Gaia Barazzetti, Alberto Bondolfi, Samia Hurst, and Alex Mauron



Introduction

This chapter describes the development and the current status of bioethics in Switzerland with special emphasis on the historical evolution and the social and cultural contexts that have shaped the debate in the country. Medical ethics

G. Barazzetti (⊠)

ETHOS-Interdisciplinary Ethics Platform, University of Lausanne, Lausanne, Switzerland e-mail: gaia.barazzetti@unil.ch

A. Bondolfi

Faculté de théologie, University of Geneva, Geneva, Switzerland e-mail: alberto.bondolfi@unige.ch

S. Hurst • A. Mauron

Institute for Biomedical Ethics, University of Geneva, Geneva, Switzerland e-mail: Samia.Hurst@unige.ch; Alexandre.Mauron@unige.ch

developed in the late 1970s and was progressively institutionalized in the following decades through the establishment of ethical committees, guidelines for health care professionals, academic training in medical schools, and ethical consultation in Swiss hospitals.

Over the past three decades, discussions within academia, policy making, and the public arena have resulted in the adoption of regulations on several bioethical issues. As elsewhere in Western Europe, major issues of discussion include abortion and the status of prenatal life, assisted suicide, end-of-life care, organ transplantation, reproductive technologies, ethical issues of genetic technologies, and protection of human subjects of research. Nevertheless, these issues have a considerable bearing on Swiss public debate because of the system of semi-direct democracy, in which citizens can be called upon to vote on legislative proposals or on challenges to parliamentary bills. Decentralized governance, cultural and confessional differences, as well as the value placed on individual choices have largely influenced discussions, laws, and practices regarding many bioethical issues outlined in this chapter.

Bioethics Development

When and How Has Bioethics Started?

Certain aspects of ethical issues in medical care were part of graduate courses of moral theology and forensic medicine before the existence of bioethics as a distinct field. From the 1970s, medical ethics began to be considered as a specific field grounded in philosophical ethics and dealing with normative questions in medical practice and research.

In 1979, the Swiss Academy of Medical Sciences (SAMS) (http://www.samw.ch/en/News/News.html), founded by medical schools and health care professions, set up a SAMS Central Ethical Committee (http://www.samw.ch/en/Ethics/CEC.html) in charge of establishing guidelines on controversial issues in medical practice. Over time, some of these guidelines have acquired binding authority, either through endorsement by the Swiss Medical Association (http://www.fmh.ch/index.html) as part of the professional code of physicians or by being referred to by laws or by case law. In the following decades, academia progressively took an interest in ethics, in general and medical ethics in particular. Progressively, Swiss universities established chairs in ethics within philosophy departments and medical schools.

Who Have Been the Major Actors/Forces?

Switzerland is a multicultural federal republic with a system of semi-direct democracy where governance is strongly decentralized. This is also reflected in bioethics. The major actors in the field are as follows:

- The Swiss Academy of Medical Sciences (SAMS), based in Basel

The Zurich University Centre for Ethics (ZUCE) (http://www.ethik.uzh.ch/index_en.html).

- The Institute for Biomedical Ethics (IEB) (http://www.unige.ch/medecine/ib/accueil.html) at the University of Geneva.
- More recently, the University of Basel's Institute for Biomedical Ethics (IBMB) (http://ibmb.unibas.ch/) and the University of Lausanne's ETHOS Interdisciplinary Ethics Platform (http://www.unil.ch/ethos/page60109 en.html).

In December 1998, the Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE) (http://www.bag.admin.ch/nek-cne/04236/index.html?lang=en) was set up as an independent, extra-parliamentary deliberative body, with the mission to promote public debate and advise policymakers on ethical issues in the field of biomedical research and practice. The Federal Ethics Committee on Non-Human Biotechnology (ECNH) (http://www.ekah.ch/en/index.html) was established the same year as an independent expert committee to advise authorities on ethical issues of nonhuman biotechnology and gene technology. Ethics commissions providing advice for clinical practice are increasingly present in Swiss hospitals.

The Confederation also established the Centre for Technology Assessment TA-SWISS (http://www.ta-swiss.ch/en/) with a view to investigate the social impact of new technologies and advise the Parliament and the Federal Council on controversial technologies. Research in the field of biomedical ethics is mainly sustained by the Swiss National Science Foundation (SNSF) (http://www.snf.ch/E/Pages/default.aspx) through various forms of financial support to academic institutions and individual researchers and through national programs on specific topics. Among nonacademic institutions, the Brocher Foundation (http://www.brocher.ch/pages/default.asp?lang=en) supports research on ethical, social, and legal issues of biomedical technologies.

The Swiss Society for Biomedical Ethics (SGBE/SSEB) (http://www.bioethica-forum.ch/content/e_SGBESSEB.php) — a multidisciplinary, multilingual, and non-confessional association of scholars and practitioners joining various ethical perspectives and a pluralistic approach to bioethical issues — promotes research and training in bioethics (see section "What Resources Have Been Developed (e.g., Books, Programs, Media, Networks, Societies)?" below).

What Have Been the Major Concerns Over Time?

During the 1990s, the Swiss debate was characterized by lively public discussions on ethical dilemmas related to genetics, reproductive technologies, and end-of-life care. Beside these major topics, the bioethical debate within academia, policy making, and the public arena has focused on organ transplantation, the protection of human subjects of research, experimentation on animals, abortion, and the ethical status of human prenatal life, the prevention of infectious diseases, and patient rights.

What Resources Have Been Developed (e.g., Books, Programs, Media, Networks, Societies)?

Numerous publications in the field are produced at the local level in the various linguistic regions of the country. In addition, several resources in bioethics have been developed at the national level. The Swiss Academy of Medical Sciences (SAMS) and the Swiss Medical Association promoted the publication of a textbook of biomedical ethics discussions and regulations in the country (Bondolfi and Müller, 1999).

