people in various ways. Here the rules have been improved a lot.”

If there are “no strange features” about the judgements in question in the Administrative Court of Appeal, as the Science Council's ethics expert chooses to formulate it, the promises that are now being issued to participants should reasonably have the following wording, in order to meet the Minister's requirements on clarity:

“You should know that the information about yourself that you give can be released to anyone, even private individuals, who can justify to the administrative Court of Appeal that they have legitimate interest in gaining access to them, and who gives assurances not to disseminate them further.”

Only if we formulate it like this, can we clearly and comprehensively inform the participants about the risks that the documents will be passed on to others. The disadvantage is understandably that few will choose to participate in research projects if these conditions apply.

The wording suggested by the Central Ethical Council, that “no unauthorised person” will gain access to the documents, and that according to the National Agency for Higher Education means that the current question is resolved, is unfortunately not ethically acceptable, in so far as that the wording is entirely meaningless, and possibly intends to give participants the wrong idea.

Alongside stating that “no unauthorised person” will gain access to the records one can also give an assurance that

*“Only s/he who may read your records will get to read your records”*

Alternatively:

*“S/he who may not read your records will not get to read your records ”.*

It is clear that the value of the information in these statements is more or less nil.

The danger of the Central Ethical Council’s wording is that the participants may not clearly understand that there is actually a risk of their records being released to private individuals. Using dishonest wording to avoid clearly presenting the risks is a clear breach of current regulations. Again we have reason to refer to the internationally accepted research ethical principles that were presented, with quotations from one of Medical Research Council/Science Council documents, on p. 16-17. The Central Ethical Council’s recommended wording constitutes a clear breach of these rules. It is furthermore a lot more likely that many prospective participants, when faced with the wording that “no unauthorised person” will gain access to the documents, will ask the responsible researcher what this means, i.e. what does the concept “unauthorised” mean? Therefore it is urgent, from a judicial point of view, especially in the light of what has happened to Gillberg, that researchers are clearly told by concerned authorities how this question should be responded to.

We could, when we are asked this, refer to the Secrecy Act about reverse indemnity, according to which this type of information may be released only if it “is clear” that this will not cause harm to those to whom it applies (for example discomfort). But participants who have followed the debate about Gillberg's group's study must reasonably ask the question how it happened that in this case sensitive records were released on legal authority, despite the participants feeling great discomfort because of it, and pleading that it must not happen.

We could, on the other hand, reply that the new ethics examination law would have made it impossible to release the records to Eva Kärfve, since researchers are now forced to apply for an ethics review before they gain access to this type of document. But against this we can state that Leif Elinder is not a researcher, and consequently is not obliged to follow the ethics examination law. If judgements in the Administrative Court of Appeal are correct it means that one can now assure participants in studies that no *researchers* will read their records without previous ethics examination, but on the other hand any private person who only wants to read them for educational purposes is free to do so. This is a strange order that can hardly be in accordance with the legislators’ intentions.

Johan Munck wrote to us, in connection with our question about the wording that “no unauthorised person” will read the documents (annex 9):

“A promise thus formulated would probably seem entirely sufficient to research participants”.

With our own experience of medical research we want to oppose this view with determination. When research participants, like those in Gillberg's study, are requested to submit information about extremely private matters, such as drug misuse, social abuse,

sexual disposition etc they should demand that they want very detailed information about how collected data will be handled.

### **11. Is what Gillberg has been put through an expression of temporary or systematic error in the exercise of authority?**

An individual case often exposes extensive weakness in the function of authority. If what Gillberg has been put through is an expression of systematic error in the exercise of authority, or individual, temporary errors, is difficult to decide. But we know that what Gillberg has been put through must not be repeated.

To summarise:

Despite Gillberg wholly following the practise that authorities implemented concerning undertakings of confidentiality in clinical research he has been blamed for having promised his participants confidentiality – not only by those carrying out a slander campaign against him, but also by public officials.

Despite regulations implemented by authorities showing that researchers definitely may not break promises of confidentiality, and moreover despite this being a self-evident ethical principle to most research doctors, Gillberg has been sentenced by the Administrative Court of Appeal for doing exactly this. The decisions were probably wrong but could not be appealed against for formal reasons.

Even though the decisions obliging Gillberg to release sensitive information were not in accordance with Swedish law according to legal assessors, not only those carrying out a campaign against Gillberg but also public officials, stated in the media that the decisions were correct.

Despite it being Gillberg who had assured participants confidentiality in writing, and despite seeing himself as a moral guarantor that this promise should be held, he did not have the right to appear in court when the question about a release was heard, and neither was he considered as party in the matter when he requested legal review. On the other hand he was party to the matter in as far as he could be indicted for not having contributed to the breaking of the promises.

Even though Gillberg, if he had contributed to a release of documents, would have broken the promise to the research participants, against fundamental medical/research ethical principles, and against the officially implemented ethical regulation of clinical research, the District Court saw no extenuating circumstances when it had to take a position on the fact that he regarded himself as unable to participate in the release of the documents.

Despite that there being no reasons to believe that Gillberg conducted research fraud, and despite an investigation performed in accordance with current regulations leading to an acquittal, not only those who are running a campaign against him, but also several public officials, have stated in the media that he has not been exonerated, and that it is regrettable that he has not been further reviewed.

Even though what Gillberg has been put through is clearly unacceptable in many respects, concerned authorities have stated that there is nothing to object to in the current regulations, and that there are no reasons to review them.

Due to the well established confidence which Gillberg has long enjoyed as a researcher, and due to the fact that the accusations aimed against him are so clearly without substance, he is probably still renowned in the scientific circles that deal with the issues in question, despite court processes, slander campaigns and the authorities' unfortunate actions. But for a researcher whose position is not as strong as Gillberg's, and for those whose antagonists succeed in formulating accusations that appear more insidious than those aimed against Gillberg, a similar campaign to that aimed against Gillberg can have devastating consequences. That regulations and laws are now reviewed in connection with what has happened, both with respect to research confidentiality and with respect to the processing of accusations of fraud, seems absolutely necessary. We find it remarkable that the National Agency for Higher Education has come to a different judgement.