

SUMMARY OF OPINION 129

CONTRIBUTION OF THE
*COMITÉ CONSULTATIF
NATIONAL D'ÉTHIQUE*
TO THE REVISION OF
THE BIOETHICS LAW





COMITE CONSULTATIF NATIONAL D'ETHIQUE POUR LES SCIENCES DE LA VIE ET DE LA SANTE

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25 SEPTEMBER 2018

The purpose of this document is to summarize the opinion of the Comité consultatif national d'éthique (CCNE; National Consultative Ethics Committee) before the scheduled 2019 revision of the bioethics law by the French Parliament. This reflection is part of the Etats généraux de la Bioéthique (National Consultation on Bioethics¹) organized by the CCNE in the first half of 2018.

Through this opinion, made public on 25 September 2018, the CCNE wishes to contribute to the forthcoming review of the bioethics law by making proposals. This opinion is addressed to the various public stakeholders who will draft, propose, and then vote on the new bioethics law, and to civil society, which was much involved during public consultations¹.

A strong attachment to ethical questions and to democratic involvement in health policy has underpinned France's pioneering role in bioethics legislation. A specific so-called "bioethics" law has defined a set of legal rules governing medical and/or research practices relating to the human body and human embryos. The first law was approved in 1988 and is revised regularly.

The last revision of the bioethics law dates from 7 July 2011² and a new revision is scheduled for 2019³. The law asserts, among other things, that "*any planned reform concerning ethical and social issues arising out of advances in biology, medicine, and health must be preceded by public debate in the form of consultations, organized on the initiative of the Comité consultatif national d'éthique.*"

Comité consultatif national d'éthique

The *Comité consultatif national d'éthique* (CCNE) is an independent French institution whose mission stipulated by law is "*to formulate opinions on ethical and social issues arising out of advances in biology, medicine, and health.*" Since 2011, the CCNE's remit has been to organize and stimulate public debate in the run-up to the revision of the bioethics law.

Currently presided over by Professor Jean-François Delfraissy, the CCNE has 39 members from various disciplines that raise bioethical questions: medicine, philosophy, research, law, religion... It has produced nearly 130 opinions and reports since its creation, by a process of self-referral or direct referral.

The National Consultation on Bioethics, *les Etats généraux de la Bioéthique*, was held in the first half of 2018 and all studies, arguments, and opinions were included in a synthesis report⁴ published in June 2018.

The CCNE also formed an opinion on all subjects that were debated, based on all the views voiced during consultations and on the principal conclusions of its previous studies.

¹ Public consultations and debates about contemporary bioethical issues which were summarized in a synthesis report in June 2018.

² See Box no. 2 – "The law of 2011: key points"

³ The 2011 law provides for a review within seven years.

⁴ A summary in English of the synthesis report is available at: http://www.ccne-ethique.fr/sites/default/files/synthese_anglaise_v1909.pdf

The present opinion – and the considerations it contains – serves above all to provide guidance on our scientific, medical, social, and legal context (1), ethical bearings (2), the main subjects of the various forums for discussion (3), and future perspectives for ethical reflection, which must constantly be renewed (4).

The opinion is therefore designed both for civil society, which was deeply involved in the public debate, and for public stakeholders who will draft, propose, and then vote on the new bioethics law.

Relying on institutions, the CCNE calls for a law of confidence that rises to the challenges posed by constantly evolving bioethical questions and their accompanying social issues.

1. The background and what has changed since 2011: science, medicine, society, law

Scientific and technological innovations in the life sciences

Without being exhaustive, there are various fields and approaches in which major scientific findings lead to innovations. Such findings have a substantial impact in the medical field and raise the need for calm and forward-looking bioethical reflection:

- innovation has in recent years led to great advances in analytical techniques and in targeted genome modification, for instance, but also in epigenetics, medical imaging, and digital technology, which increasingly are spreading throughout all health sectors;
- our understanding of the complexity of living beings is constantly growing, thanks to ever increasing analytical capabilities and changes in experimental approach that favor inter-disciplinarity;
- new therapeutic possibilities for some diseases (for example, in oncology, with personalized treatments, regenerative medicine, etc.), whereas other diseases remain unsolved (neurodegenerative, chronic).

These advances are occurring in a global context unsettled by environmental problems, leading notably to the concept of “global health,” at a time when the relations between science, medicine, and society are undergoing major changes. The National Consultation on Bioethics thus highlighted civil society’s vital need for information, which may explain society’s increasing mistrust of science and medicine.

Changes in health systems

Although changes in the health system represent progress, in parallel they create new weak points that destabilize the healthcare system and worsen inequalities:

- So-called chronic diseases are frequent and affect 20% of the population of France: they thus constitute a new paradigm for our health system.
- The advent alongside “curative” medicine of preventive medicine, the real impact of which is as yet unknown, drives medicine towards a forward-looking approach.
- The medical field (healthcare organization, medication, medical devices...) is increasingly becoming a major economic issue.

The emergence of new vulnerabilities poses ethical questions

From the point of view of the community, advances in understanding and their application to healthcare represent progress towards better health, but they also engender new risks and individual situations of great vulnerability. One of their characteristics is the tension they generate between the common interest (questions of public health, the economy...) and the interest of the individual (questions of autonomy, individual well-being...).

Legal changes since 2011

Beyond the framework of the revision of the law planned for 2019, some notable legal changes were made that come within the scope of the National Consultation on Bioethics. The main ones will be reported for each subject in the rest of this summary.

The law of 2011: key points

Research projects on embryos and embryonic stem cells are authorized if a certain number of conditions are met (scientific relevance of the research project, no alternative way of achieving the desired result, etc.)

Concerning assisted reproductive technology (ART), the condition of two years of conjugal life for partners and cohabitantes has been waived. ART is reserved for heterosexual couples with fertility problems. The technique of fast freezing of oocytes is authorized. The oocyte donor no longer has to have given birth before donation.