Since the early 1990s, the universities of Zurich and Geneva initiated formal bioethics courses for medical students. Until 2006, the Swiss Society for Biomedical Ethics (SGBE/SSBE) has organized a summer school for health care professionals and researchers who did not have the opportunity to have training in bioethics during their education. Every 2 years since 2005 and annually since 2009, the SGBE/SSBE organizes workshops where research projects are presented and discussed.

Two main book series on bioethical research in Switzerland are published in German and French by Schwabe editions in Basel within the collection *Ethik und Recht* and by Georg editions in Geneva within the reader's collection *Controverses en éthique*. The SGBE/SSBE publishes the journal *Bioethica Forum* (http://www.bioethica-forum.ch/e_index.php), as well as a collection of thematic essays in French and German entitled *Folia Bioethica*.

What Have Been the Steps/Measures Taken?

Over the past three decades, Switzerland has adopted regulations on several bioethical issues, such as reproductive technologies (http://www.admin.ch/ch/d/sr/c810_11.html), genetically modified organisms (http://www.admin.ch/ch/d/sr/c814_91.html), research on human embryonic stem cells derived from spare embryos (http://www.admin.ch/ch/d/sr/810_31/index.html), human genetic testing (http://www.admin.ch/ch/d/sr/810_12/index.html) including prenatal testing and newborn screening, and organ transplantation (http://www.bag.admin.ch/transplantation/00694/01739/index.html?lang=de). A new law on biomedical research on human subjects will soon become effective (http://www.bag.admin.ch/themen/medizin/00701/00702/07558/index.html?lang=de), and a far-reaching revision of the civil code will make advance directives recognized on a federal level in 2013 (http://www.ejpd.admin.ch/content/ejpd/de/home/themen/gesellschaft/ref_gesetzgebung/ref_vormundschaft.html).

Whereas the cantons hold legal prerogative in the field of health care policy, on most of the issues listed above, the Confederation enlarged the scope of its power, otherwise limited to infectious disease control. Giving the Swiss Parliament the authority to enact laws on additional topics requires a change in the Constitution, which in turn requires that citizens be called upon to vote. In the last 30 years, this happened regularly on many issues regarding medical practice and research.

It should be noted that abortion and assisted suicide are regulated by the Swiss criminal code and that no specific legislation on these practices has been

introduced. In particular, Articles 118–120 of the code authorize abortion on demand in the first trimester and on medical indication thereafter, and Articles 115 and 114 legally condone assisted suicide for altruistic reasons and outlaw "murder on demand by the victim" or voluntary active euthanasia.

The Swiss law on epidemics dates back to 1974 and has never been amended over time. During the AIDS pandemic, no specific standards were introduced, although information campaigns were strongly supported by public authorities to prevent the spreading of the disease in the country.

Besides the regulatory activity of the Confederation, the Swiss Academy of Medical Sciences (SAMS) regularly provides recommendations and guidance for health care professionals on various topics relevant to medical practice and research as outlined above.

Current Bioethics Infrastructure

Teaching of Bioethics at University and Other Levels

The teaching of bioethics is currently present in all the faculties of human and veterinary medicine, in some faculties of sciences, and in many bachelor- and master-level training programs for health professionals. The Swiss Academy of Medical Sciences (SAMS) is compiling a complete list of teaching institutions and programs. The federal law defining training for the medical profession requires academic programs to include courses on the ethical aspects of the professional activity, with a view to develop students' personal skills and social competences. Although education in bioethics is compulsory for medical students, training programs can be defined by universities with a high degree of autonomy.

Bioethics Committees

Research involving animals or human participants needs to obtain clearance from an ethics committee, as is the case in all countries recognizing international ethical principles of biomedical research. A new federal law on biomedical research on human subjects will come into force by 2014. Until then, the ethical review of research protocols and the establishment of ethics committee fall under the jurisdiction of cantons. At present, cantons where universities have faculties of medicine have set up cantonal ethics committees, organized in various subcommittees covering different research fields. Where no faculty of medicine exists, an inter-cantonal ethics committee is established, with the exception of Ticino where the cantonal committee was created because of intense research activities in the canton and because of its geographic isolation.

In addition to ethics committees for the review of research protocols, clinical ethics committees are present in almost half of all Swiss hospitals to provide ethical consultation to health care professionals (Hurst et al., 2008). The functioning of each clinical ethics committee is regulated by its statute.

Expert Bodies/Centers

At the national level, two ethics committees exist in Switzerland to promote public debate and advise policymakers on ethical issues: the Federal Ethics Committee on Non-Human Biotechnology (ECNH) examines ethical issues of biotechnological interventions on plants and animals, whereas the Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE) considers ethical and health policy issues in the field of biomedicine.

Relevant Legislation

The relevant Swiss legislation in the field of bioethics is detailed in section "What Have Been the Steps/Measures Taken".

Public Debate Activities

In Switzerland, public discussion of bioethical issues is largely determined by the political agenda set by the Parliament. However, the system of semi-direct democracy, in which parliamentary bills can be called into question, new laws can be proposed, and constitutional amendments can be passed by popular vote, have a considerable bearing on public debate activities in the country. Bioethical issues that are currently under discussion in the public debate include the following:

- The use and reimbursement of reproductive technologies, especially preimplantation diagnosis.
- Various issues in environmental ethics, especially the regulation and use of genetically modified organisms.
- The relevance of further regulating the legal practice of suicide assistance, and/or of legalizing voluntary euthanasia.
- The application of patient rights within the health care system.
- The costs of the Swiss health care system and the ethical and health policy issues relating to access to health care.
- Ethical issues of direct-to-consumer genetic testing.

Major Bioethics Issues and Discussions

Beginning of Life

Within academic discourse, dilemmas surrounding the ethical standing of human prenatal life and reproductive technologies are discussed largely in the same terms in Switzerland as elsewhere in Western Europe, and controversies run along similar lines. Nevertheless, these issues have been particularly visible in Swiss public life on account of the system of semi-direct democracy, in which citizens are regularly

called upon to vote on legislative proposals or on challenges to bills adopted by Parliament. In the last two decades, this occurred a number of times for topics relevant to this section. In 2002, Parliament adopted a far-reaching reform of criminal law as regards abortion, basing the protection of embryos and fetuses on a "gradualist" view of their moral status – the view according to which the appropriate protections grow, as it were, along with it. This made Swiss criminal law much more liberal than the (nominally) conservative status quo. Conservatives and certain religious circles gathered the requisite number of signatures to put the issue before the people, but their challenge to a liberal abortion law was resoundingly defeated (72.2 % votes were in favor of the new law; a competing proposal to prohibit abortion in most situations was defeated by 81.7 % of votes).

