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## THE STATUS OF GENETIC MATERIAL AND GENETIC INFORMATION IN THE NETHERLANDS

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**Abstract**—The moral status of genetic material and information, and the ethics of controlling and manipulating them, is a topic of hot debate in many European countries, including The Netherlands. That heat is due partly to the complexity of the topic, and partly to researchers' fear that their investigations will be hampered by restrictions on the use of personal data or body material. But there is little doubt that manifold diverging interpretations about the status of the human body, body materials, and personal information in Dutch law, written and unwritten, contribute to the intensity of the debates. This article intends to structure the debate by creating more clarity at the conceptual level. By carefully examining relevant articles of the Constitution and Civil Codes, as well as policy documents and authoritative publications, notably in reference to prominent legal concepts such as property, ownership and privacy, an answer should be provided to the following crucial question: is the status of genetic material and information in any sense special in comparison with other body parts and other kinds of information about a person? This paper first discusses the status of human body materials and personal information in general, and then continues with a more specific discussion about the status of genetic material and information. It concludes that the Dutch legislature had carefully avoided (or not felt the need to employ) the concept of ownership in regulating biomedical research; rather, privacy is found to be the prime regulatory concept. © 1997 Elsevier Science Ltd

*Key words*—ownership, body material, genetic material, genetic information

### INTRODUCTION

The moral status of genetic material and information, and the ethics of controlling and manipulating them, is a topic of hot debate in many European countries, including The Netherlands. That heat is due partly to the complexity of the topic, and partly to researchers' fear that their investigations will be hampered by the restrictions on the uses of personal data and body material. But there is little doubt that manifold diverging interpretations about the status of the human body, body materials, and personal information in Dutch law, written and unwritten, contribute to the intensity of the debates.

This article structures the debate by clarifying the conceptual level. By carefully examining relevant articles of the Constitution and Civil Codes, as well as policy documents and authoritative publications, notably in reference to prominent legal concepts such as property, ownership and privacy, an answer should be provided to the following crucial question: is the status of genetic material and information in any sense special in comparison with other body parts and other kinds of information about a person?

First, we will discuss the status of human body materials and personal information more in general. Then, we will continue with a more specific discussion about the status of genetic material and information. It will be concluded that the Dutch legislature has carefully avoided (or not felt the need to employ) the concept of ownership in regulating biomedical research; rather, privacy will be found to be the prime regulatory concept.

### THE STATUS OF THE HUMAN BODY AND BODY MATERIAL

According to various health lawyers, a living human being is a unity of mind and body. The person that figures in Dutch law as the subject of rights is this unity of mind and body (and not some bodiless creature). In The Netherlands, the body of the living human being has never been considered an object with respect to which ownership is possible. It falls outside the scope of property law (Leenen, 1978; Gevers, 1990).

If the living human body as a whole is not owned by the person, what about body materials (fluids, cells, tissues) that are separated from the body? In Dutch legal doctrine there is no consensus with regard to the status of body material. Some lawyers argue that body material falls within the bounds of property law. When separated from the body, the

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body material changes its character from an integral part of the body to an object that is susceptible to human control. Due to the separation, body material turns into an item that can be owned, and the person from whom the material is taken becomes the owner (Leenen, 1978; Gevers, 1989, 1990). Ownership of one's body material does not imply that a person is completely free to decide what to do with his "property". For example, the sale of organs is commonly considered immoral and only donation is legally permitted. Financial gain for blood donations is explicitly prohibited by law.

Because difficulties arise when body material is dealt with in terms of ownership (owners do not have all the rights defined in the Civil Code as property rights), some authors avoid the concept of "ownership" when discussing body material and derive the right to control body material from constitutional rights to privacy and to integrity of the body (Frankena and de Graaf, 1990).