Pregnant women are given information and told of suggested tests so as to generalize prenatal diagnosis.

Since 2011, any revision of the bioethics law must be preceded by public debate organized by the CCNE and must take place within no more than 7 years.

2. Ethical reflection: benchmarks, balance, applications

The CCNE has identified benchmarks and some cross-functional problems that shed light on the fundamental questions at the heart of issues that are often highly technical, increasingly complex, and always raise new uncertainties.

There is a gap between what is technically possible and what is ethically desirable, a divide that legitimizes ethical reflection, notably by taking into account what can be anticipated in terms of the impact of today's scientific and technological applications on the future of humanity. Not all technical advances can be considered as progress: some, in fact, can worsen the quality of life and health of part of humanity, sometimes with dramatic consequences. What is possible is therefore not always desirable.

To shed light on questions of research and biomedical innovations, we have benchmarks that serve as invariable principles. These form the specificity of what has been designated as "French ethics" (refusal of commodification of the body, non-payment for donations, affirmation of the autonomy of individuals...).

There may be tension between these values that requires a balance to be found and these markers can help us in various subjects where they are applicable. For example, the principle of the respect of the dignity of the human person, which can lead to various general definitions, nonetheless constitutes an ethical and legal requirement measured in the concrete terms that everyone's material life is consistent with the quality of being human. The principle stipulates that the person is never considered solely as a means, but always as an end, that he or she is not instrumentalized.

And does not the ethical approach lead to consolidation of the notion of choice and of free and informed consent and to ensuring that the person is able to make health-related decisions, with the support of the doctor, thus strengthening his or her independence? Moreover, what becomes of the affirmation of the rights of the person and his or her loved ones, of the person's autonomy, freedom, and right to know or not to know, of the acceptance and respect of difference, or of the affirmation of identity when the very notion of "person" is no longer limited to the body, but is transformed into digital health data that are shared, stored, sold, and largely beyond the person's control?

Note too that one of the ethical benchmarks, that of individual freedom, is often under permanent pressure from the collective. Tension between the personal and the collective, between the subjective and the general, is central and makes it difficult to move to the notion of principles.

So, a person's autonomy is not an end in itself, but has to be completed by the principles of solidarity and responsibility, at the risk of eliciting contradictory needs for autonomy, even a corrupted conception of autonomy that conflicts with respect of public interest.

Scientific and technical advances lead to questioning of the definition and purpose of medicine, notably introducing the notions of predictive medicine and personalized medicine. At the same time, French medicine and the health system are confronted by challenges that have to be met: improve prevention, preserve the funding of healthcare by the social security system, reduce geographic inequalities in access to care. The risk of a loss of expertise by the doctor and the development of medicine centered on techniques and sometimes concealing the relational aspect, the very definition of care, upset the traditional practices and missions of medicine, which is also called upon to respond to all forms of suffering.

Numerous questions remain unanswered. Do scientific and technical discoveries always result in medical progress? How can the notion of progress, of benefit for the patient be defined today? How can the patient participate and be a genuine stakeholder in reflection concerning the major challenges of health democracy? Just how far should medicine go for a particular individual and for the community? Is individual benefit for the patient always compatible with the collective interest, that of the greater number? And what of access to costly care and techniques in a context of increasing economic constraints? What criteria should be applied to the allocation of limited resources?

All these questions go beyond the notion of medical purpose and of the definition of "good." Yet it can prove particularly complex to define what a patient considers "good," insofar as this evaluation has various dimensions: the patient's own definition of well-being as he or she sees it; the medical conception of beneficence; or a more collective idea of a medical procedure's benefit, which can vary greatly: cure of the disease, alleviation of a symptom, efficacy of the medical technique, for example.

The CCNE National Consultation on Bioethics was an extremely privileged moment of collective deliberation, ie, a time of broad-ranging and open questioning, of reflection, and of calm exchanges on the purpose of research and the human consequences of biomedical practices. Is it not the most open collective deliberation possible that will bear witness to our responsibility and to our ability to make democracy live?

3. Opinion of the CCNE on the subjects addressed during the National Consultation on Bioethics

The National Consultation on Bioethics greatly broadened the scope of the subjects considered, not only those traditionally within the framework of bioethics law (genetic testing, organ donations, organ transplants, prenatal and pre-implant diagnosis, ART, research on embryos and embryonic stem cells, neuroscience, and medical imaging), but also on other subjects that could create new areas of consideration in terms of health and care policy (artificial intelligence and big data, environment). Lastly, end-of-life questions were also addressed during the National Consultation on Bioethics.

The formulation of this opinion is in many ways exceptional because of its great range of content and complexity, the method used to create it, the methodology used, the timeframe of its realization, which was relatively short but nonetheless actively mobilized CCNE members⁵.

The reflection that the CCNE undertook was based on the results of the public consultations and debates and on the history of the CCNE, its published opinions and reports, and the conclusions of four CCNE working groups (on genomic medicine, research on embryos and embryonic stem cells, the neurosciences, and artificial intelligence). The full scope of this combination is taken into account, including when certain questions are debated by the CCNE and often within society. The CCNE strives to respect diversity of opinion by presenting arguments leading to divergent positions all of which contribute to the ethical action. This opinion therefore reflects not a

⁵ The opinion of the CCNE was formulated at eleven plenary sessions of the committee between early June and mid-September 2018, based on the proposals of so-called "ephemeral" working groups set up during this period to study topics discussed in the National Consultation on Bioethics.

general consensus of CCNE members on all questions addressed, but a majority agreement.

Proposals are formulated in terms of extension of law or possible introduction of a new law or a new treatment.

