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Council of State

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Ms. Hagelsteen, President

Mr. Luc Derepas, Rapporteur

Mr. Devys, Government commissioner

SCP VIER, BARTHELEMY, MATUCHANSKY, lawyers

Reading of September 26, 2005

FRENCH REPUBLIC

IN THE NAME OF THE FRENCH PEOPLE

Given the summary request and the supplementary factum, registered on 21 July and 19 November 2004 to the secretariat of the Council of State, presented for the FRENCH NATIONAL MEDICAL COUNCIL, based on 180, boulevard Haussmann in Paris (75389); the FRENCH NATIONAL MEDICAL COUNCIL asked the Council of State:

- 1) To cancel the decision of 26 June 2004 in which the Minister of Health and Social Welfare has implicitly rejected its request for the withdrawal of the decree of 5 March 2004 of the Minister of Health, Family and People with Disabilities as it carries approval of the third paragraph of IV and the second sentence of the 23d paragraph of IV-1 of the best practices recommendations regarding the access to information about the health of a person, including support for such access;
- 2) to cancel such decree because it approves those contested dispositions;
- 3) to charge the State 3000 euros in the name of article L. 761-1 of the Code of Administrative Justice;

Considering the other documents in the files;

Considering, registered on 19 September 2005, the note deliberately produced by the FRENCH NATIONAL MEDICAL COUNCIL;

Considering the Code of Public Health; Considering the Law n° 2002-303 of 4 March 2002;

Considering the Code of Administrative Justice;

After hearing in open sessions:

- the report of Mr. Luc Derepas, Master of Requets (Maître des Requêtes),
- the observations of the SCP Vier, Barthelemy, Matuchansky, lawyer of the FRENCH NATIONAL MEDICAL COUNCIL,
- the conclusions of Mr. Christophe Devys, Government commissioner;

Considering that, under Article L. 1111-9 of the Code of Public Health, in the version in force at the date of the contested decree: (...) The procedures for access to information about the health of a person, including the support for such access, are the subject of recommendations for the best practices established by the French National Health Evaluation and Accreditation Agency and approved by decree by the Minister of Health; that, if the recommendations of best practices so defined, normally designed to give professionals and healthcare facilites directions and guidance for the application of laws and regulations on patients' access to medical information, do not have, even after their approval by the Minister of Health, the character of a decision having an adverse effect. They however must be regarded as having such an effect, like the refusal to withdraw them, when they are written in an imperative way;

On the possibility of using the mandate;

Considering that under the third paragraph of IV of the best practices recommendations approved by the contested decree: Health information may be disclosed to a person authorized by the patient, by her/his legal guardian (in case of a minor or an adult under guardianship) or her/his entitled beneficiaries in case of death, if the person has a specific mandate and can prove her/his identity. The authorized person cannot have any conflict of interest and cannot defend interests other than those of the principal (the subject of the health information). It is recommended to remind the principal of the personal nature of the information that will be communicated to the authorized person; that given the mandatory nature of the first two sentences of this paragraph, these provisions are likely to be challenged by way of appeal for abuse of power;

Considering that under Article L. 1110-4 of the Code of Public Health: Any person supported by a health professional, facility, network or any other organization involved in healthcare has the right to privacy and the confidentiality of information. / Except in cases of derogation expressly provided by law, the confidentiality covers all the information about the person that came to the knowledge of the health professional or any staff member of such institutions or organizations and any other person who is related, by her/his activities, to those institutions and organizations. This confidentiality is imposed on every

health professional or person working in the health system. (...) / To obtain or try to obtain this information in a way that violates this article is punishable by one year of imprisonment and a 15,000 Euros fine. /In case of a serious diagnostic or prognostic, the medical confidentiality does not preclude the family, the relatives of the patient or the authorized person defined by Article L. 1111-6 from receiving the necessary information to provide direct support to the person, except if the person is opposed. Only a doctor is authorized to issue, or to order the issue under her/his responsibility, the information. / Medical confidentiality does not preclude the entitled beneficiaries from having access to information about a deceased person if it is necessary in order to know the cause of death, to defend the memory of the deceased or to assert their rights, except if the person expressed her/his opposition before her/his death; that under Article L. 1111-7 of the Code of Public Health: Everyone has access to all information about her/his health held by health professionals and facilities (...). / She/He can access such information directly or via a designated doctor and obtain the communication, under conditions defined by regulations (...) / Subject however to the opposition under Article L. 1111-5, in the case of a minor, the right to access the information is exercised by the holders of the parental authority. At the request of the minor, this access occurs via a doctor. (...):

Considering that it is not the result of the above definitions of the Code of Public Health that the legislator intended to exclude a person's possibility to access her/his medical information held by health professionals and facilities by using, under the conditions of ordinary law, a mandated person if the latter can prove her/his identity and has an express mandate, that is to say duly justified; that therefore, the FRENCH NATIONAL MEDICAL COUNCIL is not entitled to request the cancellation of the third paragraph of IV of the recommendations approved by the contested decree;

Considering the issue of medical information to the beneficiaries of a deceased person: Considering that under the 23d paragraph of IV-1 of the recommendations approved by the contested decree: Article L. 1110-4 of the Code of Public Health establishes that the medical confidentiality does not preclude the entitled beneficiaries to have access of information about a deceased person if it is necessary in order to know the cause of death, to defend the memory of the deceased or to assert their rights, except if the person expressed her/his opposition before her/his death. When these conditions are met, the beneficiary has access to all medical records (...), excluding information obtained by third parties not involved in the therapeutic care or about such third parties; that the second sentence of this paragraph is, because of its imperative nature, likely to be challenged by way of appeal for abuse of power;