The ethics and politics of reproductive technologies as well as related issues such as research using human embryonic stem cells show a far more complex picture. Broadly speaking, Swiss legislation on reproductive technologies rests on the paradigm of application within a nuclear family, recognizes an individual's right to know her biological ascendency, and has strictly banned the production of embryos for any purpose other than implantation. At the same time, however, research is highly valued, and this extends to human embryonic stem cells. In the early 1990s, a fairly restrictive constitutional amendment was adopted (Article 119 of the Constitution) with strong popular support at the time. Among other restrictions, oocyte donation, embryo donation, and preimplantation genetic diagnosis (PGD) were outlawed, as were the production of more than three embryos in vitro per cycle of fertility treatment; keeping frozen spare embryos for an ulterior treatment cycle was also forbidden. In the early years of this century, a bill softening these prohibitions in order to make human embryonic stem cell research possible was put to the popular ballot and accepted (66.4 % "yes" votes). Among other elements, this new law establishes a requirement for parental consent for the use of surplus embryos in human embryonic stem cell research (Porz, Bürkli, Barazzetti, Scully and Rehmann-Sutter, 2008). The climate of public opinion on these issues seems to have changed. The prohibition of PGD is currently challenged, and a correspondingly revised legislation is being discussed.

End of Life

The Swiss debate on end-of-life care can be traced back to the 1960s. Discussions were nourished by philosophers, theologians, and health care professionals, confronting new dilemmas of end-of-life care raised by medical progress. There are many publications on the topic in Switzerland, although this literature is relatively fragmented due to its multilingual character. Early discussion on end-of-life care centered on a medical decision to limit life support of a dying person. Eventually, this decision was not enacted, but it brought about an energetic debate on withdrawing medical care at the end of life. In the wake of this discussion, the Swiss Academy of Medical Sciences (SAMS) drew ethical recommendations that allow doctors to withhold futile treatments to dying patients. Issued in 1976, the SAMS guidelines have been regularly reviewed as the debate on end-of-life care in

the country continued to evolve (revisions were published in 1981, 1988, 1995, and 2004). The analysis of the successive versions of the document shows a growing consensus on the moral wrongness of futile medical care.

Besides issues of end-of-life care, the practice of assisted suicide has been extensively discussed in the country (Pfister and Biller-Andorno, 2010). Assisted suicide is legally condoned by Article 115 of the Swiss criminal law if the motive is altruistic, and it can be performed by nonphysicians (Hurst and Mauron, 2003). The viewpoint of the SAMS on assisted suicide has changed over time. While the 1995 revision of the SAMS guidelines (Available at http://www.samw.ch/de/Ethik/Richtlinien/Archiv.html) stated that assisted suicide is "not a part of medical activity," the last version of the document (Swiss Academy of Medical Sciences, 2004a) acknowledges that a conscientious decision by a doctor to assist suicide should be respected. During the last few years, the political discussion has focused on whether to regulate both assisted suicide and voluntary euthanasia by law. In June 2011, the Parliament decided to maintain the status quo.

Discussions about palliative care and advanced directives were less controversial and have rapidly reached a general consensus. Palliative care is promoted and sustained by the Confederation and the cantons. Advanced directives, which already exist in several cantons, are recognized on a federal level by a revision of the Swiss civil code, as of 2013.

Health and Disease

In Switzerland, coverage by medical insurance is based on the presence of disease and the indication for medical treatment, making the definition of what constitutes disease, or not, a key element. Excluded areas include long-term care, viewed as required by old age rather than disease, but also contraception and fertility treatments, both of which are considered lifestyle choices rather than health issues. More recently, coverage for vision correction in childhood has been excluded from coverage: based on statistical frequency, it was argued that it was normal and thus not a health condition.

Health Care System, Access to Health Care

The Swiss health care system is a universal coverage system based on an individual mandate for the purchase of state-regulated but privately managed health insurance, with subsidies toward this purchase for lower income groups (Gagnebin and Sprumont, 2009). Voluntary additional insurance can be purchased by individuals who so choose; it covers greater comfort and choice of provider in hospitals, as well as certain interventions not covered by basic health insurance such as travel insurance or some forms of alternative medicine. Despite universal coverage and a very well-funded health system with dense regional access, barriers to access exist. The most visible one is a high rate of

out-of-pocket payments, which have been shown to lead some persons to forgo needed care (Wolff, Gaspoz and Guessous, 2011). Moreover, as outlined above (see section "Health and Disease"), coverage under basic insurance is predicated on interventions targeting disease, making the definition of what constitutes disease, or not, a key element. Dental care is also excluded from health care coverage. Rather than being based on a link between dental care and personal behavior in the prevention of dental disease, however, this exclusion is based on early requests by dentists to be excluded from what they viewed as obligations linked to their interventions' inclusion under the basic health insurance mandate.

Coverage for alternative medicine has been the object of a long-standing debate in Switzerland, where some forms of alternative therapy have originated and where several have been in use for a long time. Coverage of medical interventions is legally predicated on the intervention being "effective, appropriate, and efficient." Thus, one part of the discussion regarding alternative medicine has centered on its effectiveness. Despite a negative recommendation by the official commission on health coverage, however, the exclusion of these forms of alternative medicine proved so unpopular that they were covered despite not being proven effective.

Moreover, discussions regarding the possibility of excluding marginally beneficial interventions have taken place (Zimmermann-Acklin, 2005). These have been politically difficult and hence sporadic.