Finally, it is essential to reiterate one of the main learnings of the National Consultation on Bioethics: the need for information before collecting the patient's free and informed consent, for medical support, and for the cross-functional training of healthcare professionals in all subjects.

Research on embryos and embryonic stem cells

Embryos, embryonic stem cells, reprogrammed pluripotent adult stem cells: what are they?

Supernumerary embryos are preimplantation embryos⁶ from an IVF procedure⁷, which in France is done for parents planning to have children, and which have not been transferred and have been frozen. If these embryos are no longer part of such a parental project or of transfer to a recipient, they are in the medium term destined for destruction. In this setting, the couple can donate them to research⁸.

Embryonic stem cells are produced by the culture of cells of the internal cellular mass of a preimplantation embryo 5 to 6 days after fertilization. After their culture, some of these cells proliferate unrestrictedly, while retaining their pluripotent potential: they then constitute *lines* of embryonic stem cells. These cells are pluripotent, ie, able to differentiate into any body tissue. The first lines were derived 20 years ago. In 2007, a new class of pluripotent stem cells was described: *adult (and not embryonic) stem cells*, which can be obtained by the artificial reprogramming of differentiated adult cells into *pluripotent* cells, whence their name: *induced pluripotent stem cells*.

In humans, the emergence of ART procedures, by creating embryos *in vitro*, has enabled analysis of early embryonic development.

⁶ The preimplantation stage, ie, until the embryo acquires the capacity to be implanted in the uterus.

⁷ IVF: *in vitro* fertilization.

⁸ This may also apply to embryos in which a preimplantation diagnosis detects the genetic abnormality that prompted IVF and preimplantation diagnosis.

Lines of human embryonic stem cells are of great value in research: they come from the only pluripotent stem cells present in the physiological state. They are cell lines because they propagate indefinitely, thus permitting unlimited production of cells. Many are reference lines used for standardization of procedures and for quality control in laboratories worldwide. Specialized cells produced by the differentiation of these lines of embryonic stem cells have been tested in clinical trials of cellular therapy since 2010.

Induced pluripotent cells – also propagated in the form of immortal lines – have capacities very like those of embryonic stem cells, but cannot replace them because of incompletely understood characteristics, lower efficacy in terms of differentiation, and uncertainty regarding their safety. The essential property of embryonic stem cells and induced pluripotent cells, apart from their immortality, is their pluripotency.

There has been a two-pronged trend in research since the last revision of the law in 2011: (1) the individualization of research specific to the preimplantation embryo designed to shed light on the first stages of embryonic development; (2) a change in the way of considering the use of embryonic stem cells: whereas their embryonic origin is still a subject of debate in their legislative framework, this is no longer the determinant factor. It is the *pluripotent* character and the potential that this confers that pose today's thorniest ethical questions regarding the possible applications of this potential.

What the law says

Initially banned, embryo research is now subject to a structured authorization procedure. Only supernumerary embryos no longer needed for a parental project can be used for this research (with prior consent from the couple). Research on embryos or embryonic stem cells today comes under the same legal regime.

Current legal texts define precise research methods by fixing prerequisites and prohibitions. Three prerequisites are necessary in France to "authorize" research: apart from the scientific relevance and quality of the research team, the project must have a medical objective and there must be no alternative to the use of cells from an embryo. Furthermore, the creation of transgenic embryos and chimeric embryos is prohibited, as is the creation of embryos for research purposes or the transfer to the uterus of an embryo used for research.

Preserve the ethical principles of research without hindering progress potentially beneficial for all

The decision to undertake embryo research in a way also means influencing the future of humanity and of the human species and considering essential questions, such as knowing who we are and in what world we wish to live tomorrow. No important decision should therefore be taken before reaching a broad consensus on the relevance of such research.

On another note, it seems feasible that the law – instead of defining with precision what is and what is not allowed – could establish legal framework and safeguards, define boundaries not to be crossed, and delegate to an *ad hoc* body the responsibility for strict assessment, with a wide margin of interpretation, of the modalities and possible applications of a research project. This body could therefore ensure that ethical principles are followed and coincide with the chronology of scientific advances.

Proposals:

- The CCNE considers justified the authorization of research on supernumerary embryos (preimplantation embryos from IVF procedures for which parental projects have been abandoned), including genetic modifications, provided there is no embryo transfer.

- The CCNE reiterates the ethical relevance of the ban on the creation of embryos for research purposes.

- The CCNE proposes using different legal regimes for embryo research and for research on embryonic stem cell lines, as the ethical issues associated with these two types of research are different.

The CCNE considers it legitimate not to apply the legal regime for embryos to human embryonic stem cells, as is currently the case in France, but rather to use a simple declaration. It is, however, necessary to envisage a new legal framework to cover the research made possible by the availability of pluripotent stem cells (embryonic stem cells and induced pluripotent cells - induced pluripotent stem cells).

- The CCNE wants the new legislative framework pertaining to embryo research to be specific and clear on the following points: creation of transgenic embryos, creation of chimeric embryos, time limit on the length of embryo culture.

- The CCNE considers that there is a need to include in law the two prerequisites to embryo research, ie, medical purpose and lack of an alternative. A more general framework could

guarantee the principle of the respect of the embryo, without curbing research, while ensuring the scientific quality of the research team, the soundness of the protocol, and the scientific rationale.

- Given the diversity of protocols for embryo research and embryonic stem cell research, and in view of new ethical questions related to the emergence of sensitive applications derived from induced pluripotent cells, the CCNE calls for in-depth review of the procedures used to inform patients and collect their consent in these new situations.

Genetic testing and genomic medicine

The development of new techniques of analysis and of genomic engineering leads not to new concepts but to scientific facts on the genome and epigenome, with new techniques of high-throughput sequencing and their generalization as well as understanding of identified genetic variations. More recently, targeted interventions at the level of a gene or even a single letter (nucleotide) of the genome constitute a major technical advance in our understanding and management of genetic diseases.