This "move" away from the concept of ownership is supported by the *Dutch Constitution*, for in neither of the two relevant constitutional articles is there mention of such a concept:

Article 10, *Dutch Constitution*:

- (1) Everybody has, barring or under restrictions to be set by law, a right to respect for his personal domain of life.
- (2) The law will set rules for the protection of the personal domain of life with regard to the registration and provision of personal data.
- (3) The law will set rules concerning the claims (titles) of persons to inspection of the registered data concerning their person, and the use that is made thereof, as well as to the correction of such data.

Article 11, *Dutch Constitution*:

Everybody has, barring or under restrictions to be set by law, a right to the inviolability of his body.

Article 10 underscores that information (personal data) falls under the concept of the "personal domain of life" or "privacy". In spite of the linguistic suggestion that the body is an entity worthy of respect, regardless the private intentions of the person embodying it, Article 11 is meant to emphasize that the human body is part of the personal domain of life and deserves the same kind of protection as is warranted under Article 10.

Since *identifiable* body material contains personal information, it falls under the protection of Article 10. It is unclear, however, whether a person has control over the use of his *anonymous* body material. Some lawyers argue that Article 11 implies that a person not only has control over what hap-

pens to his body, but also the power to decide about the future (use) of his (separated) body material. Others argue that Article 11 does not pertain to the use of anonymous body material (i.e. the donor's informed consent is not required for the use of the material) (Het verworven immuun deficiëntiesyndroom, 1989-1990; van Galen-Herman, 1992).

This disagreement over the applicability range of Article 11 has been solved in a new addition to the *Dutch Civil Code* (Book 7, Section 5) which concerns the *Medical Treatment Contract* (*Wet geneeskundige behandelingsovereenkomst*). According to this law, *anonymous* body material may be used for medical research if the patient has *not* explicitly *withheld* consent for this particular use (Article 467). The body material referred to in this Article is body material that is removed for diagnostic and/or therapeutic purposes with the consent of the patient. With regard to the use of such body material for medical research a policy of "no objection" is adequate and valid. The health care provider need not inform the patient about the possible research uses of his (anonymous) body materials. However, the public should be informed by the responsible authorities about these possible uses of their discarded (anonymous) body material.

Article 467 deals only with the use of *anonymous* body material in biomedical research. The legislature made no provision for research with non-anonymous, *identifiable* body material. Since most research is carried out with the latter, it has been suggested that the use of such material be regulated the same way as identifiable personal data, i.e. biomedical research will only be allowed if all four criteria mentioned in Article 458 are met (see hereunder) (Nationale Raad voor de Volksgezondheid, 1991; Doppegieter, 1991; Roscam Abbing, 1989).

#### THE STATUS OF MEDICAL INFORMATION

Information is not usually dealt with in terms of ownership, but in terms of privacy. According to Gevers, it is difficult to predicate ownership of something as "volatile" as personal data. Furthermore, ownership of information would demand virtually absolute control. Hence, it would not be possible to take legitimate interests of third parties into account (Gevers, 1988). The fact that the concept of ownership is not used with respect to information does not mean that an individual has no control over personal information. For as we have seen, Article 10 of the *Dutch Constitution* explicitly protects the personal domain of life as well as personal information.

The *Law on the Registration of Personal Data* (*Wet personenregistratie*) is an elaboration of paragraphs 2 and 3 of Article 10 of the *Dutch*

*Constitution.* This law applies to all automated and/or systematized registrations of personal data. A registration can only be made for a specified purpose; the data must be obtained legitimately and can only be used for the purpose for which they have been collected. For registrations of sensitive personal data (e.g. medical data) special rules must be formulated.

Providing personal data to third parties is only possible if this follows from the purpose of the registration, is required by law, or is done with the consent of the person concerned. For scientific or statistical research or other important reasons, personal data can be provided without the consent of the person concerned only if the personal domain of life of this person will not be disproportionately harmed. Providing personal data to third parties is not allowed if the keeper has a professional duty of confidentiality (secrecy).

The keeper of the registration has to inform the person the first time his data are being registered. The person has a right to receive, at his own request, a full summary of these data and can request correction, addition, or removal of information. Such a request must be honoured unless it conflicts with other interests (e.g. the interests of third parties).