Traditional Medicine

As outlined above (see section "Health Care System, Access to Health Care"), coverage for alternative medicine has been the object of a long-standing debate in Switzerland, where some forms of alternative therapy have originated and where several have been in use for a long time. Several forms of alternative medicine – phytotherapy, homeopathy, Chinese traditional medicine, neural therapy, and anthroposophic medicine – are practiced by physicians with officially recognized courses of training. Coverage of medical interventions, however, is legally predicated on the intervention being "effective, appropriate, and efficient." Thus, one part of the discussion regarding alternative medicine has centered on its effectiveness. Despite a negative recommendation by the official commission on health coverage, however, the exclusion of these forms of alternative medicine proved so unpopular that they were covered despite not being proven effective.

Another part of the discussion has centered on the place of alternative medicine in medical training. Since 2009, Switzerland is required by its Constitution to "take alternative medicines into account". Although it is not entirely clear what this might mean for medical schools, it is broadly accepted that making students critically aware of alternative medicines and their claims will be the main application of this law in universities.

Genetics

Discussions about human genetics in Switzerland cover a wide range of topics, as it is the case elsewhere: from presymptomatic and susceptibility testing to DNA fingerprinting for criminal investigations; from disclosure and confidentiality of test results to gene therapy. A *Federal Act on Human Genetic Testing* (http://www.admin.ch/ch/e/rs/c810_12.html) was enacted in 2004 to regulate human genetic testing in the country.

Ethical and science policy issues that have been extensively discussed in the Swiss context have centered on the use of genetically modified (GM) crops in agriculture and on the commercialization of GM food, ensuing from the lack of specific regulations and transparent authorization procedures. For nearly 15 years, from the first field experiments in the early 1990s to the moratorium for GM crops that was passed in 2005, the debate spread out across the country in the form of a controversy about safety and environmental risks. The controversy was triggered by the action taken by ecologist groups who proposed an initiative for a restrictive regulation of various aspects of GM food, including patenting and commercialization. In response, molecular biologists organized protest marches in defense of new genetic technologies, also supported by pharmaceutical companies. Farmers concerned about the coexistence of traditional and genetically modified crops also called for a careful consideration of environmental and economic impacts of GM crops onto the small-size Swiss agriculture. The spreading controversy forced public authorities to accelerate the process of planning regulations. A directive on the labelling of food containing GM organisms was enforced in 1996, and the Federal Ethics Committee on Non-Human Biotechnology (ECNH) was set up in 1998 to examine ethical issues of developments in gene and biotechnology with a view to assess their impacts on humans and the environment. The ECNH should work in cooperation with the Swiss Expert Committee for Biosafety (SECB) (http://www.efbs.admin.ch/en/index.html) to review experimental protocols of GM crops field experiments and to inform the Federal Office for Environment (FOEN) (http://www.bafu.admin.ch/index.html?lang=en) in charge of giving the final clearance. The initiative proposed by ecologists was eventually voted in 1998 and rejected by a majority of the electorate (66 %). This result did not close the controversy in the country, which turned to be focused on field experiments. Notwithstanding the approval of the SECB and the favorable evaluation from several scientists, between 1999 and 2001, the FOEN repeatedly denied authorization of field experiments on the basis of the precautionary principle. The decision of the FOEN was contested by scientists who considered field experiments essential to their research work, which was conducted under a national research strategy on biotechnology financed by the Swiss National Science Foundation (SNSF). This crisis in national science policy was the consequence of various ethical and social issues of GM food that were still under discussion in the public debate. Indeed, in the course of the controversy, the evaluation and management of risks has evolved from a model where decision making is restricted to a qualified group of experts and policy makers,

to a model of public negotiation of risks (Audétat, November and Kaufmann, 2005). Although the agenda for discussion was initially focused on potential risks of GM food, the widening controversy contributed to democratize and enrich the public debate, which eventually included economic, environmental, and health-related issues of genetically modified crops (Kaufmann et al., 2004).

In 2005, a referendum was held to decide whether or not to prohibit the use of GM plants for a period of 5 years. The majority of the voters accepted the five-year moratorium, which was later extended to November 2013. The ostensible purpose of the moratorium was to provide time for evaluation of potential benefits and risks of GM plants, as well as their social acceptability. To this end, a national research program was implemented by the SNSF (NRP 59) (http://www.nrp59.ch/e_index.cfm). Since the empirical part of this research necessitates field testing of GM plants, and since such tests raise fierce opposition by legal and illegal means, it is doubtful whether this research program will provide enough results to inform public policy on this matter.

Reproductive Medicine

Discussions regarding reproductive medicine in Switzerland have centered on what should be allowed on the one hand and what should be covered by health insurance on the other. Broadly speaking and as outlined above (see section "Beginning of Life"), Swiss legislation on reproductive technologies rests on the paradigm of application within a nuclear family and recognizes an individual's right to know her biological ascendency.

As regards abortion, the Swiss Parliament adopted a reform of criminal law in 2002, basing the protection of embryos and fetuses on a "gradualist" view of their moral status – the view according to which the appropriate protections grow, as it were, along with it. As outlined in section "Health and Disease," contraception and fertility treatments are generally excluded from health coverage, as both are considered lifestyle choices rather than health issues.

Medical Research

International principles and guidelines are applied to research with human subjects in Switzerland. Swiss law makes explicit reference to the ICH guidelines for Good Clinical Practice, and Swiss Academy of Medical Sciences (SAMS) recommendations (http://www.samw.ch/de/Ethik/Richtlinien/Archiv.html) refer to the declaration of Helsinki. Specific issues have nevertheless been raised in the Swiss context, in particular, since the first project for a federal law on research with human subjects was put to public consultation in 2006. Three issues have been the object of particular debate.