Considering that it is the result of the provisions of Articles L. 1110-4 and L. 1111-7 of the Code of Public Health cited above, clarified by parliamentary works regarding the law of 4 March 2002 on the patients' rights and the quality of the health system from which they arise, that the legislator intended to authorize the communication to the entitled beneficiaries of a deceased person only the information necessary to achieve the objectives of those beneficiaries, namely to know the cause of death, to defend the memory of the deceased or to assert their rights; that these contested provisions, which establish that the communication to the beneficiaries may refer to all the information in the medical file,

ignore these principles; that such provisions, therefore, should be cancelled, like the decision by which the Minister of Health and Social Welfare has refused to withdraw them;

Considering it is appropriate, under the circumstances of this case, to apply the provisions of Article L. 761-1 of the Code of Administrative Justice and to charge 3,000 Euros at the expense of the State for costs incurred by the FRENCH NATIONAL MEDICAL COUNCIL;

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First Article: The decision of 26 June 2004 of the Minister of Health and Social Welfare is cancelled as it refuses to withdraw the provisions by which the decree of 5 March 2004 approves the provisions of the second sentence of the 23rd paragraph of IV-1 of the best practices recommendations regarding the access to information about a person's health, including support for such access

Second Article: The provisions of the decree of 5 March 2004 of the Minister of Health, Family and People with disabilities mentioned in the preceding section are cancelled.

Third Article: The State will pay 3,000 Euros to the FRENCH NATIONAL MEDICAL COUNCIL pursuant to Article L. 761-1 of the Code of Administrative Justice.

Fourth Article: The surplus of the conclusions of the request is rejected.

Fifth Article: This decision shall be notified FRENCH NATIONAL MEDICAL COUNCIL and the Minister of Health and Social Welfare.

ABSTRACTS: 26-06-03 CIVIL AND INDIVIDUAL RIGHTS. ACCESS TO ADMINISTRATIVE DOCUMENTS. THE RIGHT TO ACCESS AND TO VERIFICATION ON A BASIS OTHER THAN ON THE LAWS OF 17 JULY 1978 AND 6 JANUARY 1978. – RIGHT TO ACCESS TO THE INFORMATION HELD BY HEALTH PROFESSIONALS AND HEALTH FACILITIES (ART. L. 1111-7 OF THE CODE OF PUBLIC HEALTH) – POSSIBILITY FOR THE PATIENT TO USE A REPRESENTATIVE – CONDITION – WITH A FULLY JUSTIFIED MANDATE.

54-01-01-01 PROCEDURE. BEGINNING OF PROCEEDINGS. DECISIONS THAT MAY OR MAY NOT BE CHALLENGED BEFORE THE COURT. ACTS THAT MAY BE CHALLENGED BEFORE THE COURT. - RECOMMENDATIONS OF BEST PRACTICES ESTABLISHED BY THE FRENCH NATIONAL HEALTH EVALUATION AND ACCREDITATION UNDER ARTICLE L. 1111-9 OF THE CODE OF PUBLIC HEALTH, WHEN THEY HAVE BEEN APPROVED BY THE MINISTER OF HEALTH AND ARE WRITTEN IN AN IMPERATIVE MANNER[RJ1].

61 PROCEDURE. BEGINNING OF PROCEEDINGS. DECISIONS THAT MAY OR MAY NOT BE CHALLENGED BEFORE THE COURT. ACTS THAT MAY BE CHALLENGED BEFORE THE COURT. - ACCESS TO INFORMATION HELD BY MEDICAL PROFESSIONALS AND HEALTH

FACILITIES - ABILITY TO USE A REPRESENTATIVE - CONDITION – WITH A FULLY JUSTIFIED MANDATE.

Summary: 26-06-03 It does not result from the provisions of Articles L. 1110-4 and L. 1111-7 of the Code of Public Health that the legislature intended to exclude the possibility for the individual to access health information concerning her/his health held by professionals and health facilities by using, under common law, a representative when the latter can prove his identity and has a clear mandate, i.e. duly justified .

54-01-01-01 Under Article L. 1111-9 of the Code of Public Health, in the version in force at the date of the contested order: "(...) The terms of access to information about the health of a person, and especially with a support, subject to best practice recommendations set by the French National Health Evaluation and Accreditation and approved by order of the Minister of health." If the recommendations of best practices so defined, normally designed to give professionals and healthcare policy direction and guidance for the application of laws and regulations on patient access to medical information, do not have, in principle, even after their approval by the Minister of Health, the character of an adverse decision, they must however be regarded as having such a character, and so does the refusal to withdraw them, when they are written in an imperative manner.

61 It does not result from the provisions of Articles L. 1110-4 and L. 1111-7 of the Code of Public Health that the legislature intended to exclude the possibility for the patient to access medical information about her/his health held by health professionals and health facilities by using, under conditions of ordinary law, a representative when the latter can prove her/his identity and has a clear and duly justified mandate.

[RJ1] Cf. Section, 18 December 2002, Ms. Duvignères, p. 463