Genetic testing raises ethical questions regarding the objective and detailed information given to people with a view to obtaining their free informed consent. What is one consenting to when offered a genetic diagnosis or participation in a research protocol involving examination of genetic characteristics? Information and consent are influenced by understanding of, or by failure to understand, the analysis and its results, interpretation of which involves probability and uncertainty. Ethical principles concerning respect of the patient and of collective solidarity come under pressure from freedom of access to this information or from the decision not to know certain results, in particular when there is no therapeutic possibility, and the obligation to warn biological relatives should a serious genetic alteration be detected, as is stipulated in French law, whether the disease is curable or incurable, early- or late-onset.

It is important to recall that the transformation of sequencing data into medical information is a real challenge calling for multidisciplinary research in numerous fields of science and medicine.

Genomic medicine and genetic testing reduce the incidence of some serious genetic diseases and open up new leads for suitable treatments.

However, this progress should not be accompanied by stigmatization of the carriers of these genetic mutations (parents and patients) or by decreased social solidarity with the treatment of these diseases. Lastly, it behooves us to remember that each person's fate is far from sealed in his or her genes.

What the law says

The law authorizes genomic testing of a person only for medical and scientific research purposes (in these cases, informed consent is collected).

Genetic testing, performed in a medical setting, is intended to make, confirm, or reject the diagnosis of a genetic disease, to screen for the characteristics of one or more genes likely to influence the development of a disease, and to adapt the medical management of a patient according to his or her genetic characteristics. Tests also enable implementation of medical or preventive measures and informed decision-making when there is a parental project.

Genetic tests yield results of value not only to the person tested, but also to family members. This has led to a particular procedure for ensuring the passing on of information to family members potentially concerned.

Furthermore, prenatal and preimplantation diagnoses are covered by the bioethics law: preimplantation diagnosis is only authorized in the case of hereditary disease and is limited to the analysis of the single gene linked to this disease.

Proposals:

- The CCNE suggests preconception genetic diagnosis to be offered to everyone of childbearing age who wishes, following genetic counseling. This preconception diagnosis would be based on screening for healthy carriers of mutations responsible for serious hereditary monogenic, and not polygenic, diseases, whatever the technique used: gene panel, sequencing of the exome or of the whole genome. As a preventive medicine procedure, this would be covered by the national sickness insurance fund.

- The CCNE wishes to examine in greater depth the possibilities of extending genetic testing to the general population. It urges rapid initiation of a pilot study in several regions and for various age ranges so as to assess the consequences in terms of public health, psychological impact, and cost.

- The CCNE favors the authorization of screening for aneuploidies, during IVF, for couples undergoing preimplantation diagnosis and for certain infertile couples.

- The CCNE suggests a new definition of prenatal diagnosis⁹ to be drawn up, aligned with therapeutic practices and recent possibilities developed for *in utero* or postnatal use.
- The CCNE considers it desirable to broaden neonatal screening to include hereditary immunodeficiencies.
- The CCNE favors the authorization of genetic tests on samples taken from a deceased patient, except if he or she expressed refusal when alive.
- The CCNE proposes the creation in France of a status of genetic counselor, including non-physicians, in response to the exponential growth in genetic tests.
- The CCNE proposes the drawing up of informed consent forms extended to include genetic analyses, explicitly mentioning data collection methods and conditions, in a research or standard care setting.

Organ donations and transplants

What the law says

The legal framework concerning organ, tissue, and cell donations and transplants was established in France by the law of 22 December 1976 relating to organ collection, the so-called Caillavet Law. There is a consensus concerning the main principles underpinning the development of this therapeutic activity: respect of the body of the person, living or dead, non-ownership of the human body, consent and anonymity of the donor, and unpaid donation.

The law thus presumes that each French person is a potential donor of organs and tissues. Everyone can oppose this by signing a national register of refusal or by expressing refusal in writing or orally to family or friends.

Despite the efforts of healthcare professionals and the public authorities, too many people still die each year because they are unable to receive an organ transplant in time. Over 6000 organ transplants were performed in France in 2017, but the number of patients on the waiting list is nearly four times that and, at the same time, 550 of them on average die every year. The modalities of organ transplantation can be questioned. Too many people die pending an organ transplant and this in itself is a major medical and ethical concern. The allocation of this "rare resource" and equality of access to transplants in France are also important considerations. Current regional inequalities stem in large part from differences in the

⁹ Prenatal diagnosis does not necessarily induce abortion, and can lead to treatment of the child, either *in utero* or postnatally.

practices of medical teams in terms of early or late inclusion of their patients in the waiting list.

Proposals:

In terms of the collection of organs from dead patients:

- The CCNE wishes current regional inequalities in transplant availability to be reduced, notably by decreasing discrepancies between medical teams in early/late inclusion of their patients in the organ transplant waiting list.
- In light of a national protocol concerning the so-called "Maastricht 3" collection techniques¹⁰, the CCNE suggests more information to be made available to intensive care teams and to the general public. It is essential to give families clear information on decisions to withdraw care, so as to reassure them that the decisions are not motivated by the opportunity to collect organs.
- The CCNE considers it desirable to develop the training of healthcare professionals in provision of psychological support for the families of deceased donors.
- The CCNE wants continued information campaigns on organ donations, and particularly on the current framework of consent to donation and the possibility of signing the national register of refusals at any time.

Regarding organ transplants from living donors:

- The CCNE insists that professionals should be vigilant when overseeing the procedure for collection of the donor's consent, in view of potential family pressure in favor of donation.
- The CCNE considers desirable a change in French legislation concerning kidney paired donation (today possible between two pairs of donors) that authorizes the setting up of a chain of successive donors, possibly initiated with a kidney from a deceased donor, while ensuring respect of the informed consent of donors and of transplant recipients.