First, the scope of protections for human subjects of research outside of biomedical sciences is controversial. On the one hand, it is difficult to see how the area of

research where human subjects incur risks should make a difference to the protection they are given. On the other hand, ethical codes and oversight bodies are often younger, fewer, or even nonexistent in fields other than biomedical science. When it came to defining the required protections' scope of application, the authors of the law project rejected application based on the discipline or professional group of the investigators as too difficult to define exhaustively and too likely to include research involving no risk to human participants. They also rejected application based on the degree of risk, based on the lack of bodies competent to review such research outside the scope of biomedicine. They defined the scope of protection, which includes ethics committee review, based on two criteria (Duetz and Gruberski, 2009):

- Research on human disease and the development and functioning of the human body, where the term "disease" is understood broadly and includes psychological health impairments.
- A risk threshold based on the possibility of harm to human dignity and personal integrity: This is defined by the exclusion of research on in vitro embryos, anonymous biological material, and anonymously obtained or completely anonymized health-related data.

Second, federalism has led to decentralized review of multicenter studies even within Switzerland, and coordination of ethics review by different ethics committees has proved difficult. Recently, the working group of Ethics Review Committees has implemented a rotating centralized review to facilitate multicenter review.

Third, the interface between research with animals and research with human subjects is a particular point of tension in Switzerland. Research with animals is particularly strictly regulated in Switzerland, based on a constitutional clause protecting the integrity of living organisms – or the "dignity of creatures" in the German version. The "dignity" of animals is explicitly different from human dignity: it means that animal interests must be considered in the balance of risks and benefits but can nevertheless be subordinated to greater human interests (ECNH, 2008). In practice, application predictably remains difficult. In 2008, a decision to stop two experiments on monkeys was upheld by the Swiss Supreme Court based on the uncertainty and distance of the expected clinical applications in view of the burden imposed on nonhuman primates. As such decisions illustrate, the appropriate thresholds to apply in balancing human and animal interests remain controversial.

Public Health

Ethical issues in public health tend to cluster around three main issues: tensions between public health efforts and individual self-determination, questions regarding legitimacy and appropriate decision makers, and difficulties in distinguishing public interventions for the prevention of disease on the one hand and the moralization of health on the other. In Switzerland, a strong focus on individual self-determination, combined with the cantonal organization of many aspects of the health care system, has tended to make concerted public

health efforts more difficult. Antismoking campaigns, for example, have tended to focus on individual efforts rather than on limits to the availability of tobacco. It is only when it became clear that smoking was harmful to others that bans on smoking in public spaces were implemented. Information campaigns for organ transplantation have also been criticized for focusing on neutrality and avoiding any appearance of promoting organ donation. This focus on individual self-determination extends to the prevention of infectious diseases, with very few mandatory vaccinations and some resurgence, for example, of measles as one consequence. During the beginning of the AIDS pandemic, public health interventions struck many as signalizing a shift away from the moralization of sexuality as advertisement for condoms were used in public spaces to promote effective protection. More recently, however, health itself has tended to risk becoming moralized as part of prevention campaigns aimed, for example, at the prevention of smoking or obesity.

Infectious Diseases

As outlined above (see section "What Have Been the Steps/Measures Taken"), the Swiss law on epidemics dates back to 1974 and has never been amended since. At the beginning of the AIDS pandemic and during concerns regarding avian flu outbreaks, no specific standards were introduced, although information campaigns were strongly supported by public authorities to prevent the spreading of the disease in the country. As outlined under Public health, however, a strong focus on individual self-determination, combined with the cantonal organization of many aspects of the health care system, has tended to make concerted public health efforts in prevention more difficult. This focus on individual self-determination extends to the prevention of infectious diseases, with very few mandatory vaccinations and some resurgence, for example, of measles as one consequence.

Transplantation Medicine and Organ Donation

In 2004, the Confederation adopted a federal law on organ transplantation. Before that date, this practice was regulated by the directives of the Swiss Academy of Medical Sciences (SAMS) (Available at http://www.samw.ch/en/Ethics/Guide-lines/Archive.html) and by 15 different cantonal laws. Notwithstanding the new federal regulation and the information campaigns for the promotion of organ donation, the practice is limited by the significant shortage of organs available for transplantation. There are important differences in the attitude of Swiss citizens with regard to transplantation. The paucity of cadaveric donations in the country has contributed to increase the number of transplants from living donors, a practice strictly regulated by the new federal law. According to the current legislation, explicit consent to organ donation should be given by persons before death or should be witnessed by family members after death.

The Confederation mandated the SAMS to draw recommendations for clinicians on both the definition of brain death and the procedures to assess it. The SAMS regularly updates these directives (Updated versions are available at http://www.samw.ch/en/Ethics/Guidelines/Currently-valid-guidelines.html).

More recently, the Swiss Parliament has discussed the adoption of an implicit consent to organ donation. The Swiss National Advisory Commission on Biomedical Ethics raised several concerns on the ethical implications of this measure for medical practice.

New legal provisions have been introduced on allocation of organs available for transplantation, with a view to establish stringent eligibility criteria for patients on the basis of urgency and efficacy. At present, the practice of xenotransplantation, which was extensively discussed as an alternative to organ transplantation, has been progressively abandoned and eventually prohibited by law due to the high risks of transmission of zoogenic pathogens.

Emerging Technologies

Discussion of new emerging technologies in Switzerland is mainly, although not exclusively, focused on nanotechnology. Similarly to what happened in the case of the GMO controversy, the agenda for discussion is dominated by concerns about risks and safety of nanoparticles. This approach is manifested in the national research program founded by the Swiss National Science Foundation (SNSF) to investigate impacts of biomedical and environmental use of nanomaterials (NRP 64) (http://www.nfp64.ch/E/Pages/home.aspx), as well as in the initiatives launched by the Federal Office of Public Health (FOPH) (http://www.bag.admin.ch/index.html? lang=en), such as the platform for public dialogue NANO and the *Precautionary Matrix for Synthetic Nanomaterials*, a method to assess potential risks of the production of nanomaterials.

Very recently, some arenas of discussions have been developed, such as the following: the publifocus organized by the Centre for Technology Assessment TA-SWISS (http://www.ta-swiss.ch/en/projects/nanotechnologies/); the newsletter published by the Innovation Society, an independent consulting company based at the Technology Center of the Federal Institute of Materials Science and Technology in St. Gallen (http://www.innovationsgesellschaft.ch/index.php?page=93); and *Nanopublic* (http://www.unil.ch/nanopublic/page32013.html), the nanotechnologies and society interdisciplinary platform aiming at fostering dialogue between the Swiss nanotechnology stakeholders.