The *Law on the Medical Treatment Contract* underscores the patient's right to correct, add or destroy personal data contained in his medical chart. A health care provider must destroy information about a patient within three months after the request from the patient, unless preservation of the record is of overriding interest to third parties, or destruction is prohibited by law (Article 455). No information concerning a patient is to be given to third parties without the consent of the patient (Article 457).

Providing *identifiable* personal data without consent of the patient to third parties for scientific or statistical research is permitted only if the following criteria are met: (1) the request for consent is not reasonably feasible; (2) the research serves a public interest; (3) the research cannot be conducted without these data; and (4) the personal domain of life of the person(s) concerned will not be disproportionately harmed (Article 458). Since the demand for informed consent could be a hindrance to important medical research, no consent is required for the use of information that is *anonymous* (i.e. traceable to the person only with disproportionately great effort or costs), although the patient may override this presumed consent by objecting explicitly.

#### THE STATUS OF GENETIC MATERIAL

Having surveyed the opinions and regulations regarding body material and medical information,

we now turn to the status of genetic material and genetic information. Genetic material is considered body material and legally treated as such. However, its peculiar nature requires additional regulative measures.

Due to recent developments in genetics, the preservation of cell material in cell banks (DNA banks) has become customary. In his proposal for the Dutch Society of Health Law, Gevers suggests that when cell material is stored for a longer period, such storage is sufficiently similar to the registration of personal data to warrant a similar regulation. Preservation of *genetic* material requires further protection because the privacy of the donor is at risk. After all, the very purpose of storage in genetic cell banks is to preserve the material for future applications that may not benefit the donor, yet violate his privacy (e.g. the counselling of third parties such as relatives). Gevers worries that the status of genetic material stored in cell banks for longer periods of time is unclear (although he elsewhere suggests that the original donor retains ownership—Gevers, 1990). He recommends that regulations be drafted clarifying the purpose of the cell bank, the time period for which the material may be kept, and the possible uses of the material. The cell bank should transmit this information to the person whose material is being kept, so (s)he can provide or withhold an informed consent. In addition, the person should have a right to have his or her material made anonymous, or destroyed (Gevers, 1987).

In its report on genetics, the Health Council (an advisory board of the government) explicitly states that under present-day law a person retains ownership of his cell material being stored in a cell bank (Gezondheidsraad, 1989). Leenen points out that this follows from the nature of "keeping" goods: after all, the owner of a storage facility (normally) does not own what is stored (Leenen, 1988). However, some forms of handing over body materials may be considered a "donation" with subsequent loss of ownership. Leenen considers the giving of blood or sperm to be such donations, but he makes no mention of genetic material. The Health Council is less willing to assume loss of ownership when handing over body material. It claims that even when body materials are developed into new products, the original "donor" remains the owner of these products.

Like Gevers, the Health Council sees a certain similarity between the use of cell material and personal data: the material should only be used for the purpose for which it was given. To use the material for different purposes requires the informed consent of the donor. In an attempt to balance the rights of the individual and those of third persons who may be benefited by research with those materials, the Health Council favours a code of conduct which prescribes to record in writing whether a person

wants to be informed of new information obtained from his cell material; whether he or she will allow the material to be used for the counselling of relatives; and whether he or she consents to the use of this material in scientific research. For the donor to provide an *informed* consent, the keeper of the cell bank should provide all necessary information (e.g. purpose of the cell bank, feasible research, possible future findings). According to the Health Council, the donor of the material has the right to withdraw his or her consent, and to have the material destroyed. As de Wert and de Wachter point out, keeping material in a cell bank against the will of the person from whom the material was taken conflicts with his or her right to control the material and is likely to negatively influence the willingness of people to store their material in cell banks (de Wert and de Wachter, 1990).