¹⁰ Concerning people who die because of prolonged irreversible cardiac arrest, a publication by surgeons and intensivists at the Maastricht Hospital in the late 1990s defined four situations posing different types of ethical problems. Situation I: cardiac arrest in the home that is irreversible despite attempts at resuscitation, and *post mortem* transfer of the deceased to hospital with a view to organ collection; situation II: irreversible cardiac arrest in a hospital setting with failure of all attempts at resuscitation; situation III: cardiac arrest in intensive care of a brain dead person. Situation IV anticipates organ collection after cardiac arrest following withdrawal of treatment from a person in a deep coma considered to be irreversible who hitherto has been kept alive by artificial feeding and mechanical ventilation. In the latter situation, it must be certain that the decision to withdraw treatment is totally independent of the planned organ collection.

- The CCNE proposes the creation of a donor "status," in respect of the principle of fairness among patients on the waiting list, and highlights the need to accelerate reimbursement of costs advanced by the living donor, so that he or she does not have to bear the financial consequences of this generous act.

Neuroscience

Neuroscience is the study of nervous system functioning from its most basic features (molecular, cellular, synaptic) to more functional aspects such as behavior and mental processing. This embraces a vast family of research disciplines, both clinical (neurology, psychiatry, psychology, neurosurgery, etc.) and basic. Neuroscience touches the very identity of the human person and so is linked to anthropology and sociology. It also raises fundamental philosophical questions.

Progress in neuroscience stems largely from advances in techniques used in exploration of the brain. Other techniques are used to explore not the brain, but changes in its functioning. Some of these techniques have a long history, such as the use of drugs (psychostimulants, anxiolytics, etc.), while others are more recent, like electrical and magnetic transcranial stimulation and deep brain stimulation.

What the law says

The text of the bioethics law is ambiguous on the subject of neuroscience, because it authorizes the use of brain imaging in the context of an expert legal evaluation, without specifying the type of imaging that is usable. Yet the anatomical and functional potentials of MRI¹¹ do not correspond to the same purposes: anatomical imaging can detect anomalies that may help explain a particular behavior, whereas functional imaging observes brain activity so as to deduce effects on the psyche.

In the context of this opinion, the CCNE has used some examples to examine how neuroscience strengthens or alters the concept of human dignity, as well as the principles of autonomy, non-maleficence, and equality, by using functional MRI to examine cognitive enhancement, ie, techniques to modify brain functioning in a healthy subject and brain-machine interfaces, which enable direct communication between an individual's brain and an electronic device.

¹¹ MRI: magnetic resonance imaging.

Furthermore, the changes induced by artificial intelligence and big data are leading to profound upheavals in the field of psychiatry.

Ethical evaluation of research projects

One of the points the CCNE wants to underscore concerns the management of neuroscientific research, particularly cognitive and behavioral neuroscience.

The CCNE also considers it necessary to address the question of the ethical evaluation of neuroscience research projects. As we are concerned with clinical research, special attention should be paid to the management of techniques for deep brain stimulation, extension of the indications for which could raise important ethical issues, notably those of free and informed consent and possible modification of the "self."

Proposals:

- In light of current knowledge, the CCNE firmly opposes the use of the functional MRI in the legal field.
- The CCNE advises against use of functional MRI in "social" applications such as neuromarketing.
- The CCNE is opposed to the use of functional MRI in selection of job applicants or in insurance practices.
- The CCNE suggests the general public to be given more information on techniques of cognitive enhancement concerning non-medical devices.

Digital technology and health

Digital science and technology and their uses and innovations in health are often seen, experienced, or endured as technological, contributions, sometimes needlessly restrictive, but henceforth inescapable and accompanying the global digitalization of society. While this is acknowledged, the fundamental role of digital science and technology in the processing of information is in fact a primordial feature of data processing in health and biology.

The rapid spread of things digital in our health system is irreversible. Nationally and internationally, it is clear that digital technology is a source of major advances that improve the quality and efficiency of the whole health system. The benefits likely to accrue in the fields of teaching and research are also considerable. The mobilization of this potential is only beginning.

An ethical path must be found between the necessity to respect the law and personal freedom, the protection of health data, and the importance of sharing these data to increase the clinical quality and efficiency of our health system.

Two major ethical issues associated with the spread of algorithmic medicine were identified and should be subject to controls: (i) the risk that, when confronted by decisions proposed by algorithms, the patient will be deprived of a large part of his or her ability to participate in the construction of the treatment process; (ii) the danger of taking less account of individual situations when thinking is based on models that can be calibrated so as to limit inclusion of each patient's specific characteristics.

What the law says

French law defines a general framework for the protection of data, with a broad conception of health data, covering data on the health of a person and data likely to provide an indication of a state of health.

The European General Data Protection Regulation (GDPR; 2016) concerning the protection of natural persons in terms of the processing of personal data has been applicable in French law since 25 May 2018. It protects the rights of natural persons regarding personal data and creates new rights, such as the right to delete data or the "right to be forgotten," and the right to data portability. The regulations also stipulate that companies should obtain their users' consent before collecting and using their data.

The law of 7 October 2016 for a "digital republic" anticipated some European laws, notably by affirming the principle of the individual's control over personal data. The CNIL (French Data Protection Authority) ensures in France that data processing procedures for research purposes protect the confidentiality of data kept only for a period needed for treatment. The law allows access to all algorithms used by government agencies. The agencies are therefore obliged to publish the algorithmic source codes that led to the decision.

Lastly, the law protects the right to the respect of private life and to the confidentiality of personal information for everyone treated by a healthcare professional or by a provider of prevention and care.