Intensive Care

Discussion of ethical issues in intensive care has focused on questions raised at the end of life and on admission criteria in triage situations. It is generally accepted in Switzerland that competent patients have a right to refuse medical interventions, including life-sustaining measures. Consequently, withholding and withdrawing

therapy is an accepted part of medical practice. It is further accepted that futility, the absence of hope that an intervention will bring sufficient benefit to the patient to warrant the burden to that patient, can justifiably ground a decision to withhold or withdraw medical interventions. One consequence is that, among patients who die in Swiss intensive care units, a significant number does so following a decision to limit life-sustaining measures. Such decisions are usually based on consensus within interdisciplinary teams, on agreement with competent patients, and in the case of incompetent patients on discussions with family members regarding what the patient would have wanted. A revision of the Swiss Civil Code, giving greater representation power to family members of incapacitated patients, should result in a shift toward greater participation of families in such decisions in the near future.

Issues arising in the allocation of intensive care beds have been minimized by nationwide coordination among intensive care units. As indications for intensive care grow, however, such issues have been increasingly debated at the local level.

The Swiss Academy of Medical Sciences (SAMS) published guidelines on ethical issues in intensive care in 1999 (SAMS, 1999). Separate guidelines for the treatment of severely premature newborns have been regularly updated by the Swiss Society for Neonatology.

Palliative Care

As outlined in section "End of Life", discussions about palliative care and advanced directives have rapidly reached a general consensus. Palliative care is promoted and sustained by the Confederation and the cantons. Advanced directives, which already exist in several cantons, are recognized on a federal level by a revision of the Swiss civil code, as of 2013.

Care for the Elderly

Although discussions on care for the elderly are similar in Switzerland and other countries, four issues can be noted. First, the medical specialty of geriatrics or gerontology is rather new in clinical medicine, and in Switzerland, it has faced difficulties in identifying its specificities in clinical settings. As clinical approaches in gerontology tend to be rather different from those in other areas of medicine treating elderly patients, this has meant that ethical issues in the care of the elderly have varied with the clinical setting. Second, discussions of ethical issues in old age have tended to focus on practical clinical issues (Monod, Chiolero, Büla and Benaroyo, 2011), such as adapting medical interventions to old age, how to define the proper aims of medicine in old age, attempting to avoid both critiques of "agism," or doing too little, and concerns that medicine is doing too much. Third, antiaging medicine has been a focus of research, and this has led to considerable discussions regarding ethical issues raised by medical enhancements. Fourth, as in many other western countries, issues are raised by the coverage of elder care.

As resource constraints meet rising needs, concerns have also been voiced that the elderly could become a population particularly vulnerable to unjustified rationing. In Switzerland, coverage by medical insurance is based on the presence of disease and the indication for medical treatment. Dependence for the activities of daily living is not considered a disease, and thus it is not covered by insurance. Any such costs are paid out of pocket by individuals, with state help available for those who become indigent as a result. Although this still affects a minority of the population aged >85, its unpredictability has led to calls to extend insurance to cover long-term care. Tensions arising between the costs which this would involve and the requirements for solidarity in facing old age are an ongoing debate.

Ethical guidelines for the care of dependent elderly patients were published by the Swiss Academy of Medical Sciences (SAMS) in 2004 (SAMS, 2004b). They focus on issues including appropriate care, continuity of care, interdisciplinary collaboration and collaboration with family members, advance directives, informed consent, decisions for incapacitated patients, adaptation of prevention, acute care, rehabilitation and palliative care to old age, and end-of-life issues.

Chronic Diseases

Issues related, among others, to access to health care and indications for palliative care do arise in the context of chronic diseases, they are not different from those outlined in the sections "Health and Disease, Health Care System, Access to Health Care, Traditional Medicine" above.

Psychiatric Care

All the main issues raised in other areas of medicine are also raised in psychiatric care. A further focus has centered in Switzerland on whether suicide assistance should be allowed in the case of competent patients suffering from psychiatric diseases. In 2006, a Swiss Supreme Court ruling established that suicide assistance could be allowed in the case of competent psychiatric patients on the strict condition that their wish to die be well-considered, durable, and free of any outside influence based on an expert psychiatric evaluation. Controversies on this topic, however, are still ongoing.

Pediatric Care

Various issues outlined in the above sections are also relevant to pediatric care (Kind, 2009). In the Swiss context, it should be noted that the threshold which allows a patient to make her own decisions regarding health care is not adulthood but decision-making capacity regarding the choice at stake. "Mature minors" who are patients in Switzerland can thus consent to – or refuse – medical interventions, including life-saving interventions. Specific laws require additional parental

consent in cases where greater protection is necessary – such as consent for participation in research – and in some cases, minors are excluded from particularly risky altruistic medical interventions entirely – such as live donation of solid organs. Such cases, however, are exceptions. Competent minors' consent is also required to divulge any confidential information to their parents or other guardians.

Emergency Care

Aside from a brief attempt in 2007 to exclude illegal immigrants from emergency care, which was swiftly rejected by the Swiss Supreme Court, the Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE), and Swiss health care providers in their practice, no specific ethical issues have been raised in Switzerland regarding emergency care.

General Practice

All the main issues raised in other areas of medicine are also raised in general practice. More recently, policy issues regarding general practice, such as the usefulness of a gatekeeper role within the health care system or the importance of increasing the attraction of general practice for young physicians, have been increasingly debated within the health policy discussion. Moreover, Switzerland is a destination country in the global medical brain drain, which clearly raises ethical issues far beyond those which have been addressed to date.

Health Promotion and Education

See section "Public Health" above.