Although the person who provides the material is the owner of the genetic material, it should not be possible for the person to receive financial compensation for the use of his or her material by industry. Body parts are not to be viewed as objects of transactions for compensation (Gezondheidsraad, 1989).

In their response to the report of the Health Council, the former Secretary for Welfare, Public Health and Culture and the Minister of Justice agreed with the Health Council that the framework of existing legislation should be complemented by a code of conduct concerning the storage of cell material. Under present-day law, identifiable body materials can only be used for the purposes for which they were stored. The donor's consent to different uses of cell material should be set out in writing (Erfelijkheidsdiagnostiek en genterapie, 1990–1991).

On the basis of the proposal by Gevers and the report of the Health Council, the Society of Health Law has issued its guidelines for genetic screening. The Dutch Society stresses the right of everyone to decide for themselves whether their genetic information and material should be kept (stored) after the screening and counselling is completed. This right is broader than the rights formulated in the *Law on the Registration of Personal Data* and the *Law on the Medical Treatment Contract*. It implies as well one's right to have the material destroyed. The guidelines also follow the *Law on the Medical Treatment Contract* with regard to body materials used for other than specified purposes. However, greater responsibility is placed on the physician (he or she has to inform the patient and request consent for the use of material for scientific research, etc.) (Richtlijnen Vereniging voor Gezondheidsrecht, 1991).

#### THE STATUS OF GENETIC INFORMATION

With regard to genetic information, the *Law on the Registration of Personal Data* and the *Law on*

*Medical Treatment Contract* continue to apply. However, some organizations such as the Health Council have suggested that the private nature of genetic information requires additional regulation. For example, the Council contends that the central registration of personal data should be possible only *after* an informed consent is provided, while the person always retains the right to have his or her data made anonymous, or to have them destroyed, *even if the information is of importance to his relatives*. The Council suggests that since formal law is less strict, the organizations establishing registrations should commit to such stricter guidelines. The Health Council believes that the rules concerning the use of personal data are also too permissive, and recommends that the exceptions for this use (Article 458) should be interpreted very strictly. According to the Health Council, unrestricted use of anonymous data for health policy is not self-evident due to the danger of stigmatization of or discrimination against certain population groups (Gezondheidsraad, 1989).

The former Secretary for Welfare, Public Health and Culture and the Minister of Justice shared these concerns of the Health Council but did not consider additional legislation on genetic information indicated. For the practical implementation of the *Law on the Registration of Personal Data*, they pointed to the recommendations by the Health Council itself, which should secure a restrained use of genetic information.

In the various reports and articles mentioned earlier, genetic information is discussed in reference to the concept of "privacy" (or personal domain of life). The term "ownership" is hardly ever used. Rare examples are found in the writings of ten Kate and Kuitert. Due to the conflicts of duty that a genetic counsellor faces when a person refuses to provide permission to inform his relatives of important genetic information, ten Kate has suggested that genetic information be regarded as "family property"—that is, genetic information is by its nature not only information about the individual *but also about his relatives* (ten Kate, 1976). According to Kuitert (1989), the medical information that a physician acquires about his patient is only in the *possession* of the physician; the patient is the true *owner* of the information. However, Kuitert seems to think in ethical rather than legal terms—that is, genetic information is confidential and has the character of a life secret. Breaking confidentiality would amount to a violation of the integrity of the person (Kuitert, 1989).

#### CONCLUSION

Although the system of Dutch law would allow the concept of "ownership" to be applied to body material, it is not a concept that figures prominently in discussions concerning the status of genetic ma-

terial. The Health Council and the ethicists de Wert and de Wachter (1990) alone contend that a person is the "owner" of his or her genetic material. With regard to genetic information, "ownership" is seldom mentioned, and then only by geneticists or ethicists rather than lawyers. Even in documents pertaining to the possibility of the use of genetic information by third parties outside the area of health care, that is, employers or insurance companies, the term is rarely if ever employed. Of importance in these discussions, however, is the right of the person to protection regarding his personal domain of life or "privacy".

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