Proposals:

- The CCNE considers the dissemination of digital technologies in the health sphere a priority and wishes to minimize enforceable rights. Given the gain in quality and efficiency enabled by greater use of digital technologies in our health system, it would not be ethical to erect regulatory barriers. The CCNE calls for

reflection in the months ahead on the creation of regulatory instruments such as a "soft law" applicable to the dissemination of digital technologies in our health system, the aim being general supervision, a role which could be given to the *Haute Autorité de Santé* (French National Authority for Health). This would increase the effectiveness and efficiency of our health system, while preserving the operational flexibility needed to support innovation.

- The CCNE proposes that the legislation should include the fundamental principle of guaranteed supervision of all use of digital technologies in human health, and the obligation to put anyone who wishes in contact at any time with someone able to provide comprehensive information on the conditions of use of digital technologies along the care pathway.

- The CCNE considers that any person using artificial intelligence in the care pathway should be informed beforehand so that he or she can give free informed consent.

- The CCNE does not want the digital revolution to penalize citizens without digital technologies, who are often in a precarious situation, particularly in terms of health.

- The CCNE proposes the creation in France of a secure national platform for the collection and processing of health data so as to address associated ethical issues.

- The CCNE will fully engage in ethical reflections about digital technologies and health, and help in the setting up of an ethics committee specialized in issues related to digital technologies.

Health and environment

The CCNE insists on the need to examine human health through the prism of the environment, because human-made ecological perturbations account for a large number of health crises, ranging from lack of vital resources for certain populations to the global development of chronic diseases and the emergence of new infectious diseases, and necessitate collective awareness.

In parallel, the impact of the "ecological crisis" on human health is often correlated with the vulnerability of populations and so we need an ethical and supportive approach to include the fight against poverty and health prevention in the long-term management of natural resources and health. The poorest populations are often the first to suffer the consequences of environmental crises and the resulting depletion of resources, and can also be negatively

affected by measures to fight global warming implemented without consulting them.

Awareness raising should inspire laws and guide executive and managerial decisions. It therefore behooves communities and businesses to pay more attention to these environmental and health concerns.

What the law says

The subject of environmental health is not mentioned in the 2011 bioethics law. In contrast, the 2016 law on modernization of the health system stipulates that populations be informed about and protected against environmental health risks. Public health warnings regarding the environment have been enshrined in law since 2013.

More generally, the third national health-environment plan of 2015-2019 (PNSE3) in France is designed to draw up a governmental roadmap to reduce the impact of environmental changes on health.

Such an objective would highlight the importance of modifying the corporate purposes of businesses, as currently defined in French law. A bill (PACTE) under consideration by the French Parliament at the time of writing of the CCNE opinion, proposed rewriting article 1833 of the Civil Code and enshrining in law that “*society is managed in its social interest and taking into consideration the social and environmental challenges of its activity.*” The government, prompted by this bill, invites the legislator to put social and environmental questions at the heart of management decision-making by company directors, without forgetting corporate purpose¹².

Proposals:

- The CCNE proposes “health and environment” to be the object of interdisciplinary reflections, the results of which would support ministerial actions.

- The CCNE proposes inclusion of this ambition in the preamble to the bioethics law and favors modification of the corporate purpose of companies that take into consideration the social and environmental consequences of their activities.

- The CCNE would like companies to present each year to their shareholders and their

¹² Articles 225-35 and 225-64 of the French Commercial Code acknowledge these two issues for the largest businesses, and the management board and the boards of directors of limited partnership with a share capital would determine “*the orientations of the company’s activity in line with its social value and taking into account its social and environmental implications.*”

economic and social committee (elected representatives of the company personnel) an ethics document, also made available to their clients, outlining their policy for inclusion of environmental concerns in their functioning and their strategies for development.

Procreation

By separating sexuality from procreation, a couple’s wish “to have a child” when deemed optimal becomes a shared responsibility. It implies, when spontaneous procreation proves difficult, the use of assisted reproductive technology (ART) to provide a medical answer to an infertility problem. ART covers a range of techniques designed by the medical profession and organized by the legislator to respond to infertility resulting from somatic dysfunction. ART raises general ethical concerns that from the outset have been at the heart of work done by the CCNE (and which even led to its creation).

Social demand for access to ART covers the use of these techniques for purposes other than overcoming infertility in heterosexual couples.

What the law says

ART is currently authorized for therapeutic purposes, to overcome infertility in living heterosexual couples of childbearing age, and to avoid transmission to the child or to one member of the couple of a particularly severe disease. In this regard, the following are authorized: *in vitro* fertilization with gametes from at least one member of the couple, preservation of gametes, germinal tissue, and embryos, and embryo transfer and artificial insemination.

In gamete donation, the donor cannot know the identity of the recipient nor the recipient that of the donor. No parentage can be established between the donor and the child resulting from the fertilization and no action for liability can be brought against the donor. The consent of the donor and of the other member of the couple, if they form a couple, is collected in writing.

Storage of gametes or germinal tissue is only allowed in France in the case of diseases or treatments that affect fertility. Donors who have not yet had children can undergo collection and storage of their gametes with a view to subsequent personal use of ART (see below).

Reproductive cloning, surrogate motherhood, and medically unsupervised insemination are prohibited.

Reflections on storage of oocytes in return for donation

The CCNE is critical of the change in the provisions introduced by decree in 2015 which authorizes adult women who have not given birth to donate oocytes and, should they become infertile before they give birth, to keep the oocytes for their own benefit (article L.1244-2 of the French public health code).

Reflections on the possibility of proposing, without encouraging, storage of oocytes independently of donation

Postponement of motherhood increases the frequency of age-related infertility in women, as well as the number of consultations in accredited ART centers. This tendency to delay pregnancy may stem from a legitimate desire among women to enjoy a longer period without family responsibilities or from an equally legitimate desire to find a partner who is also the desired father. Delayed pregnancies are also explained by material difficulties and by organizational failings in society that may discourage young women from having children. But this postponement of pregnancy runs up against declining fertility rates caused by age-dependent decrease in oocyte numbers.