Scientific and Professional Integrity, Conflict of Interest, Corruption

Issues of scientific fraud and other breaches of scientific integrity have regularly surfaced in Swiss academic life, as is the case elsewhere. Beginning in the 1980s, there was increased controversy and dissatisfaction about the informal manner with which these cases were traditionally handled by academia. In particular, the lack of clear procedural rules meant that investigations of alleged scientific misconduct by academic authorities were easy targets for legal challenge. This led universities and the Swiss Academies of Arts and Sciences (http://www.swiss-academies.ch/en/index/Portrait.html) to adopt more detailed, formal regulations. The Swiss Academy of Medical Sciences (SAMS) released a set of regulations on scientific integrity in 2002 (SAMS, 2002). This document defined the nature and scope of scientific misconduct in biomedical research and perhaps even more importantly, established a detailed procedure to investigate

accusations of scientific misconduct. The document was in line with similar guidelines on this topic issued by various national and international bodies (e.g., European Science Foundation – US Office of Research Integrity: Research Integrity: global responsibility to foster common standards (http://www.esf.org/index.php?id=4479). These guidelines were influential in getting universities to develop their own framework for issues of scientific integrity, by adapting the rules that had evolved in the context of medical faculties and biomedical research institutes to a broader range of scientific and scholarly fields.

In 2007, the Swiss Academies of Arts and Sciences issued a memorandum in which they define basic principles and offer to help research institutions in setting up specific rules and procedures. This was followed by setting up a permanent commission on scientific integrity, which issued a much more detailed document in 2008 delineating ethical principles and procedural rules (Swiss Academies of Arts and Sciences, 2008). The principles tend to go beyond the "FFP core" (fabrication or falsification of research results, plagiarism) familiar to Anglo-American researchers and include attitudinal goals concerning, for instance, the role model provided by senior researchers, the importance of quality vs. quantity of research output, and the responsible use of the constitutionally guaranteed freedom to do research. The procedural rules involve a four-pronged organization of integrity protection. This includes an ombudsperson who deals with initial complaints and may arbitrate minor cases and an integrity protection commissioner who selects a suitable fact-finding panel to conduct the inquiry and, in case solid evidence of misconduct is found, passes the results to a decision-making panel to whom authority to decide the case has been delegated by the dean, university president, or director of the research institution. This somewhat complex system was felt to be needed in order to guarantee due process and the presumption of innocence as well as protecting whistleblowers and safeguarding relevant evidence.

Relations with Industry and Donors/Sponsors

The relationship between the pharmaceutical industry on the one hand and academic biomedical research and medical practitioners on the other has special significance in Switzerland. Some of the largest pharmaceutical companies in the world have originated in this country, where they still maintain their headquarters and a significant proportion of research and manufacturing facilities (for how long is unclear). This means that the pharmaceutical industry enjoys a great deal of political influence, for instance in negotiating drug prices with Swiss health authorities. It also entails a strong presence of industry in postgraduate medical education and academic medicine. As regards medical research, this close connection between academia and industry is not always, or necessarily, problematic. In fact, during the "golden age" (roughly from the 1950s to the 1980s), when biomedical advances quickly resulted in the availability of whole classes of important new drugs, this relationship was quite constructive and useful. In recent decades, however, important global changes have affected

both sides of this divide. As a result, it has become more and more apparent that the primary interests of universities, industry, and public health are often at odds with each other. The old "cozy" relationship came increasingly under fire, and it was again the Swiss Academy of Medical Sciences (SAMS) which took the lead in setting up regulations to deal with these issues. Its guidelines on this subject were initially greeted with skepticism and controversy but are now firmly established (SAMS, 2005). These include not only general principles but also specific and practical rules, especially as regards industry-initiated or industry-supported grand rounds and postgraduate training sessions.

One industrial sector that poses a unique challenge to scientific integrity and public health is the tobacco industry. Several world companies involved in cigarette manufacturing have established their headquarters in Switzerland, where they happen to be beyond the reach of American and European law. They enjoy a position of enviable privilege and influence, with dismal consequences as regards scientific integrity (University of Geneva, 2004; Diethelm et al., 2005) and health policy, as evidenced by the fact that Switzerland is one of the few countries that has not ratified the WHO tobacco convention.

Other: Addiction

Since 1994, Switzerland has had a rather unique policy on illegal addictive drugs, based on a fourfold objective: prevention, therapy, risk reduction, and repression. Risk reduction entails the setting up of "injection rooms," where persons addicted to opioids can inject themselves in safe conditions and, more controversially, the provision of heroin under medical supervision to prescreened, highly dependent drug users (foundation Sucht Info Schweiz: http://www.suchtschweiz.ch/de/ themen/). From its onset, this program was considered experimental and involved continuous evaluation of its efficacy in improving the health and social integration of long-term drug users. This attracted a great deal of attention and often skepticism on the domestic and international scene. In a sense, this reaction is understandable since the pragmatic and evidence-based Swiss approach is inherently alien to the "moral crusade" which often energizes the "war on drugs" on a global scale. This risk reduction policy was confirmed by a majority of Swiss voters in a referendum held in 2008. Recently, the Swiss experiment has been viewed more sympathetically from abroad, as the failure of a purely prohibitionist stance is increasingly and more openly discussed internationally.

Future Challenges

The ongoing debate on eligibility criteria for patients to be listed for organ transplantation and the paucity of organs available in the country show that cultural forces and individual preferences have important impacts on the implementation of health care policies and need to be carefully examined. This debate shows that the authority

of the state to deal with health policy issues through nudge campaigns aiming to affect individual choices should be reconsidered. However, it also raises the question of whether the state can endorse some ethical perspective or should be neutral on bioethical issues. Further discussion is needed to develop a richer understanding of the societal implications of individual choices and of the role of the state in this field.

Although the Swiss health care system guarantees a universal coverage based on individual health insurance, the increasing rate of out-of-pocket payments has raised ethical concerns regarding barriers to access to needed care. The concept of personal responsibility that fuels the ethos of health care coverage needs to be reconsidered to prevent the state-regulated but privately managed health insurance system from producing health care inequalities in the country.