In this context, the possibility of storing oocytes seems like an arena where women could experience freedom without compromising future motherhood.

Reflections on requests for assisted reproductive technology by female couples or single women¹³

This request for artificial insemination using donor sperm so as to have a child without a male partner does not involve infertility and is part of a demand for freedom and equal access to ART so as to be able to have children. Such a request profoundly alters the relations of the child with the family environment, in terms of family references and father absence, which is institutionalized *ab initio*.

It also raises questions on the relation of children to their origins, as gamete donation is anonymous and free in France, and on growing

up without a father. Reliable research on the impact of this situation would be valuable in this regard.

However, the CCNE analysis, which was based on recognition of the autonomy of women and the relation of the child to new family structures, led the CCNE to suggest that artificial insemination using donor sperm should be open to all women.

The CCNE considers that ART could be made available to people who are not infertile, notably to alleviate suffering generated by inability to have children because of personal sexual orientations. This suffering should be taken into account because the seeking of a technique already authorized in other situations does not imply abuse in the relations between the people involved.

This CCNE's position does not mean that all members agreed. This request to give all women access to artificial insemination using donor sperm was also debated by the CCNE, in particular in terms of the effects on the child of the institutionalization of father absence and of the absence of male-female difference in mental development, but also the increased risk of commodification of the body. This request should be weighed against the current rarity of gametes, which risks lengthening the waiting time or breaking the principle of free donation. This could lead to commodification of products of the human body and call into question the French health system, which is based on the principle of altruism.

Reflections on the lifting of donor anonymity

It should first be remembered that donor anonymity was designed to preserve various distinctions: biological, which is subject to donation; filiation, which is subject to intention and legal recognition; and parental, which is subject to care and education.

These distinctions should continue to be strictly maintained. Far from confusing them, ART makes them even clearer. Filiation is always legal and parenthood is always relational (and temporal, whence the importance of the question of the age of the child, which enables parenthood to be established), but their separation from the genetic or biological, because of ART, further strengthens the respective specificities of these distinctions.

In 2005, the CCNE recommended: (i) lifting of secrecy regarding the method of conception; (ii) respecting the anonymity of donors and recipients; (iii) allowing the child access to non-

¹³ These requests for the use of ART were recently the subject of an in-depth study by the CCNE that led to opinion 126, published on 15 June 2017. The opinion is available in English on <https://www.ccne-ethique.fr/en/publications/ccne-opinion-societal-requests-medically-assisted-reproduction-mar>

identifying information while maintaining the anonymity of donors.

The CCNE proposes that reflection on the lifting of anonymity should be conducted on these bases. Most CCNE members are in favor of lifting of anonymity, which will require additional reflection on how this will be implemented. This lifting of anonymity will not concern donations already made.

Proposals:

- The CCNE reiterates its proposal to make ART available to female couples and single women.
- The CCNE considers it essential to anticipate how making ART more available will affect the capacity of centers for the study and storage of oocytes and human sperm (which are in charge of collecting and distributing sperm donations) to meet this new demand for donated sperm.
- The CCNE favors maintaining the ban on surrogacy.
- The CCNE favors the possibility of proposing, without encouraging, storage of oocytes for all women who wish (the only restrictions being minimum and maximum ages), following medical advice.
- The CCNE proposes lifting of anonymity for future sperm donors, for the children resulting from these donations. The modalities of this lifting of anonymity should be specified and regulated in the decrees of application, notably in terms of respect of the donor's choice.
- The CCNE favors the availability of ART *post mortem*, ie, the *in utero* transfer of a cryopreserved embryo after the death of the man, provided the spouse receives medical and psychological support.

End-of-life care

The previous opinions of the CCNE, the numerous debates of recent years, and particularly the exchanges reported in the synthesis report of the 2018 public consultations and debates show that positions on end-of-life issues, even if well argued, are irreconcilable. Although there may be ethical exceptions, on the one hand, and a genuine distinction between the notions of assisted suicide and euthanasia, on the other hand, the CCNE considers that the irreconcilable nature of opinions on this subject underscores the legislator's responsibility: because certain end-of-life situations raise the question of the meaning of life; because the responsibility for the decision must clearly lie with those involved, notably the patient and the person of trust if the patient is unable to express his or her wishes;

because these situations, which are widely publicized by the media and some nonprofit organizations, have for several years generated interest among the public.

What the law says

The law of 2 February 2016, the so-called Claeys-Leonetti Law¹⁴, affirms that "every person has a right to a dignified and peaceful end of life" insofar as is possible, and that medical procedures should not be implemented or pursued when they result from futile medical care.

Any sick person has the right of access to palliative care and support if required. Every person has the right to a dignified and peaceful end of life.

Any adult can write advance directives in anticipation of a time when he or she may no longer be able to express personal wishes. The Claeys-Leonetti Law has made these directives binding, except where noted. Any adult can designate a person of trust who will be consulted should the adult be unable to express personal wishes or to receive the information necessary for this purpose. In the absence of these advance directives, a process of collective deliberation must be put in place for all medical decisions concerning the continuation, limitation, or discontinuation of a treatment likely to be life-sustaining.

Deep and continuous sedation until death, inducing alteration or even disappearance of consciousness, combined with analgesia and the withdrawal of all life-sustaining treatments, can be implemented if requested by the patient, in the following cases: (i) the patient has a serious and incurable illness that is life-threatening in the short term and is suffering from intractable pain; (ii) the decision of the patient with a serious and incurable illness to stop treatment is life-threatening in the short term and is likely to result in unbearable suffering.

Lastly, the law does not authorize the right to assisted suicide or to euthanasia.

To avoid these questions being limited to a possible change in the law – a change that may be necessary but will never be sufficient – the CCNE proposes to study the conditions to be put in place before any change. These conditions constitute a call for an ethical foundation of social and health policies that ensure the respect of the most vulnerable people and that the end of life is not a time that is denied in France. Three reflections and proposals can be mentioned: (i) ensure that modern medicine does not lead to unreasonable survival situations; (ii) ensure that society does not lead certain people to feel unworthy: a duty of solidarity; (iii) examine the

¹⁴ There are no end-of-life provisions in previous bioethics laws.

conditions of application of the law in certain precise circumstances.

Proposals:

- The CCNE does not propose any change to the existing end-of-life law (Claeys-Leonetti Law) and underscores the pressing need for this law to be better known, applied, and respected.

- The CCNE suggests funding for a new governmental development plan for palliative care, the main aims of which would be to inform the medical profession of the provisions of the Claeys-Leonetti Law and to develop training and research through the creation of a university course and the publication of calls for research proposals on end-of-life issues and palliative medicine. The initial and continuous training of all healthcare stakeholders (to develop reflective and scientific skills in communication and team work, and in terms of the law in force) is necessary to achieve a true "palliative culture" incorporated into the practice of health professionals. Only the results of rigorous research will usefully fuel the often heated and ideological debate on end-of-life issues.

This plan should seek to reduce regional inequalities and to expedite local organization of palliative care, favoring home-based care when wanted and broadening the scope and missions of mobile palliative care teams. Lastly, the plan should encourage a reflective and discursive process leading to fair end-of-life decisions to avoid medical care that is futile or disproportionate, while prioritizing relational care and support (in particular, to facilitate the anticipation of what may happen and to favor the drawing up of advance directives).

- Lastly, the CCNE wants descriptive and comprehensive research work to be done on exceptional situations not dealt with by the law and which could possibly advance the legislation.

4. A vision for the future

The publication of CCNE opinion 129 signals the end of a process started on 18 January 2018, during which the CCNE organized public consultations and debates on revision of the bioethics law. It is now time to draw lessons from this 9-month exercise on the role of the CCNE, on its partnerships with *les Espaces de Réflexions Éthiques Régionaux*, the regional forums for ethical reflection¹⁵, on the

organization of public debate on complex and ever-changing subjects and, more generally, on the CCNE's remit, including the acquisition or not of new missions.

Proposals:

- The CCNE considers that the French model, which organizes the periodic revision of bioethics laws after public consultations and debates, is a vital feature of our health democracy and should be preserved. To take account of the temporal dimension inherent in social and scientific changes, bioethics laws should be revised every 5 years. The CCNE should continue as the initiator of public consultations and debates.

- The CCNE calls for greater participation of civil society in debates on bioethics and suggests public debates henceforth to be conducted well in advance of consultations on bioethics. The CCNE also wishes public debate to continue between revisions of the bioethics law, initiated by the CCNE in partnership with regional forums for ethical reflection.

- The CCNE advocates that it should – in partnership with the regional forums for ethical reflection – assume a role of oversight and early warning regarding new ethical questions that may arise because of scientific advances between revisions of the bioethics law.

- The CCNE suggests more research in the human and social sciences and more assessments of programs, in particular on major social questions (procreation, end of life). The CCNE also considers that the teaching of ethics should be developed, in particular in the framework of studies and training leading to the healthcare professions.

- The CCNE wishes to include in its reflections questions on the interaction between health and digital technologies, and offers to help constitute a future ethics committee on digital technologies that would specialize in digital issues in general.

- Lastly, the CCNE considers it would be timely to heighten reflections on bioethics internationally, and particularly in Europe, and possibly to reach shared ethical positions. The CCNE offers to play a more active part in the development of collaborations with foreign ethics committees, particularly those that are French-speaking.

¹⁵ The regional forums for ethical reflection are held near university hospitals under the responsibility of regional health agencies (in charge of defining and

implementing regional healthcare policies) and are a key element of bioethics in France.

Conclusion – Strengthening the international dimension¹⁶

Dialogue and listening, collective deliberation, and the exchange of different outlooks are all actions inherent to ethical reflection and are put into practice in Europe and internationally (through the Global Summit of National Ethics and Bioethics Committees, the European Bioethics Forum, and tripartite meetings). However, there is room for progress in reaching identified objectives, inasmuch as this international outlook is proving increasingly useful for ethical reflection on global questions concerning all populations. In the words of our fellow citizens during the National Consultation on Bioethics: How can we collaborate better internationally?

The organizational and cultural heterogeneity of different national ethics committees and their relations to policy were apparent during the meetings run by the CCNE with various committees organized alongside the National Consultation on Bioethics¹⁷. This structural heterogeneity is accompanied by distinct legislative, regulatory, and jurisprudential responses to different questions by each country. The CCNE's understanding of cultural differences would be enhanced by more in-depth exchanges with foreign ethics committees.

CCNE Opinion 129

“Contribution of the *Comité consultatif national d'éthique* to the revision of the bioethics law,”

September 2018, 160 pages (*in French*).

- Downloadable from www.ccne-ethique.fr and www.etatsgenerauxdelabioethique.fr
- Available on demand (free) from the CCNE at: etatsgeneraux@comite-ethique.fr

¹⁶ Extract from chapter IV, part 6 of Opinion 129

¹⁷ The CCNE has consulted a number of foreign ethics committees because it is convinced that better understanding of the reflections conducted in these countries, prior to the drawing up of legislation relating to bioethical questions, is necessary and will enrich its own reflection. In formulating this opinion, the CCNE consulted the ethics committees of the following countries: Canada, Switzerland, Belgium, Japan, Mexico, Germany, Portugal, and England.