A significant proportion of academic biomedical research in Switzerland is funded by pharmaceutical companies, and even modest changes in the pharmaceutical industry may have important consequences on medical research and practice. Therefore, future challenges also include the discussion of ethical issues in the governance of biomedical research in the country.

Since Switzerland has developed an outstanding environment for technological innovation and industrial development in the life sciences, it is likely that issues related to science policy, both on the national level and internationally, will become more urgent in the near future.

Summary Conclusions

The Swiss debate over controversial bioethical issues in the country is characterized by the coexistence of academic expertise on the one hand and of public participation in the discussion of possible solutions on the other. Occasionally, public engagement has influenced the roadmap for regulation, as was the case for genetically modified plants.

Over the last decade, scholars in the field of bioethics have progressively abandoned the role of exclusive experts in the field and have turned into participants into a wider debate involving multiple competences and varied public actors. Most importantly, however, direct democracy, decentralized governance, and the value placed on individual choices have largely influenced debates, laws, and practices regarding many bioethical issues.

References

Audétat, M., November, V., & Kaufmann, A. (2005). Négocier les risques: Acteurs, expertises et territoires. In A. Da Cunha, P. Knoepfel, J.-P. Leresche, S. Nahrath (Eds.), Enjeux du développement urbain durable, transformations urbaines, gestion des ressources et gouvernance (pp. 425–444). Lausanne: Presses Polytechniques et Universitaires Romandes. Bondolfi, A., & Müller, H. J. (Eds.). (1999). Medizinische Ethik im ärztlichen Alltag. Basel:

Sondolfi, A., & Müller, H. J. (Eds.). (1999). *Medizinische Ethik im ärztlichen Alltag*. Basel: Schwabe Verlag.

Diethelm, P. A., Rielle, J., & McKee, M. (2005). The whole truth and nothing but the truth? The research that Philip Morris did not want you to see. *Lancet*, 366(9479), 86–92.

- Duetz, M., & Gruberski, T. (2009). Gesetzgebung über die Forschung am menschen: Konzipierung des Geltungsbereich. *Bioethica Forum*, 2(2), 90–91.
- Ethics Committee on Non-Human Biotechnology (ECNH). (2008). *La dignité de l'animal*. Available at: http://www.ekah.admin.ch/fileadmin/ekahdateien/dokumentation/publikationen/EKAH Wuerde des Tieres 10.08 f EV3.pdf
- Gagnebin, J., & Sprumont, D. (2009). Le système de santé suisse: Présentation générale. In D. Bertrand, J.-F. Dumoulin, R. La Harpe, & M. Ummel (Eds.), Médecin et droit médical (pp. 83–91). Genève: Médecine & Hygiène.
- Hurst, S. A., & Mauron, A. (2003). Assisted suicide and euthanasia in Switzerland: Allowing a role for non-physicians. *BMJ*, 326, 271.
- Hurst, S. A., Reiter-Theil, S., Baumann-Hölzle, R., Foppa, C., Malacrida, R., Bosshardt, G., et al. (2008). The growth of clinical ethics in a multilingual country: Challenges and opportunities. *Bioethica Forum*, 1(1), 15–24.
- Kaufmann, A., Perret, H., Bordogna Petriccione, B., Audétat, M., & Joseph, C. (2004). De la gestion à la négociation des risques: Apports des procédures participatives d'évaluation des choix technologiques. Revue européenne des sciences sociales, XLII(130), 109–120.
- Kind, C. (2009). Evaluation of risk in research with children It's time to clear misconceptions. *Bioethica Forum*, 2(2), 74–79.
- Monod, S., Chiolero, R., Büla, C., & Benaroyo, L. (2011). Ethical issues in nutrition support of severely disabled elderly persons: A guide for health professionals. *Journal of Parenteral and Enteral Nutrition*, 35(3), 295–302.
- Pfister, E., & Biller-Andorno, N. (2010). Physician assisted suicide Views of Swiss health care professionals. *Bioethics Inquiry*, 7(3), 283–285.
- Porz, R., Bürkli, P., Barazzetti, G., Scully, J. L., & Rehmann-Sutter, C. (2008). A challenged choice: Donating spare embryos to stem cell research in Switzerland. Swiss Medical Weekly, 138(37–38), 551–556.
- Swiss Academies of Arts and Sciences. (2008). *Integrity in scientific research. Principles and procedures*. Available at: http://www.akademienschweiz.ch/en/index/Portrait/Kommissionen-AG/WissenschaftlicheIntegritaet.html
- Swiss Academy of Medical Sciences. (1999). *Grenzfragen der Intensivmedizin*. Available at: http://www.samw.ch/de/Ethik/Richtlinien/Aktuell-gueltige-Richtlinien.html
- Swiss Academy of Medical Sciences. (2002). Scientific integrity in medical and biomedical research and for the procedure to be followed in cases of misconduct. Available at: http://www.samw.ch/en/Ethics/Guidelines/Archive.html
- Swiss Academy of Medical Sciences. (2004a). Care of patients in the end of life. Available at: http://www.samw.ch/en/Ethics/The-end-of-life.html
- Swiss Academy of Medical Sciences. (2004b). *Treatment and care of elderly persons who are in need of care*. Available at: http://www.samw.ch/en/Ethics/Guidelines/Currently-valid-guidelines.html
- Swiss Academy of Medical Sciences. (2005). Collaboration between medical professionals and industry. Available at: http://www.akademien-schweiz.ch/en/index/Portrait/Kommissionen-AG/Wissenschaftliche-Integritaet.html
- University of Geneva. (2004). Report on the inquiry conducted on the Ragnar Rylander affair. Available at: http://ebookbrowse.com/rylander-pdf-d111543601
- Wolff, H., Gaspoz, J.-M., & Guessous, I. (2011). Health care renunciation for economic reasons in Switzerland. *Swiss Medical Weekly*, 141, w13165.
- Zimmermann-Acklin, M. (2005). Rationierung im schweizerischen Gesundheitswesen. Überlegungen aus ethischer Sicht. *Deutsche Medizinische Wochenschrift*, 130, 2343–2346.